EVALUATION PLAN OVERVIEW

The OPTN Evaluation Plan explains to OPTN Member transplant centers, OPOs and histocompatibility labs how UNOS, as the OPTN contractor, assesses compliance by those members with OPTN Policies and By-laws. The Plan also includes specific expectations as to how Members remain in compliance.

The Evaluation plan has the following sections:

I. Evaluation Plan Background
II. General Background on Monitoring Compliance
III. Interested and Affected Parties
IV. Membership Criteria and Evaluation of Applications
V. Designated Transplant Program to Receive Organs for Transplantation
VI. OPTN/UNOS Committee Statements on Organ Allocation Policy Goals
VII. Measuring Compliance
VIII. Corrective Actions for Violations of Policy
IX. Interviews and hearings – Due Process Rights of the Member
X. Communications
XI. Charts
XII. Resource Materials
XIII. Evaluation Plan Change Log

Text outlined in a solid red line designates a hyperlink. Links open resource materials in a separate window to enable quick research and easy access to supporting documentation. Look for these features:

- Links on each page in Section VII addressing policy compliance to the related policy or by-law document
- Links to resource materials such as the Final Rule, the National Organ Transplant Act, and other source documents
- Links to background and support materials such as information from the CDC, educational brochures, and other pertinent information
- Evaluation Plan Change Log, listing the changes to the Plan with links to the modified sections
- Changes to the Evaluation Plan are highlighted in blue

In addition, the Evaluation Plan includes, where possible, specific guidance on how to comply with particular policies.

June 30, 2009 Publication Updates

The June 30, 2009 publication includes the following changes:

- Updates to the Evaluation Plan addressing policy and bylaw changes that have been implemented since the March 31, 2009 publication
- Enhanced explanations about how certain policies are monitored
- Enhanced explanations about compliance expectations for certain policies
- Links to additional resource materials for certain policies.

Inquiries and comments regarding the Evaluation Plan should be made to the appropriate UNOS Regional Administrator at 804-782-4800.

I. EVALUATION PLAN BACKGROUND: The Final Rule and the OPTN Contract

The Department of Health and Human Services (HHS) published the Final Rule governing the operation of the Organ Procurement and Transplantation Network (OPTN) in April 1998. Further comment was invited regarding its provisions and the Rule's provisions took effect in March 2000. Many Members of the transplant community, both through that formal regulatory comment process and through the OPTN committee process, have expressed concern and interest in how to promote compliance with OPTN Policies, thereby ensuring to the greatest extent possible the equitable treatment of all candidates and increasing the public's confidence that the national system works in the best interest of the candidates awaiting transplant.

Several sections of the Final Rule address compliance issues. Section 121.10 of Title 42 of the Code of Federal Regulations requires the OPTN to review OPTN Membership applications and applications for transplant program "designated" status. The Rule specifies that the OPTN will design appropriate survey instruments, a peer review process, and data systems for those purposes. Upon the approval of the Secretary of Health and Human Services, the OPTN will distribute to each Member Organ Procurement Organization (OPO) and Transplant Center the review plans and procedures, and will also send future revisions after their review and approval by the Secretary. The OPTN, using those plans and procedures, is required to review and evaluate each Member OPO and transplant program for compliance with the Final Rule and OPTN Policies.

In addition, if the Secretary has reason to believe that Member OPOs or Transplant Centers are not in compliance with OPTN Policies, or may be acting in a manner that poses a risk to candidate health or safety, he or she may request that the OPTN conduct a special review. The special review would be in accordance with a schedule specified by the Secretary. The OPTN would make periodic reports regarding the progress of the special reviews.

Section 121.10 also has specific provisions regarding notice to the Secretary regarding activities of the OPTN and compliance. Section 121.10 (b)(4) requires that the OPTN notify the Secretary within three days of all OPTN/UNOS Committee and Board of Director meetings at which compliance with the Final Rule or OPTN Policies is discussed. In addition, Section 121.10 (c) requires the OPTN Board of Directors to advise the Secretary when the Board makes a determination, based upon the review and evaluation processes described above, of noncompliance with the Final Rule or OPTN Policies, or that a risk to candidate health or public safety exists. This section also requires that the OPTN recommend appropriate enforcement actions the Secretary might take in those circumstances.

The United Network for Organ Sharing (UNOS) serves as the OPTN. The following sections of the Evaluation Plan describe in detail how UNOS acting as the OPTN will meet these requirements of the Final Rule. As the OPTN contractor, UNOS is also required to submit an evaluation plan pursuant to its OPTN Contract Task 2 for the purpose of reviewing applications submitted for Membership in the OPTN; reviewing applications submitted to be designated a transplant program; and, conducting ongoing and periodic reviews and evaluations of each Member OPO, Histocompatibility Lab and Transplant Center for compliance with OPTN Policies and applicable federal law. This document is submitted in satisfaction of that requirement.

II. GENERAL BACKGROUND ON MONITORING COMPLIANCE*

a. Introduction to Compliance Monitoring

There are several prerequisites to discussing the monitoring of OPTN Member compliance with policy. One has to have an understanding of the model used to develop policy; gather information; and provide feedback. These very basic steps are described as follows:

Step 1: Formulate the policy.
Step 2: Determine appropriate measurements for assessing Member compliance with policy.
Step 3: Gather information.
Step 4: Provide feedback to the Member and inform policy-makers.

The policy development cycle begins by engaging affected entities (e.g., Members, governmental bodies, institutions or individuals who are interested or invested in successful operations of the OPTN). The perspectives that each interest group brings to the discussion ensure that issues surrounding organ allocation and transplantation policy are fully considered. Identifying and engaging the following three principal groups of stakeholders are critical:

- those who are involved in transplant program operations (e.g., physicians, surgeons, OPO personnel);
- those who are served or affected by the transplant program (e.g., recipients, donor family members); and
- those who are primary users of the policy compliance report or policy evaluation data (e.g., the transplant program, OPTN/UNOS Membership and Professional Standards Committee, Division of Transplantation, OPTN/UNOS Liver and Intestinal Organ Transplantation Committee, and candidates).

UNOS, serving as the OPTN contractor, has relied on its committee system, regional structure, inclusion of candidate and donor family perspectives, and consideration of all aspects of the transplantation field in its efforts to involve stakeholders.

Step 1: Formulate the Policy
Formulating the policy includes addressing a specific goal in the community served by the OPTN. The policy is proposed with an expected effect in mind, e.g. that the allocation will better serve the candidate population.

Step 2: Determine the Appropriate Measurements for Assessing Member Compliance with Policy
The focus of the policy compliance monitoring process is the assessment of the issues of greatest concern to stakeholders while using time and resources as effectively as possible. The OPTN has endeavored to make its compliance monitoring useful, feasible, ethical, and accurate. As policy is drafted, Department of Evaluation and Quality staff propose a monitoring and evaluation plan that includes a description of how the policy might be monitored for compliance.

Step 3: Gather Information
Policy compliance monitoring collects information that will convey a well-rounded picture of the program so that the primary users see the information as credible and useful. For each aspect of

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policy compliance monitoring, standard operating procedures are written and kept up-to-date as OPTN Policies are modified.

Step 4: Provide Feedback to Member Programs and Inform Policy Makers
A report on a program's compliance with a policy is "justified" when its conclusions are founded upon the data collected and are judged against agreed-upon standards. In addition, feedback must be given to a Member on the outcome of its being monitored for policy compliance in a timely manner. Information must be given in a constructive way with the idea that the results are intended to assist a program improve.

Policy makers need the results of the evaluations of policy in order to amend policy, adopt new policy or repeal policy as appropriate. Their conclusions will need to be based on standards, analysis and interpretation, as well as professional judgment. The OPTN/UNOS Committees have received various components of compliance monitoring data, including reports of Review Boards activities and special cases, improper listing of candidates, organ payback issues and many others. This information not only helps the Committees understand how some of the issues are confronting the country as a whole, but how allocation policy may have to be amended. Individual Members receive timely feedback on potential compliance problems. Feedback on allocations is given within the next quarter, and feedback on a site survey is given within weeks of the visits. Some feedback is immediate. For example, if an OPO is working with the Organ Center to place an organ, the Organ Center will advise the OPO if there is a potential policy violation in the course of action the OPO wants to take.

The scope of the evaluation plan requires an explanation of several areas of operation within the OPTN. Monitoring Member compliance with policies and by-laws is a coordinated effort throughout many different processes, including:

1. adopting policies or amendments to policies;
2. modifying the computer system to reflect change in policy, regulation or law;
3. evaluating Membership applications or applications for designated centers; and,
4. reviewing data, both on-site at the Member location and as submitted by the Member to the OPTN.

b. Policy Development and Implementation
Through the OPTN/UNOS's committee system and committee composition, public comment protocol and policy development protocols, stakeholders have several opportunities to be engaged in the process to formulate policy.

Organ Procurement and Transplantation Network (OPTN)/United Network for Organ Sharing (UNOS) Board of Directors. The OPTN/UNOS Board of Directors (BOD) is responsible for developing and implementing, with the advice of the OPTN Membership and other interested parties, policies and standards within the mission of the OPTN. The process for this effort is depicted in **Chart 1, Policy Development Process**. Throughout the process, stakeholders are engaged, whether through the committee process, public comment, etc.

Formulation. Proposals for new or modifications to existing policies or standards are developed by or submitted to one or more of the OPTN/UNOS Committees. Any interested party may forward proposals directly to the Committee Chair or through the President of the OPTN/UNOS Board of Directors or other OPTN Principal Officers or their respective representatives. Proposals may be distributed to one or more Committees as appropriate. Data, analyses, and other information deemed relevant by the reviewing Committees to assess the merits and

disadvantages of proposals are provided by the organizations awarded contracts to operate the OPTN and the Scientific Registry of Transplant Recipients (SRTR). In developing allocation policy, such data (stratified by appropriate and feasible geographic units) include transplant volumes, inter-transplant program organ-specific analyses, risk-adjusted total life-years pre- and post-transplant, risk-adjusted post-transplant recipient and graft survival rates, risk-adjusted waiting time, risk-adjusted transplantation rates, performance of OPOs, performance of the OPTN contractor, and/or other data determined to be appropriate by the reviewing Committees. One charge to the Committees is to select performance indicators to measure the effect of the proposal, using baseline data to indicate how the current policy is performing and projected data to estimate results from the policy proposal. Review of such information may result in additional questions and the need for further study and analysis, dismissal of the proposal, or formulation of a proposal that is approved by the Committee.

In developing policy proposals, the OPTN/UNOS Committees assess and articulate the particular objectives the proposal is intended to achieve. The Committees also develop performance measures for use following implementation of a proposal to evaluate how well the policy is accomplishing the stated objectives. Policy performance measures may include, for example (but without limitation), one or more of the following: risk-adjusted total life years pre- and post-transplant, risk-adjusted recipient and graft survival rates following transplantation, risk-adjusted waiting time, risk-adjusted transplantation rates, days hospitalized pre- and post-transplant, days in intensive care unit (ICU) pre- and post-transplant, quality of life post-transplant, organ ischemic time, organ discard rates, and organs procured per donor.

Evaluation. Before a policy proposal is submitted to the Board of Directors for consideration, it is distributed for public comment. Exceptions to this general rule include: matters that require immediate action due to patient health and safety factors, proposals that clarify or correct existing policy rather than substantively change policy, and proposals that are otherwise administrative versus substantive in nature. The period for public comment is 45 days, or a shorter period as may be appropriate in light of relevant time constraints or other intervening events, while still providing realistic opportunity to receive and reply to the information. Proposals issued for public comment are distributed via posting to the OPTN Web site, http://optn.transplant.hrsa.gov, and/or mailing to a list of individuals including all OPTN Members and interested persons who request to be placed on the list. Public comment proposals also shall be distributed for discussion at meetings of the Regions[1], as feasible.

Proposals issued for public comment are accompanied by briefing papers that provide historical information and rationale to help explain the intent and function of the proposal as well as any issues that were considered in developing the proposal. Proposals addressing allocation policy specify which organ or combination of organs the policy is applicable. Proposals include an executive summary of the policy rationale and how the proposal meets requirements of the OPTN

[1] Regions are defined in the OPTN Bylaws as: Region 1 - Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont; Region 2 - Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania, Northern Virginia, West Virginia; Region 3 - Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, Puerto Rico; Region 4 - Oklahoma, Texas; Region 5 - Arizona, California, Nevada, New Mexico, Utah; Region 6 - Alaska, Hawaii, Idaho, Montana, Oregon, Washington; Region 7 - Illinois, Minnesota, North Dakota, South Dakota, Wisconsin; Region 8 - Colorado, Iowa, Kansas, Missouri, Nebraska, Wyoming; Region 9 - New York; Region 10 - Indiana, Michigan, Ohio; and Region 11 - Kentucky, North Carolina, South Carolina, Tennessee, Virginia (excluding Northern Virginia).

Final Rule, 42 CFR Part 121. Section V below provides guidance for issues that may be addressed by the reviewing Committees and included in policy briefing papers as appropriate.

In the deliberation of policy proposals, OPTN/UNOS Committees consider whether to recommend as mandatory, *i.e.,* designated by the Secretary of HHS as covered by Section 1138 of the Social Security Act; voluntary, *i.e.,* not designated by the Secretary as covered by Section 1138 of the Social Security Act; or adopted into HHS regulation. Recommendations from the Board to make a policy mandatory must be approved by the Secretary or the policy remains voluntary. Compliance with OPTN Policies determined to be voluntary shall be monitored by the OPTN and pursued in accordance with applicable provisions of the OPTN Bylaws.

Public comments received by the close of the public comment period are reviewed and responded to by the reviewing Committees. Comments received after the response deadline may be reviewed and responded to at the discretion of the Chairs of the reviewing Committees. Following consideration of the comments and receipt of any additional information requested by the Committees, the Committees modify the proposal as appropriate, including dismissal of the proposal for further consideration. The policy briefing paper is updated to include responses to the public comments and the final proposal.

Adoption. Recommendations for new or modifications to existing policy are offered to the OPTN/UNOS Board of Directors for deliberation and action. The Board of Directors may approve the recommendation without amendment, approve the recommendation with amendment, disapprove the recommendation, refer the recommendation back to the reviewing Committees or to other Committees or sources for additional consideration, or take such other action as the Board deems appropriate. The OPTN/UNOS Executive Committee can also consider recommendations in the interim and act upon them between meetings of the Board of Directors and on behalf of the Board subject to final determinations by the full Board.

(a) Policies approved by the Board of Directors with or without amendment and recommended to be enforced as mandatory policies or otherwise directed for submission to the Secretary of HHS are forwarded to the Secretary for review and comment in accordance with Section 121.4(b)(2) of the OPTN Final Rule and at least 60 days prior to their proposed implementation. The Secretary may solicit guidance from the Secretary's Advisory Committee on Organ Transplantation in accordance with the OPTN Final Rule. Policy documentation shall include the background information and rationale used in developing the proposal (updated as may be necessary to reflect additional deliberations of the Board of Directors). Depending upon the results of the Secretary's review and action, such policies may be referred back to the OPTN/UNOS Board of Directors and/or reviewing Committees for additional deliberation and recommendations in accordance with the Secretary's direction or implemented in accordance with the implementation procedures described below.

(b) Policies approved by the Board of Directors with or without amendment and recommended for voluntary status without direction otherwise from the Secretary are implemented in accordance with the procedures described below.

(c) Proposals disapproved by the Board of Directors or referred for additional input are forwarded to the appropriate Committees or other source as indicated by the Board's action.

Implementation. Policies finally approved by the OPTN/UNOS Board of Directors are implemented pending incorporation into the UNet^{SM} computer allocation and matching algorithm, as necessary, and appropriate notice to OPTN Members and the Secretary of the new or modified policy using, for example, mailings, newsletters, or the Internet. Such policies are also posted to the OPTN Web site at http://optn.transplant.hrsa.gov.

Post Implementation Assessment. OPTN Policies are re-evaluated periodically by the applicable reviewing Committees using performance measures established by the Committees, in an effort to assess whether they are meeting stated objectives and in light of applicable scientific and technological advances. Depending on the outcomes of these assessments, proposals for additional policies or further modifications to existing policies may be formulated consistent with the policy evaluation process described above.

The Policy Oversight Committee also has as one of its specific charges, a review of all existing policies. Part of the review includes exploring issues such as:

- Does the policy state the intended goal/purpose of the policy?
- Is the policy being monitored to assess if it is meeting that goal?
- Is this policy relevant to what the OPTN is currently doing? Does it still fit within the policy now?
- Does the policy meet the performance measures from the OPTN Final Rule?
- Does the policy appear to contribute to the goals of the OPTN?
- Is it possible to determine the effect of modifying the policy?

The Policy Oversight Committee reports to the Board of Directors at each Board meeting.

Guidelines for issues to consider in allocation policy development. The following are guidelines for issues to consider in developing OPTN organ allocation policies:

- Listing and de-listing criteria used in the proposal, including medical bases and analyses used in their development.
- Organ allocation system, including categories for prioritizing transplant candidates, whether they are based on medical urgency or not, and their medical basis and supporting research and medical practice.
- Geographic unit(s) used for allocating organs, addressing how criteria such as place of candidate residence or place of listing are attempted to be overcome by geographic allocation unit definition, in light of considerations including, for example, organ ischemic time, logistical matters, availability of specialized transplant and post-transplant care, and other constraints that result from available medical science.
- Overall allocation protocol, demonstrating how organs are allocated according to degrees of medical urgency or other relevant categories within appropriate geographic unit(s) consistent with the following factors (if not sufficiently addressed in other sections): sound medical judgment, best use of donated organs, preservation of physician judgment in declining organ offers or use for the potential recipient, suitability for the specific organ or combination of organs, avoidance of organ wastage and futile transplants and promotion of candidate access to transplantation and efficient management of organ placement, periodic review and revision as

appropriate, and disassociation with candidate's place of residence or place of listing as feasible in light of the previously listed elements.

- Considerations of access and socio-economic equity, including how the proposal addresses/reduces any ethnic barriers to transplantation, any disparities on the waiting list by ethnicity, pediatric candidate access to transplantation, and any other barriers to transplantation such as those resulting from economic factors.
- Review mechanisms to promote and assess policy compliance, including prospective review protocols, as appropriate, retrospective review protocols, educational measures, and appropriate actions that might be recommended to the Secretary of HHS in the event of non-compliance.
- Transition provisions to address candidates on the waiting list under the former policy and their equitable treatment under the policy proposal, including anticipated impact of the proposal on these candidates and preservation of their former priority, within reasonable limits and to the extent appropriate.
- Performance indicators and evaluation components of the policy, including the performance indicators to be used to evaluate the policy's effect and their bases, the measure(s) for the performance indicators, baseline data for evaluating performance of the current policy using the indicators, projected data showing expected benefit from the proposal with respect to the performance indicators, and a plan for periodic review to assess effectiveness of the policy in achieving its goals.
- Consideration for experimental systems that test methods of improving organ allocation (variances), including an assessment of whether they are accompanied by a research design and include data collection and analysis plans and time limitations, standards/parameters for approving variances, and a determination of whether existing variances would be continued under the policy proposal.

c. OPTN System Modifications Procedures

The second area of critical importance in understanding how compliance is measured is by understanding that many of the policies of the OPTN have built-in checks and cross-checks through their programming. Most policies are adopted pending the modification of the computer system for matching donors and candidates. It is the first step in implementing policies passed by the OPTN/UNOS Board of Directors as authorized or required under the Final Rule. The computer programming is frequently the only step in implementing policy. Once the computer algorithm is modified, what remains to be done is compliance monitoring. This monitoring may be assisted with additional programming.

The following is a detailed description of the current procedures for handling any candidate waiting list or donor match modification approved by the OPTN/UNOS Board of Directors. **Chart 2, OPTN System Modifications Procedures,** shows the details of this process**.**

<u>Submission</u>
Modifications to any organ waiting list, placement or match system must be first presented to and approved by a sponsoring OPTN/UNOS Committee. Preliminary meetings with appropriate staff and/or external Members may be held to discuss the item in detail. The IT Development staff develops a detailed specification document (DSD) for each request. Questions and/or issues must be resolved before the DSD is finalized. This may include sending issues back to the full committee or a subcommittee within the sponsoring committee for resolution, such as the Implementation Subcommittee for the organ-specific committees.

Coding
The scheduling of programming time is dependent upon whether or not the source code requiring the modification is currently being modified for another work order. IT determines the estimated testing date and an estimated date of implementation for the item. When the programming of the system modification is complete, the code undergoes peer review and is tested by one or more developers. Once the code has passed development testing and code review, the testing stage begins.

Testing
The Committee Liaison is notified of the scheduled testing period and estimated date of implementation. Once the IT Testing Coordinators complete their testing and the results are successful, an IT Testing Coordinator notifies any external beta testers by e-mail. The beta testers' accounts are set up on a testing site and each beta tester is provided a step-by-step test plan to follow. This testing site is independent and separate from the production systems. Beta testers are notified where and how to test the modification. They are given the e-mail address and phone number of the IT Testing Coordinator to contact if they have any questions or problems with testing. The beta testers are e-mailed a testing sign-off form.

Once the beta testing has been completed and is successful meeting their expectations, the beta testers must sign and have their Executive Director sign the testing sign-off form and fax it back to the IT Testing Coordinator. If the beta testing involves more than one OPO, Transplant Center or Lab, all testing sign-off forms must be received prior to an implementation date being set. IT notifies all necessary UNOS staff, including the Committee Liaison and/or Regional Administrator(s), when testing is completed.

Implementation
The implementation date is determined by when the testing sign-off has been received in relation to the next scheduled production release. With alternative organ distribution/allocation systems, Transplant Centers and/or Labs requesting the modifications are contacted to determine when would be an appropriate date to implement the programming modifications for them. Determining the actual implementation date may require coordination between any or all of the following: OPOs, involved Labs and Transplant Centers, Policy, Regional Administration, Committee Liaison, Organ Center, Evaluation and Quality, and IT.

Once an implementation date is determined, the appropriate OPTN Members and UNOS staff are notified of the implementation date. A final announcement and system notice are distributed. The Committee Liaison or Regional Administrator distributes the final announcement. This announcement may include only a tentative implementation date or no implementation date and refer the recipient to the system notice to be distributed prior to actual implementation. The Manager of Technology Communications distributes the system notice, and the modification is implemented by 9:00 a.m. Eastern time on the scheduled implementation date.

Post-Implementation Monitoring
Once a modification is implemented, IT QA staff provides an additional layer of monitoring to ensure the modifications are working as intended and expected. This monitoring includes daily reporting of specific data within the system for matching donors and recipients.

III. INTERESTED AND AFFECTED ENTITIES*

a. Members. The OPTN includes both organizations and individuals as Members. Members may be directly involved in the procurement of organs for transplantation and/or the care of candidates in need of transplantation; engaged in the delivery of some activity or service related to organ donation or transplantation; or otherwise actively interested in and involved with the fields of organ donation or transplantation, as evidenced by criteria described below.

i. Membership Requirements. OPTN Members are grouped into five categories. These include Institutional Members, Medical/Scientific Members, Public Organization Members, Business Members, and Individual Members.

Institutional Members includes:

- Organ procurement organizations (OPOs) designated as such by the Secretary of HHS,
- Hospitals that perform organ transplantation and participate in the Medicare or Medicaid programs (Transplant Hospitals), and
- Histocompatibility laboratories that serve at least one active Transplant Hospital and are independent from their Transplant Hospital(s) (Histocompatibility Laboratories).

Hospitals may have as a component of their memberships either a hospital based histocompatibility laboratory or a hospital-based organ procurement organization.

Medical/Scientific Members includes non-profit medical or scientific Membership organizations whose Membership includes professional Members involved in organ transplantation; or non-profit organizations or institutions supported by letters of recommendation from other organizations that meet criteria for OPTN Institutional Membership.

Public Organization Members includes

- non-profit organizations that engage in organ donation activities or represent or provide direct support or services to transplant candidates, recipients, or their families;
- non-profit organizations or institutions supported by letters of recommendation from other organizations that meet criteria for OPTN Institutional or Public Organization Membership; or
- hospitals that participate in the Medicare or Medicaid programs and refer at least one potential organ or tissue donor per year for donation.

Business Members includes organizations that engage in commercial activities with two or more active Institutional Members. Business Members are the only category of OPTN Membership with no voting privileges in OPTN affairs.

Individual Members includes persons who meet one of the following criteria:

* In an effort to assist readers easily identify updates to the Evaluation Plan within the "Interested and Affected Entities" section, updates to the section will be highlighted in blue. Information that no longer applies will be removed from the section and will not appear in any form.

- Have served or are presently serving on the OPTN/UNOS Board of Directors, or an OPTN/UNOS Committee;
- Are themselves or are family Members of a transplant candidate, transplant recipient, or organ or tissue donor;
- Are presently employed by or are independent contractors with OPOs, Transplant Hospitals, or Histocompatibility Laboratories;
- Were formerly employed by or were formerly independent contractors with OPOs, Transplant Hospitals, or Histocompatibility Laboratories;
- Were formerly employed by Federal or State government agencies involved in the field of organ donation and transplantation, and demonstrate continued active interest in and involvement with the fields of organ donation or transplantation; or
- Are individuals who otherwise have an interest in and involvement iwht the fields or organ donation or transplantation demonstrated by letters of recommendation from other persons who meet criteria for Individual Members.

ii. Member Obligations. By accepting Membership in the OPTN, Members agree to comply with all applicable provisions of the National Organ Transplant Act, as amended, 42 U.S.C. 273 *et seq*.; OPTN Final Rule, 42 CFR Part 121; and OPTN Bylaws and Policies as in effect from time to time. Members also agree to submit to reviews (including on-site reviews) and requests for information as may be necessary to determine compliance with the aforementioned requirements. Failure to comply shall be cause for corrective action as described in Section VI below. Members agree in responding to any adverse ruling related to their Membership in the OPTN to exhaust the administrative remedies afforded by the OPTN Bylaws and applicable Federal regulations before resorting to formal legal action. Members further agree that information involved in these processes may be released to HHS. OPTN Members are invited and encouraged to participate in OPTN activities through Committee service, consultation with Members of Committees and the Board of Directors, and participation at Region meetings.

b. Regions. UNOS has divided the country into 11 regions. Each region is assigned a Regional Administrator and has a review board for liver and for thoracic organs. Each Review Board may, if necessary, meet twice per year to discuss UNet[SM] system changes,

i. Regional Review Board Role

The Regional Review Board (RRB) process was implemented to establish a peer review system whose primary purpose is to determine the appropriateness of urgent status listings, exceptional points, estimated values or specific diagnosis for liver, lung[*], and heart candidates. RRB Members review all candidate requests for exceptions or high status listings in a blinded format. The RRB Members only review objective clinical data to make a determination about the appropriateness of the listing.

ii. Regional Review Boards' Responsibilities

The Regional Review Board is responsible for determining whether a listing is appropriate and it has the ability to deny a request for additional points or a more urgent status. If the request is denied, the listing Transplant Center may

1) appeal the decision;

[*] Exceptional scores, estimated values and/or specific diagnosis are submitted to the National Lung Review Board for review and determination.

2) withdraw the request; or
3) downgrade the candidate to an appropriate status on the waiting list.

The listing center is provided with the review board members' comments if the request is denied.

If the listing center chooses to appeal, the process allows for further review by the same Regional Review Board after the listing center provides more information to support the request. Should the case again be denied a conference telephone call affords the review board members an opportunity to speak directly with the listing or attending physician.

If after a conference call with the review board the listing is again denied, the Transplant Center has the option of

1) withdrawing the request;
2) appealing to the organ specific committee; or
3) downgrading the candidate.

If the candidate has been transplanted during the appeals process and the matter was again denied by the review board, the request will be referred to the appropriate organ specific committee for further review.

c. Membership and Professional Standards Committee (MPSC)

i. Role. The Membership and Professional Standards Committee (MPSC) advises the Board on issues regarding initial qualification for Membership in the Organ Procurement and Transplantation Network (OPTN) and continued qualification for Membership. The MPSC reviews Membership applications, monitors OPOs, transplant centers and histocompatibility labs for ongoing compliance with OPTN Membership criteria and policies, and reviews their performance. The MPSC also manages due process procedures regarding adverse actions it recommends, under a confidential medical peer review system.

ii. Responsibilities. The MPSC is charged with ensuring that OPTN/UNOS member transplant centers, organ procurement agencies, tissue typing laboratories, and non-institutional members meet and remain in compliance with OPTN/UNOS criteria for membership.

To accomplish this, the MPSC:

- Develops and recommends membership criteria for each class of membership to the Board of Directors
- Recommends additions and revisions to membership criteria as needed
- Reviews each membership application for Institutional Membership and adopts recommendations for Board action
- Reviews transplant program performance including outcomes and activity levels
- Monitors member compliance with OPTN/UNOS Policy and Bylaw requirements
- Reviews reported policy violations and makes recommendations to the Board

iii. Committee Action. The MPSC utilizes two standing subcommittees, the Data Subcommittee and the Policy Compliance Subcommittee, to fulfill its charges of peer review and monitoring. All Committee members are appointed to one of the standing subcommittees.

The **Data Subcommittee (DSC)** is charged with monitoring transplant program performance. This is accomplished by using clinical outcome and volume triggers for inquiry relating to one-year post-transplant patient and graft survival rates and periods of inactivity.

- *Survival Rates*: The DSC monitors all kidney, liver, heart, and lung transplant programs for outcomes using reports provided by the Scientific Registry of Transplant Recipients (SRTR). The reports detail each program's expected survival rates and observed survival rates and provide an indication of statistical significance.

  The Data Subcommittee conducts an inquiry into transplant program operations if a program has lower than expected outcomes. Data Subcommittee members review program responses and request details regarding quality improvement efforts. The MPSC may recommend a peer visit by a team of transplant professionals (surgeon, physician, administrator) to encourage performance improvement. The team reports its findings to the Data Subcommittee and the MPSC. The MPSC in turn reports to the Member Center.

  If a program performs too few transplants to be analyzed as described above, the Data Subcommittee conducts inquiries into those instances in which nine or fewer transplants are performed by a program in a consecutive two and a half year period and there has been at least one death or graft failure.

- *Inactivity*: OPTN/UNOS Bylaws and Policies require, as a condition of membership, that all institutional members (including transplant hospitals) be active in the field of transplantation. A program is considered to be functionally inactive if a transplant has not been performed during a designated time period. The period of review for kidney, liver, and heart transplant programs is three months; pancreas and lung programs is six months; and stand alone pediatric hospitals is 12 months. The DSC considers changes in key personnel when reviewing program activity levels and routinely requests that programs provide a plan for future program performance.

The **Policy Compliance Subcommittee (PCSC)** is charged with ensuring that Members comply with OPTN/UNOS Policies and Bylaws and reviews potential violations. The PCSC conducts confidential medical peer review of potential violations identified through routine surveys conducted by UNOS staff, allocation analyses, metrics analyses, Regional Review Board cases, the Patient Safety System, and Member and patient complaints. The PCSC evaluates each potential violation to determine its severity and whether it is an indication of continued noncompliance. Based on its review, the PCSC may recommend action against the Member to the full MPSC.

iv. Peer Review. MPSC work is conducted using the **confidential medical peer review process**. This process assures quality patient care by *developing consensus recommendations and feedback from peers to achieve collective compliance* with applicable standards or policies. This peer review process is fundamental to the OPTN/UNOS system for evaluating membership applications and monitoring and enforcing member compliance and performance. The Committee focuses on working with members to achieve voluntary compliance. The sanctions described in the Bylaws may be utilized to achieve compliance with policies when voluntary actions are unsuccessful. Confidentiality of medical peer review is assured to the extent permitted in the Bylaws, while also assuring the Secretary's

access to information when and in the format the Secretary of the Department of Health and Human Services (DHHS) requests.

The evaluation of all applications is a peer review function. Several of the criteria for Membership are subjective and it is up to the Committee to interpret the standard and determine if the applicant meets the criteria. Generally four Committee Members with expertise in that particular field review each new member/program application as a subcommittee and render an interim determination on the application. Recommendations for interim approval are reported to the full MPSC at its next meeting as consent agenda items. Recommendations for "approval pending" or "incomplete" will be placed on the discussion agenda for the full Committee. The entire Committee votes after receiving these reports. Subcommittees are comprised, whenever possible, of specialists for that particular organ. Anyone who trained the applicants or is in the same region excuses himself from the process. Likewise, when a non-institutional Member is being considered for Membership, the representatives from non-institutional Members and/or candidates, donor families, or recipients may conduct the review.

The MPSC discusses any potential issues of non-compliance in a confidential, medical peer review process that includes notification of the OPO, transplant center or histocompatibility lab involved and solicitation of additional information from the Member. The peer review process is a standard of medical fact-finding. Confidentiality is maintained to provide an environment conducive to full disclosure by the parties involved. Confidentiality is also maintained to prevent release of any information that may be incomplete or inaccurate or may violate the privacy rights of specific transplant candidates or donors. UNOS cannot publicly disclose the specifics of any such review unless a final action is taken and unless the OPTN/UNOS Board of Directors approves a public release of information. Moreover, peer review is always conducted pursuant to the procedural due process or Member's rights and is triggered when the MPSC is considering taking an adverse action against the Member.

Although the main goal of the process is to ensure equitable organ allocation by bringing OPOs, transplant centers, and histocompatibility labs into compliance, MPSC actions may include requiring corrective action plans; requiring additional monitoring at the Member's expense; or recommending that the OPTN Board of Directors declare the Member "Not in Good Standing" (public disclosure that a Member is out of compliance after due process has been followed). Based on MPSC findings of non-compliance, Members may choose to take additional actions on their own initiative. Changes that have come about as a result of MPSC action include: conducting internal audits; suspending operation of transplant programs while corrections are being made and closing transplant programs when necessary; changing key transplant program personnel; implementing improved medical record keeping systems. Other potential implications of MPSC actions could include: referral to HHS for consideration of the whether the hospital's eligibility for Medicare and Medicaid reimbursement should be terminated; notification about the infraction to the state department of health and patients of the center involved; the loss of professional reputation or standing for either a transplant institution or senior transplant professionals.

d. Board of Directors

i. Role. The OPTN Board of Directors governs the OPTN and is responsible for developing policies and criteria within the mission of the OPTN. The Board of Directors is composed of various individuals with an interest in organ transplantation including physicians, transplant candidates, transplant recipients, organ donors and family Members,

representatives of OPOs, transplant hospitals, public organizations, transplant coordinators, histocompatibility experts, non-physician transplant professionals, and the general public. (OPTN Final Rule §121.3). To the extent practicable, these Members represent the diversity of the population served by the OPTN.

ii. Responsibilities. The Board of Directors sets the priorities and goals for the OPTN/UNOS Committees and is responsible for approving all proposed modifications to organ allocation policies and alternative allocation systems. The Board of Directors provides opportunities for public comment on such proposed policies and takes into account the comments received in developing and adopting policies for implementation by the OPTN. (OPTN Final Rule §121.4). The Board of Directors also provides to the Secretary, proposed policies it recommends to be enforceable under Section 1138 of the Social Security Act, however, these policies will not be enforceable until approved by the Secretary. (OPTN Final Rule §121.4). The Board of Directors makes copies of policies available to the public as they are adopted, and continuously maintains OPTN Policies for public access via the Internet (OPTN Final Rule §121.4).

iii. Peer Review. The Board presently meets regularly four times each calendar year, and may have other meetings as necessary. Portions of meetings of the Board of Directors convened to address activities of the OPTN involving confidential matters are reserved for closed sessions as appropriate and consistent with applicable laws and regulations. Such confidential matters include medical peer review, OPTN Member admission, credentialing, monitoring, and/or disciplinary matters. Consistent with the overwhelming authority of state statutes and Federal common law providing protection for confidential medical peer review, the Board will treat as confidential all pre-decisional traditional peer review proceedings. The Board will only disclose these materials to the Secretary and his agents upon request pursuant to the requirements of § 121.11 of the OPTN Final Rule. The Board will treat the OPTN's medical peer review proceedings with the same strict confidentiality customarily accorded to traditional peer review to the fullest extent provided under federal and state laws.

Within the disciplinary process, the Board of Directors possesses an integral role. The Board may be requested to act upon reports from the Membership and Professional Standards Committee following disciplinary hearings and will consider the same and affirm, modify, or reverse the MPSC recommendation or action in the matter. In the event the applicant, or Member, exercises its rights to appellate review under By-law 3.03A, the Board provides appellate review of the decision of the MPSC and if necessary, the Board will make appropriate recommendations to the Secretary of the Department of Health and Human Services.

IV. MEMBERSHIP CRITERIA AND EVALUATION OF APPLICATIONS*

Another area that overlaps with adopting policies and programming them is the evaluation of applications for Membership, status as a designated transplant program, and changes in key personnel. How policies are established and programmed on the UNet℠ computer system has been illustrated. This section describes criteria for OPTN Membership and designation as a transplant program, which is required to enable receipt of organs for transplantation, as well as the applicable application processes. Reviewing applications to ensure that they meet Membership criteria is one of the first "compliance" procedures a Member undergoes. **Chart 3, Application and Hearing Procedures for Members and Designated Transplant Programs,** outlines the Membership application process.

a. Organ Procurement Organizations

i. General Requirements. An OPO must be designated as an organ procurement organization by the Secretary of HHS under Section 1138(b) of the Social Security Act. OPOs may have independent membership or they may be approved as a hospital based OPO under the membership of the transplant hospital. In addition, OPOs must meet the following requirements:

ii. Key Personnel. OPOs must identify and maintain key personnel. These include an Executive Director and, if the OPO chooses, a Medical Director. Changes in key personnel must be reported to the OPTN at least 30 days (if possible) in advance, along with the name of the individual's replacement and credentials.

iii. Plan for Public Education on Organ Donation. OPOs must submit to the OPTN written descriptions of their activities regarding public education about organ donation.

iv. Communication of Information for Organ Donation. OPOs are responsible for equitable organ allocation within their respective service areas according to OPTN Policies. OPOs must be able to communicate in a timely manner appropriate information necessary to facilitate equitable organ distribution as well as perform other functions necessary to discharge their responsibilities regarding organ allocation.

v. Donation after Cardiac Death (DCD): OPOs must develop, and once developed must comply with, protocols to facilitate the recovery of organs from DCD donors.

vi. Definition of Independence. While not a condition of Membership in the OPTN, OPOs must be independent of the Transplant Hospitals they serve in order to vote on OPTN affairs. An OPO is independent if it has a distinct governing body separate and not under the direct or indirect control of the governing body of any of its Transplant Hospitals or of the governing body of a commonly controlled group of its Transplant Hospitals.

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* In an effort to assist readers easily identify updates to the Evaluation Plan within the "Membership Criteria and Evaluation of Applications" section, updates to the section will be highlighted in blue. Information that no longer applies will be removed from the section and will not appear in any form.

b. Transplant Hospitals.

i. General. A Transplant Hospital must perform organ transplants or have submitted an active application for designated transplant program status for at least one organ type, and participate in the Medicare or Medicaid programs. In addition, in order to receive organs for transplantation, transplant hospitals must be an OPTN Member Transplant Hospital and shall abide by applicable provisions of the National Organ Transplant Act, the OPTN Final Rule, and OPTN Bylaws and Policies, and shall meet the following:

- Approved as a transplant program by the Secretary of HHS for reimbursement under Medicare,
- A transplant program in a Department of Veterans Affairs, Department of Defense, or other Federal hospital, or
- Qualified as a transplant program in accordance with the following requirements:

  - Facilities and Resources. The program's Transplant Hospital must allocate sufficient operating and recovery room resources, intensive care resources, and surgical beds and personnel to the transplant program.
  - Remain functionally active. See "Inactive Programs" under Transplant Hospitals below.
  - OPO Affiliation. The program must have letters of agreement or contracts with an OPO.
  - Histocompatibility Laboratory Affiliation. The program must use, for its histocompatibility testing, a laboratory that is approved for OPTN Membership and meets the standards for histocompatibility testing described under Histocompatibility Laboratories. The laboratory may be either a member of the OPTN itself, or have approval as a hospital based lab under the transplant center's membership.
  - Key Personnel: Transplant Surgeon and Physician. See "Key Personnel" under Transplant Hospitals below.
  - Report Changes in Key Personnel. See "Key Personnel" under Transplant Hospitals below.
  - Collaborative Support. The program must show evidence of collaborative involvement with experts in the field of radiology, infectious disease, pathology, immunology, anesthesiology, physical therapy and rehabilitation medicine, histocompatibility and immunogenetics, and, as appropriate, hepatology, pediatrics, nephrology with dialysis capability, and pulmonary medicine with respiratory therapy support.
  - Ancillary Services. The program must have immediate access to sophisticated microbiology, clinical chemistry, histocompatibility testing, and radiology services, as well as facilities required or capacity for monitoring immunosuppressive drugs.
  - Blood Bank Support. The program must have extensive blood bank support, including access to large quantities of blood.
  - Social Support. The program must have access to mental health and social support services.
  - Pancreatic Islet Transplantation. To receive pancreata for islet transplantation, programs must meet separate facility, reporting, ancillary personnel,

collaborative support, and regulatory compliance requirements in addition to meeting the above criteria.

ii. **Survival Rates.** The OPTN, through the Membership and Professional Standards Committee, evaluates Transplant Hospitals according to a defined algorithm to identify institutions that have experienced low one-year transplant survival rates compared to the expected survival rates for that program. The Data Subcommittee requested that the Scientific Registry of Transplant Recipients identify a method that could be used to analyze a program's one-year graft and/or patient survival rates, with adjustments made for the case mix of the patient population. The Scientific Registry of Transplant Recipients provides the Membership and Professional Standards Committee with a report detailing outcomes for all transplant programs for each Committee meeting (four times a year). This report provides organ specific information on the number of transplants performed during the evaluation period; the number of patients who have undergone transplantation; the observed number of graft failures and deaths; the expected number of graft failures and deaths; actual and expected survival rates; and a measure of statistical significance (p-value). Programs identified for further review by the Membership and Professional Standards Committee must meet all of the following criteria: (1) p-value less than 0.05, (2) observed minus expected events greater than three, and (3) observed divided by expected events greater than 1.5. If a transplant program is identified as meeting all three criteria during a two-and-a-half year period, either for graft survival, patient survival, or both, the Membership and Professional Standards Committee will send an inquiry to the center.

Using the Scientific Registry of Transplant Recipients methodology, transplant programs that have a small volume of activity (performing nine or fewer transplants in a two-and-a-half-year interval) are rarely identified as having outcomes that are significantly below expected. Therefore, the Data Subcommittee must systematically review these small volume programs. To do so, the Scientific Registry of Transplant Recipients provides the Membership and Professional Standards Committee with a report listing all small volume programs that experienced at least one death and/or graft failure within one year of transplant during a specified time period for evaluation. The Data Subcommittee then reviews the raw data on patient outcomes using blinded transplant data the program has entered into UNet^{sm}. These data included transplant volume summaries, causes for death/and or graft failure, comparisons to national survival statistics, and performance in years subsequent to the initial period of review.

The graft and patient survival rates of all transplant programs, both large and small volume, are reviewed by the Membership and Professional Standards Committee at each Committee meeting. The review of these hospitals determines whether their outcomes are accounted for by candidate mix or some other unique clinical aspect of the transplant program in question. Programs that are identified for further review will be requested to provide information regarding the program staff as well as a synopsis of the graft failures and/or deaths. Programs will continue to be reviewed by the Membership and Professional Standards Committee until improvements in one-year survival rates have been demonstrated in subsequent years.

iii. **Inactive Programs.** Transplant Hospitals are expected to inform their candidates on the waiting list if there will be an extended period of time when a designated transplant program will be unable to perform transplants. Transplant Hospitals that fail to remain functionally active with respect to any designated transplant program have the option of

(i) voluntarily inactivating that transplant program for up to 12 months, or (ii) relinquishing designated transplant program status for the program. "Functionally inactive" (for the purposes of this provision) is defined as the inability to serve patients, as a group, for a sustained and significant time period. A period of 15 days or more is presumed to be sustained and significant.

iv. **Functional Inactivity Review.** The Membership and Professional Standards Committee reviews program activity rates for all Transplant Hospitals. Programs are considered to be functionally inactive if a transplant has not been performed during a specified interval. The period of review for kidney, liver, and heart programs is three months. Pancreas and lung programs are reviewed on a six-month basis. Stand-alone pediatric hospitals are reviewed on a yearly basis. The Membership and Professional Standards Committee is concerned that such programs may not meet requirements for being active in the field of organ transplantation, which may result in the members of the transplant team not maintaining a current working knowledge. The audit is conducted in a blinded manner and requests that the program identify how the staff is maintaining a current working knowledge in organ transplantation and the reasons for inactivity. The Membership and Professional Standards Committee will review the center's response to determine if further inquiry is required. Transplant programs identified to be functionally inactive may be encouraged to either voluntarily inactivate or relinquish designated transplant program status for the program until the circumstances affecting the status of the program have been resolved.

v. **Program Inactivation/Relinquishment of Active Status.** Upon inactivating a transplant program or relinquishing the program's status as a designated transplant program, the program must (i) promptly suspend transplantation, (ii) notify its candidates in writing, providing a copy to the OPTN, of the need for inactivation and removal of candidates from the program's waiting list or, if a candidate desires, transfer to the list of another OPTN Member Transplant Hospital, and (iii) assist its candidates in identifying designated transplant programs to which they can transfer.

vi. **Key Personnel.** Key personnel requirements differ to some degree depending upon the pathway by which a transplant program qualifies to receive organs for transplantation. For any designated transplant program qualified to receive organs by virtue of (i) approval of the program by the Secretary of HHS for reimbursement under Medicare, or (ii) location of the program in a Federal Hospital, the Transplant Hospital must identify the primary surgeon and primary physician reported to the Center for Medicaid and Medicare Services (CMS) and demonstrate whether these individuals meet the requirements specified for primary surgeon and primary physician by the OPTN for designated transplant programs that do not qualify as a transplant program by virtue of the criteria listed under (i) or (ii) above (*i.e.*, approval for reimbursement under Medicare or location in a Federal Hospital).

For any designated transplant program that does not qualify to receive organs by virtue of approval for reimbursement under Medicare or location in a Federal Hospital, Transplant Hospitals must have key personnel who meet certain minimum levels of commitment to and knowledge of organ procurement and transplantation. Such key personnel include a primary surgeon and primary physician. Qualifications for these individuals include, but are not limited to:

- Completed Transplant Hospital credentialing process; individual is a current Member of the hospital in good standing.
- Licensed to practice medicine in his/her state; individual is accepted onto the medical staff of and on-site at the applicant Transplant Hospital.
- Certified (or achieved eligibility if applicable) by applicable surgery/medical Boards or their foreign (or other applicable) equivalent.
- Meets applicable requirements for training and/or experience, including without limitation, demonstration of competence and currency by performance of sufficient numbers of transplant procedures in the case of primary surgeon, and involvement with the primary care of sufficient numbers of transplant patients, in the case of primary physician.

Changes in key personnel must be reported to the OPTN at least 30 days (if possible) in advance of the effective date, along with the name of the individual's replacement, Curriculum Vitae, and information demonstrating and documenting compliance with OPTN criteria for a designated transplant program. This information should be submitted in the form of an application for Change in Key Personnel.

vii. Candidate Notification. Transplant Hospitals are expected to notify candidates in writing (i) that they either have been placed or have not been placed on the waiting list following their evaluation as a candidate for transplantation, and (ii) that they have been removed from the waiting list when removed for reasons other than transplantation or death. Documentation of the notifications is to be maintained and made available to the OPTN upon request. The notification must also include information about the Patient Services Hotline.

viii. Clinical Transplant Coordinators. A Transplant Hospital's transplant program(s) are encouraged to identify one or more Members of the transplant team who will be responsible for coordinating clinical aspects of candidate care. The coordinator works with candidates and their families beginning with the evaluation for transplantation and continuing through and after transplantation, in a compassionate and tactful manner to help facilitate access to and provide continuity of care. The coordinator also works with other members of the transplant team, including physicians, surgeons, nurses, social workers, financial coordinators, and administrative personnel. It is recommended that the transplant coordinator be a registered nurse or other licensed clinician who performs or oversees a team of other healthcare personnel and support staff in performing functions related to the evaluation of candidates for transplantation, and care of candidates accepted for and following transplantation.

ix. Financial Coordinator. Transplant Hospitals are encouraged to identify one or more Members of the transplant team who will be responsible for coordinating and clarifying candidate-specific financial aspects of care. The coordinator works with candidates and their families beginning with the evaluation for transplantation and continuing through and after transplantation, in a compassionate and tactful manner to help facilitate access to and provide continuity of care. The coordinator also works with other members of the transplant team, insurers, and administrative personnel at the Transplant Hospital. It is recommended that responsibilities of the coordinator include, for example, obtaining detailed candidate insurance benefit information for all aspects of the transplant process, serving as a resource for candidates and their families on financial matters, obtaining payor authorizations, and facilitating resolution of billing issues.

x. Transplant Mental Health and Social Support Services. Mental health and social support services are essential for the total care of transplant recipients, living donors and their families. Such services must be available. All transplant programs should identify appropriately trained individuals who are designated members of the transplant team and have primary responsibility for coordinating the psychosocial needs of transplant candidates, recipients, living donors and families. They will work with patients and families in a compassionate, culturally competent and tactful manner in order to facilitate access and provide continuity of care.

xi. **Routine Referral Procedures.** Transplant Hospitals are expected to implement and practice appropriate routine referral procedures for all potential donors, and demonstrate compliance based upon an annual medical record review performed in collaboration with their OPOs.

xii. Investigation of Personnel. A transplant hospital are expected to conduct an investigation of its personnel if so requested by the Membership and Professional Standards Committee, and report its final determination to the Committee in a way that is consistent with and protects the institution's own peer review process.

xiii. Donation after Cardiac Death (DCD). Transplant hospitals must develop, and once developed must comply with, protocols to facilitate the recovery of organs from DCD donors. Transplant Hospital DCD recovery protocols must address the required model elements.

c. Histocompatibility Laboratories.

i. General. To be a classified as a member a Histocompatibility Laboratory must be independent of the Transplant Hospitals it serves, which must include at least one Transplant Hospital active in the field of organ transplantation. Alternatively, a laboratory may be hospital based, in which case approval was granted under that of the transplant hospital. Histocompatibility Laboratories also must meet requirements for accuracy and completeness of testing as established from time to time by the OPTN/UNOS Board of Directors, as well as criteria for testing itself, including, for example, performing tests only at the written or electronic request of an authorized person or upon oral request followed by written authorization within 30 days and maintaining procedures in a manual with annual review. In addition, Histocompatibility Laboratories must meet the following requirements:

ii. Definition of Independence. A Histocompatibility Laboratory is independent if it has a distinct governing body separate and not under the direct or indirect control of the governing body of any of its Transplant Hospitals or of the governing body of a commonly controlled group of its Transplant Hospitals.

iii. Key Personnel. A Histocompatibility Laboratory must have a Director, a Technical Supervisor, and a Clinical Consultant. It is possible that one individual may serve more than one or all three positions. The Director/Technical Supervisor must meet specified education/training and experience requirements. The Director also must meet competency standards and be on-site commensurate with the Histocompatibility Laboratory's workload. The Clinical Consultant must be qualified to consult with and render opinions to the Laboratory's clients concerning the appropriateness of human

histocompatibility and/or transplantation immunology tests ordered and the interpretation of test results in relation to candidate diagnosis and management. All personnel must be licensed or meet standards required by federal, state, and local laws. Changes in these key personnel must be reported to the OPTN at least 30 days (if possible) in advance, along with the name of the individual's replacement, Curriculum Vitae, and information demonstrating and documenting compliance with OPTN criteria for a Histocompatibility Laboratory.

V. DESIGNATED TRANSPLANT PROGRAM TO RECEIVE ORGANS FOR TRANSPLANTATION*

a. Facilities and Resources. The program's Transplant Hospital must allocate sufficient operating and recovery room resources, intensive care resources, and surgical beds and personnel to the transplant program. Note that for pancreatic islet transplantation, in order to receive pancreata for islet transplantation, programs must meet separate facility, reporting, ancillary personnel, collaborative support, and regulatory compliance requirements in addition to meeting the above criteria.

b. Inactive Programs. Upon inactivating a transplant program or relinquishing the program's status as a designated transplant program, the program must (i) promptly suspend transplantation, (ii) notify its candidates in writing, providing a copy to the OPTN, of the need for inactivation and removal of candidates from the program's waiting list or, if a candidate desires, transfer to the list of another OPTN Member Transplant Hospital, and (iii) assist its candidates in identifying designated transplant programs to which they can transfer.

c. Changes in Key Personnel. Changes in key personnel must be reported to the OPTN at least 30 days (if possible) in advance of the effective date, along with the name of the individual's replacement, Curriculum Vitae, and information demonstrating and documenting compliance with OPTN criteria for a designated transplant program.

d. OPO Affiliation. The program must have letters of agreement or contracts with an OPO.

e. Histocompatibility Laboratory Affiliation. The program must use, for its histocompatibility testing, a laboratory that is approved for OPTN Membership and meets the standards for histocompatibility testing described below under Histocompatibility Laboratories.

f. Transplant Surgeon and Physician. Key personnel requirements differ to some degree depending upon the pathway by which a transplant program qualifies to receive organs for transplantation. For any designated transplant program qualified to receive organs by virtue of (i) approval of the program by the Secretary of HHS for reimbursement under Medicare, or (ii) location of the program in a Federal Hospital, the Transplant Hospital must identify the primary surgeon and primary physician reported to the Center for Medicaid and Medicare Services (CMS). The program must demonstrate that these individuals meet the OPTN requirements for primary transplant surgeon and primary transplant physician in order to obtain designated transplant program status if the program does not qualify as a transplant program by virtue of the criteria listed under (i) or (ii) above (*i.e.*, approval for reimbursement under Medicare or location in a Federal Hospital). Changes in these key personnel must be reported to the OPTN at least 30 days (if possible) in advance of the effective date, along with the name of the individual's replacement and credentials.

For any designated transplant program that does not qualify to receive organs by virtue of approval for reimbursement under Medicare or location in a Federal Hospital, Transplant Hospitals must have key personnel who meet certain minimum levels of commitment to and

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* In an effort to assist readers easily identify updates to the Evaluation Plan within the "Designated Transplant Program to Receive Organs for Transplantation" section, updates to the section will be highlighted in blue. Information that no longer applies will be removed from the section and will not appear in any form.

knowledge of organ procurement and transplantation. Such key personnel include a primary surgeon and primary physician. Qualifications for these individuals include, but are not limited to:

- Completed Transplant Hospital credentialing process; individual is a current Member of the hospital in good standing.
- Licensed to practice medicine in his/her state; individual is accepted onto the medical staff of and on site at the applicant Transplant Hospital.
- Certified (or achieved eligibility if applicable) by applicable surgery/medical Boards or their foreign (or other applicable) equivalent.
- Meets applicable requirements for training and/or experience, including without limitation, demonstration of competence and currency by performance of sufficient numbers of transplant procedures in the case of primary surgeon, and involvement with the primary care of sufficient numbers of transplant patients in the case of primary physician

g. Collaborative Support. The program must show evidence of collaborative involvement with experts in the field of radiology, infectious disease, pathology, immunology, anesthesiology, physical therapy and rehabilitation medicine, histocompatibility and immunogenetics, and, as appropriate, hepatology, pediatrics, nephrology with dialysis capability, and pulmonary medicine with respiratory therapy support.

h. Ancillary Services. The program must have immediate access to sophisticated microbiology, clinical chemistry, histocompatibility testing, and radiology services, as well as facilities required or capacity for monitoring immunosuppressive drugs.

i. Blood Bank Support. The program must have extensive blood bank support, including access to large quantities of blood.

j. Transplant Mental Health and Social Services Support. The program must have access to mental health and social support services.

k. **Clinical Transplant Pharmacist.** A Transplant Hospital's transplant program(s) are encouraged to identify one or more pharmacists who will be responsible for providing pharmaceutical care to solid organ transplant recipients. The clinical transplant pharmacist should be a designated member of the transplant team and will be assigned primary responsibility for providing comprehensive pharmaceutical care to transplant recipients in a culturally competent manner. The transplant pharmacist will work with patients and their families, and members of the transplant team, including physicians, surgeons, nurses, clinical coordinators, social workers, financial coordinators and administrative personnel at the transplant program. The transplant pharmacist should be a licensed pharmacist with experience in transplant pharmacotherapy, who performs or oversees a team of other healthcare personnel and support staff.

l. **Investigation of Personnel**. A transplant hospital is expected to conduct an investigation of its personnel if so requested by the Membership and Professional Standards Committee, and report its final determination to the Committee in a way that is consistent with and protects the institution's own peer review process.

m. Evaluation of Application. The OPTN/UNOS Membership and Professional Standards Committee investigates and considers under confidential medical peer review each application for Membership, designation as a transplant program, and change in key personnel.

Recommendations regarding such applications for Membership and designated transplant program status are forwarded to the Board of Directors for final action. Favorable recommendations with respect to applications for key personnel changes are adopted as final actions by the MPSC. Applications must be submitted in writing on the form prescribed by the MPSC and signed by a representative of the applicant. Applicants are required to produce information that is adequate to enable proper evaluation of the applicant's qualifications.

PHASE 1: Applicant Inquiry:
Inquiries for applications for new Members, new program designation, and changes in key personnel are received by staff that prepares letters and informational application packets for the requestor and enters the information into an automated tracking system. Changes in key personnel that involve the departure of the key individual should be submitted 30 days prior to the departure effective date.

PHASE 2: Application Processing:
UNOS Membership staff receives applications, checks them for completeness and communicates issues requiring clarification back to the applicant's contact person. Once complete, new applications for Membership and designated transplant status are acted upon within 90 days of the application being classified as complete. *Per Section 1.04A of the OPTN Bylaws , Designated staff representatives will conduct a preliminary review of all applications (including the required support documentation and such other information that may be relevant to consideration of the applicant's qualifications) for the purpose of assessing completeness before presenting it to the Membership and Professional Standards Committee (MPSC) for review. This review will be conducted for all application types. Applications that are not appropriately completed and that are missing the key supporting information and/or documents will not be forwarded to the MPSC for review. Key information and/or documents for applying for changes in key personnel include, without limitation, physician or surgeon Curriculum Vitae, letter of commitment, transplant log, and Board certification, as well as surgeon transplant operative notes, where applicable, and procurement notes and/or log. Key information and/or documents for applications for Membership or designated transplant program status include, without limitation, OPO or Histocompatibility Laboratory contract/letter, where applicable, in addition to the information/documentation associated with key personnel listed above. Applications not completed in the appropriate manner will be deemed "incomplete." The Chair or the Executive Director or the designated representative of the MPSC will notify the applicant of the incomplete status as well as their available options.*

PHASE 3: Committee Review:
As a part of the medical peer review process, all new Member, new program designation, and personnel change applications are assigned to Members of the MPSC for review. The Committee uses the OPTN Bylaws and Final Rule as guidelines during the review. To ensure timely review of new applications, the MPSC or an Ad Hoc Subcommittee of Committee Members of the MPSC is authorized to make determinations regarding applications for Membership or designation as a transplant program. Such determinations shall be advisory to the Board of Directors, which is the body responsible for final decisions with respect to Membership and transplant program designation applications, and shall be effective on an interim basis pending final decisions by the Board or action as may be directed through due process.

Care is given to assign applications in a manner that will avoid conflicts of interest. Committee Members are not assigned applications from other programs in close proximity or

within their OPO Service area. Additionally, Committee Members are encouraged to inform staff and the Committee when programs under review are in direct competition with their own program, or involve individuals with whom they may have worked or trained to avoid conflicts of interest in both assigning and considering applications.

Application materials are posted on a secured intranet site for the Committee Members to review as soon as they have been processed and deemed complete by staff review. New applications are assigned to a subcommittee of four individuals and changes in key personnel are assigned to a subcommittee of three. If the Members of the Subcommittee unanimously vote for approval, it will be granted to the applicant on an interim basis lasting until the next meeting of the full MPSC when it will be further considered either on the consent or discussion agenda. Votes and points of discussion are cast electronically initially on the Web site.

The Committee Members may vote for Interim Approval, Approval Pending, Incomplete (i.e., recommendation for rejection) or they may abstain (see Outcomes section). Staff remains available to answer questions raised during the Committee's deliberations and records the final decisions and comments of the Committee. If a decision for approval cannot be reached by this initial subcommittee review, then the application is placed on the discussion agenda for the next in-person meeting of the Committee. Individual Committee Members also submit ballots during the in-person meeting.

The Staff will work with the committee chair to draft follow-up letters to all programs under consideration. Letters describing an adverse finding by the Committee are assigned a high priority and explain the applicants/members right to appeal the decision through due process. Due process includes a protocol for informing the Member or applicant of the nature of the Committee's action and providing opportunity for the Member/applicant to respond to the Committee's findings using initial informal interview to more formal hearing and appellate review mechanisms. The Committee Chair or Vice Chair approves and signs MPSC outcome letters. The Executive Director signs Board action letters.

If an application is ruled "Approved Pending," then the process noted in "Outcome 2" will be followed.

PHASE 4: Committee Meeting:
Pursuant to the Contract for operation of the OPTN, all portions of Committee meetings dealing with medical peer review, credentialing, and Member due process are deliberated in closed session. These sessions are closed to the public but not to the HRSA project officer or designees.

The Committee's Consent Agenda will include those applications and other member related actions, which were granted interim approval by Subcommittee. The Discussion Agenda will include applications that were not granted interim approval. When the full committee meets an item may be removed from the consent agenda at the request of any committee member who feels that further discussion is warranted. These applications may include situations where the applicant or member did not appear to meet the requirements or may include situations where a split vote occurred within the Subcommittee and additional discussion is needed. Once a determination is made by the full Committee a letter will be sent to the applicant/member in the same manner as described in Phase 3.

Outcome 1 – Applications recommended for "Interim Approval"
Applicants who meet all requirements and have their supporting documentation in order will be recommended for interim approval by a subcommittee and/or the full Committee. Upon issuing a recommendation for approval, the applicant is approved on an interim basis. This approval is effective until review by the full MPSC (if not already accomplished) and final determination by the Board of Directors. Such interim approval shall (subject to final action by the full Board) grant the applicant status as a Member or designated transplant program, as applicable; it shall expire if the Board or full Committee does not approve the interim action.

A letter informing the applicant of the recommendation will be sent under the signature of the Committee Chair or Vice Chair. A final determination letter will be sent from the Executive Director once the Board of Directors approves the application. For Personnel Change Applications, the letter will be sent under the signature of the MPSC Committee Chair and/or Vice Chair when an interim or final action is taken by the Committee.

Outcome 2 – Applications receiving a recommendation of "Approved Pending"
An application may receive a recommendation of "Approved Pending" if it is apparent from the documentation presented that the applicant meets the minimum requirements but is missing supporting documentation such as a hospital credentialing committee letter. "Approval Pending" may be recommended in circumstances where, for example, a proposed primary transplant surgeon or primary transplant physician's arrival on site is pending.

If an application is ruled "Approved Pending" a letter will be sent under the signature of the Committee Chair or the Vice Chair that communicates the concerns of the Committee. Upon receipt of the requested items, a subcommittee of the MPSC can be formed to review this information and make a final recommendation. The Subcommittee should consist of the previous reviewers for the application whenever possible. The Committee Chair will also review the application and sign off on the final approval letter when the application is for a key personnel change. If the application is for a new program or new program designation the final determination letter will be under the signature of the Executive Director.

If an applicant fails to return information in a timely manner the application will be placed back on the agenda for reconsideration at the following MPSC meeting.

Outcome 3 – Applications determined to be "Incomplete (Recommendation for Rejection)"
The MPSC can find an application "Incomplete/Recommended for Rejection" when it is not apparent from the documentation presented that the proposed Member/program or personnel change can meet all requirements for approval. Upon issuing a recommendation for rejection of a new Member/new designated transplant program, the application is rejected on an interim basis. This rejection is effective until review by the full MPSC (if not already accomplished) and final determination by the Board of Directors. Such interim rejection shall (subject to final action by the full Board) result in denial of Membership or designated transplant program status pending due process, including any rights of appeal to the Secretary, and a different decision. Rejection of key personnel change applications result in denial of approval of the proposed change in key personnel pending due process.

If an application is determined to be "Incomplete" then the member is given the opportunity to appear the decision through due process. Staff will work with the Chair to prepare a letter for the Chair's or the Vice Chair's signature that explains the options afforded to the applicant/member. Acceptance of the offer for due process must be in writing. Alternatively, the applicant may also submit new information for Committee consideration or choose to

withdraw the application. In the case of a change in key personnel the center may choose to inactivate the programs membership and waitlist status until such time as it can meet the requirements.

If an interview or hearing is accepted, staff will coordinate the interview/hearing time with the applicant. Prior to the meeting, a letter will be sent to the applicant confirming the date, time, and location. Normally, interviews and hearings are scheduled to take place during the regular MPSC meetings. If necessary a subcommittee can conduct the interview or hearing. If the interview/hearing takes place before a subcommittee it can take an interim action for approval or can rule that the application remains incomplete. This recommendation would move forward to the full Committee or Board, which can either support the recommendation for approval or, in the case of "Incomplete," result in opportunity for appellate review before the Board. An applicant seeking Membership or designation as a transplant program shall have the right to appeal decisions of the MPSC, MPSC subcommittees, or the Board of Directors regarding these applications to the Secretary of HHS in accordance with the OPTN Final Rule, 42 CFR Part 121. The due process protocol's rights to interviews, hearings, appellate review, and appeal to the Secretary are more fully described in Section IX below.

For additional information regarding the Membership application process and to review sample Membership applications, please see the attached Exhibits file. The file contains the following information:

Exhibit I - New Transplant Hospital Application (complete set). This application is used by transplant hospitals that are not presently Members.
Exhibit II - Designated Transplant Program Application. (Same as the individual organ new program application, which is incorporated within the New Transplant Hospital Application, as seen in Exhibit I. The only differences are the cover and instructions.) This application is used by current Transplant Hospital Members, which plan to expand into performing additional organs.
Exhibit III - OPO Application. This application is used by new OPOs.
Exhibit IV - Histocompatibility Laboratory Application (incorporated within the New Hospital Application, as seen in Exhibit I.)
Exhibit V - Change of Personnel Application (same as designated transplant program application, which is incorporated within the New Transplant Hospital Application, as seen in Exhibit I. The only difference is the cover and instructions.) Programs utilize this form when there is a change of primary surgeon or primary physician.
Exhibit VI - Medical/Scientific Member Application
Exhibit VII - Public Organization Member Application
Exhibit VIII - Business Member Application
Exhibit IX - Individual Member Application

Membership Evaluation Reports - On a quarterly basis, following regular meetings of the MPSC, UNOS will submit Membership application evaluation reports to the Project Officer. These reports will summarize issues identified during the evaluation process as shown in examples 1-3 below. The report will also address any pervasive problems that have been identified.

Example 1. Number of Applications Received for New OPTN Membership & Renewal of Medical/Scientific, Public Organization, Business, & Individual OPTN Membership – By Category

Membership Type	**Number of Applications Received for New OPTN Membership**	**Number of Applications Received for Renewal of Medical/Scientific, Public Organization, Business, & Individual OPTN Membership**	**Number of Applications Approved**
Transplant Hospital			
Organ Procurement Organization			
Histocompatibility Laboratory			
Medical/Scientific Member			
Public Organization Member			
Business Member			
Individual Member			

Example 2. Number of Applications - by Organ/Type

Action	**KI**	**~~KI Living Donor~~**	**LI**	**LI Living Donor**	**PA**	**HR**	**HL**	**LU**	**IN**	**IS**	**OPO**	**LAB**
Number of Applications Received												
Number of Applications Reviewed by Full MPSC												
Number of Applications Recommended for Interim Approval by Full MPSC												
Number of Applications Found to Be Incomplete - Recommended for Rejection by Full MPSC												
Number of Applications Ruled "Approved Pending" by Full MPSC												
Number of Times Member is Finally Determined to be Non-compliant by Full MPSC												
Number of Applications Reviewed by Subcommittee Only												
Number of Applications												

Recommended for Interim Approval by Subcommittee Only												
Number of Applications Found to be Incomplete by Subcommittee Only												
Number of Applications Ruled “Approved Pending” by Subcommittee Only												

Example 3. Number of Personnel Changes Applications - by Organ/Type

Action	**KI**	**KI Living Donor**	**LI**	**LI Living Donor**	**PA**	**HR**	**HL**	**LU**	**IN**	**IS**	**OPO**	**LAB**
Number of Applications Received												
Number of Applications Reviewed by Full MPSC												
Number of Applications Recommended for Approval by Full MPSC												
Number of Applications Found to be Incomplete – Recommended for Rejection by Full MPSC												
Number of Applications Ruled "Approved Pending" by Full MPSC												
Number of Times Member is Finally Determined to be Non-compliant by Full MPSC												
Number of Applications Reviewed by Subcommittee Only												
Number of Applications Recommended for Interim Approval by Subcommittee Only												
Number of Applications Found to be Incomplete by Subcommittee Only												
Number of Applications Ruled "Approved Pending" by Subcommittee Only												

VI. OPTN/UNOS COMMITTEE STATEMENTS ON ORGAN ALLOCATION POLICY GOALS*

At the June 2004 OPTN/UNOS Board of Directors meeting, each organ specific Committee including the OPTN/UNOS Pediatric Transplantation Committee submitted to the Board for approval policy goal statements for the organ allocation policies. These statements outline objectives the Committees intend to accomplish as policies are developed and implemented. The Board approved these statements. Please note, the OPTN/UNOS Thoracic Organ Transplantation Committee submitted its statement to the Board in November 2004, and the OPTN/UNOS Minority Affairs Committee submitted its statement in December 2006. The Board approved both statements.

a. OPTN/UNOS Kidney and Pancreas Transplantation Committee Statement on Policy Goals

Kidney Allocation/Distribution Policy

Objectives Statement. The objectives of OPTN Policy for allocating and distributing deceased donor kidneys are to provide candidates with a donor kidney best suited to the candidate as quickly as possible while (i) balancing other medical considerations that contribute to organ, transplant, and overall system utility, as well as medical factors unique to particular patient populations, (ii) increasing the availability of organs, and (iii) preserving the public's trust in the national organ allocation system.

Listing. A candidate can be listed for a kidney or combined kidney/pancreas transplant based upon his/her physician's medical judgment regarding suitability for transplantation. Once added to the waiting list, adult candidates begin accruing waiting time when they meet minimum, objective measures of renal function. Pediatric candidates (< 18 years old) begin accruing waiting time upon listing. The intent is to better standardize initiation of waiting time as well as comparisons of waiting time across the country without delaying opportunities for children to be transplanted.

Allocation. The allocation algorithm addresses two categories of donor kidneys: standard criteria donor (the majority of deceased donor kidneys) and expanded criteria donor kidneys (defined by relative risk of graft failure using donor age, creatinine, cerebral vascular accident, and hypertension). ***HLA Matching for Zero Mismatch.*** Human leukocyte antigen (HLA) matching has been a factor in kidney allocation from initiation of the OPTN/UNOS organ allocation systems. This is because differences in HLA or tissue type between kidney donor and recipient stimulate the recipient's immune system to reject the donor kidney. Pharmacologic immunosuppression is required in order to impede the immune responses and, hopefully, prevent rejection and enable long-term acceptance of the donor kidney. Transplants between recipients and donors well matched for HLA generally function longer and with less immunosuppression, thereby maximizing utility of the donors' organs. Significant improvement in outcomes due to HLA matching presently is demonstrated currently only with a zero antigen mismatch (the highest level of match based upon degree of HLA identity between donor and candidate) and

* In an effort to assist readers easily identify updates to the Evaluation Plan within the "OPTN/UNOS Committee Statements on Organ Allocation Policy Goals" section, updates to the section will be highlighted in blue. Information that no longer applies will be removed from the section and will not appear in any form.

matches at the HLA DR locus. HLA match also provides greatest opportunity for transplanting patients who have developed anti-HLA antibodies directed against a relatively substantial proportion of the donor pool, as further discussed below. Therefore, for both standard and expanded criteria donor kidneys, priority is given nationally to zero antigen mismatched candidates, due to the documented graft survival benefit experienced by recipients of such kidneys and enhanced access to transplantation for sensitized patients. These zero antigen mismatched candidates are stratified based on a number of factors including, blood type, panel reactive antibody, payback status, age and location. ***Blood Group Compatibility.*** The systems for allocating standard and expanded criteria donor kidneys are similar also in ensuring compatibility between donor and candidate ABO blood group, which is necessary for success of the transplant procedure, while directing that organs are allocated based upon blood group identity or to particular compatible blood groups (i.e., blood types O and B) to avoid disadvantaging these patients based upon blood type. ***Waiting Time.*** Waiting time is an additional factor used in the allocation of standard as well as expanded criteria donor kidneys. Patients with end-stage kidney failure can be sustained on dialysis over a period of time with good results, with exceptions noted below for children. Dialysis therapy has adverse quality of life implications, however. Additionally, studies now show improved long-term patient survival for recipients of kidney transplantation versus individuals waiting for kidney transplantation on dialysis. Differences in survival may be impacted by patient medical condition such as diabetes, glomerulonephritis, or other causes of end-stage renal disease. The potential patient survival advantage attributable to kidney transplantation and its role in the allocation system is being explored. At the present time, however, relative patient waiting time plays a unique role in kidney allocation in defining system fairness.

Standard Kidney Allocation. Within the standard donor allocation system additional allocation priority is awarded as follows. ***HLA Matching.*** Points are awarded for less than the optimal (zero antigen mismatch) degree of HLA identity between donor and candidate based upon significantly improved transplant outcomes with matching at the HLA DR locus. ***Anti-HLA Sensitization.*** Kidney transplant candidates who have been exposed to the HLA antigens of another individual as a consequence of pregnancy, blood transfusions, or previous transplantation are at risk for developing antibodies against foreign HLA antigens. Anti-HLA antibodies prevent candidates from receiving transplants from donors with HLA antigens to which the antibodies are directed. Candidates who have developed high levels of these antibodies generally need donors with a very good HLA match to avoid rejection. Due to the documented difficulty such candidates experience in obtaining a donor kidney with a negative crossmatch, they are assigned extra points. ***Prior Living Donors.*** Candidates who need a kidney and who previously donated a living donor organ for transplantation are awarded additional allocation priority with the intent of encouraging organ availability through living donation and acknowledging these candidates' sacrifice and exposure to medical risk. ***Age for Pediatric Patients.*** Young children and adolescents experience unique problems associated with dialysis, including disruption of expected growth and development processes due to renal failure. Early reversal of uremia through transplantation can avoid the special problems of dialysis and ameliorate many of the adverse effects of end stage renal disease which confront these patients. Rapid treatment provides the best opportunity for reversing the growth and development deficits and preventing lifelong adverse consequences. Threshold times to transplant these candidates are, therefore, established in policy with additional priority assigned when children reach these thresholds without being transplanted. The intent is to expedite access for these patients to donor kidneys considered medically suitable for use in pediatric transplant candidates.

Expanded Criteria Donor Kidney Allocation. The allocation algorithm for expanded criteria donor kidneys allocates kidneys to candidates who have agreed to accept them based only on

accrued waiting time and blood type considerations after the zero antigen mismatched level of priority. The intent is to maximize procurement and use of these kidneys, providing a mechanism for more rapid placement of the organs while minimizing cold ischemic time. The policy recognizes the additional risk expected with expanded criteria donor kidney transplantation and establishes a protocol for offering them under conditions intended to improve acceptance and enhance outcomes. Pediatric candidates waiting for a kidney transplant generally are not considered good candidates for expanded criteria donor kidneys due to long-term graft survival concerns and possibility of sensitization. It is anticipated that ongoing review of outcome data will help in better defining the most appropriate candidates for such kidneys.

Evaluation. Policies for kidney allocation are based on objective, measurable criteria and then reviewed on a periodic basis to ensure policy objectives are being achieved. For instance, the point system for HLA matching has been modified over time as data have demonstrated diminished impact of matching on graft survival. Such revisions have unique consequences for minority patients due to differences in HLA and blood group biology among the various ethnic groups and between donor and candidate populations. Assigning less emphasis to HLA matching in kidney allocation is expected to increase opportunities for transplantation for minority patients and reduce present disparities in waiting times to transplant. This is especially true since variability in DR antigens among ethnic groups is less pronounced than at the other HLA loci. Disparities in access to kidney transplantation among patient populations continue to be an area of study for further policy refinement intended to address these disparities. This includes, for example, an OPTN/UNOS Board of Directors approved study to permit kidney waiting time accrual to commence from the initiation of chronic maintenance dialysis to address differences in patient waiting time not explained by differences in renal function. Additionally, the policies are being assessed to further define the best outcome ─ be it graft survival rates, years of life gained, quality of life measures or net benefit ─ hoped to be achieved through the kidney allocation system.

Medical Judgment. Sound medical judgment and right of organ refusal are maintained by the kidney allocation system. The ultimate determination of whether a particular kidney offer should be accepted and transplanted into a particular candidate resides with the responsible transplant surgeon or physician. The surgeon or physician can base the decision on a number of factors including, but not limited to, candidate medical status and donor history. The intent is to promote best use of kidneys.

Payback System. The kidney payback system stipulates that OPOs receiving kidneys for transplantation under certain situations will incur a debt to the national system, requiring that the shared kidney must be paid back to the system through the UNOS Organ Center. A payback debt is created when a kidney is shared pursuant to (i) the zero antigen mismatch sharing policy, or (ii) voluntary arrangements for sharing donor kidneys with an organ other than a kidney for transplantation into the same recipient, or for sensitized patients. The intent of the payback system is to compensate for disparities in the distribution of the optimally matched (zero antigen mismatched) deceased donors and recipients. This objective can be accomplished only if the kidneys used to satisfy payback debts function relatively well. Studies have shown that requiring a payback for shared zero antigen mismatched kidneys does not appear to jeopardize graft survival of these payback kidneys.

Distribution. With exceptions for the optimally matched (zero antigen mismatched) kidneys and kidneys shared in satisfaction of payback obligations, organs are offered initially to patients on the local list (generally defined as patients listed for transplantation at transplant centers within the organ procurement organization (OPO) designated service area), then regionally (other non-

local patients listed for transplantation at transplant centers within the OPTN region), and then nationally (other patients listed for transplantation at transplant centers in all other OPTN regions). The rank order of patients on the local, regional, or national lists is determined by the allocation system described above. The organ distribution system is intended to enhance placement efficiency and minimize cold ischemic time, thereby resulting in increased organ usage and outcomes.

Importantly, both the systems for sharing optimally matched kidneys, as well as the system for allocating payback kidneys to the pool of available kidneys, contribute to disassociating candidate place of listing (residence) with distribution/allocation. In each case, organs are allocated to patients who meet specified criteria and who are listed for transplantation anywhere in the country before they are offered for other patients locally. In the case of zero antigen mismatched organs, patient eligibility is defined by factors such as HLA match, blood group, and sensitization. In the case of payback kidneys, patient eligibility is defined by factors such as blood group and time debt has been owed. There is, therefore, no direct reciprocity between transplant centers or even OPOs in the allocation of payback kidneys. Each of the systems expands the geographic area over which organs are distributed.

Further expansion of the geographic area within which it is reasonable to distribute kidneys is impacted by practical limitations upon the ability to share patient sera to determine if a candidate has antibodies against a particular donor. A positive reaction indicates the likelihood of hyperacute rejection if a kidney from that donor is used to transplant the original intended candidate. Renal transplants are rarely donor prior to testing (crossmatching) patient serum against the donor's cells or if the test is positive.

Policy Performance Measures. Whether kidney allocation policies are approaching their goals will be assessed on an ongoing basis using modeling and other approaches that incorporate a number of metrics including but not restricted to the following:

- Pre- and post-transplant graft and patient survival;
- Listing, transplant, death and removal rates for various patient groups (*e.g.*, diagnostic groups, allocation point ranges, demographic (*e.g.*, blood type, ethnicity, age), and geographic groups);
- Indicators of morbidity and quality of life (functional status), as measured by available data and current methodologies;
- Time on dialysis;
- Profile of recipient characteristics that are factors in kidney allocation (*e.g.*, HLA mismatch level, CPRA level, age)
- Risk of progression of disease;
- Organ discard rates;
- Impact upon organ availability.

Policy Compliance Measures. Compliance with OPTN Policy for allocating/distributing kidneys is assessed using processes and protocols developed by the OPTN Contractor in accordance with the contract with the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) to operate the Organ Procurement and Transplantation Network (OPTN).

Pancreas and Pancreatic Islet Cell Allocation/Distribution Policy

Objectives Statement. The objectives of OPTN Policy for allocating and distributing deceased donor pancreata are to provide candidates with a donor pancreas best suited to the candidate as quickly as possible while (i) balancing other medical considerations that contribute to organ, transplant, and overall system utility, as well as medical factors unique to particular patient populations, (ii) increasing the availability of organs, and (iii) and preserving the public's trust in the national organ allocation system.

Allocation. The allocation algorithm addresses two categories of donor pancreata, pancreata used primarily for whole organ transplantation and pancreata used for islet cell transplantation after certain priorities for whole organ transplantation are exhausted. ***HLA Matching for Zero Mismatch.*** Human leukocyte antigen (HLA) matching has been a factor in pancreas allocation from relatively early in development of the OPTN/UNOS organ allocation systems. This is because differences in the HLA or tissue type between pancreas donor and recipient stimulate the recipient's immune system to reject the donor pancreas. Pharmacologic immunosuppression is required in order to impede the immune responses and, hopefully, prevent rejection and enable long-term acceptance of the donor pancreas. Data no longer show improved transplant outcomes based upon HLA match between recipients of kidney/pancreas combinations and donors, even at the highest level of match based upon degree of HLA identity between donor and candidate (zero antigen mismatch). For isolated pancreas transplantation there is a trend toward improved outcomes, although the results do not demonstrate statistical significance. HLA match does, however, provide greatest opportunity for transplanting patients who are sensitized against a relatively substantial proportion of the donor pool. Optimally (zero antigen mismatched) matched organs provide the best chance for avoiding rejection for these candidates and a large donor pool provides greater options for locating such matches. Therefore, for all donor pancreata, priority is given nationally to zero antigen mismatched combined kidney/pancreas sensitized candidates, first, and then to zero antigen mismatched isolated pancreas sensitized candidates (with exceptions for mismatched sensitized candidates at the local level of organ distribution), due to enhanced access to transplantation for these patients and, in the case of isolated pancreas transplants, demonstration of at least a trend toward improved graft survival benefit experienced by recipients of such kidneys. These zero antigen mismatched candidates are stratified based on waiting time.

Donor Characteristics. After zero antigen mismatched candidates, allocation of pancreata is dependent upon characteristics of the donor. The distinction is based on analyses of organ discard rates and pancreas islet cell yields. The intent is to balance transplant opportunities for whole organ candidates with opportunities to test the efficacy of islet transplantation by providing first priority for local use of pancreata to patients in need of whole organ transplantation, and then allocating those pancreata most suitable for islet transplantation for patients in need of islets, first, locally, then regionally, and then nationally. Pancreata procured from donors aged less than or equal to 50 years and with body mass indexes (BMI) less than or equal to 30 kg/m^2 are allocated locally for isolated pancreas candidates, combined kidney/pancreas candidates, or combined solid organ/islet candidates based on waiting time. The rationale for local donor service area emphasis is to minimize cold ischemic time and maximize graft survival. Such pancreata would then be allocated regionally and nationally for whole organ transplantation or combined kidney/pancreas transplantation based on waiting time and then for islet cell transplantation.

Pancreata procured from donors aged greater than 50 years or with BMIs greater than 30 kg/m^2 are allocated locally to isolated pancreas candidates, combined kidney/pancreas candidates, or combined solid organ/islet candidates and then to clinical islet candidates based on medical need and transplant candidate length of waiting time. The intent is to determine whether islet cell

transplantation is a viable alternative for diabetics on insulin, ensure the application of medical judgment, and minimize the wastage of pancreata and islet cells.

Facilitated Placement. The pancreas allocation system provides a further mechanism to minimize organ wastage and maximize organ utilization. The facilitated pancreas allocation system is available after five hours of placement effort or if organ retrieval is imminent. Transplant centers must notify the UNOS Organ Center of their intent to participate in the facilitated pancreas system and an expedited placement is managed based on candidate waiting time.

Policy Performance Measures. Whether pancreas allocation policies are approaching their goals will be assessed on an ongoing basis using modeling and other data that reflect a number of metrics including but not restricted to the following:

- Pre- and post-transplant graft and patient survival;
- Listing, transplant, death and removal rates for various patient groups (*e.g.*, diagnostic groups, allocation point ranges, demographic (including, for example, calculated panel reactive antibody (CPRA) level, blood type, ethnicity, age), and geographic groups);
- Indicators of morbidity and quality of life (functional status), as measured by available data and current methodologies;
- Risk of progression of disease;
- Organ discard rates;
- Impact upon organ availability.

Policy Compliance Measures. Compliance with OPTN Policy for allocating/distributing pancreata is assessed using processes and protocols developed by the OPTN Contractor in accordance with the contract with the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) to operate the Organ Procurement and Transplantation Network (OPTN).

b. OPTN/UNOS Liver and Intestinal Organ Transplantation Committee Statement on Policy Goals

For the OPTN/UNOS Liver and Intestinal Organ Transplantation Committee, the overall goal of deceased-donor liver and intestinal allocation policies is the ongoing development of a patient-specific and evidence-based allocation system that ranks each patient using objective, measurable clinical criteria such that the practice of liver transplantation increases patient benefit. In this context, “patient-specific” refers to clinical variables that, in aggregate, can be used to stratify patients based on the risks and benefits of transplantation. The concept "net benefit" incorporates directing deceased donor livers and intestines to candidates who are likely to have increasing mortality risks and/or burden of disease and for whom liver and intestinal transplantation will offer the largest possible reduction in mortality risk and/or burden of disease. For liver and intestinal allocation, the overall policy goal of net transplant benefit may include the following components:

- Reduced waiting list mortality;
- Increased post-transplant survival;
- Reduced post-transplant morbidity and burden of disease;
- Increased quality of life;
- Allow optimal patient access for transplantation;
- Efficient placement of organs; and

- Enhanced utilization of extended-criteria donors.

In pursuing these goals, the Committee should attempt to maintain or increase organ availability, preserve the public's trust in the national allocation system, and maintain a balance between justice and utility. An important aspect of maintaining trust requires that the allocation system be as transparent as possible. This requires that only objective, non-discriminatory variables are used in this process and that there is regular auditing of results. In addition, medical justice must be maintained by focusing the allocation criterion on patient-specific criteria and utility is assessed by regular evaluation of the overall results of the system.

Whether liver and intestinal allocation policies are approaching their goals will be assessed on an ongoing basis using data that reflect a number of metrics including but not restricted to the following:

- Pre- and post-transplant graft and patient survival;
- Listing, transplant, death and removal rates for various patient groups (e.g., diagnostic groups, allocation score ranges, demographic and geographic groups);
- Indicators of morbidity and quality of life, as measured by available data and current methodologies;
- Risk of progression of disease; and
- Distances traveled by patients for their transplant care.

Geographic criteria are not patient-specific and therefore are not to be emphasized in organ allocation or distribution. However, the Committee recognizes that scientific studies have continued to document the potential negative effects of increasing cold ischemic time on liver graft survival. Therefore, in order to maximize transplant benefit, some form of sharing boundary is necessary given current organ preservation limitations. The impact of distribution units used in liver and intestinal allocation should be evaluated in the context of patient-specific liver transplant benefit criteria.

c. OPTN/UNOS Thoracic Organ Transplantation Committee Statement on Policy Goals

Lung Allocation Policy

For the OPTN/UNOS Thoracic Organ Transplantation Committee, the overall goal of deceased-donor lung allocation policies is the ongoing development of an evidence-based allocation system that ranks each patient using objective, measurable clinical criteria such that the practice of lung transplantation increases patient benefit. In pursuing this goal, the policies should attempt to maintain or increase organ availability, preserve the public's trust in the national allocation system, and maintain a balance between justice and utility. The policy operates by employing an algorithm that incorporates clinical diagnostic variables that data suggest are predictive of the additional amount of time a patient would live on the waitlist without a transplant, (waitlist urgency) and the additional amount of time a patient would live following a lung transplant (post-transplant survival). The difference between waitlist urgency and post-transplant survival, as measured by additional days of life lived both on the waitlist and following a transplant, is predictive of transplant benefit. Lung transplant candidates are ultimately prioritized by an allocation score that is calculated to reflect the difference between transplant benefit and waitlist urgency.

The specific goals of these deceased donor lung allocation policies include:

- Reducing the number of deaths on the lung transplant waiting list;
- Increasing the transplant benefit for candidates who receive a lung transplant; and
- Ensuring the efficient and equitable allocation of lungs to active transplant candidates.

Whether lung allocation policies are approaching their goals will be assessed on an ongoing basis using data that reflect a number of metrics including but not restricted to the following:

- Waitlist death rates and post-transplant survival rates ;
- Listing, transplant, death and removal rates for various patient groups (e.g., diagnostic groups, allocation score ranges, demographic and geographic groups);
- Indicators of morbidity and quality of life, as measured by available data and current methodologies.

The Committee will conduct regular reviews of the clinical diagnostic variables used, patient survival data, and the allocation mechanism itself to ensure that the lung allocation policy is meeting the established goals. It is anticipated that the Committee will be able to evaluate the achievement of the performance goals of these lung allocation policies by reviewing on a regular basis the impact of the algorithm on both waitlist death rates and post-transplant survival rates.

Heart Allocation Policy

For the OPTN/UNOS Thoracic Organ Transplantation Committee, the overall goal of heart allocation policies is to identify heart candidates who have the most urgent medical need for a transplant and who have a high likelihood of survival following the transplant and to expedite heart allocation to those candidates. In pursuing this goal, the policies should attempt to maintain or increase organ availability, preserve the public's trust in the national allocation system, and maintain a balance between justice and utility. The policy accomplishes this goal by establishing a three-tiered status system in which patients are classified by medical urgency and receive higher priority for heart offers based on higher levels of medical urgency. The allocation policies base the determination of medical urgency upon specific clinical criteria that suggest severity of illness and urgency. Candidates must meet specific criteria predictive of elevated urgency to receive the highest priority for heart allocation. Because the highest status levels are allowable for limited periods of time, transplant center must regularly re-certify a candidate’s eligibility for these status levels. Fairness of the allocation mechanism is assured by Regional Review Boards that review and approve candidate’s applications for listing at the elevated status levels.

The heart allocation policies use the following additional factors to prioritize heart allocation: time accumulated on the waiting list, ABO compatibility, and geography. Waiting time is accumulated by candidates at each status level to allocate organs among other candidates at that status level. Candidates receive higher priority at each status level for ABO identical donor matches than ABO compatible donor matches. To ensure donor organ quality and reduce ischemic time, donor hearts are allocated first to candidates within local areas before being distributed to increasingly larger allocation zones.

Whether heart allocation policies are approaching their goals will be assessed on an ongoing basis using data that reflect a number of metrics including but not restricted to the following:

- Pre- and post-transplant graft and patient survival;

- Listing, transplant, death and removal rates for various patient groups (e.g., diagnostic groups, allocation score ranges, demographic and geographic groups);
- Indicators of morbidity and quality of life, as measured by available data and current methodologies;
- Risk of progression of disease.

The Committee evaluates the achievement of the performance goals of the heart allocation policy by periodically reviewing the impact of the algorithm on both waiting list death rates and post-transplant survival rates, and reviewing any additional issues that arise in relation to status determination and geographic distribution.

d. OPTN/UNOS Constituent Committees

In the formulation of organ allocation policies, several OPTN/UNOS Committees work in conjunction with the OPTN/UNOS organ-specific transplantation Committees to ensure that factors within their respective areas of expertise are continuously evaluated, acted upon, re-evaluated, and adjusted, when and as appropriate, as part of the policy development process. This is accomplished, at least in part, through design of the organ-specific Committees to include representation from the various specialties as well as by using joint subcommittees or work groups. The factors addressed include, for example, differences and unique health care needs of children, other populations with special needs including ethnic minorities and patients with limited access to transplantation, and matters impacting availability of human organs for transplantation, all as outlined in the National Organ Transplant Act of 1984, as amended. Specific issues addressed include, without limitation:

(i) The Ad Hoc International Relations Committee considers issues relating to importing and exporting organs and the medical, scientific, and ethical aspects of transplanting non-resident aliens. The committee considers the broad implications of such issues and deals with specific individual issues or situations.

(ii) The Communications Committee defines communications objectives and the needs of UNOS membership, the public, the transplant community at large, and the media with respect to UNOS activities. The committee is responsible for overseeing all aspects of UNOS communications activities.

(iii) The Ethics Committee considers ethical issues related to the process of organ procurement, distribution, and transplantation. These issues include social impact, the relationship of cost to benefit, impact on patients, and their families as well as society at large, legal issues, and related public policy, and access to transplantation. The committee considers the broader implications presented by such issues and does not consider individual patient's issues or disputes.

(iv) The Histocompatibility Committee considers issues relating to donor and recipient histocompatibility, organ allocation, tissue typing consistency, and histocompatibility laboratory and personnel qualifications. The committee also considers cost-to-benefit ratio and impact on organ transplantation in its recommendations.

(v) The Living Donor Committee considers issues relating to the donation and transplantation of organs from living donors to recipients. The committee makes recommendations to improve the process of living donation and transplantation.

(vi) The Membership and Professional Standards Committee (MPSC) ensures that UNOS member clinical transplant centers, independent organ procurement agencies, and independent tissue typing laboratories meet and remain in compliance with UNOS Criteria for Institutional Membership.

(vii) The OPTN/UNOS Minority Affairs Committee develops policy with the principal goal of equitable access to the benefits of transplantation for all recipients. The OPTN/UNOS Minority Affairs Committee seeks to develop policies that will directly address challenges faced by minorities in need of transplantation, candidates, recipients, and donors in the United States. The Committee will also periodically review living donor issues as they pertain to minorities. Through periodic review of data including rates of referral for transplant evaluation, listing, and transplantation, waiting list morbidity and mortality, graft and patient survival, and indicators of morbidity and quality of life for different ethnic groups, the Committee will assess the impact of OPTN/UNOS policy on minority transplant candidates and recipients.

(viii) The Operations Committee is charged with systematically ensuring that OPTN policies and systems provide for efficient, effective and monitorable organ allocation and distribution, with the aims of increasing the utility of donated organs and providing for the health and safety of transplant patients while instilling public trust in the national transplant system.

(ix) The OPO Committee considers issues relating to organ procurement organizations and increasing organ procurement efficiency and effectiveness to include medical, scientific, and ethical aspects. The committee provides input to other UNOS Committees as well as to the UNOS Board of Directors. As necessary, the committee conducts research related to specific issues under consideration.

(x) The Organ Availability Committee considers issues related to organ procurement. This includes investigating and recommending the approval of new organ preservation and shipment techniques, establishing practices to increase the supply of donated organs, and educating public and professional audiences about the need to increase donation.

(xi) The Patient Affairs Committee advises the UNOS Board of Directors and other committees about patient and donor family perspectives on proposed policies and issues. This committee also serves as an advocate for patients and their families. Patient Affairs provides information to patients, families, and patient groups about UNOS, the OPTN, and its policies. Members of the Patient Affairs Committee have personal experience with organ transplantation or organ donation, or are active with a national organization that works with patients who have been transplanted, or who have end-stage organ disease.

(xii) The OPTN/UNOS Pediatric Transplantation Committee evaluates and proposes policy for pediatric patients. Areas of specific monitoring include, but are not limited to: disruption to growth and development processes due to end-stage organ failure; differences in physiology, disease processes and progression, treatment protocols, and morbidity and mortality; benefits available from prioritizing donor organ offers based upon suitability of donor to candidate; as well as experiences unique to children during the wait for and subsequent to a transplant.

(xiii) The Transplant Administrators Committee considers issues related to the administration of transplant programs. Historically, these issues have included transplant costs and charges, development of transplant program staffing models, patient rehabilitation and return to work, legislative activity, and the impact of managed care on transplant programs. The committee provides input to other OPTN/UNOS committees, including the organ-specific committees in the development and assessment of organ allocation policies, as well as to the Board of Directors. The committee also assists in the planning of the annual UNOS Transplant Management Forum.

(xiv) The OPTN/UNOS Transplant Coordinators Committee is charged with considering issues that affect the coordination of efforts related to organ procurement, organ allocation, and the entire transplant process. The issues to be considered are: organ procurement, organ allocation and the impact of technical innovations on allocation, operations, policies and all aspects of patient/family care. Underlying this charge is the strong advocacy position of these frontline healthcare providers for donors, donor families, transplant candidates and transplant recipients.

The Committee's scope of activities includes prioritization of issues, interpretation of data and policy development and educational projects. The Committee will also provide advice and input to the OPTN/UNOS Board of Directors and other OPTNUNOS Committees.

Consistent with general principles of policy development, matters of clinical as well as statistical significance are important. This may be particularly relevant in considering issues of special needs populations due to relative size of the subsets of patients being assessed. Small study groups should not prevent otherwise meaningful analysis or proposals from being considered. In this regard, it is necessary that policy performance measures evaluating impacts upon pediatric patients and other special needs populations be addressed throughout policy development. The process acknowledges that subjects of concern to the Committees may exist outside the limits or realistic influence of the organ allocation policies. The Committees are, therefore, involved with initiatives in addition to allocation policy development in an attempt to address these subjects.

e. Annual Goals for the OPTN/UNOS Committees

Committees also establish annual goals that support the accomplishment of the Board-approved organ allocation policy goals. Please see the document entitled, “Organ Procurement and Transplantation Network Annual Set of Goals 2008-2009” for the annual goals established for the current year.

VII. MEASURING COMPLIANCE

This section of the Evaluation Plan provides explanatory information for each policy and bylaw currently monitored. The information is organized by policy number or bylaw reference and includes:

- Policy or bylaw title
- Policy or bylaw number and related subsections
- Purpose of the policy or bylaw
- How to comply with the policy or bylaw
- How OPTN/UNOS will evaluate member compliance with the policy or bylaw
- Detailed guidance on compliance, when available

BYLAWS

This section of the Evaluation Plan provides explanatory information for some of the bylaws currently monitored. Please note that OPTN Bylaws and UNOS Bylaws are separate documents. Many of the requirements exist in both the OPTN and UNOS Bylaws. For simplicity, the OPTN reference is included.

OPTN Bylaws		
Bylaw Description	**OPTN Bylaw Reference**	**Page Number**
Membership and Professional Standards Committee Action	OPTN Bylaws Appendix A, Section 2.06A	Bylaws-2
Restoration of Membership Privileges	OPTN Bylaws Appendix A, 3.01A, 5.05A, 5.07A	Bylaws-3
Survival Rates	OPTN Bylaws Appendix B, II.B	Bylaws-4
Inactive Membership Status / Inactive Program Status	OPTN Bylaws Appendix B, II.C, OPTN Bylaws Appendix B, Attachment I, Section II.	Bylaws-5, Bylaws-6
Patient Notification	OPTN Bylaws Appendix B, II.F	Bylaws-7
Transplant Surgeon and Physician	OPTN Bylaws Appendix B, Attachment I, Section VII	Bylaws-8
Model Elements for Controlled DCD Recovery Protocols	OPTN Bylaws Appendix B, Attachment III	Bylaws-9
UNOS Bylaws		
Bylaw Description	**UNOS Bylaw Reference**	**Page Number**
Kidney Transplant Programs that Perform Living Donor Kidney Transplants	UNOS Bylaws Appendix B, Attachment I, Section XIII, D.(2)	Bylaws-10
Liver Transplant Programs that Perform Living Donor Liver Transplants	UNOS Bylaws Appendix B, Attachment I, Section XIII, D.(4)	Bylaws-11, Bylaws-12
Conditional Approval of Living Donor Liver Transplant Programs	UNOS Bylaws, Appendix B, Attachment I, Section XIII, D. (4), c.	Bylaws-13

1. **Bylaw description** Membership and Professional Standards Committee Action	2. **Bylaw reference** Appendix A of OPTN Bylaws, Section 2.06 A

3. Purpose of bylaw

The purpose of this bylaw is to:

- Help transplant patients to make informed decisions about their treatment
- Increase transparency in the current transplant center performance review system
- Help to preserve and even enhance the public trust in the donation and transplantation system

4. How to comply with this bylaw

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Comply with all notification requirements outlined by the OPTN/UNOS Board of Directors or OPTN/UNOS Executive Committee.
- Notify all patients associated with the transplant program of the adverse action in writing, in the patient's spoken language, within 30 days of the transplant center receiving formal notification of the adverse action. Patients is defined by this Bylaw as patients undergoing the program's evaluation process, candidates on the waiting list, candidates added to the waiting list during the duration of the action, and recipients being followed by the program.
- Maintain documentation of all patient notifications and provide this documentation upon request.

OPOs are expected to:

- Comply with all notification requirements outlined by the OPTN/UNOS Board of Directors or OPTN/UNOS Executive Committee.

Histocompatibility laboratories are expected to:

- Comply with all notification requirements outlined by the OPTN/UNOS Board of Directors or OPTN/UNOS Executive Committee.

5. How OPTN/UNOS will evaluate member compliance with this bylaw

The Member will be informed of the requirement to notify its patients (as applicable) when the Board or Executive Committee communicates its decision to impose an adverse action. The UNOS Department of Evaluation and Quality will monitor for compliance with candidate notification requirements.

6. Detailed guidance on bylaw compliance

- Implementation date: August 7, 2007

1. Bylaw description Restoration of Membership Privileges	**2. Bylaw reference** Appendix A of OPTN Bylaws, 30.1A, 5.05A, 5.07A

3. Purpose of bylaw

The purpose of this bylaw is to:

- Define the privilege restoration process for a Member who has been placed on Probation, suspended, or declared Member Not in Good Standing

4. How to comply with this bylaw

Compliance strategies may include, but are not limited to, the expectations stated below.

Members will be expected to:

- Fully implement any action plan requested by the OPTN/UNOS Membership and Professional Standards Committee (MPSC), OPTN/UNOS Board of Directors, or OPTN/UNOS Executive Committee
- Demonstrate that the underlying cause of the adverse action has been corrected or eliminated
- Demonstrate that there are no outstanding compliance issues that could lead to a Category I violation, and that the type of violation that resulted in the adverse action is unlikely to occur again
- Submit a request to the MPSC for consideration of restoration of membership privileges when the Member is able to demonstrate that restoration is appropriate

5. How OPTN/UNOS will evaluate member compliance with this bylaw

UNOS staff will monitor the actions requested of the Member by the MPSC, Board, or Executive Committee, in accordance with the OPTN/UNOS Policies and Bylaws, to assist the MPSC, Board, or Executive Committee in assessing Member compliance. UNOS staff will collect, assemble, and provide information related to Member compliance to the MPSC, Board, or Executive Committee as requested.

6. Detailed guidance on bylaw compliance

- Implementation date: June 20, 2008

- The Member may not request restoration of membership privileges until on or after:
    - twelve months after the approval of a corrective action plan, or
    - twelve months after the approval of an action plan subsequent to the Board of Director's or Secretary's adverse action.

1. Bylaw description Survival Rates	**2. Bylaw reference** Appendix B of OPTN Bylaws, Section II.B

3. Purpose of bylaw

The purpose of this bylaw is to codify the Membership and Professional Standards Committee (MPSC) Data Subcommittee review of one-year, post-transplant outcomes.

4. How to comply with this bylaw

Transplant Centers are expected to:

- Respond to inquiries regarding one year post-transplant outcomes
- As applicable, formulate a plan for quality improvement.

5. How OPTN/UNOS will evaluate member compliance with this bylaw

The one-year graft and/or patient survival rates for all OPTN transplant programs are reviewed by the MPSC Data Subcommittee at each meeting. Using a statistically driven method, the Scientific Registry of Transplant Recipients (SRTR) uses blinded data derived from UNet^{SM} to identify programs in which actual one-year patient and/or graft survival falls below the expected rates given individual center donor and recipient characteristics.

Programs with one-year graft and/or patient survival rates below expected identified for review based on three criteria:

- If a program's observed minus expected events is greater than three (i.e. the program experienced an excess of three deaths/failures over the number of expected events),
- the ratio of observed to expected events is greater than 1.5 (i.e. the program experienced 50% more deaths/failures than were expected), and,
- the p-value is less than 0.

The MPSC Data Subcommittee will send inquiries to programs identified to have experienced lower than expected outcomes during a specified 2.5 year cohort.

6. Detailed guidance on bylaw compliance

Based upon its review, the MPSC may require one or more of the following:

- The MPSC may recommend that the program undergo a confidential peer visit, to gain further program insight and to provide pertinent advice to the program's key personnel as to possible improvements in their outcomes.
    - Peer visit expenses will be billed to center.
    - Report will be issued to center, identifying opportunities for improvement.
    - Program must submit detailed plan for quality improvement.
- Develop and implement a plan for quality improvement.
- Participate in an informal discussion with MPSC Data Subcommittee.
- Provide synopses of patient deaths and/or graft failures that occurred within one year of transplant.
- Provide details of external or internal consultation and/or internal quality assurance/performance improvement initiatives.

Programs will continue to be reviewed by the MPSC until improvements in one-year survival rates are demonstrated in subsequent years.

1. Bylaw title	2. Bylaw description
(a) Inactive Membership Status (b) Inactive Program Status	(a) Appendix B to OPTN Bylaws, Section II.C (b) Attachment I to Appendix B of OPTN Bylaws, Section II

3. Purpose of bylaw

The purpose of this bylaw is to codify the Membership and Professional Standards Committee (MPSC) Data Subcommittee review of transplant program functional activity and inactive membership status.

4. How to comply with this bylaw

Transplant Centers are expected to:

- Remain functionally active
- Explain reasons for functional inactivity upon request
- Provide notice of inactivity to the OPTN and patients as described in the bylaw

If a transplant program is unable to remain functionally active, the Member may:

- voluntarily inactivate a transplant program's membership status for up to 12 months, or
- voluntarily withdraw (relinquish) designated transplant program membership status.

Please review section six for a description of what is involved with inactivation or relinquishment of program status.

5. How OPTN/UNOS will evaluate member compliance with this bylaw

Functionally inactivity is defined as:

- The inability to serve patients, as a group, for a period of 15 days or more, or
- No transplant performed for a period of time:
  - three months in the case of kidney, liver, and heart transplant programs,
  - six months in the case of pancreas and lung programs,
  - one year in the case of transplant programs located in stand-alone pediatric transplant hospitals.

Programs identified to be functionally inactive are given the opportunity to submit an explanation for program inactivity and assurance that the program remains qualified to provide transplant services.

6. Detailed guidance on bylaw compliance

For periods of inactivity greater than 12 months, the Member should voluntarily withdraw (relinquish) its transplant program membership status.

Based upon its review, the MPSC may require one or more of the following:

- Develop and implement a plan for quality improvement.
- Participate in an informal discussion with MPSC Data Subcommittee.

- Provide details of external or internal consultation and/or internal quality assurance/performance improvement initiatives.

Program inactivation or relinquishment of designated transplant program status involves:

(i) prompt suspension of transplantation,

(ii) written notice to candidates (with a copy to UNOS) to be distributed within 5 business days of inactivation date, explaining: (1) the program's reasons to inactivate (2) that while still on the waiting list of the inactive program the candidate cannot receive an organ offer and (3) options for candidates to transfer with the phone number of the administrative office of the inactivating center to help with patient transfers,

(iii) expedited removal of these candidates from the program's waiting list, or - if the candidate desires - transfer of the candidate to the list of another OPTN Member Transplant Hospital, and

(iv) assistance for candidates in identifying the designated transplant programs to which they can transfer.

Furthermore, it is necessary that an inactivated program keep UNOS informed of its progress in transferring candidates by:

(i) providing a list of all the center's transplant candidates on the transplant waiting list at the time of inactivation and updating it throughout this process.

(ii) ensuring that any active candidate hospitalized at the inactive center is transferred to an accepting transplant center within 7 days unless discharge is anticipated within that time.

(iii) providing a priority list of the most urgent candidates listed with an individualized plan of transfer, potential center, and a timeline.

(iv) indicating on the list whether each candidate has chosen to transfer or not.

a) if a candidate has chosen *not* to transfer, provide the reason and indicate whether the candidate has been completely informed of the implications of this decision; or,

b) if a candidate has chosen to transfer, indicate to which transplant program a candidate is transferring. Periodic updates will be required as to the status of that candidate's transfer process until the candidate is evaluated by the accepting program and an official decision is made regarding the candidate's listing status.

A program that wishes to reactivate, or re-start transplantation after inactivation, must submit appropriate application materials demonstrating that the program meets all OPTN membership criteria.

1. **Bylaw description** Patient Notification	2. **Bylaw reference** Appendix B to OPTN Bylaws, section II.F

3. Purpose of bylaw

The purpose of this bylaw is to:

- Ensure that Transplant Hospitals provide appropriate notification to patients upon being placed on or removed from the Waiting List
- Establish the information that must be included in patient notifications

4. How to comply with this bylaw

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Notify patients in writing within ten business days of the patient's being placed on the Waiting List or the determination that the patient will not be placed on the Waiting List
- Notify patients in writing within ten business days of the a candidate's removal from the Waiting List for reasons other than transplantation or death
- Include all the information required by the bylaw in the written notifications, including the date of listing, if applicable, and indication that they have included the UNOS Patient Information Letter
- Send a copy of the UNOS Patient Information Letter with these notifications
- Maintain documentation of these notifications and make it available upon request for compliance monitoring purposes

5. How OPTN/UNOS will evaluate member compliance with this bylaw

Through on-site reviews, staff verifies the presence of appropriate notifications to candidates concerning their Waiting List status. Staff refers potential policy violations to the appropriate committee for review.

6. Detailed guidance on bylaw compliance

- As of March 7, 2001, send written notification to patients within 10 business days of:
  - Completion of the transplant evaluation (if patient is not going to be listed)
  - Being placed on the waiting list (notification must **include date of listing in body of letter**)
  - Being removed from the waiting list for reasons other than transplant or death
- As of February 15, 2007, **include the Patient Services Line telephone number** in the required notifications: (888) 894-6361 (This requirement is in effect during the period February 15, 2007 through June 30, 2009. See next bullet.)
- As of July 1, 2009, **include a copy of the UNOS Patient Information letter** with all notifications
  - Include a statement in the notification letters referencing the inclusion of the UNOS Patient Notification Letter. Centers are encouraged to use this sample language:

    "Attached is a letter from the United Network for Organ Sharing (UNOS). It describes the services and information offered to patients by UNOS and the Organ Procurement and Transplantation Network."

- Link to the UNOS Patient Information letter: http://optn.transplant.hrsa.gov/resources/professionalResources.asp. Select UNOS Patient Information Letter from the drop-down menu.

- If a candidate expires before the 10th business day following removal from the waiting list, the transplant center is not required to send the candidate written notification of removal from the waiting list for reasons other than transplant or death.
- If a candidate is removed from the waiting list by UNOS because the candidate has transferred to a different transplant center, the transplant center where the candidate is no longer listed is required to send the candidate written notification of removal from the list for reasons other than transplant or death.
- Link to the Notice for Change to Patient Notification Bylaw
- Link to the Clarification of Change to Patient Notification Bylaw

2. Bylaw description Transplant Surgeon and Physician, Program Coverage Plan	**2. Bylaw reference** Attachment I to Appendix B of OPTN Bylaws, section VII

3. Purpose of bylaw

The purpose of this bylaw is to:

- Define what "on site" means with relation to the availability of transplant surgeons and physicians to provide service to their candidates in need of organ transplant
- Require all transplant programs to develop a program coverage plan to ensure there is appropriate surgeon/physician coverage
- Require all transplant programs to submit this coverage plan to the OPTN
- Require transplant programs to notify their candidates of the coverage plan when the candidates are listed, and notify all patients when there are significant program changes

4. How to comply with this bylaw

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Develop program coverage plans to ensure appropriate surgeon/physician coverage for each program
- Submit coverage plans to the OPTN
- Provide candidates a written summary of the program coverage plan when the candidates are listed
- Provide candidates a written summary of the program coverage plan when there are significant program or personnel changes

5. How OPTN/UNOS will evaluate member compliance with this bylaw

Staff will verify the submission of coverage plans to the OPTN as required. During site surveys of transplant centers, staff will verify that candidates are notified of the Program Coverage Plan at the time of listing and also that all patients were notified if there are significant program or personnel changes.

Staff refers potential policy violations to the appropriate committee for review.

6. Detailed guidance on bylaw compliance

- Implementation date: May 9, 2007

1. Bylaw description Model Elements for Controlled DCD Recovery Protocols	**2. Bylaw reference** Attachment III to Appendix B of the OPTN Bylaws

3. Purpose of bylaw

The purpose of this bylaw is to:

- Require OPOs and Transplant Hospitals to develop and comply with protocols to facilitate the recovery of organs from DCD donors
- Require members to use the model elements in the members' DCD protocols

4. How to comply with this bylaw

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs and transplant centers are expected to:

- Develop DCD protocols that include the required model elements set forth in Attachment III to Appendix B of the OPTN Bylaws

5. How OPTN/UNOS will evaluate member compliance with this bylaw

Through on-site reviews of OPOs and Transplant Centers, staff verifies the presence of DCD protocols. Staff refers potential policy violations to the appropriate committee for review.

6. Detailed guidance on bylaw compliance

- As of January 1, 2007, all OPOs and transplant centers are responsible for having DCD protocols in place
- By July 1, 2007, the protocols must include the model elements

1. **Bylaw description** Kidney Transplant Programs that Perform Living Donor Kidney Transplants	2. **Bylaw reference** Attachment I to Appendix B of UNOS Bylaws, Section XIII, D.(2)

3. Purpose of bylaw

The purpose of this bylaw is to:

- Develop a minimum set of criteria for granting designated program status to programs that perform living kidney donor transplants
- Ensure adequate donor education/informed consent
- Further protect the health and safety of all living kidney donors

4. How to comply with this bylaw

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Develop, implement, and comply with written protocols that address all phases of living kidney donation outlined in the Bylaws
- Document that all phases of the living kidney donation process were performed in adherence to protocols, maintain this documentation, and make this documentation available upon request

5. How OPTN/UNOS will evaluate member compliance with this bylaw

- The applications for living kidney donor programs will be reviewed by UNOS staff to ensure that the applications are complete. Following staff review, applications will be forwarded to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for its evaluation and recommendation. Living kidney donor program applications will be approved by the OPTN/UNOS Board of Directors or OPTN/UNOS Executive Committee.
- <u>After a program receives approval as a living kidney donor program according to the requirements implemented on October 18, 2007, UNOS staff will incorporate a review of living kidney donor programs into the routine site survey process.</u> During site surveys of transplant centers with approved living kidney donor programs, UNOS staff will review the program's written protocols and a sample of living donor/recipient records. UNOS staff will review the documentation in the donor and recipient records to verify that all phases of the living kidney donation process were performed in adherence to the program's protocols. Any potential policy violations identified by UNOS staff will be forwarded to the MPSC for its review and potential action.

6. Detailed guidance on bylaw compliance

- Implementation date: October 18, 2007
- Beginning in September 2008, transplant centers that perform living donor kidney transplants will be required to submit an application for approval of the living donor kidney transplant program. The application process is being staggered by region; UNOS will send notification to key staff members at each existing kidney transplant program to inform them of the schedule for submission.
- As of August 18, 2008, the transplant center must give to the living donor, during the informed consent process, the telephone number that is available for reporting concerns and grievances to the OPTN. The telephone number is: (888) 894-6361.
- Resources on living donation are available at: http://www.unos.org/living_donation.asp

1. **Bylaw description** Liver Transplant Programs that Perform Living Donor Liver Transplants	2. **Bylaw reference** Attachment I to Appendix B of UNOS Bylaws, Section XIII, D.(4)

3. Purpose of bylaw

The purpose of this bylaw is to:

- Develop a minimum set of criteria for granting designated program status to programs that perform living liver donor transplants
- Ensure adequate donor education/informed consent
- Further protect the health and safety of all living liver donors

4. How to comply with this bylaw

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Develop, implement, and comply with written protocols that address all phases of living liver donation outlined in the Bylaws
- Document that all phases of the living liver donation process were performed in adherence to protocols, maintain this documentation, and make this documentation available upon request

5. How OPTN/UNOS will evaluate member compliance with this bylaw

- The applications for living liver donor programs will be reviewed by UNOS staff to ensure that the applications are complete. Following staff review, applications will be forwarded to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for its evaluation and recommendation. Living liver donor program applications will be approved by the OPTN/UNOS Board of Directors or OPTN/UNOS Executive Committee.
- <u>After a program receives approval as a living liver donor program according to the requirements implemented on October 18, 2007, UNOS staff will incorporate a review of living donor liver programs into the routine site survey process.</u> During site surveys of transplant centers with approved living donor liver programs, UNOS staff will review the program's written protocols and a sample of living donor/recipient records. UNOS staff will review the documentation in the donor and recipient records to verify that all phases of the living donation process were performed in adherence to the program's protocols. Any potential policy violations identified by UNOS staff will be forwarded to the MPSC for its review and potential action.

6. Detailed guidance on bylaw compliance

- Implementation date: October 18, 2007
- If a program is an approved living donor liver (LDL) transplant program, UNOS will send a request for additional information in August 2008. The purpose of this request it to assess if programs meet the additional requirements that were approved for living donor liver programs. This "Request for Required Additional LDL Transplant Program Application Information" must be completed by all programs approved to perform living donor liver transplantation.
- New applicants will receive applications upon request. New applications for programs that intend to perform living donor liver transplants include the same questions that are included in the request for information.
- As of August 18, 2008, the transplant center must give to the living donor, during the informed consent process, the telephone number that is available for reporting concerns and

grievances to the OPTN. The telephone number is: (888) 894-6361.

- Resources on living donation are available at: http://www.unos.org/living_donation.asp

1. **Bylaw description** Liver Transplant Programs that Perform Living Donor Liver Transplants	2. **Bylaw reference** Attachment I to Appendix B of UNOS Bylaws, Section XIII, D.(4), c

3. Purpose of bylaw

The purpose of this bylaw is to:

- Describe the reporting requirements and expectations for programs that are conditionally approved to perform living liver donor transplants. Transplant programs can be granted one year to fully comply with applicable membership criteria with a possible one year extension.

4. How to comply with this bylaw

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to comply with all applicable policies and procedures and must demonstrate continuing progress toward full compliance with Criteria for Institutional Membership. The Member will be informed of the reporting requirements when the Board or Executive Committee communicates its decision regarding conditional approval.

5. How OPTN/UNOS will evaluate member compliance with this bylaw.

The progress of each program towards meeting the requirements for full approval will be monitored and reported to the Membership and Professional Standards Committee (MPSC) on an ongoing basis.

The Committee will review a report, provided by the transplant center, prior to the conclusion of the first year of conditional approval. If the program continues to be conditionally approved for a second year, the MPSC will review a final report prior to the end of the approval term. This final report must document the Member's ability to meet the requirements for full approval.

6. Detailed guidance on bylaw compliance

- Implementation date: June 20, 2008.
- The transplant center must submit reports describing the surgeon's progress towards meeting the requirements and such other operating conditions as may be required by the MPSC to demonstrate ongoing quality and efficient patient care.
- The transplant center must provide a report prior to the conclusion of the first year of conditional approval. The report must document:
  - the surgeon's progress towards meeting the bylaws requirements, or
  - that the program is making sufficient progress in recruiting a transplant surgeon who meets the criteria for a qualified live donor liver surgeon.
- If the surgeon meets the requirements prior to the end of the period of conditional approval, the program may submit a progress report and request review by the MPSC.
- If at the end of the 2-year conditional approval period the program is unable to demonstrate that it has two designated surgeons on-site who can fully meet the primary living donor liver surgeon requirements, it must stop performing living donor liver transplants by either:
  (i) inactivating the living donor part of the program for a period up to 12 months; or
  (ii) relinquishing the designated transplant program status for the living donor part of the liver transplant program until it can meet the requirements for full approval.
- Resources on living donation are available at: http://www.unos.org/living_donation.asp

1. Policy title Host OPO	**2. Policy number** 2.1 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Identify and define the role of the Host OPO within the organ transplant process. Host OPOs identify the donor, evaluate and maintain the donor, obtain consent for the removal of organs, and allocate organs.
- Outline the Host OPO's responsibilities for registering each donor in UNet[sm], executing match runs, obtaining the donor's social history, and preserving and shipping donor organs. This policy also specifies what documentation should accompany the organ.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Comply with all the specific provisions related to minimum procurement standards for procuring and allocating an organ
- Make reasonable attempts to obtain a medical/behavioral history from individual(s) familiar with the donor

5. How OPTN/UNOS will evaluate member compliance with this policy

During the site review, staff selects a random sample of donor records, based on the number of donors the OPO had in the previous year and reviews the donor file documentation to verify that the OPO has complied with all policies related to the evaluation of potential donors.

1. Policy title Evaluation of Potential Donors	**2. Policy number** 2.2 **Subsections** 2.2.1

3. Purpose of policy

The purpose of the policy is to

- Ensure that the donor has been declared dead prior to organ procurement

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Develop policies and procedures regarding how OPO staff is to verify that the donor has been declared legally dead

5. How OPTN/UNOS will evaluate member compliance with this policy

During the site review, staff selects a random sample of donor records and staff reviews donor file documentation to verify

- That the donor has been declared dead in accordance with applicable laws

6. Detailed guidance on policy compliance

- Retain all documentation related to the determination of brain death in the donor file
- Retain all declaration of death progress notes for all Donation after Cardiac Death (DCD) donors in the donor file
- Educate clinical coordinators in these requirements
- Maintain of copy of the brain death law for every state in which it provides services
- Educate staff in pertinent brain death law(s)
- Include compliance with document retention policies in OPO's routine quality assurance process

2. **Policy title** Evaluation of Potential Donors	2. **Policy number** 2.2 **Subsections** 2.2.2

3. Purpose of policy

The purpose of the policy is to

- Make the OPO responsible for ensuring that all required testing is performed and that the results are communicated to transplant centers with organ offers
- Ensure that the OPO has thoroughly evaluated the donor and that the results of the evaluation are communicated to transplant centers with organ offers

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Ensure that all required evaluations are performed, documented, and communicated to the OPO or transplant centers with organ offers
- Thoroughly evaluate the donor, document the evaluation, and make the results of the evaluation available to transplant centers with organ offers
- Document in the donor record the circumstances when such information is not available

5. How OPTN/UNOS will evaluate member compliance with this policy

During the site review, staff selects a random sample of donor records and staff reviews donor file documentation to verify

- That the donor has been properly evaluated. The Host OPO must:
  - Obtain the donor's medical/behavioral history
  - Review the donor's medical chart
  - Perform a physical examination of the donor
  - Obtain the donor's vital signs
- That all required evaluations are performed as specified by this policy and its subsections

6. Detailed guidance on policy compliance

- Evaluate all donors in accordance with established policies
- Educate clinical coordinators in these requirements
- Obtain history from persons familiar with the donor by conducting interviews in person or by telephone
- Interview more than one person when necessary to clarify or obtain additional information about the donor
- Maintain clear documentation of interviews in the donor file, including the relationship of the person(s) interviewed to the donor
- Maintain the following records in the donor file: a completed donor history form, evidence

that the OPO has reviewed the donor's medical record, written evidence that the OPO has performed a physical examination, records of the donor's vital signs

- Document circumstances when such information is not available
- Include compliance with document retention policies in OPO's routine quality assurance process

1. **Policy title** Performing Pertinent Tests on all Potential Donors	2. **Policy number** 2.2.3 **Subsections** 2.2.3.1 2.2.3.2 2.2.3.3 2.2.3.4 2.2.3.5 2.2.3.6

3. Purpose of policy

The purpose of the policy is to:

- Require the Host OPO to perform pertinent tests and provide this information to the OPO or transplant center
- Specify the types of clinical testing the OPO is required to perform for all donors
- Specify the additional clinical testing the OPO is required to perform for each organ donated

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Educate all procurement coordinators in the clinical tests required to be performed for all potential donors (policy subsection 2.2.3.1). As of April 21, 2008, this policy also includes the requirement for a urinalysis to be performed within 24 hours of cross-clamp for all donors. Previously this requirement was only stated in Policy 2.5.1.
- Educate all procurement coordinators in the additional clinical tests required to be performed for potential renal donors (2.2.3.2), potential liver donors (2.2.3.3), potential heart donors (2.2.3.4), potential pancreas donors (2.2.3.5), and potential lung donors (2.2.3.6)
- Perform all specified tests as required and maintain hard copies of the results of all tests performed in the donor file
- Document when such information is not available in the donor record

5. How OPTN/UNOS will evaluate member compliance with this policy

During the site review, staff reviews a sample of donor records based on the number of donors the OPO had in the previous year. Staff verifies that the OPO has performed the required clinical tests by reviewing documentation maintained in the donor file.

6. Detailed guidance on policy compliance

- OPO policies and procedures should include requirements to conduct all required tests. The OPO should monitor compliance with this policy as part of its own quality assurance process
- The OPO must maintain documentation that required tests were performed and document unavailability of pertinent testing in progress notes in donor file
- As of August 18, 2008, serologic diagnostic tests may be used in place of screening tests to detect hepatitis, EBV, RPR/VDRL, HTLV, and CMV. Diagnostic tests may be FDA licensed, approved, or cleared. (Policy 4.1 still requires FDA licensed screening tests to be used for detecting HIV I/II.)

1. **Policy title** Donor Maintenance	2. **Policy number** 2.3 **Subsections** 2.3.1 2.3.2 2.3.3 2.3.4 2.3.5

3. Purpose of policy

The purpose of the policy is to:

- Specify the OPO's responsibility for donor maintenance and for the documentation of donor maintenance.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Make reasonable efforts to maintain the deceased donor, document these efforts, and communicate this information to the OPO or transplant center
- Develop policies and procedures specific to donor maintenance
- Monitor compliance with these policies as part of quality assurance process

5. How OPTN/UNOS will evaluate member compliance with this policy

During the site review, staff reviews a sample of donor records based on the number of donors in the previous year. Staff verifies that the OPO has documented a donor's vital signs and fluid intake and output. Staff also verifies that the OPO has documented any donor management medications.

6. Detailed guidance on policy compliance

- Ensure that all procurement staff are competent in donor management and documenting all aspects of donor maintenance
- Ensure staff are familiar with the OPO's donor management regimes and medication administration protocols
- Document any medications given to the donor in the donor file
- Include the date, time, and duration a medication was administered in the documentation
- Include documentation of the donor's vital signs and the donor's fluid intake and output in the donor record

1. Policy title Obtaining Consent	**2. Policy number** 2.4 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Specify that the OPO must properly document the consent for organ donation

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Ensure that the donor files contain evidence of consent for donation and that there is evidence of consent with states that have first person consent laws
- Maintain documentation in the donor file to reflect the donor's wishes if consent for donation was based on documentation of the donor's wishes

5. How OPTN/UNOS will evaluate member compliance with this policy

During the site review, staff reviews a sample of donor records based on the number of donors the OPO had in the previous year. Staff verifies that all donor files include documentation of consent for organ donation.

6. Detailed guidance on policy compliance

- Include copies of documentation in the donor file such as a copy of the driver's license, donor card, donor registry information
- Include compliance with document retention policies in the OPO's routine quality assurance process

1. Policy title Organ Procurement Quality	**2. Policy number** 2.5 **Subsections** 2.5.1 2.5.2 2.5.3

3. Purpose of policy

The purpose of the policy is to:

- Verify that the donor file includes documentation of all items in section 2.2, the use of standard surgical techniques in a sterile operating environment, maintaining preservation media at appropriate temperature, and the use of flush solutions and additives.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Maintain flush solutions and preservation media at appropriate temperatures and maintain specified data in the record (2.5.3)
- Ensure donor medications are given at appropriate times and that medication administration, including flush solutions and additives, is recorded during the retrieval process
- Ensure that procurement staff is aware that these factors maintaining donor quality are to be documented in the donor file
- Reflect donor quality factors as outlined in OPTN Policy in the OPO's policies and procedures

5. How OPTN/UNOS will evaluate member compliance with this policy

During the site review staff reviews a sample of donor records based on the number of donors the OPO had in the previous year. Staff verifies that all donor files include documentation of donor quality factors.

1. **Policy title** Organ Procurement Quality	2. **Policy number** 2.5.4 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Ensure that OPOs and their respective histocompatibility laboratories define and document the minimum tissue typing material required to generate match runs for local or regional placement of all organs.
- Since kidneys and pancreata are frequently shipped outside of the OPO's service area, this policy outlines the minimal amount of tissue typing material that must be sent with each kidney and pancreas.
- For all other organs, the OPO will provide lymph nodes if requested and available.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Ensure that they, along with the histocompatibility laboratories in their service area, have written requirements for tissue typing materials
- Ensure that their policies and procedures for shipping kidneys and pancreata meet the minimum requirements for tissue typing materials
- Ensure that their policies and procedures for all other organs address providing lymph nodes if requested and available.
- Ensure that procurement staff is familiar with these requirements and that the amount of tissue typing materials sent with each kidney or pancreas and, for all other organs, the provision of lymph nodes is documented in the donor file

5. How OPTN/UNOS will evaluate member compliance with this policy

During the site review, staff reviews the OPO's policies and procedures to determine if the OPO's policies for tissue typing materials meet this requirement.

6. Detailed guidance on policy compliance

- Best practice suggestion: Some OPO's include a quality assurance feedback form with the tissue typing materials to obtain feedback regarding the adequacy of materials sent
- Link to "Specimens for Histocompatibility Testing Guidelines for OPOs"
- Review the OPTN's Recommended Histocompatibility Guidelines
- As of December 18, 2007, policy was modified to clarify that one red topped tube needs to be sent with each kidney or pancreas for ABO verification.

1. Policy title Organ Procurement Quality	**2. Policy number** 2.5.5 2.5.6 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Require proper packaging for organs
- Specify the documentation that must accompany each organ

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Ensure that their policies and procedures meet these requirements and that their coordinators are familiar with the requirements
- Include the following information with each organ:
    - ABO typing source documents
    - Serology results
    - Medical/Behavioral History form
    - Donor evaluation
    - Complete record of donor management
    - Consent form
    - Organ quality as described in policy 2.5

5. How OPTN/UNOS will evaluate member compliance with this policy

During the site review, staff will observe how a procurement coordinator would pack a kidney for shipping. Staff inspects the shipping supplies and labels, and asks a coordinator what documentation accompanies the organ for shipping. Staff also reviews the OPO's policies and procedures for compliance with these requirements.

6. Detailed guidance on policy compliance

- Refer to Policy 5.0 for information about proper packaging of organs for transplant http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_17.pdf

1. Policy title Organ Procurement Quality	**2. Policy number** 2.5.7 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Specify the Host OPO's responsibilities regarding maintaining complete documentation for all organs recovered. The Host OPO is responsible for arranging local transportation for procurement teams.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Maintain complete documentation on all organs recovered
- Arrange transportation to and from the local airport for non-local procurement teams

5. How OPTN/UNOS will evaluate member compliance with this policy

During the site review, staff reviews a sample of donor files based on the number of donors the OPO had in the previous year. Staff verifies the documentation of donor management medications and information on all organs recovered pursuant to this policy.

1. Policy title Initiating Organ Procurement and Placement	**2. Policy number** 2.6 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Specify when OPOs should initiate tissue typing

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Ensure that, if possible, pre-procurement tissue typing is performed

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS monitors all allocations and investigates instances in which an OPO offers an organ prior to performing tissue typing. In such cases, staff writes a letter of inquiry and forwards the results to the MPSC for review.

6. Detailed guidance on policy compliance

- Link to "Specimens for Histocompatibility Testing Guidelines for OPOs" http://optn.transplant.hrsa.gov/SharedContentDocuments/Histo_Brochure_2006.pdf
- Review the OPTN's Recommended Histocompatibility Guidelines: http://optn.transplant.hrsa.gov/SharedContentDocuments/Histocompatibility_Guidelines.pdf

1. Policy title Removal of Non-Renal Organs	**2. Policy number** 2.7 **Subsections** N/A
3. Purpose of policy The purpose of the policy is to: • Give the extra-renal transplant team the option to procure extra-renal organs	
4. How to comply with this policy *Compliance strategies may include, but are not limited to, the expectations stated below.* OPOs are expected to: • Allow for extra-renal procurement teams to procure extra-renal organs in their policies and procedures	
5. How OPTN/UNOS will evaluate member compliance with this policy During the site review, staff reviews and verifies that the OPO's policies and procedures allow for the procurement of extra-renal organs.	

1. Policy title Multiple Abdominal Organ Procurement	**2. Policy number** 2.7.1 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Ensure that both the liver and pancreas are procured, if transplantable, and to maximize the number of recovered organs. If both cannot be procured, the surgeon(s) should document in writing on the donor form the specific reason(s) for failure to procure both organs.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Require procurement teams to work together in order to procure the optimal number of donor organs
- Document the specific reason for non-recovery of an authorized organ
- Complete the related questions on the DDR

5. How OPTN/UNOS will evaluate member compliance with this policy

During the site review, staff reviews a sample of donor files based on the number of donors the OPO had in the previous year. If all authorized organs are not recovered, UNOS site surveyors verify that this documentation is in the donor record.

6. Detailed guidance on policy compliance

- As of April 21, 2008, the OPO should document in the donor workbook the clinical findings that do not allow pancreas recovery for organ transplant.
- Include compliance with documentation requirements in the OPO's routine quality assurance process

1. Policy title Organ Recovery from a DCD Donor	**2. Policy number** 2.8 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Set standards for organ recovery from a DCD donor

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Develop and implement protocols that contain the standards of the DCD Model Elements as adopted in the OPTN Bylaws, Appendix B, Attachment III.

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS examines any complaints or potential policy violations and refers them to the appropriate OPTN/UNOS committee.

1. Policy title Multi-Cultural and Diversity Issues	**2. Policy number** 2.9 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Ensure that the OPO develops and implements a plan to address multi-cultural issues related to organ donation

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Develop and implement plans addressing and educating the public about cultural issues that serve as barriers to organ donation.

5. How OPTN/UNOS will evaluate member compliance with this policy

No monitoring efforts are required.

1. Policy title OPO	**2. Policy number** 3.1.1 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Define an Organ Procurement Organization (OPO)
- State the purpose of OPOs and explain OPOs work within geographic territories

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

No specific action is required of members.

5. How OPTN/UNOS will evaluate member compliance with this policy

No monitoring efforts are required.

1. **Policy title** Transplant Center	2. **Policy number** 3.1.2 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Define a transplant center
- Outline the responsibility of the transplanting surgeon at the transplant center receiving an organ. The transplant surgeon is responsible for ensuring medical suitability between donor and recipient.
- Ensure that transplant centers establish, document and perform a verification of the recorded ABO of the donor, UNOS Donor ID, and recorded ABO of the recipient upon receipt of an organ and prior to implantation.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Verify and document the accuracy of the UNOS Donor ID number, donor ABO, and recipient ABO after receipt of a live or deceased donor organ and prior to its implantation.

5. How OPTN/UNOS will evaluate member compliance with this policy

During surveys of transplant centers, Department of Evaluation and Quality (DEQ) staff verifies that donor ABO, recipient ABO, and UNOS donor ID verification is documented after receipt of an organ and prior to its implantation. DEQ staff requests a corrective action plan if the center's documentation does not comply with the requirements of OPTN Policy 3.1.2 and forwards the results of surveys to the OPTN/UNOS Membership and Professional Standards Committee for review.

6. Detailed guidance on policy compliance

- As of February 1, 2004, the policy:
  a. places the responsibility to ensure medical suitability between donor and recipient, including ABO compatibility, on the transplanting surgeon; and
  b. requires the transplant center to verify and document verification of recorded donor ABO and recipient ABO after receipt of an organ and prior to implantation.
- As of September 1, 2007, the policy requires that the Donor ID be included in the verification performed after receipt of a live or deceased donor organ and prior to its implantation.
- Refer to OPTN Policy 5.0 for live donor organ ABO verification and packaging requirements.

1. **Policy title** Waiting List	2. **Policy number** 3.1.4 **Subsections** 3.1.4.1 3.1.4.2 3.1.4.3

3. Purpose of policy

The purpose of the policy is to:

- Define the OPTN waiting list
- Ensure the accuracy of ABO data for transplant candidates listed within UNet^{SM}
- Ensure that only transplant candidates whose ABO has been verified in UNet^{sm} by two different users appear on organ match runs

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Ensure that each candidate is ABO typed on two separate occasions prior to listing (see Detailed Guidance for definition of "two separate occasions").
- Ensure that the individual who **adds a candidate to the waiting list** reviews the source document from each of the two ABO typings to **enter the candidate's ABO** on the waiting list
- Ensure that the individual who **reviews the candidate's ABO**, after the candidate has been added to the waiting list, reviews the source document from each of the two ABO typings to **verify the candidate's ABO** on the waiting list
- Ensure that verification of the transplant candidate occurs by an individual other than the person initially entering the ABO data
- Maintain written documentation that the candidate's ABO was entered and verified by two separate individuals reviewing both of the source documents from each ABO typing and make the documentation available for audit

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS staff monitors newly listed candidates to ensure transplant centers are performing the ABO verification in a timely manner because a candidate is not eligible to appear on a match run until the candidate's ABO has been verified. When a candidate's ABO remains unverified for more than 24 hours, UNOS staff contacts the listing transplant center.

UNOS staff monitors the waiting list for any changes made to a candidate's ABO. A change may occur when:

- A candidate is listed for multiple organs
- A candidate is listed at multiple transplant centers
- The user changes the ABO before the ABO has been verified by a second user
- A candidate is removed from the waiting list and relisted with a different ABO

When a change is detected, UNOS staff contacts the transplant center to request source documentation of the candidate's ABO and an explanation of the event. If an error has occurred, a corrective action plan may be requested.

UNOS staff also reviews a sample of candidate records during site surveys of transplant centers for:

- Accuracy of ABO
- Two separate typings prior to listing
- Procedures to ensure that entry and verification occurs by two separate individuals reviewing source documentation.

UNOS staff forwards all potential policy violations to the OPTN/UNOS Membership and Professional Standards Committee for its review and potential action.

6. Detailed guidance on policy compliance

- Transplant centers are expected to develop, implement, and comply with a procedure(s) that ensures:
    - Each candidate is ABO typed on two separate occasions prior to listing
    - Both source documents are used to enter and verify a candidate's ABO in UNet^{sm}
    - That adherence to this process is adequately documented for each candidate who is added to the waiting list

  Policy 3.1.4 was implemented on October 4, 2004.

- It is the transplant center's responsibility to ensure that each candidate's ABO is accurate and that the source documents are reviewed by the users who enter and verify a candidate's ABO in UNet^{sm}. Delegation of this duty to another institution such as a histocompatibility laboratory does not negate the transplant center's membership responsibility to ensure the accuracy of candidate ABO data on the waiting list.
- As of April 21, 2008, "two separate occasions" is defined as two samples, taken at different times, sent to the same or different labs.
- To view instructions on performing the initial ABO entry when adding a candidate to the waiting list, follow these steps:
    - In UNet^{SM}, select Waitlist^{SM} Help, select Index, and then search for "Adding a Candidate to the WaitList^{SM}."
- To view instructions on verifying a candidate's ABO after the candidate has been added to the waiting list, follow these steps:
    - In UNet^{SM}, select Waitlist^{SM} Help, select Index, and then search for "Verifying a Candidate's ABO."

1. Policy title Match System	**2. Policy number** 3.1.5 **Subsections** N/A
3. Purpose of policy The purpose of the policy is to: • Define the Match System	
4. How to comply with this policy *Compliance strategies may include, but are not limited to, the expectations stated below.* No specific action is required of members.	
5. How OPTN/UNOS will evaluate member compliance with this policy No monitoring efforts are required.	

1. Policy title Host OPO	**2. Policy number** 3.1.6 **Subsections** N/A
3. Purpose of policy The purpose of the policy is to: • Define Host OPO	
4. How to comply with this policy *Compliance strategies may include, but are not limited to, the expectations stated below.* No specific action is required of members.	
5. How OPTN/UNOS will evaluate member compliance with this policy No monitoring efforts are required.	

1. Policy title Alternative Allocation/Distribution System (AAD Systems)	**2. Policy number** 3.1.7 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Define local organ allocation that is different from the standard organ allocation outlined in OPTN policy. These AAD systems are designed to increase organ availability and/or quality while addressing possible distribution inequities that are unique to that geographical area.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Follow the allocation algorithm agreed upon when recovering organs in areas that follow an AAD system

5. How OPTN/UNOS will evaluate member compliance with this policy

All organ allocations are examined by UNOS for compliance with OPTN policies and AAD systems approved by the OPTN/UNOS Board of Directors and implemented in the UNet^{SM} system.

1. Policy title Variances	**2. Policy number** 3.1.8 **Subsections** N/A
3. Purpose of policy The purpose of the policy is to: • Define the term "variance"	
4. How to comply with this policy *Compliance strategies may include, but are not limited to, the expectations stated below.* No specific action is required of members.	
5. How OPTN/UNOS will evaluate member compliance with this policy No monitoring efforts are required.	

1. Policy title Committee-Sponsored Alternative System	**2. Policy number** 3.1.9 **Subsections** N/A
3. Purpose of policy The purpose of the policy is to: • Define the term "Committee-Sponsored Alternative System"	
4. How to comply with this policy *Compliance strategies may include, but are not limited to, the expectations stated below.* No specific action is required of members.	
5. How OPTN/UNOS will evaluate member compliance with this policy No monitoring efforts are required.	

1. Policy title Local and Alternative Local Unit	**2. Policy number** 3.1.10 **Subsections** 3.1.10.1 3.1.10.2 3.1.10.3 3.1.10.4 3.1.10.5 3.1.10.6

3. Purpose of policy

The purpose of the policy is to:

- Define "Local Unit" and "Alternative Local Unit" (ALU)
- Define the number of waiting lists utilized in each local area; the tabulation of data concerning organ recovery, distribution, quality, and function; the on-going assessment of organ distribution equity within the Local Unit; and the on-going assessment of organ recovery to ensure the enhancement of organ supply.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs that are themselves a Local Unit or a region of their Donor Service Area is an Alternative Local Unit are expected to:

- Allocate organs recovered within that same Local Unit or Alternative Local Unit first. If the Alternative Local Unit is the first area, the second shall be the Local Unit prior to regional or national distribution.

5. How OPTN/UNOS will evaluate member compliance with this policy

All organ allocations are examined by UNOS for compliance with OPTN policies and ALU's approved by the OPTN/UNOS Board of Directors. OPOs that deviate from the previously mentioned policies or agreements are asked to respond in writing with details describing the circumstances of the deviation.

1. Policy title Sharing Arrangement and Sharing Agreement	**2. Policy number** 3.1.11 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Allow two or more OPOs who share geographical boundaries in their Donor Service Areas to allocate organs interregionally or intraregionally between or among the OPOs

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Distribute organs according to the waiting lists established by the sharing agreements or by Alternative Local Units (ALUs) approved by the OPTN/UNOS Board of Directors

5. How OPTN/UNOS will evaluate member compliance with this policy

All organ allocations are examined by UNOS for compliance with OPTN Policies and ALU's approved by the OPTN/UNOS Board of Directors. OPOs that deviate from the previously mentioned policies or agreements are asked to respond in writing with details describing the circumstances of the deviation.

1. Policy title Alternative Point Assignment Protocols	**2. Policy number** 3.1.12 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Allow OPTN Members participating in a OPTN/UNOS Board of Directors approved Alternative Local Unit (ALU) or Sharing Arrangement to assign points outside of those listed in OPTN Policies 3.5 through 3.11

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs and transplant centers are expected to:

- Remain cognizant of policy changes and continually assess the benefit and equity of the ALU or Sharing Arrangement if they are participating in an approved Alternative Point Assignment Protocol

5. How OPTN/UNOS will evaluate member compliance with this policy

All organ allocations are examined by UNOS for compliance with OPTN Policies and ALU's approved by the OPTN/UNOS Board of Directors. OPOs that deviate from the previously mentioned policies or agreements are asked to respond in writing with details describing the circumstances of the deviation.

1. Policy title Definition of Directed Donation	**2. Policy number** 3.1.13 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Permit OPOs to allocate an organ (s) to a specific transplant candidate named by the person who authorized the donation, unless prohibited by state law
- Require that all recipients of a deceased donor organ(s) from a directed donation be added to the waiting list prior to transplantation

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate directed donation organs to a specific transplant candidate named by the person authorizing the donation

Transplant centers are expected to:

- Add recipients of a deceased donor organ from a directed donation to the waiting list prior to transplantation
- Maintain documentation if the center deems it necessary to transplant a candidate who does not appear on at least one of the deceased donor's match runs for at least one organ type and provide written justification to the OPTN upon request

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS conducts on-site reviews and desk reviews to verify that:

- Directed donation organs are offered to the transplant candidate named by the person who authorized the donation

UNOS staff conducts inquiries of all potential policy violations and forwards the results of the inquiry to the OPTN/UNOS Membership and Professional Standards Committee for its review and potential action.

6. Detailed guidance on policy compliance

- Members should be familiar with how to determine why a candidate does not appear on a match run and the reasons why a candidate may not appear on a match run.
    - To find out why a specific candidate does not appear on a match run, follow these steps: In DonorNet®, select online Help, select Index, and then search for "Finding a Specific Candidate on the Match Results List."
    - To view the list of reasons why a candidate may not appear on a match run, follow these steps: In DonorNet®, select online Help, select Index, and then search for

"Reason not on the match code."

- If a candidate does not appear on a match run and the transplant center deems it necessary to transplant this candidate, the following documentation should be maintained and provided to the OPTN upon request:
    - Rationale for transplanting a candidate who did not appear on a match run
    - Reason that the candidate did not appear on the match run
    - The center is willing to accept an expanded criteria donor organ or a DCD donor organ as applicable
    - Documentation that the center verified suitability between donor organ and recipient prior to transplant

1. Policy title Permissible Access to UNet^{SM}	**2. Policy number** 3.2.1.2 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Provide explicit requirements to protect the confidentiality and security of data when any Institutional Member gives a third party access to UNet^{SM}

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers, OPOs, and histocompatibility laboratories are expected to:

- See that the third party agent adheres to all applicable policies and bylaws
- Have in place a data use agreement with the third party agent that thoroughly addresses issues of confidentiality and security

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS conducts on-site and off-site reviews of OPTN members. During the review process, UNOS will request copies of data use agreements and review them to verify the member fulfilled the requirements.

6. Detailed guidance on policy compliance

- Agents acting on behalf of OPTN Institutional Members (transplant centers, OPOs, and histocompatibility laboratories) may require access to UNet^{SM} to match transplant candidates with donor organs and collect information on candidates, recipients, and donors.
- Review Policy 3.2.1.2 for a list of elements to include in data use agreements
- Review the System Notice dated June 9, 2008, for information about other applicable policies and bylaws.
- Policy modifications effective September 19, 2008

1. Policy title Waiting Time Transferal and Multiple Listing	**2. Policy number** 3.2.3 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Ensure that every transplant program provides each candidate with written material on the options of listing at multiple transplant centers, transferring primary waiting time from one transplant center to another, and transferring their care to a different transplant center without loss of time accumulated while on the waiting list

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- During the evaluation process, provide each candidate with written material on the options of listing at multiple transplant centers and the option to transfer their care to another transplant center without losing accumulated time on the waiting list
- Maintain documentation that this requirement was fulfilled

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS conducts on-site and off-site reviews of transplant centers. During the review process, UNOS will request documentation that supports the center fulfilled the requirement.

6. Detailed guidance on policy compliance

- Review the OPTN's brochure entitled, "Questions and Answers for Transplant Candidates and Families about Multiple Listing and Waiting Time Transfers":

  http://optn.transplant.hrsa.gov/SharedContentDocuments/multiple_listing(2).pdf (English)

  http://optn.transplant.hrsa.gov/SharedContentDocuments/span_multiple_listing(2).pdf (Spanish)

1. **Policy title** Match System Access	2. **Policy number** 3.2.4 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Promote safe and fair distribution of organs by requiring that all applicable donor information be entered in UNet^{SM} correctly, and that distribution of organs be made through the UNOS Match System
- Promote candidate safety by requiring that an individual other than the person initially entering the donor's blood type verify donor's blood type

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Enter all required donor information into UNet^{SM} and assist in distribution of all organs through the UNOS Match System using UNet^{SM}
- Provide and carry out their own procedure for providing online verification of donor blood type by an individual other than the person initially entering the data
- Document the double verification of a donor's blood type and have the documentation available for review by UNOS
- Use the source document(s) to enter and verify the donor's blood type in UNet^{sm}. A source document is documentation of the donor's blood type from the laboratory that performed the blood type testing.
- Obtain two separate determinations of the donor's blood type prior to incision
- Allocate organs according to the match run sequence and to candidates who appear on the match run

Transplant centers are expected to:

- Release the organ back to the Host OPO or the Organ Center for distribution in instances where the organ is accepted but cannot be used for the original candidate
- Maintain documentation if the center deems it necessary to transplant a candidate who does not appear on at least one of the deceased donor's match runs for at least one organ type and provide written justification to the OPTN upon request

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS conducts on-site reviews and desk reviews to verify that:

- OPOs document and use protocols to ensure that an individual other than the person who initially entered a donor's blood type verifies the donor's blood type online prior to the execution of a match run;
- Organs are offered according to the match run sequence and to candidates who appear on the match run;
- OPOs obtain two determinations of donor ABO prior to incision; and

- OPOs document the double verification of donor ABO.

UNOS staff conducts inquiries of all potential policy violations and forward the results of the inquiry to the OPTN/UNOS Membership and Professional Standards Committee for its review and potential action.

6. Detailed guidance on policy compliance

- The OPO should ensure that staff uses ABO source documents when entering and verifying the donor's ABO in UNet℠
- Retain source documents from two ABO tests in donor file
- Ensure OPO policies and procedures require that both source documents are referenced when confirming the ABO of a potential donor in UNet℠
- Include compliance with document retention requirements in OPO's routine quality assurance process
- Two separate determinations of donor ABO is defined as: two samples sent to two labs, or two samples from separate draws sent to the same lab
- Members should be familiar with how to determine why a candidate does not appear on a match run and the reasons why a candidate may not appear on a match run.
    - To find out why a specific candidate does not appear on the match run, follow these steps: In DonorNet®, select online Help, select Index, and then search for "Finding a Specific Candidate on the Match Results List."
    - To view the list of reasons why a candidate may not appear on a match run, follow these steps: In DonorNet®, select online Help, select Index, and then search for "Reason not on the match code."
- If a candidate does not appear on a match run and the transplant center deems it necessary to transplant this candidate, the following documentation should be maintained and provided to the OPTN upon request:
    - Rationale for transplanting a candidate who did not appear on a match run
    - Reason that the candidate did not appear on the match run
    - The center is willing to accept an expanded criteria donor organ or a DCD donor organ as applicable
    - Documentation that the center verified suitability between donor organ and recipient prior to transplant

1. Policy title Removal of Kidney Transplant Candidates from Kidney Waiting Lists when Transplanted or Deceased	**2. Policy number** 3.2.4.1 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Maximize the efficiency of the organ allocation system by requiring that candidates who receive a transplant or die be immediately removed from the waiting list
- Describe waiting time for kidney, kidney/pancreas, and kidney/islet candidates who receive a transplant and are re-listed

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Remove a candidate from the waiting list within 24 hours of transplantation (living or deceased donor transplant) or death

5. How OPTN/UNOS will evaluate member compliance with this policy

During routine site surveys, UNOS staff reviews a sample of records to verify that candidates were removed from the waiting list within 24 hours of transplant or death.

6. Detailed guidance on policy compliance

- If you learn of a candidate's death more than 24 hours after the death, document in the candidate's record the date you become aware of the death. Remove the candidate from the waiting list within 24 hours of learning of the candidate's death. Include documentation in the candidate's record to support the date of death, if available.

1. Policy title Waiting Time Adjustment for Candidates Needing a Life Saving Organ Transplant when the Need for a Second Organ Transplant Arises	**2. Policy number** 3.2.10 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Clarify waiting time accumulated for a candidate who is initially listed for one life-saving transplant and may also be accumulated for a second organ, when it is determined at a later time that the candidate requires a multi-organ transplant

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Maintain complete and accurate documentation regarding the candidate's organ function and the need for additional transplanted organs

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS conducts on-site and off-site reviews to confirm the candidate's status listings when multiple organs are needed for transplant.

1. Policy title Donor Acceptance Criteria	**2. Policy number** 3.3.1 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Help facilitate efficient procurement and to maximize the number of organs procured by OPOs

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Establish clear criteria for what constitutes an acceptable donor organ and to offer organs that do not meet their own criteria to OPOs with more liberal acceptance criteria

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS monitors OPOs' procurement and discard rates, and analyzes whether offers were made to other OPOs. The analyses are reported to the MPSC.

1. Policy title Non-renal Organ Acceptance Criteria	**2. Policy number** 3.3.2 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Help facilitate safe and efficient allocation of organs

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Clearly define their acceptance criteria for non-renal organs and enter this information into the UNet^{sm} system

5. How OPTN/UNOS will evaluate member compliance with this policy

Acceptance criteria for non-renal organs are programmed into the UNet^{SM} system. UNOS reviews all allocations and checks that organs were allocated in accordance with specified criteria.

1. Policy title Renal Acceptance Criteria	**2. Policy number** 3.3.3 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Help facilitate safe and efficient allocation of organs

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Clearly define their acceptance criteria for renal organs and enter this information into the UNet^{sm} system

5. How OPTN/UNOS will evaluate member compliance with this policy

Acceptance criteria for renal organs are programmed into the UNet^{SM} system. UNOS reviews all allocations and checks that organs were allocated in accordance with specified criteria.

1. Policy title Antigen Mismatch Criteria	**2. Policy number** 3.3.4 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Help facilitate safe and efficient allocation of organs

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Enter in the maximum acceptable number of mismatched antigens for their candidates

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS reviews all allocations and checks that organs were allocated in accordance with specified antigen mismatch criteria.

1. Policy title Transplant Recipient Backup for Organ Offers	**2. Policy number** 3.3.5 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Facilitate efficient allocation of organs

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOS are expected to:
- To make back-up offers; however, this is not a requirement
- Notify the back-up transplant center of any changes in the donor status or organ disposition

Transplant centers are expected to:
- Respond to the OPO within an hour of receiving a back-up offer

5. How OPTN/UNOS will evaluate member compliance with this policy

Staff reviews all allocations and examines complaints related to back up offers and issues with communication related to change in donor status or organ disposition.

1. Policy title Center Acceptance of Organ Offers	**2. Policy number** 3.3.6.1 3.3.6.1.1 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Require OPOs to re-allocate organs when a Donation after Cardiac Death (DCD) donor converts to brain death to help ensure that the most appropriate candidate receives each organ
- Ensure that each OPO allocates organs consistently when a DCD donor converts to brain death
- To increase the number of transplanted organs by encouraging OPOs to initiate the allocation of additional organs (i.e., heart, lungs, pancreas) when a DCD donor converts to brain death

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOS are expected to:

- Re-execute the match system for every organ when a donor converts from a DCD donor to a brain dead donor. Note: exceptions apply for certain circumstances; refer to policy language.
- Re-allocate organs according to the match run(s)
- Document the reason for not re-allocating organs from a donor who converts from DCD to brain death and make this documentation available upon request

5. How OPTN/UNOS will evaluate member compliance with this policy

Staff monitors all organ allocations and makes a written inquiry into allocations that do not occur according to policy. The OPTN/UNOS Membership and Professional Standards Committee (MPSC) reviews potential policy violations.

6. Detailed guidance on policy compliance

- Implementation date: August 7, 2007

1. Policy title Center Acceptance and Transplant of Organs from Living Donors	**2. Policy number** 3.3.7 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Prevent living donor programs from accepting or transplanting living donor organs recovered at non-OPTN member hospitals
- Restrict the recovery of living donor organs to hospitals required to abide by OPTN/UNOS policies and bylaws
- Promote the same level of safety and protection for living donors

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Accept and transplant living donor organs only when the organs were recovered at OPTN Member Institutions
- Accurately indicate the recovery facility on the Living Donor Registration Form
- Maintain documentation to support information submitted to Tiedi® about the living donor
- Present documentation to UNOS staff upon request

5. How OPTN/UNOS will evaluate member compliance with this policy

Department of Evaluation and Quality (DEQ) staff may detect potential violations of this proposed policy by:

- researching confidential reports received through the OPTN Member Reporting Line or Patient Services Line;
- reviewing living donor records during site surveys of transplant centers with approved living donor programs;
- reviewing OPTN data; or
- receiving referrals from OPTN/UNOS Committees, OPTN/UNOS Staff, or OPTN/UNOS Members.

DEQ staff will inquire into all potential policy violations and forward the results of such inquiry to the OPTN/UNOS Membership and Professional Standards Committee for confidential medical peer review.

6. Detailed guidance on policy compliance

- Effective date: January 19, 2009

1. Policy title Allocation of Deceased Donor Kidneys	**2. Policy number** 3.5 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Ensure all deceased donor kidneys are allocated according to established policies
- Establish that the final decision to accept a particular organ will remain the prerogative of the transplant surgeon and/or physician
- Require that a notation of the reason for declining an organ is made on the appropriate form for submission to UNOS

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:
- Allocate all kidneys in accordance with the donor match run
- Complete and submit donor PTR information in UNet^{SM}

Transplant centers are expected to:
- Provide an OPO with the appropriate organ refusal code when declining an organ offer

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. Through on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if the organs have been allocated in accordance with the match runs. Staff reports all instances where the match run was not followed for allocation to the appropriate OPTN/UNOS Committee.

6. Detailed guidance on policy compliance

- Retain all documentation used for allocation
- Document all allocation attempts including telephone calls

1. Policy title Definition of Expanded Criteria Donor and Standard Donor	**2. Policy number** 3.5.1 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Distinguish between an expanded criteria donor and a standard donor. The policy provides a detailed list of what variables are considered to qualify a donor as an expanded criteria donor. Transplant centers may elect to list candidates who agree to receive expanded criteria donor kidneys.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:
- Accurately list deceased donors as expanded or standard

Transplant centers are expected to:
- Obtain consent from candidates prior to their being listed for expanded criteria donor kidney transplantation

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. Through on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if the organs have been allocated in accordance with the match runs. Staff reports all instances where the match run was not followed for allocation to the appropriate OPTN/UNOS Committee.

6. Detailed guidance on policy compliance

- Link to ECD brochure (English)
  http://www.unos.org/SharedContentDocuments/ExpandedCriteriaDonor_KidneysBrochure.pdf

- Link to ECD brochure (Spanish)
  http://optn.transplant.hrsa.gov/SharedContentDocuments/Answers_to_Questions-Spanish.pdf

1. Policy title ABO "O" Kidneys into ABO "O" Recipients and ABO "B" Kidneys into ABO "B" Recipients	**2. Policy number** 3.5.2 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Address waiting time disparities among candidates with different blood types. The policy allows ABO "O" kidneys to be allocated only to ABO "O" recipients and ABO "B" kidneys to be allocated only to ABO "B" recipients. Exceptions to this policy are for zero antigen mismatch recipients.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:
- List donors with accurate ABO type
- Maintain donor record documentation of ABO typing and provide, upon request, such documentation for review
- Allocate deceased donor kidneys according to the match run generated by UNet^{SM}

Transplant centers are expected to:
- List transplant candidates with the accurate ABO typing
- Maintain medical record documentation of ABO typing and provide, upon request, such documentation for review

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. Through on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if the organs have been allocated in accordance with the match runs. Staff reports all instances where the match run was not followed for allocation to the appropriate OPTN/UNOS Committee.

1. Policy title Mandatory Sharing of Zero Antigen Mismatched Kidneys	**2. Policy number** 3.5.3 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Ensure optimal kidney match and survival. The policy for isolated kidney allocation was developed based on data showing that deceased renal transplants with zero antigen mismatches have the highest graft survival rates. Additionally, opportunities for transplanting highly sensitized (i.e., relatively high panel reactive antibody levels) candidates are increased based upon HLA match and low probability of a positive crossmatch match.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:
- Allocate all kidneys according to the system match run
- Make zero antigen mismatch kidney offers according to the requirements stated in Policy 3.5.3.5

Transplant centers are expected to:
- List transplant candidates with the accurate HLA typing and PRA information

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. Through on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if the organs have been allocated in accordance with the match runs. Staff reports all instances where the match run was not followed for allocation to the appropriate OPTN/UNOS Committee.

1. Policy title Definition of Zero Antigen Mismatch	**2. Policy number** 3.5.3.1 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Define a zero antigen mismatch

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:
- List candidates with accurate HLA typing
- List candidates with the accurate ABO type

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to the system through the use of system notices and documentation updates.

1. Policy title Computer Entry	**2. Policy number** 3.5.3.2 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Ensure that every deceased kidney donor is registered on the UNOS computer system prior to kidney allocation

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Register all deceased kidney donors into the UNOS computer system prior to kidney allocation
- Obtain pre-procurement tissue typing
- Submit a written explanation if pre-procurement tissue typing is not initiated

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs of modifications to system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. Through on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines whether donors were registered appropriately and whether pre-procurement tissue typing occurred prior to kidney allocation. Staff forwards potential policy violations to the appropriate OPTN/UNOS Committee.

1. **Policy title** Mandatory Sharing	2. **Policy number** 3.5.3.3 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Define the mandatory sharing requirements for kidney allocation

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs centers are expected to:

- OPOs are expected to allocate all kidneys according to the match run

Transplant centers are expected to:

- List all kidney candidates with accurate HLA, ABO and PRA information and with accurate expanded donor acceptance information

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. Through on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if the organs have been allocated in accordance with the match runs. Staff reports all instances where the match run was not followed for allocation to the appropriate OPTN/UNOS Committee.

1. Policy title Sequence of Zero Antigen Mismatched Kidney Allocation	**2. Policy number** 3.5.3.3.1, 3.5.3.3.2 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Specify the sequence of kidney allocation for zero antigen mismatch candidates

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs centers are expected to:
- Allocate all kidneys according to the match run

Transplant centers are expected to:
- List all kidney candidates with accurate HLA, ABO and PRA information

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. Through on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if the organs have been allocated in accordance with the match runs. Staff reports all instances where the match run was not followed for allocation to the appropriate OPTN/UNOS Committee.

1. Policy title Kidney/Non-Renal Exception	**2. Policy number** 3.5.3.4 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Outline the process for when kidneys are procured for the purpose of combined kidney/non-renal organ transplantation. Only one of the kidneys must be shared as a zero antigen mismatch. In the event, however, that the combined kidney/non-renal transplant is not performed, the kidney retained for that transplantation must be immediately offered for other zero antigen mismatch candidates.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Place zero antigen mismatch kidneys according to the requirements stated in Policy 3.5.3.5

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs of modifications to system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. Through on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if the organs have been allocated in accordance with the match runs. Staff reports all instances where the match run was not followed for allocation to the appropriate OPTN/UNOS Committee.

6. Detailed guidance on policy compliance

- Organ Center telephone: (800) 292-9537

1. **Policy title** Organ Offer Limit	2. **Policy number** 3.5.3.5

3. Purpose of policy

The purpose of the policy is to:

- Promote efficiency in placement of zero antigen mismatch kidneys. The policy's offer limit for placement of these organs is intended to help address concerns with prolonged cold ischemic time during the offer and acceptance process. This policy defines specific offer limits for zero antigen mismatch kidney placement.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Share all zero mismatch kidneys, either through DonorNet® or through the UNOS Organ Center, according to policy:
    a. Standard Criteria Donor (SCD) – within 8 hours of cross clamp to the first 10 zero mismatch potential recipients on the match run, in sequential order
    b. Expanded Criteria Donor (ECD) – within 4 hours of cross clamp to the first 5 zero mismatch potential recipients on the match run, in sequential order
- Submit a completed Kidney Payback Accounting Sheet to the Organ Center for all zero mismatch kidneys that are placed by the Host OPO (it is not necessary to complete this sheet for zero mismatch kidneys placed by the Organ Center on behalf of the Host OPO)

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet℠ system according to current approved policies and notifies OPOs of modifications to system through the use of system notices and documentation updates. UNOS staff monitors all deceased donor kidney match runs to ensure:

- organs were allocated according to the match run sequence, and
- mandatory shares were offered according to policy.

When insufficient information is provided by the OPO, UNOS staff makes a written inquiry into any allocations that do not follow the match run sequence. During on-site surveys of organ procurement organizations, staff reviews a sample of kidney allocations and validates data entered into DonorNet® and Tiedi® for donors in the review sample. UNOS staff forwards potential policy violations to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review.

6. Detailed guidance on policy compliance

- Organ Center telephone: (800) 292-9537
- The Host OPO will **not** be entitled to a payback if the kidney is accepted for a zero antigen mismatched potential recipient beyond the 10th potential recipient for a SCD or the 5th potential recipient for an ECD
- To receive a payback credit, OPOs must:
    - Fax a completed Kidney Payback Sheet to the Organ Center within 5 business days of organ recovery
    - Enter the final acceptance in DonorNet®
    - Enter the cross-clamp date/time in DonorNet®

1. Policy title Sharing of Zero Antigen Mismatched Kidneys to Combined Kidney-Pancreas Candidates	**2. Policy number** 3.5.4 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Ensure that an offer of a zero antigen mismatch donor kidney to a candidate who is registered for a combined kidney-pancreas transplant is accompanied by an offer of the pancreas from the same donor

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Offer the pancreas with a kidney if there is a zero antigen mismatch candidate on the waiting list who requires both organs for transplant

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs of modifications to system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. Through on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if the organs have been allocated in accordance with the match runs. Staff reports all instances where the match run was not followed for allocation to the appropriate OPTN/UNOS Committee.

1. Policy title Mandatory Sharing	**2. Policy number** 3.5.4.1 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Define the requirements for mandatory sharing of combined kidney/pancreas to highly sensitized zero antigen mismatch candidates on the waiting list
- Further define that allocation of these organs shall be first locally, then regionally and then nationally, based upon length of time waiting

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate all zero antigen mismatch kidney/pancreas according to the match run
- Make zero antigen mismatch kidney/pancreas offers according to the requirements stated in Policy 3.5.3.5 and Policy 3.8.1.6.1

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs of modifications to system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. Through on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if the organs have been allocated in accordance with the match runs. Staff reports all instances where the match run was not followed for allocation to the appropriate OPTN/UNOS Committee.

1. **Policy title** Payback Requirements	2. **Policy number** 3.5.5 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Ensure that no area of the country or candidate population would be disadvantaged by disproportionate sharing of zero antigen mismatched kidneys from the pool of locally available organs, in light of the number of imported zero antigen mismatched organs. For example, localities with relatively high candidate populations having uncommon antigens could be required to export many more of these organs out of the area than they might be expected to receive due to lower likelihood of finding zero antigen mismatches in these populations. The payback system promotes justice in the system, while the mandatory sharing rules for zero antigen-mismatched kidneys promote organ utility.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate all organs according to the match run
- Contact the UNOS Organ Center for placement of all payback kidneys

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs of modifications to system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. Through on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if the organs have been allocated in accordance with the match runs. Staff reports all instances where the match run was not followed for allocation to the appropriate OPTN/UNOS Committee.

1. Policy title Deferment of Kidney/Non-Renal Exception	**2. Policy number** 3.5.5.1.1 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Limit the number of payback obligations an OPO can accrue within each blood type and still be allowed to keep a kidney locally for a combined kidney/non-renal transplant

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate all organs according to the match run
- Offer both kidneys in satisfaction of payback debts if they have accumulated six or more obligations within the donor blood type
- Contact the Organ Center for placement of all payback kidneys

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs of modifications to system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. Through on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if the organs have been allocated in accordance with the match runs. Staff reports all instances where the match run was not followed for allocation to the appropriate OPTN/UNOS Committee.

1. Policy title Deferment of Voluntary Arrangements	**2. Policy number** 3.5.5.1.2 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Prohibit an OPO that has accumulated six or more paybacks within a blood type from voluntarily accepting a kidney/pancreas from the same blood type until the OPO has reduced its payback obligations to less than six. This policy does not include voluntarily shared zero antigen mismatch kidney/pancreas.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate organs according to the match run
- Refuse voluntary kidney/pancreas offers, other than zero antigen mismatch, if they have six or more debts in the same blood type of the donor

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs of modifications to system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. Through on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if the organs have been allocated in accordance with the match runs. Staff reports all instances where the match run was not followed for allocation to the appropriate OPTN/UNOS Committee.

1. Policy title Exceptions for Prior Living Organ Donors	**2. Policy number** 3.5.5.2 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Establish priorities for previous living organ donors for the allocation of kidneys. Locally, prior living organ donors shall be allocated kidneys before they are offered in satisfaction of payback obligations.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:
- Allocate kidneys according to the match run

Transplant centers are expected to:
- List kidney candidates accurately and at the appropriate status
- Maintain medical record documentation of patient's donation status and provide, upon request, such documentation for review

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. Through on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if the organs have been allocated in accordance with the match runs. Staff reports all instances where the match run was not followed for allocation to the appropriate OPTN/UNOS Committee.

1. Policy title Kidney Payback Debt Limit	**2. Policy number** 3.5.5.3 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Limit the number of kidney payback debts that an OPO can incur. Violations of this policy will result in referral to the MPSC. Additionally, priority for zero antigen mismatch kidney offers will be adjusted.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:
- Pay back kidney debt obligations in a timely manner
- Adhere to the kidney payback debt limit of nine

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs of modifications to system through the use of system notices and documentation updates. UNOS monitors payback debt balances for each OPO monthly. Instances of violation of this policy are referred to the appropriate OPTN/UNOS Committee.

1. Policy title Geographic Sequence of Deceased Kidney Allocation	**2. Policy number** 3.5.6 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Establish that kidneys are to be allocated locally first, then regionally and then nationally

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate kidneys according to the match run

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs of modifications to system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. Through on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if the organs have been allocated in accordance with the match runs. Staff reports all instances where the match run was not followed for allocation to the appropriate OPTN/UNOS Committee.

1. **Policy title** Local Allocation	2. **Policy number** 3.5.6.1 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Specify that except for kidneys that are 1) shared as a result of a zero antigen mismatch, 2) offered as payback as defined in Policy 3.5.5, or 3) allocated according to voluntary organ sharing arrangement as provided in policy 3.4.7, all kidneys will be allocated locally first to local candidates as defined in Policy 3.1.10

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:
- Allocate kidneys according to the match run
- Maintain a complete record of all organ offers

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs of modifications to system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. With on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if the organs have been allocated in accordance with the match runs. Staff reports all instances where the match run was not followed for allocation to the appropriate OPTN/UNOS Committee.

1. Policy title Regional Allocation	**2. Policy number** 3.5.6.2 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Specify that if a donor kidney is not accepted by any local transplant center the kidney is to be allocated next via the regional list
- Provide instruction for allocating Expanded Criteria Donor (ECD) kidneys regionally if a local recipient is not identified within a certain period of time

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate kidneys according to the match run
- Maintain a complete record of all organ offers

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs of modifications to system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. With on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if the organs have been allocated in accordance with the match runs. Staff reports all instances where the match run was not followed for allocation to the appropriate OPTN/UNOS Committee.

1. **Policy title** National Allocation	2. **Policy number** 3.5.6.3 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Outline how kidneys are to be allocated nationally

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:
- Allocate kidneys according to the match run
- Maintain a complete record of all organ offers

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet℠ system according to current approved policies and notifies OPOs of modifications to system through the use of system notices and documentation updates. UNOS staff monitors all deceased donor kidney match runs to ensure:
- organs were allocated according to the match run sequence, and
- national organ offers were made according to policy.

When insufficient information is provided by the OPO, UNOS staff makes a written inquiry into any allocations that do not follow the match run sequence. During on-site surveys of organ procurement organizations, staff reviews a sample of kidney allocations and validates data entered into DonorNet® and Tiedi® for donors in the review sample. UNOS staff forwards potential policy violations to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review.

6. Detailed guidance on policy compliance

- Organ Center telephone: (800) 292-9537
- The OPTN/UNOS Executive Committee approved a decision to require the UNOS Organ Center to make all national kidney, kidney-pancreas, and pancreas offers; this change was effective on May 23, 2007. Until further notice, all OPOs will turn over kidney, kidney-pancreas, and pancreas placement to the Organ Center upon reaching national-level potential recipients on the match run.
    - System notice sent May 21, 2007 to announce and describe the changes
    - System notice sent on May 29, 2007 that includes additional information

1. Policy title Regions	**2. Policy number** 3.5.6.4 **Subsections** N/A
3. Purpose of policy The purpose of the policy is to: • Name the states in each of the 11 regions	
4. How to comply with this policy *Compliance strategies may include, but are not limited to, the expectations stated below.* No specific action is required of members.	
5. How OPTN/UNOS will evaluate member compliance with this policy No monitoring efforts are required.	

1. Policy title Double Kidney Allocation	**2. Policy number** 3.5.7 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Define the conditions that an adult donor must meet for double kidney allocation

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate kidneys according to the match run
- Clearly document in the donor record if a donor meets the conditions for double kidney allocation
- Maintain a complete record of all organ offers

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs of modifications to system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. With on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if the organs have been allocated in accordance with the match runs. Staff reports all instances where the match run was not followed for allocation to the appropriate OPTN/UNOS Committee.

1. Policy title Expanded Criteria Donor Kidney Allocation	**2. Policy number** 3.5.8 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Establish that kidneys from expanded criteria donors must be offered locally first, then regionally and then nationally

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:
- Allocate kidneys according to the match run
- Maintain a complete record of all organ offers

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs of modifications to system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. With on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if the organs have been allocated in accordance with the match runs. Staff reports all instances where the match run was not followed for allocation to the appropriate OPTN/UNOS Committee.

1. Policy title Minimum Information/Tissue for Kidney Offer	**2. Policy number** 3.5.9 **Subsections** 3.5.9.1 3.5.9.2

3. Purpose of policy

The purpose of the policy is to:

- Specify the minimum information the OPOs must provide to recipient centers with each kidney offer

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Educate organ recovery and placement staff with the requirements for kidney offers
- Provide transplant program personnel with the minimum information required when making kidney offers
- Maintain documentation of the minimum information required and provide such documentation, upon request, for review
- Maintain a complete record of all organ offers

5. How OPTN/UNOS will evaluate member compliance with this policy

With on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if the organs have been allocated in accordance with the match runs. Staff reports all instances where the match run was not followed for allocation to the appropriate OPTN/UNOS Committee.

6. Detailed guidance on policy compliance

- As of May 10, 2007, policy includes standardized renal biopsy procedures. Please refer to 3.5.9.2 for detailed recommendations.
- As of December 18, 2007, policy was modified to clarify that one red topped tube needs to be sent with each kidney for ABO verification.

1. Policy title [RESERVED]	**2. Policy number** 3.5.10 **Subsections** N/A
3. Purpose of policy To be developed.	
4. How to comply with this policy *Compliance strategies may include, but are not limited to, the expectations stated below.* To be developed.	
5. How OPTN/UNOS will evaluate member compliance with this policy To be developed.	
6. Detailed guidance on policy compliance To be developed.	

1. Policy title The Point System for Kidney Allocation	**2. Policy number** 3.5.11 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Specify that all candidates who are active on the waiting list will be assigned points and priority for kidney allocation

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:
- Allocate each organ according to the match run

Transplant centers are expected to:
- List all transplant candidates with accurate information (e.g., ABO, HLA) on the waiting list

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. For on-site OPO reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if the organs have been allocated in accordance with the match runs. Staff reports all instances where the match run was not followed for allocation to the appropriate OPTN/UNOS Committee.

1. **Policy title** Time of Waiting	2. **Policy number** 3.5.11.1 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Define precisely what criteria kidney transplant candidates must meet prior to accruing waiting time on the waiting list

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List kidney transplant candidates with accurate dialysis and lab data
- Maintain medical record documentation of:
  - The date a candidate started chronic maintenance dialysis
  - The date a candidate's creatinine clearance or GFR was less than or equal to 20 ml/min
- Maintain documentation to support all candidate data entered into UNet^{sm,} and provide such documentation upon request

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to the system through the use of system notices and documentation updates. UNOS staff monitors changes made to candidate data, and makes an inquiry to ensure policy compliance and data accuracy as appropriate. UNOS staff forwards potential policy violations to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review and potential action.

6. Detailed guidance on policy compliance

Transplant centers must retain medical record documentation to support candidate data entered into UNet^{sm}. It is not acceptable to enter clinical data, such as a dialysis date or creatinine clearance / GFR value or test date, based on verbal information alone, because documentation must be presented upon request.

1. Policy title Time of Waiting Points	**2. Policy number** 3.5.11.1.1 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Define specifically how waiting time points are accrued by candidates on the waiting list

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

No specific action is required of members.

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to the system through the use of system notices and documentation updates.

1. Policy title Quality of Antigen Mismatch	**2. Policy number** 3.5.11.2 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Assign points to kidney transplant candidates on the basis of antigen mismatch with the donor

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List kidney transplant candidates with accurate HLA information
- Maintain medical record documentation of candidate HLA and provide, upon request, such documentation for review

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy.

1. Policy title Panel Reactive Antibody	**2. Policy number** 3.5.11.3 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Assign 4 additional points to kidney transplant candidates who have a PRA level of 80 percent or greater

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List kidney transplant candidates with accurate and current PRA data
- Maintain medical record documentation of candidate's PRA and provide, upon request, such documentation for review

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy.

6. Detailed guidance on policy compliance

- Click here to link to a LiveMeeting recording of a CPRA training session.
  Note: when you click on this link, you will be taken to a site where you will need to enter your name. No meeting key is required to view the LiveMeeting recording.
- A waiting list candidate with a PRA of 80% or greater will receive 4 additional points if at least one unacceptable HLA antigen is identified in UNet^{SM}.

1. Policy title Medical Urgency	**2. Policy number** 3.5.11.4 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Allow a candidate's physician to use medical judgment in assignment of points for medical urgency to candidates awaiting a kidney transplant. If there is more than one local renal center, a cooperative medical decision is required prior to assignment of medical urgency points.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:
- Allocate kidneys according to the match run

Transplant centers are expected to:
- Maintain documentation of a candidate's medical urgency and provide it, upon request, for review
- Reach a cooperative agreement between other local transplant centers prior to assigning medical urgency points and maintain documentation of this agreement

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. With on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if the organs have been allocated in accordance with the match runs. Staff reports all instances where the match run was not followed for allocation to the appropriate OPTN/UNOS Committee.

1. Policy title Pediatric Kidney Transplant Candidates	**2. Policy number** 3.5.11.5 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Assign additional points to zero antigen mismatch pediatric (<18 years) kidney transplant candidates on the basis of age

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List kidney transplant candidates with accurate date of birth, HLA typing and PRA information

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to system through the use of system notices and documentation updates. UNOS examines any reported instances for a potential policy violation and will refer any instances of potential policy violations to the appropriate committee.

6. Detailed guidance on policy compliance

- UNOS site surveyors verify date of birth

1. Policy title Pediatric Kidney Transplant Candidates Priority for Kidneys from Donors Aged Less than 35 Years	**2. Policy number** 3.5.11.5.1 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Give priority in kidney allocation to pediatric kidney transplant candidates who have surpassed the pediatric kidney transplant goals

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate kidneys according to the match run

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs of modifications to system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy.

1. Policy title Donation Status	**2. Policy number** 3.5.11.6 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Increase awareness of and focus upon the need for organ donation, while acknowledging the donation made by those persons who have served as actual living donors

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:
- Submit the required documentation of previous living donation to UNOS for review

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS reviews requests for additional donation status points and verifies that the candidate is a living donor before donation status points are assigned to the candidate.

6. Detailed guidance on policy compliance

To request donation status points for a kidney candidate who is a prior living donor, the candidate's physician must submit a request to the UNOS Organ Center via fax at (804) 697-4372, Attn: Data Operations Specialist, or via email to theorgancenter@unos.org.

Be sure to include the following information in your request:
- Name of kidney candidate (the prior living donor)
- Name of recipient who received living donation
- Name of transplant facility where transplant occurred
- Date of transplant
- Any name changes of candidate (prior living donor) or recipient
- Signature of the candidate's physician

1. Policy title The Point System for Expanded Criteria Donor Kidney Allocation	**2. Policy number** 3.5.12 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Define that when information about expanded criteria donors is entered into the match system, all candidates who have agreed to receive expanded criteria donor kidneys will be assigned points and priority for allocation

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:
- Accurately register expanded criteria donors

Transplant centers are expected to:
- Obtain consent from candidates prior to their being listed for expanded criteria donor kidney transplantation
- List candidates with the accurate HLA typing, ABO and PRA information and indicate each candidate's willingness to accept an ECD kidney

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. With on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if the organs have been allocated in accordance with the match runs. Staff reports all instances where the match run was not followed for allocation to the appropriate OPTN/UNOS Committee.

1. Policy title Time of Waiting	**2. Policy number** 3.5.12.1 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Define precisely what criteria kidney transplant candidates, who have agreed to accept organs from expanded criteria donors, must meet prior to accruing waiting time on the waiting list

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List kidney transplant candidates with accurate dialysis and lab data
- Maintain medical record documentation of candidate dialysis start date and/or GFR scores and provide, upon request, such documentation for review

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to system through the use of system notices and documentation updates.

1. Policy title Time of Waiting Points	**2. Policy number** 3.5.12.1.1 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Define specifically how waiting time points are accrued by candidates on the waiting list who have agreed to accept organs from expanded criteria donors

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

No specific action is required of members.

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates.

1. Policy title Choice of Right Versus Left Donor Kidney	**2. Policy number** 3.5.13 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Allow the recipient center of the candidate with the greater priority on the waiting list to select which kidney the candidate will receive. This policy does not apply to those kidneys that are shared for zero antigen mismatch candidates or kidney non-renal transplant.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Give the recipient transplant center of the candidate with the greater priority on the waiting list the choice of which kidney the transplant center wants to receive

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS examines any reported conflicts to determine if a policy violation has occurred and facilitates review by the appropriate OPTN/UNOS Committee.

1. Policy title Broad and Split Antigen Specificities	**2. Policy number** 3.5.14 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Define how broad and split antigens are considered for listing and matching purposes

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

No specific action is required of members.

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies Members of modifications to system through the use of system notices and documentation updates. UNOS annually updates the A, B, and DR antigens listed in Appendix 3A based on the recommendations of the OPTN/UNOS Histocompatibility Committee.

1. Policy title Local Conflicts	**2. Policy number** 3.5.15 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Provide a platform where local conflicts may be submitted for review and resolution

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs and transplant centers are expected to:

- Report any conflicts or irresolvable inequities to the appropriate OPTN/UNOS Committee for review

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS examines any reported conflicts to determine if a policy violation has occurred and facilitates review by the appropriate OPTN/UNOS Committee and the OPTN/UNOS Board of Directors. The facilitation includes the use of the alternate dispute resolution, which encourages both parties to discuss their issues with each other or an impartial subcommittee of the MPSC.

1. Policy title Allocation of Deceased Kidneys with Discrepant HLA Typing	**2. Policy number** 3.5.16 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Define a process in case there are discrepant HLA typings between the Host OPO and the recipient center

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

In a case where a discrepancy in HLA typing exists, the transplant center that received the kidney is expected to:

- Allocate the organ either with the original HLA typing or according to the new HLA typing. However, new allocation must be in accordance with existing kidney allocation policies.

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS also examines allocations with discrepant HLA typing for potential policy violations and forwards potential policy violations to the appropriate OPTN/UNOS Committee.

6. Detailed guidance on policy compliance

- See policy Appendix 3C, "Resolving Discrepant Donor and Recipient HLA Typing Results in the OPTN Database" http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_104.pdf

1. Policy title Prospective Crossmatching	**2. Policy number** 3.5.17 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Provide an exception for omission of prospective crossmatching warranted by clinical circumstances

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers and histocompatibility laboratories are required to:

- Develop a joint written policy concerning clinical circumstances which substantiate the omission of prospective crossmatching

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs of modifications to system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. With on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if the organs have been allocated in accordance with the match runs. Staff reports all instances where the match run was not followed for allocation to the appropriate OPTN/UNOS Committee.

6. Detailed guidance on policy compliance

- See policy Appendix 3D, "Guidelines for the Development of Joint Written Agreements Between Histocompatibility Laboratories and Transplant Programs" http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_109.pdf

1. Policy title Allocation of Livers	**2. Policy number** 3.6 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Equitably allocate livers and reduce mortality for those candidates awaiting transplant. Candidates are categorized based on the severity of their illness, using objective, verifiable medical criteria. The MELD/PELD score is an estimate of a candidate's risk of mortality while on the transplant waiting list. Candidates are prioritized for liver allocation according to an assigned point score based on the probability of dying on the waiting list.
- Define the status priority and geographic sequence of liver allocation
- Specify that a liver recovered from a pediatric organ donor shall be allocated to a pediatric liver candidate before the liver is allocated to an adult candidate
- Define that livers must be transplanted into the original designee or be released back to the Host OPO or to UNOS Organ Center for distribution
- Establish that the final decision to use the liver will remain the prerogative of the transplant surgeon and/or physician
- Define the sequence for allocating a liver segment

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:
- Allocate all livers in accordance with the donor match run
- Document accurate refusal reasons

Transplant centers are expected to:
- Transplant the original designee for whom the liver was accepted
- Contact the Host OPO or UNOS Organ Center for further distribution if the original designee is not available for transplant
- Document accurate refusal reasons
- Allocate the remaining portion of a liver according to the sequence in policy if a transplant center wishes to split the liver

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor liver match runs to determine if the organs were allocated according to the match run sequence as established by liver allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy.

1. Policy title Preliminary Stratification	**2. Policy number** 3.6.1 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Match only potential donors who are an acceptable size for a particular candidate and to eliminate those candidates who do not match with a specific donor

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:
- Allocate all livers in accordance with the donor match run

Transplant centers are expected to:
- List candidates with a realistic donor weight range

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor liver match runs to determine if the organs were allocated according to the match run sequence as established by liver allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. With on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if livers have been allocated in accordance with the match runs. Staff also verifies the donor weight with the donor's documentation and analyzes instances where a donor organ was turned down for size despite falling within the ranges stated by the center.

1. Policy title Blood Type Similarity Stratification/Points	**2. Policy number** 3.6.2 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Assign a specific point value on the basis of donor blood type similarity for Status 1A and 1B liver transplant candidates. (Identical ABO =10pts, Compatible ABO =5pts, Incompatible ABO =0pts.)
- Specify that within each MELD/PELD score, livers shall be offered to candidates who are ABO-identical with the donor first, then to ABO-compatible candidates, and finally to ABO-incompatible candidates

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:
- List donors with accurate ABO type
- Allocate all livers in accordance with the donor match run

Transplant centers are expected to:
- List transplant candidates with the accurate ABO typing
- Maintain medical record documentation of ABO typing and provide, upon request, such documentation for review

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor liver match runs to determine if the organs were allocated according to the match run sequence as established by liver allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. During on-site reviews, staff verifies donor and transplant candidate's ABO. Staff refers any instances of potential policy violations to the appropriate OPTN/UNOS Committee.

1. Policy title Allocation of Blood Type O Donors	**2. Policy number** 3.6.2.1 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Define how blood type O donor livers will be allocated to candidates within each status category
- Address waiting time disparities among candidates with different blood types

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:
- List donors with accurate ABO type
- Maintain donor record documentation of ABO typing and provide, upon request, such documentation for review
- Allocate all livers in accordance with the donor match run

Transplant centers are expected to:
- List transplant candidates with the accurate ABO typing
- Maintain medical record documentation of ABO typing and provide, upon request, such documentation for review

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor liver match runs to determine if the organs were allocated according to the match run sequence as established by liver allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. During on-site reviews, staff verifies donor and transplant candidate's ABO. Staff refers any instances of potential policy violations to the appropriate OPTN/UNOS Committee.

1. Policy title Liver Allocation to Candidates Willing to Accept an Incompatible Blood Type	**2. Policy number** 3.6.2.2 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Allow Status 1A or 1B liver candidates and MELD/PELD candidates with a score of 30 (as of April 11, 2007) or greater to accept a liver from a donor of any blood type and indicate that designation on the waiting list

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:
- Allocate all liver organs in accordance with the donor match run

Transplant centers are expected to:
- List candidates with accurate ABO typing
- List all candidates at the appropriate liver status
- Maintain medical record documentation of ABO typing and liver status
- Comply with all OPTN policies relating to listing candidates for transplant and allocating organs including, but not limited to, policies 3.1.4 (Waiting List), 3.6.2 (Blood Type Similarity Stratification/Points) and 3.6.4 (Degree of Medical Urgency)
- Specify in UNet^{SM} any candidates for whom they are willing to accept a liver from a donor of any blood type
- Provide, upon request, such documentation for review

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor liver match runs to determine if the organs were allocated according to the match run sequence as established by liver allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy and makes a written inquiry into any allocations that do not follow the match run sequence.

During on-site reviews, staff verifies that the laboratory data entered into UNet^{SM} and used to calculate a candidate's MELD/PELD score are accurate, and that candidates are listed with their correct blood type.

Staff refers any instances of potential policy violations to the appropriate OPTN/UNOS Committee.

1. Policy title Time Waiting	**2. Policy number** 3.6.3 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Specify how waiting time will be accrued within each liver status. Transplant candidates will accrue waiting time within Status 1A or 1B or any assigned MELD/PELD score. Waiting time accrued at a lower MELD/PELD score will not be counted toward liver allocation if the candidate is upgraded to a higher MELD/PELD score. Stratification of candidates within a particular MELD/PELD score will be based on total waiting time currently and previously accrued at that (higher) score. Waiting time will not be accrued by candidates awaiting a liver transplant while they are registered on the OPTN waiting list as inactive.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

No specific action is required of members.

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies Members of modifications to system through the use of system notices and documentation updates.

1. Policy title Degree of Medical Urgency	**2. Policy number** 3.6.4 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Assign a status code or mortality risk score that corresponds to the candidate's medical condition

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List all candidates at the appropriate liver status or mortality risk score and to maintain medical record documentation in support of each status listing
- Provide, upon request, medical record documentation in support of listing criteria for review

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. Through on-site reviews, staff verifies the status or score information submitted to UNet^{SM} with the medical documentation.

6. Detailed guidance on policy compliance

UNet^{SM} allows laboratory values supporting MELD/PELD scores to be entered with two decimal places (hundredths). When the system calculates MELD/PELD scores, it rounds the laboratory value to one decimal place (tenths) using the following rules:

- If the hundredths value is 5 or greater, round up to the next tenth (i.e., 1.05 rounds to 1.1)
- If the hundredths value is 4 or less, the tenths value stays the same (i.e., 1.04 rounds to 1.0)

System users are expected to use the same rounding rules if rounding is necessary during data entry.

1. Policy title Adult Candidate Status	**2. Policy number** 3.6.4.1 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Define the medical urgency statuses for adult (18 years and older) liver transplant candidates. An adult liver transplant candidate can be listed at Status 1A, a specified MELD score or Status 7.
- Define Status 1A as being a candidate who has fulminant liver failure with a life expectancy without a liver transplant of less than seven days
- Define the variables used to calculate the MELD score and the formula used in the calculation
- Define terms for Status 1A candidates

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List all candidates at the appropriate liver status and to maintain medical record documentation in support of each status listing
- Accurately complete the appropriate information, Status Justification Form or application in UNet^{SM} at the time of candidate listing or status extension
- Adjust a candidate's status if the medical criterion for listing changes
- Provide, upon request, medical record documentation in support of listing for review

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to system through the use of system notices and documentation updates. UNOS staff facilitates and monitors liver listings with the RRB process by communicating with transplant centers and appropriate OPTN/UNOS Committees regarding RRB decisions. Members may access downgrade information through UNet^{SM}.

Through on-site reviews, staff verifies status and/or MELD score indicated in UNet^{SM} and on Status Justification Forms with actual candidate medical record documentation. MELD score reviews include verification with medical record documentation of the laboratory values and dates indicated in UNet^{SM} at the time of listing. Status 1A reviews include verification with medical record documentation of the medical listing criteria indicated in UNet^{SM} and on the Status Justification Form at the time of listing.

UNOS staff forwards potential policy violations to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review.

6. Detailed guidance on policy compliance

- Review the MELD/PELD Calculator:

  http://optn.transplant.hrsa.gov/resources/professionalResources.asp?index=8

- Review brochures entitled "Q & A about MELD and PELD" and "MELD/PELD Calculator Q & A":

  http://www.unos.org/resources/brochures.asp

- Review the Liver Justification Form Quick Reference Guide: Log onto UNet^{SM}, select Waitlist^{SM}, select Resources, and then select Reference Docs. Look for the section entitled "Liver Justification Form and MELD/PELD Documents."

- The data entered into UNet^{sm} to calculate a candidate's MELD score must be based on the most recent clinical information

- The transplant center must enter laboratory data into UNet^{sm} using the same number of decimal places in the value as provided by the laboratory whenever possible. Review System Notice sent June 14, 2006.

- If a candidate's laboratory value is above or below the range UNet^{SM} will accept for that laboratory value, the transplant center should:
  - Enter in UNet^{SM} the value that is acceptable to UNet^{SM} and numerically closest to the value reported by the laboratory for that candidate.
  - Document in the candidate's record why you are entering into UNet^{SM} a value that is different than the value reported by the laboratory for that candidate.
  - Submit to UNOS a work order request that includes the candidate's name, the value you tried to enter, and the error message you received. This information is necessary so UNOS staff can:
    - verify the system is working appropriately;
    - track the incidence of actual laboratory values that fall outside the range UNet^{SM} will accept; and
    - evaluate the need to change the range of laboratory values UNet^{SM} will accept.
  - Maintain all of this documentation and present it to UNOS staff upon request. If this candidate's record is reviewed during a site survey, UNOS staff will need to review this documentation in addition to medical record documentation of the candidate's laboratory values.

- Continuous dialysis (CVVHD) for at least 24 hours in the week prior to the laboratory draw meets the policy definition of dialysis (at least twice in the week prior) for calculating the MELD score, as approved by the OPTN/UNOS Board of Directors in June 2008

1. Policy title Adult Candidate Reassessment and Recertification	**2. Policy number** 3.6.4.1.1 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Define a specific reassessment and recertification schedule for an assigned MELD score. The appropriateness of an assigned MELD score shall be reassessed and recertified by the listing transplant center.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Reassess and recertify transplant candidates' MELD scores in accordance with the schedule outlined in policy
- List all candidates at the appropriate liver status and to maintain medical record documentation in support of each status listing
- Accurately complete the appropriate information in UNet^{SM} at the time of candidate listing or status extension
- Provide, upon request, medical record documentation in support of listing for review

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to system through the use of system notices and documentation updates. UNOS staff facilitates and monitors liver listings with the RRB process by communicating with transplant centers and appropriate OPTN/UNOS Committees regarding RRB decisions. Members may access downgrade information through UNet^{SM}.

Through on-site reviews, staff verifies status and/or MELD score indicated in UNet^{SM} and on Status Justification Forms with actual candidate medical record documentation. MELD score reviews include verification with medical record documentation of the laboratory values and dates indicated in UNet^{SM} at the time of listing. Status 1A reviews include verification with medical record documentation of the medical listing criteria indicated in UNet^{SM} and on the Status Justification Form at the time of listing.

6. Detailed guidance on policy compliance

- Review the MELD/PELD Calculator:
  http://optn.transplant.hrsa.gov/resources/professionalResources.asp?index=8
- Review brochures entitled "Q & A about MELD and PELD" and "MELD/PELD Calculator Q & A":
  http://www.unos.org/resources/brochures.asp
- Review the Liver Justification Form Quick Reference Guide: Log onto UNet^{SM}, select Waitlist^{SM}, select Resources, then Reference Docs. Look for the section entitled "Liver

Justification Form and MELD/PELD Documents."

- Review policy Appendix 3B, "Indications for liver transplantation in children" http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_15.pdf

1. Policy title Pediatric Candidate Status	**2. Policy number** 3.6.4.2 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Define the medical urgency statuses for pediatric (<18 years) liver transplant candidates. A pediatric liver transplant candidate can be listed at Status 1A or 1B, PELD score (<12 years), MELD score (12-17 years), or Status 7.
- Define Status 1A as a candidate with acute liver failure and Status 1B as a candidate with chronic liver failure, both of whom are located in the ICU, have a life expectancy of less than seven days, and meet the additional medical criteria outlined in policy.
- Define the variables used and how to calculate a PELD score
- Define specific listing terms for Status 1A and 1B candidates

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List all candidates at the appropriate liver status and to maintain medical record documentation in support of each status listing
- Accurately complete the appropriate information, Status Justification Form or application in UNet^{SM} at the time of candidate listing or status extension
- Adjust a candidate's status if the medical criterion for listing changes
- Provide, upon request, medical record documentation in support of listing for review
- Comply with all OPTN policies related to listing candidates for transplant, including, but not limited to, 3.6.4.2 (Pediatric Candidate Status), 3.6.4.3 (Pediatric Candidates with Metabolic Diseases), and 3.6.4.7 (Combined Liver-Intestine Candidates)

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to system through the use of system notices and documentation updates. UNOS staff facilitates and monitors liver listings with the RRB process by communicating with transplant centers and appropriate OPTN/UNOS Committees regarding RRB decisions. Members may access downgrade information through UNet^{SM}.

Through on-site reviews, staff verifies status and/or MELD/PELD score indicated in UNet^{SM} and on Status Justification Forms with actual candidate medical record documentation. MELD/PELD score reviews include verification with medical record documentation of the laboratory values and dates indicated in UNet^{SM} at the time of listing. Status 1A and 1B reviews include verification with medical record documentation of the medical listing criteria indicated in UNet^{SM} and on the Status Justification Form at the time of listing.

Staff forwards potential policy violations to the OPTN/UNOS Membership and Professional Standards Committee for review.

6. Detailed guidance on policy compliance

- Growth failure is a prognostic factor in the PELD calculation. The candidate's height, weight, and age are used to calculate growth failure. The height and weight must be measured in accordance with the Pediatric Candidate Reassessment and Recertification Schedule outlined in Policy 3.6.4.2.1. The height and weight are considered laboratory values for the purposes of the PELD calculation, and the date the height and weight were measured are subject to the same requirements as other laboratory values used in the PELD calculation; these requirements are outlined in Policy 3.6.4.2.1.

- Review the MELD/PELD Calculator:

  http://optn.transplant.hrsa.gov/resources/professionalResources.asp?index=8

- Review brochures entitled "Q & A about MELD and PELD" and "MELD/PELD Calculator Q & A":

  http://www.unos.org/resources/brochures.asp

- Review the Liver Justification Form Quick Reference Guide: Log onto UNet^{SM}, select Waitlist^{SM}, select Resources, and then select Reference Docs. Look for the section entitled "Liver Justification Form and MELD/PELD Documents."

- The data entered into UNet^{sm} to calculate a candidate's MELD score must be based on the most recent clinical information

- The transplant center must enter laboratory data into UNet^{SM} using the same number of decimal places in the value as provided by the laboratory whenever possible. Review System Notice sent June 14, 2006.

- If a candidate's laboratory value is above or below the range UNet^{SM} will accept for that laboratory value, the transplant center should:
  - Enter in UNet^{SM} the value that is acceptable to UNet^{SM} and numerically closest to the value reported by the laboratory for that candidate.
  - Document in the candidate's record why you are entering into UNet^{SM} a value that is different than the value reported by the laboratory for that candidate.
  - Submit to UNOS a work order request that includes the candidate's name, the value you tried to enter, and the error message you received. This information is necessary so UNOS staff can:
    - verify the system is working appropriately;
    - track the incidence of actual laboratory values that fall outside the range UNet^{SM} will accept; and
    - evaluate the need to change the range of laboratory values UNet^{SM} will accept.
  - Maintain all of this documentation and present it to UNOS staff upon request. If this candidate's record is reviewed during a site survey, UNOS staff will need to review this documentation in addition to medical record documentation of the candidate's laboratory values.

1. Policy title Pediatric Candidate Reassessment and Recertification Schedule	**2. Policy number** 3.6.4.2.1 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Define a specific reassessment and recertification schedule of an assigned MELD/PELD score. The appropriateness of an assigned MELD/PELD score shall be reassessed and recertified by the listing transplant center.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Reassess and recertify transplant candidates' MELD/PELD score in accordance to the schedule outlined in policy
- List all candidates at the appropriate liver status and to maintain medical record documentation in support of each status listing
- Accurately complete the appropriate information in UNet^{SM} at the time of candidate listing or status extension
- Provide, upon request, medical record documentation in support of listing for review

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to system through the use of system notices and documentation updates. UNOS staff facilitates and monitors liver listings with the RRB process by communicating with transplant centers and appropriate OPTN/UNOS Committees regarding RRB decisions. UNOS also informs transplant centers of pending downgrades in status due to the expiration of a listing term.

Through on-site reviews, staff verifies status and/or MELD/PELD score indicated in UNet^{SM} and on Status Justification Forms with actual candidate medical record documentation. MELD/PELD score reviews include verification with medical record documentation of the laboratory values and dates indicated in UNet^{SM} at the time of listing. Status 1A and 1B reviews include verification with medical record documentation of the medical listing criteria indicated in UNet^{SM} and on the Status Justification Form at the time of listing.

6. Detailed guidance on policy compliance

- Growth failure is a prognostic factor in the PELD calculation. The candidate's height, weight, and age are used to calculate growth failure. The height and weight must be measured in accordance with the Pediatric Candidate Reassessment and Recertification Schedule outlined in Policy 3.6.4.2.1. The height and weight are considered laboratory values for the purposes of the PELD calculation, and the date the height and weight were measured are subject to the same requirements as other laboratory values used in the PELD calculation; these requirements are outlined in Policy 3.6.4.2.1.

1. Policy title Pediatric Liver Transplant Candidates with Metabolic Diseases	**2. Policy number** 3.6.4.3 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Define at what status pediatric candidates with metabolic disease can be listed
- Define the regional review process for metabolic disease candidates listed at Status 1B and elevated MELD/PELD scores

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List all candidates at the appropriate liver status and to maintain medical record documentation in support of each status listing
- Accurately complete the appropriate information in UNet^{SM} at the time of candidate listing, status extension or status upgrade
- Provide, upon request, medical record documentation in support of listing for review

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to system through the use of system notices and documentation updates. UNOS staff facilitates and monitors liver listings with the RRB process by communicating with transplant centers and appropriate OPTN/UNOS Committees regarding RRB decisions. Members may access downgrade information through UNet^{SM}.

Through on-site reviews, staff verifies status and/or MELD/PELD score indicated in UNet^{SM} and on Status Justification Forms with actual candidate medical record documentation. MELD/PELD score reviews include verification with medical record documentation of the laboratory values and dates indicated in UNet^{SM} at the time of listing. Status 1A and 1B reviews include verification with medical record documentation of the medical listing criteria indicated in UNet^{SM} and on the Status Justification Form at the time of listing.

1. Policy title Liver Transplant Candidates with Hepatocellular Carcinoma (HCC)	**2. Policy number** 3.6.4.4 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Define requirements for listing transplant candidates with Hepatocellular Carcinoma to receive additional priority
- Outline acceptable tumor stages for listing
- Define the specific assessment tools that must be completed prior to listing
- Outline the schedule for an increase in MELD/PELD points every three months
- Require that the explant pathology report be submitted to UNOS for every candidate who receives a liver transplant while listed with additional priority for HCC
- Require the submission of the imaging studies used to support the exception application if the pathology report does not show HCC

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List all candidates at the appropriate liver status/score and to maintain medical record documentation in support of each status listing
- Accurately complete the exception application in UNet^{SM} at the time of candidate listing or Status extension using current clinical information
- Adjust a candidate's status if the medical criterion for listing changes
- Provide, upon request, medical record documentation in support of listing for review
- Submit the explant pathology report of the liver to UNOS for every candidate with an approved HCC exception who receives a liver transplant

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to system through the use of system notices and documentation updates. UNOS staff facilitates and monitors liver listings with the RRB process by communicating with transplant centers and appropriate OPTN/UNOS Committees regarding RRB decisions. Members may access downgrade information through UNet^{SM}.

6. Detailed guidance on policy compliance

- Through on-site reviews, staff verifies that the information submitted on the exception application is supported by the medical record documentation. Staff will verify the following information submitted on HCC exception applications:
    - Chest CT to rule out metastasis performed prior to the initial HCC exception application
    - AFP level

- Laboratory values
- Tumor sizes
- Ablative therapy
- Narrative information as applicable

- The explant pathology report should be faxed to (804) 782-4680, Attention: RRB Supervisor
- If an imaging study is reviewed during an interdisciplinary conference, and it is decided that a tumor(s) size(s) is/are different from those documented by the radiologist on the imaging study report, this review and determination must be documented.

1. Policy title Pediatric Liver Transplant Candidates with Hepatoblastoma	**2. Policy number** 3.6.4.4.1 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Define the listing and review process for pediatric transplant candidates with non-metastatic hepatoblastomas

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List all candidates at the appropriate liver status/score and to maintain medical record documentation in support of each status listing
- Accurately complete the appropriate information, status Justification Form or application in UNet^{SM} at the time of candidate listing or status extension
- Adjust a candidate's status if the medical criterion for listing changes
- Provide, upon request, medical record documentation in support of listing for review

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to system through the use of system notices and documentation updates. UNOS staff facilitates and monitors liver listings with the RRB process by communicating with transplant centers and appropriate OPTN/UNOS Committees regarding RRB decisions. Members may access downgrade information through UNet^{SM}.

Through on-site reviews, staff verifies status indicated in UNet^{SM} and on Status Justification Forms with actual candidate medical record documentation. Hepatoblastoma reviews include verification with medical record documentation that recipient's hepatoblastoma was non-metastatic, that a biopsy was performed, and the candidate was a suitable transplant recipient.

1. Policy title Liver Candidates with Exceptional Cases	**2. Policy number** 3.6.4.5 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Identify the process required for a candidate to receive additional MELD/PELD points on the basis of a submitted exceptional case application and narrative
- Outline how the candidate may receive an increase in MELD/PELD score equivalent to a ten percent increase in candidate mortality every three months if the candidate continues to meet the original criteria
- Define the Regional Review Board process for the aforementioned cases

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List all candidates at the appropriate liver status/score and to maintain medical record documentation in support of each status listing
- Accurately complete the exception application in UNet^{SM} at the time of candidate listing or status extension
- Adjust a candidate's status if the medical criterion for listing changes
- Provide, upon request, medical record documentation in support of listing for review

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to system through the use of system notices and documentation updates. UNOS staff facilitates and monitors liver listings with the RRB process by communicating with transplant centers and appropriate OPTN/UNOS Committees regarding RRB decisions. Members may access downgrade information through UNet^{SM}.

Through on-site reviews, staff verifies the information submitted to UNet^{SM} to justify a candidate's score with the medical record documentation. To verify an exceptional case application, UNOS staff will review medical record documentation to support the laboratory data and narrative information submitted on the exception application.

1. Policy title Liver Candidates with Hepatopulmonary Syndrome (HPS)	**2. Policy number** 3.6.4.5.1 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Allow candidates with a clinical evidence of portal hypertension, evidence of a shunt, and a $PaO_2 < 60$ on room air to apply to the Regional Review Board for consideration of a MELD score that would provide them a reasonable probability of being transplanted within three months

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List all candidates at the appropriate liver status/score and to maintain medical record documentation in support of each status listing
- Accurately complete the exception application in UNet^{SM} at the time of candidate listing or status extension
- Adjust a candidate's status if the medical criterion for listing changes
- Provide, upon request, medical record documentation in support of listing for review

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to system through the use of system notices and documentation updates. UNOS staff facilitates and monitors liver listings with the RRB process by communicating with transplant centers and appropriate OPTN/UNOS Committees regarding RRB decisions. Members may access downgrade information through UNet^{SM}.

Through on-site reviews, staff verifies the information submitted to UNet^{SM} to justify a candidate's score. UNOS staff will review the candidate's medical record documentation to verify the laboratory data and narrative information submitted on the exception application.

1. Policy title Liver Candidates with Familial Amyloidosis or Primary Oxaluria	**2. Policy number** 3.6.4.5.2 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Allow candidates with familial amyloidosis or primary oxaluria to apply to the Regional Review Board for consideration of a MELD score that would provide them a reasonable probability of being transplanted within three months

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List all candidates at the appropriate liver status/score and to maintain medical record documentation in support of each status listing
- Accurately complete the exception application in UNet^{SM} at the time of candidate listing or status extension
- Adjust a candidate's status if the medical criterion for listing changes
- Provide, upon request, medical record documentation in support of listing for review

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to system through the use of system notices and documentation updates. UNOS staff facilitates and monitors liver listings with the RRB process by communicating with transplant centers and appropriate OPTN/UNOS Committees regarding RRB decisions. Members may access downgrade information through UNet^{SM}.

Through on-site reviews, staff verifies the information submitted to UNet^{SM} to justify a candidate's score. UNOS staff will review the candidate's medical record documentation to verify the laboratory data and narrative information submitted on the exception application.

1. Policy title On-Site Review of Status 1A and 1B Candidate Listings	**2. Policy number** 3.6.4.6 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Trigger an on-site review for a program that transplants a candidate whom the RRB has disapproved Status 1A or 1B listing on three occasions

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List all candidates at the appropriate liver status/score and to maintain medical record documentation in support of each status listing
- Complete the appropriate information in UNet^{SM} at the time of candidate listing or status extension
- Adjust a candidate's status if the medical criterion for listing changes
- Provide, upon request, medical record documentation in support of listing criteria for review

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to system through the use of system notices and documentation updates. UNOS staff facilitates and monitors liver listings with the RRB process by communicating with transplant centers and appropriate OPTN/UNOS Committees regarding RRB decisions. UNOS also informs transplant centers of pending downgrades in status due to the expiration of a listing term.

Through on-site reviews, staff verifies a recipient's status indicated in UNet^{SM} and on Status Justification Forms with actual candidate medical record documentation.

1. Policy title Combined Liver-Intestine Candidates	**2. Policy number** 3.6.4.7

3. Purpose of policy

The purpose of the policy is to:

- Allow those adult candidates awaiting a combined liver-intestine transplant who are registered on both waiting lists to automatically receive an increase in their MELD/PELD score equivalent to a 10 percent risk of three-month mortality
- Provide an increased opportunity for pediatric liver/intestine candidates (age 0-17) to receive a multivisceral transplant in a more timely manner by awarding these candidates an additional 23 point increase in their calculated MELD/PELD score (implementation date June 20, 2007)
- Require the transplant center to verify that an intestinal transplant is required and took place

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Register each candidate who needs a liver/intestine transplant on the liver waiting list and on the intestine waiting list
- List all candidates at the appropriate liver status/score and to maintain medical record documentation in support of each status listing
- Complete the appropriate information in UNet^{SM} at the time of candidate listing or status extension
- Adjust a candidate's status if the medical criterion for listing changes
- Provide, upon request, medical record documentation in support of listing criteria for review

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor liver match runs to determine if the organs were allocated according to the match run sequence as established by liver allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy.

Through on-site reviews, staff verifies a recipient's status indicated in UNet^{SM} and on Status Justification Forms with actual candidate medical record documentation.

Staff will request a written explanation from the listing transplant center if it appears an intestinal transplant was not required. Staff will forward any potential policy violations to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review.

1. Policy title Combined Liver-Intestine Allocation	**2. Policy number** 3.6.4.8

3. Purpose of policy

The purpose of the policy is to:

- Define the allocation sequence for combined liver-intestine grafts

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Make liver offers sequentially according to the liver match run (including all MELD/PELD potential recipients) through national Status 1A and 1B potential recipients **before** making offers to combined liver-intestine potential recipients sequentially according to the intestine match run

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to the system through the use of system notices and documentation updates. UNOS reviews all liver and intestine match runs to verify that the organs were allocated according to the match run sequence as established by policy and programmed into the UNet^{SM} system.

When insufficient information is provided by the OPO, UNOS staff makes a written inquiry into any allocations that do not follow the match run sequence. During on-site surveys of organ procurement organizations, staff reviews a sample of allocations and validates data entered into DonorNet® and Tiedi® for donors in the review sample. UNOS staff forwards potential policy violations to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for confidential medical peer review.

6. Detailed guidance on policy compliance

This policy language was approved by the OPTN/UNOS Board of Directors in June 2008, to clarify existing policy requirements for allocating liver-intestine grafts.

1. Policy title Center Contact and Acceptance	**2. Policy number** 3.6.5 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Streamline the organ offer process. A transplant center is allowed one hour from the time of offer to accept or decline. If a transplant center fails to respond to an organ offer within the permitted timeframe, the Host OPO may rescind the offer.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate all livers in accordance with the donor match run
- Maintain complete documentation of all organ offers
- Document the complete first and last name, and title of the person to whom the offer was made
- Document the time the offer was made and the time the center responded
- Document the appropriate refusal code

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor liver match runs to determine if the organs were allocated according to the match run sequence as established by liver allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. Staff also reviews the time elapsed between the offer of the organ and acceptance by the center to ensure that the center communicated their acceptance or decline in a timely manner.

Through on-site review, staff verifies a recipient's status as reflected by the data submitted in UNet^{SM} with the candidate's medical record documentation.

1. Policy title Execution of the Liver Match System	**2. Policy number** 3.6.5.1 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Prevent multiple matches being run with different information about recipients, which may be attempts to circumvent the allocation algorithm. The match system for liver allocation shall be executed within eight hours prior to the initial liver offer. The liver match system may be re-executed if a previously accepted liver is subsequently turned down because there is a change in donor related information.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Educate organ recovery and placement staff with this policy
- Maintain documentation pertaining to the reasons for match system re-execution
- Allocate all livers in accordance with the donor match run
- Maintain complete documentation of all organ offers and provide such documentation, upon request, for review

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs of modifications to system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor liver match runs to determine if the organs were allocated according to the match run sequence as established by liver allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy.

Through on-site reviews, staff verifies donor information submitted in UNet^{SM} with the on-site documentation.

1. Policy title Removal of Liver Transplant Candidates from Liver Waiting Lists when Transplanted or Deceased	**2. Policy number** 3.6.6 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Maximize efficiency of allocating organs to all potential recipients on the waiting list. Candidates on the waiting list who receive a transplant or who die while awaiting a transplant should immediately be removed.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Remove all candidates who have died, and all recipients of deceased or living donor organs, from the waiting list within 24 hours of the event

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. During on-site reviews, staff reviews a sample of records to verify that candidates were removed from the waiting list within 24 hours of transplant or death.

6. Detailed guidance on policy compliance

Transplant centers should document when they learn of a patient's death and remove them from the waiting list within 24 hours. Also include a copy of the death certificate in the medical record, if available.

1. Policy title Organ Center Assistance with Liver Allocation	**2. Policy number** 3.6.7 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Recommend that the UNOS Organ Center be notified when a liver donor is identified and be provided all clinical information that is necessary to offer the liver to potential recipients on the waiting list. Upon request by the OPO, staff shall attempt to locate a liver recipient on the waiting list or identify backup recipients for the liver.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Employ the assistance of UNOS for placement of livers when necessary

5. How OPTN/UNOS will evaluate member compliance with this policy

The Organ Center facilitates in the allocation of livers only upon the request of transplant centers and reports any potential policy violations to the appropriate department.

6. Detailed guidance on policy compliance

- Organ Center telephone number: (800) 292-9537

1. Policy title Local Conflicts	**2. Policy number** 3.6.8 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Provide a platform where local conflicts may be submitted for review and resolution

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs and transplant centers are expected to:

- Report any conflicts or irresolvable inequities to the appropriate OPTN/UNOS Committee for review

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS examines any reported conflicts to determine if a policy violation has occurred and facilitates review by the appropriate OPTN/UNOS Committee and the OPTN/UNOS Board of Directors. The facilitation includes the use of the alternate dispute resolution, which encourages both parties to discuss their issues with each other or an impartial subcommittee of the MPSC.

1. Policy title Minimum Information for Liver Offers, Subsection 3.6.9.1 – Essential Information Category	**2. Policy number** 3.6.9 **Subsections** 3.6.9.1

3. Purpose of policy

The purpose of the policy is to:

- Specify the minimum information that OPOs must provide to recipient centers with each liver offer

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Educate organ recovery and placement staff with the requirements for liver offers
- Provide transplant program personnel with the minimum information required when making liver offers
- Maintain documentation of the minimum information required and provide such documentation, upon request, for review
- Maintain a complete record of all organ offers

5. How OPTN/UNOS will evaluate member compliance with this policy

During on-site reviews, UNOS staff reviews a sample of donor records based on the number of donors the OPO had in the previous year and determines whether the OPO documented the minimum information for liver offers. UNOS also examines any complaints or potential policy violations and refers them to the appropriate OPTN/UNOS Committee.

1. Policy title Listing Accuracy and Appropriateness	**2. Policy number** 3.6.9.2 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Assure that organs are being allocated to appropriately listed candidates on the waiting list

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Report any suspicions of listing inaccuracy or inappropriateness to the UNOS Regional Review Board staff

Transplant centers are expected to:

- List all candidates at the appropriate liver status and to maintain medical record documentation in support of each status listing
- Accurately complete the appropriate information, Status Justification Form or application in UNet^{SM} at the time of candidate listing or status extension
- Adjust a candidate's status if the medical criterion for listing changes
- Provide, upon request, medical record documentation in support of listing for review

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS also examines any complaints or potential policy violations and refers them to the appropriate OPTN/UNOS Committee.

1. Policy title Allocation of Livers for Other Methods of Hepatic Support	**2. Policy number** 3.6.10 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Prohibit use of a liver for other methods of hepatic support prior to being offered first for transplantation

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:
- Educate organ recovery and placement staff with this policy
- Allocate all livers in accordance with the donor match run
- Maintain complete documentation of all organ offers and provide such documentation, upon request, for review

Transplant centers are expected to:
- Accurately list whether or not a candidate would accept a liver for other methods of hepatic support

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor liver match runs to determine if the organs were allocated according to the match run sequence as established by liver allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. With on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if livers have been allocated in accordance with the match runs.

1. Policy title Allocation of Livers for Segmental Transplantation	**2. Policy number** 3.6.11 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Define the sequence in which livers for segmental transplantation shall be allocated
- Initiate and facilitate discussions between organ procurement organizations (OPOs) and transplant centers concerning the feasibility of splitting donor livers
    - As of November 28, 2007, identify donors under the age of 40 and with a BMI less than or equal to 28 on every liver match run as a donor with a liver that could potentially be split.
    - As of November 28, 2007, clarify that the center getting the primary whole organ offer will determine the method of splitting and use of vessels.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:
- Educate staff regarding this policy
- Continue placement efforts for the remaining segment until the time of procurement
- Allocate all livers, and liver segments, in accordance with the donor match run
- Maintain complete documentation of all organ offers and provide such documentation, upon request, for review

Transplant centers are expected to:
- Educate staff regarding this policy

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS staff monitors all liver organ allocations and makes a written inquiry into any allocations that do not follow the match run sequence. During on-site surveys of organ procurement organizations, staff reviews a sample of liver organ allocations and validates data entered into DonorNet® and Tiedi® for donors in the review sample. The OPTN/UNOS Membership and Professional Standards Committee (MPSC) reviews instances of allocations that do not follow the match run sequence.

6. Detailed guidance on policy compliance

If the transplant center anticipates splitting the liver, and makes this decision prior to donor procurement, the transplant center must notify the OPO so that the OPO has the opportunity to attempt to place the remaining liver segment according to the match run sequence. After the decision has been made to split the liver, the remaining liver segment must be allocated according to the match run sequence until the donor procurement starts. If the remaining liver segment has not been placed by the time donor procurement starts, the remaining liver segment may be allocated to any medically appropriate candidate on the waiting list.

1. Policy title Transition of Currently Listed Candidates	**2. Policy number** 3.6.12 **Subsections** N/A
3. Purpose of policy This policy no longer applies to any candidates currently on the waiting list.	
4. How to comply with this policy *Compliance strategies may include, but are not limited to, the expectations stated below.* N/A	
5. How OPTN/UNOS will evaluate member compliance with this policy N/A	

1. Policy title Transition for Currently Listed Status 2B HCC Candidates	**2. Policy number** 3.6.12.1 **Subsections** N/A
3. Purpose of policy This policy no longer applies to any candidates currently on the waiting list.	
4. How to comply with this policy *Compliance strategies may include, but are not limited to, the expectations stated below.* N/A	
5. How OPTN/UNOS will evaluate member compliance with this policy N/A	

1. Policy title Histocompatibility Testing for Liver Transplantation	**2. Policy number** 3.6.13 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Ensure that all liver transplant programs and their histocompatibility laboratories have a joint written policy on HLA typing, antibody screening, and crossmatching

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Collaborate with histocompatibility labs to create a joint policy on HLA typing, antibody screening, and crossmatching
- Provide, upon request, documentation of this policy

5. How OPTN/UNOS will evaluate member compliance with this policy

During on-site reviews, UNOS staff verifies the existence of a written policy on histocompatibility testing.

6. Detailed guidance on policy compliance

- Review policy Appendix 3D, "Guidelines for the Development of Joint Written Agreements Between Histocompatibility Laboratories and Transplant Programs" http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_109.pdf

1. **Policy title** Exceptions	2. **Policy number** 3.7.1 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Reiterate the need to allocate organs in accordance with 3.7, unless a formalized exception has been approved and fully programmed on the UNet^{SM} system

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Apply for and obtain approval before deviating from OPTN thoracic allocation policy, if an alternative allocation system is desired
- Understand that approved variances are implemented pending programming in UNet^{SM}. If a variance, due to complexity issues, cannot be programmed in UNet^{SM}, the OPO or transplant center will be notified.
- Ensure that the variance is fully understood by their staff and followed

Transplant centers are expected to:

- Understand that approved variances are implemented pending programming in UNet^{SM}. If a variance, due to complexity issues, cannot be programmed in UNet^{SM}, the OPO or transplant center will be notified.
- Ensure that the variance is fully understood by their staff and followed

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor thoracic match runs to determine if the organs were allocated according to the match run sequence as established by thoracic allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy.

During on-site reviews, staff selects a sample of donor records and reviews the donor file documentation to determine whether thoracic organs were allocated in accordance with the match runs.

1. Policy title Exception for Sensitized Candidates	**2. Policy number** 3.7.1.1 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Allow an OPO to forgo the policies set forth in Policy 3.7 for allocation of a thoracic organ to a sensitized candidate when the results of a crossmatch between the blood serum of that candidate and cells of the thoracic organ donor are negative. All thoracic organ transplant centers within an OPO must agree prior to this type of allocation.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Obtain permission from all local thoracic transplant programs to allow their sensitized candidate to receive an organ ahead of other potential recipients if the results of a crossmatch between a specific donor and the candidate are negative

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS reviews daily all deceased donor thoracic match runs to determine if the organs were allocated according to the match run sequence as established by thoracic allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy.

In allocations where this exception is utilized, staff verifies that all the thoracic transplant centers within the Host OPO's service area agreed to bypass their own potential recipients in order to transplant the sensitized potential recipient.

1. Policy title Geographic Sequence of Thoracic Organ Allocation	**2. Policy number** 3.7.2 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Define the geographic sequence of thoracic organ allocation. As of May 16, 2007, organs are allocated locally first and then within five concentric circles or zones:
  - Zone A: 0 – 500 miles
  - Zone B: > 500 miles – 1,000 miles
  - Zone C: > 1,000 – 1,500 miles
  - Zone D: > 1,500 – 2,500 miles
  - Zone E: > 2,500 miles
- The purpose of this geographic allocation sequence is to prevent lengthy cold ischemic time related to thoracic organs.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate all thoracic organs in accordance with the donor match run

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS reviews daily all deceased donor thoracic match runs to determine if the organs were allocated according to the match run sequence as established by thoracic allocation policy and programmed into the UNet^{SM} system. Staff makes written inquiry regarding any allocations that do not follow the match run sequence. The OPTN/UNOS Membership and Professional Standards Committee (MPSC) reviews responses to written inquiries.

6. Detailed guidance on policy compliance

- The miles in the five concentric geographic zones are **nautical miles**. Click here for an explanation and conversion table for nautical miles versus statute miles.

1. **Policy title** Adult Candidate Status	2. **Policy number** 3.7.3 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Outline the adult candidate (18 years of age and older) statuses and the medical criteria required to be listed at each specific status. Each candidate awaiting a heart transplant is assigned a status code that ranks the candidate on the waiting list based on clinical acuity as determined by the medical criteria described in policy.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List all candidates at the appropriate heart status and to maintain medical record documentation in support of each status listing
- Complete the appropriate Status Justification Forms in UNet^{SM} at the time of candidate listing or status extension
- Adjust a candidate's status if the medical criterion for listing changes within 24 hours
- Provide, upon request, medical record documentation in support of listing criteria for review.

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to system through the use of system notices and documentation updates. UNOS staff facilitates and monitors thoracic listings with the RRB process by communicating with transplant centers and appropriate OPTN/UNOS Committees regarding RRB decisions.

Through on-site reviews, staff verifies candidate status listings as submitted in UNet^{SM} and on Status Justification Forms with the actual medical record documentation. UNOS staff also monitors the percentage of Status 1A listings by criterion on a monthly basis through in-house analyses.

6. Detailed guidance on policy compliance

UNet^{SM} allows only one decimal place for inotrope dosages (i.e. Dobutamine, Dopamine, and Milrinone). If the transplant center enters more than one decimal place in a dosage field, the system drops all of the numbers past the first decimal instead of rounding the value. If your candidate's dosage includes more than one decimal, round to the nearest tenth by rounding up if the hundredths value is 5 or greater, and enter that value into UNet^{SM}. If the value exceeds the upper limit of the allowable range, enter the upper limit of the range and maintain documentation in the file.

- Maintain all of this documentation and present it to UNOS staff upon request. If this

candidate's record is reviewed during a site survey, UNOS staff will need to review this documentation in addition to medical record documentation of the candidate's laboratory values.

1. Policy title Pediatric Candidate Status	**2. Policy number** 3.7.4 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Detail the pediatric candidate statuses and the medical criteria required to list at each specific status. Each candidate awaiting a heart transplant is assigned a status code that ranks the candidate on the waiting list based on clinical acuity as determined by the medical criteria described in policy. (Note that pediatric heart candidates are not required by OPTN policy to be admitted to the listing transplant center hospital to be listed as Status 1A as is the case with adult heart candidates. Compare to Policy 3.7.3.)
- Define a pediatric heart transplant candidate as less than 18 years of age at the time of listing
- Establish that pediatric heart transplant candidates, who remain on the waiting list at the time of their 18th birthday without receiving a transplant, shall continue to qualify for medical urgency status based upon the criteria set forth in Policy 3.7.4

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List all candidates at the appropriate heart status and to maintain medical record documentation in support of each status listing
- Complete the appropriate Status Justification Forms in UNet^{SM} at the time of candidate listing or status extension
- Adjust a candidate's status if the medical criterion for listing changes
- Provide, upon request, medical record documentation in support of listing criteria for review

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to system through the use of system notices and documentation updates. UNOS staff facilitates and monitors thoracic listings with the RRB process by communicating with transplant centers and appropriate OPTN/UNOS Committees regarding RRB decisions.

Through on-site reviews, staff verifies candidate status listings as submitted in UNet^{SM} with the actual candidate medical record documentation. UNOS staff also monitors the percentage of Status 1A listings by criterion on a monthly basis through in-house analyses.

6. Detailed guidance on policy compliance

UNet^{SM} allows only one decimal place for inotrope dosages (i.e. Dobutamine, Dopamine, and Milrinone). If the transplant center enters more than one decimal place in a dosage field, the system drops all of the numbers past the first decimal instead of rounding the value. If your candidate's dosage includes more than one decimal, round to the nearest tenth by rounding up if

the hundredths value is 5 or greater, and enter that value into UNet[SM]. If the value exceeds the upper limit of the allowable range, enter the upper limit of the range and maintain documentation in the file.

- Maintain all of this documentation and present it to UNOS staff upon request. If this candidate's record is reviewed during a site survey, UNOS staff will need to review this documentation in addition to medical record documentation of the candidate's laboratory values.

1. Policy title Allocation of Adolescent Donor Hearts to Pediatric Heart Candidates	**2. Policy number** 3.7.5 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Allow hearts retrieved from an adolescent donor to be allocated to a pediatric heart candidate before the heart is allocated to an adult candidate
- Define an adolescent organ donor as an individual who is 11 years of age or older, but less than 18 years of age

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate all thoracic organs in accordance with the donor match run

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor thoracic match runs to determine if the organs were allocated according to the match run sequence as established by thoracic allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. During on-site reviews, staff verifies donor and transplant candidate's ABO. Staff refers any instances of potential policy violations to the appropriate OPTN/UNOS Committee.

1. Policy title Status of Candidates Awaiting Lung Transplantation	**2. Policy number** 3.7.6 **Subsections** 3.7.6.1

3. Purpose of policy

The purpose of the policy is to:

- Establish that all candidates age 12 and older awaiting isolated lung transplantation are assigned priority for lung offers based on a Lung Allocation Score (LAS) which reflects the estimated transplant benefit measure. The transplant benefit measure equals waitlist urgency measure minus post-transplant survival measure.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Maintain medical record documentation to support each clinical variable entered into UNet^{SM} and utilized to calculate a candidate's LAS
- Update a candidate's clinical values every six months from the date of initially listing the candidate
- Provide, upon request, medical record documentation in support of listing criteria for review
- Enter accurate data into UNet^{SM} for each candidate

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to system through the use of system notices and documentation updates. UNOS staff facilitates and monitors lung listings with the Lung Review Board (LRB) process by communicating with transplant centers and appropriate OPTN/UNOS Committees regarding LRB decisions.

Through on-site reviews, staff verifies the clinical variables entered into UNet^{SM} and utilized to calculate the LAS with the actual medical record documentation. Staff also verifies all information submitted to the Lung Review Board with the actual medical record documentation.

6. Detailed guidance on policy compliance

- Web address for Lung Allocation Score information: http://optn.transplant.hrsa.gov/resources/professionalResources.asp?index=9
- As of January 9, 2008, UNet^{SM} was modified to allow the transplant center to enter a candidate's supplemental oxygen as a percentage. This means the transplant center can enter a candidate's F_iO_2 in liters per minute or as percentage. The transplant center is expected to enter a candidate's supplemental oxygen usage as it is being delivered by the oxygen delivery device.
- As of October 9, 2008, PCO_2 is included in the LAS. Transplant centers must enter PCO_2 values into UNet^{SM} as reported by the laboratory. For example, a venous value of 50 mmHg

must be entered into UNet^{SM} as 50 mmHg; the user must **not** subtract 6 mmHg from the value before entering the value into UNet^{SM}. UNet^{SM} will convert venous values to approximate arterial values as described in policy.

- Only PCO_2 values obtained from blood gas sampling may be entered into UNet^{SM} as PCO_2 values. The total CO_2 obtained from venous sampling, such as from a chemistry or metabolic panel, is not acceptable.
- When the Central Venous Pressure (CVP) is not available for entry in UNet^{SM}, it is permissible to enter the Right Atrial Pressure (RAP) into the CVP Field for lung candidates. When the RAP is available (and the CVP is not available), it is preferable to enter the RAP in the CVP field than to not report any values. The transplant center should maintain documentation in the candidate's record of: which value was entered into UNet^{SM}, and why the value was entered in place of the requested value.

1. Policy title Candidates Age 0-11	**2. Policy number** 3.7.6.2 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Establish that all candidates age 0-11 awaiting lung transplantation are assigned priority for lung offers based on waiting time

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:
- List all candidates with the appropriate clinical values requested
- Provide, upon request, medical record documentation in support of listing criteria for review

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to UNet^{SM} through the use of system notices and documentation updates.

Through on-site reviews, staff verifies candidate listings as submitted in UNet^{SM} with the actual medical record documentation.

1. **Policy title** Candidate Variables in UNet[SM]	2. **Policy number** 3.7.6.3 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Specify required candidate variables when listing a candidate for lung transplantation and to explain the use of default and least beneficial values. Missing variables may not allow a candidate to be listed, or may result in a Lung Allocation Score of zero. If a test to obtain a value cannot be performed due to the medical condition of the candidate, the transplant program can petition the Lung Review Board to determine whether estimated values are appropriate.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List all candidates with the appropriate clinical values requested and to maintain medical record documentation to support each listing
- Update a candidate's clinical values every six months from the date of initially listing the candidate
- Provide, upon request, medical record documentation in support of listing criteria for review

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet[SM] system according to current approved policies and notifies transplant centers of modifications to UNet[SM] through the use of system notices and documentation updates. UNOS staff facilitates and monitors lung listings with the LRB process by communicating with transplant centers and appropriate OPTN/UNOS Committees regarding LRB decisions.

Through on-site reviews, staff verifies candidate listings as submitted in UNet[SM] and on Exception Scores, Special Diagnosis, or Estimated Values Justification Forms with the actual medical record documentation.

1. Policy title Candidate Variables in UNet^{SM} upon Implementation of Lung Allocation Scores Described in Policy 3.7.6	**2. Policy number** 3.7.6.3.1 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Specify that candidates already registered on the lung Waiting List at the time of implementation of the Lung Allocation Score with no or incomplete data will receive the least beneficial value or the default pulmonary pressure value as appropriate

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

No specific action is required of members.

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to UNet^{SM} through the use of system notices and documentation updates.

6. Detailed guidance on policy compliance

- Web address for Lung Allocation Score information: http://optn.transplant.hrsa.gov/resources/professionalResources.asp?index=9

1. **Policy title** Updating Candidate Variables	2. **Policy number** 3.7.6.3.2 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Describe when a transplant program can update a candidate's clinical data and when they must update this data. Other than heart catheterization data, all data must be updated at least once every six months. If the New York Heart Association class or assisted ventilation variable is expired, the candidate will receive a zero Lung Allocation Score and be screened off potential lung donor match runs. If any other variable is expired, the candidate will receive the least beneficial value for that variable.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List all candidates with the appropriate clinical values requested and to maintain medical record documentation to support each listing
- Update a candidate's clinical values every six months from the date of initially listing the candidate
- Provide, upon request, medical record documentation in support of listing criteria for review

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to UNet^{SM} through the use of system notices and documentation updates. UNOS staff facilitates and monitors lung listings with the LRB process by communicating with transplant centers and appropriate OPTN/UNOS Committees regarding LRB decisions

Through on-site reviews, staff verifies candidate listings as submitted in UNet^{SM} and on Exception Scores, Special Diagnosis, or Estimated Values Justification Forms with the actual medical record documentation.

6. Detailed guidance on policy compliance

- Web address for Lung Allocation Score information: http://optn.transplant.hrsa.gov/resources/professionalResources.asp?index=9
- There are four options when entering diabetes information into the LAS calculator. If the candidate is not diabetic, select Not diabetic. If the candidate is diabetic, select one of the following:
    - (Insulin) Dependency unknown
    - Insulin dependent
    - Not insulin dependent

1. **Policy title** Lung Candidates with Exceptional Cases	2. **Policy number** 3.7.6.4

3. Purpose of policy

The purpose of the policy is to:

- Set up the function and duties of the Lung Review Board (LRB). Transplant programs may request approval of estimated values, diagnosis, or a specific Lung Allocation Score. The LRB will have seven days to review each request. If the LRB does not complete voting within seven days, the candidate will receive the requested score or value. If a request is denied, the center may request a conference call with the LRB. After each denial during this process, the transplant center also has the option to override the decision of the LRB. Any requests overridden or not voted on within seven days and granted will be referred to the Thoracic committee.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List all candidates with the appropriate clinical values requested and to maintain medical record documentation to support each listing
- Accurately complete the appropriate information, Status Justification Form, or application in UNet^{SM} at the time of candidate listing or status extension
- Update a candidate's clinical values every six months from the date of initially listing the candidate
- Provide, upon request, medical record documentation in support of listing criteria for review

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to UNet^{SM} through the use of system notices and documentation updates. UNOS staff facilitates and monitors lung listings with the LRB process by communicating with transplant centers and appropriate OPTN/UNOS Committees regarding LRB decisions

Through on-site reviews, staff verifies candidate listings as submitted in UNet^{SM} and on Exception Scores, Special Diagnosis, or Estimated Values Justification Forms with the actual medical record documentation.

6. Detailed guidance on policy compliance

- Web address for Lung Allocation Score information: http://optn.transplant.hrsa.gov/resources/professionalResources.asp?index=9
- Candidates with an approved exception score will appear on lung matches according to the approved exception score. If the candidate's actual Lung Allocation Score (LAS) exceeds the approved exception score, the transplant center must withdraw the LAS exception to use the actual score on lung matches.

1. **Policy title** Allocation of Thoracic Organs to Heart-Lung Candidates	2. **Policy number** 3.7.7 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Outline how thoracic organs should be allocated to candidates listed for a combined heart/lung transplant. Candidates for heart/lung transplant must be registered on the individual candidate waiting list for each organ. If a candidate is eligible to receive a heart, the lung should be allocated to the candidate from the same donor. If a transplant candidate is eligible to receive a lung, the heart should be allocated to the candidate from the same donor, provided there are no suitable Status 1A isolated heart candidates eligible to receive the heart.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate all thoracic organs in accordance with the donor match run
- Educate organ placement staff on this policy and should allocate heart/lung combinations accordingly

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor thoracic match runs to determine if the organs were allocated according to the match run sequence as established by thoracic allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. During on-site reviews, staff verifies donor and transplant candidate's ABO. Staff refers any instances of potential policy violations to the appropriate OPTN/UNOS Committee.

1. Policy title ABO Typing for Heart Allocation	**2. Policy number** 3.7.8 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Define how hearts will be allocated to candidates within each heart status category according to ABO matching requirements. This policy was developed to address waiting time disparities among candidates with different blood types.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:
- List donors with accurate ABO type
- Maintain donor record documentation of ABO typing and provide, upon request, such documentation for review
- Allocate all thoracic organs in accordance with the donor match run

Transplant centers are expected to:
- List transplant candidates with the accurate ABO type
- Maintain medical record documentation of ABO typing and provide, upon request, such documentation for review

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor thoracic match runs to determine if the organs were allocated according to the match run sequence as established by thoracic allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. During on-site reviews, staff verifies donor and transplant candidate's ABO. Staff refers any instances of potential policy violations to the appropriate OPTN/UNOS Committee.

6. Detailed guidance on policy compliance

- Two source documents for ABO verification need to be present in the medical record.

1. Policy title Heart Allocation to Pediatric Candidates Registered under Blood Type "Z"	**2. Policy number** 3.7.8.1 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Allow a transplant program to accept a heart from a donor of any blood type for pediatric candidates less than one year of age. This policy also allows this "Z" designation to be used in the case of in-utero candidates where the actual blood type is not known.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:
- Allocate all thoracic organs in accordance with the donor match run

Transplant centers are expected to:
- List candidates with the accurate ABO type and date of birth
- Maintain medical record documentation of ABO typing/date of birth and provide, upon request, such documentation for review

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor thoracic match runs to determine if the organs were allocated according to the match run sequence as established by thoracic allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. During on-site reviews, staff verifies donor and transplant candidate's ABO. Staff refers any instances of potential policy violations to the appropriate OPTN/UNOS Committee.

1. **Policy title** ABO Typing for Lung Allocation	2. **Policy number** 3.7.8.2 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Set priorities for lung allocation on the basis of ABO compatibility between the donor and the transplant candidate. Lungs are first allocated to potential recipients who have the same blood type as the donor. Lungs are then allocated to potential recipients with compatible blood types.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:
- Allocate all thoracic organs in accordance with the donor match run

Transplant centers are expected to:
- List candidates with accurate ABO typing
- Maintain medical record documentation of ABO typing and provide, upon request, such documentation for review

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor thoracic match runs to determine if the organs were allocated according to the match run sequence as established by thoracic allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. During on-site reviews, staff verifies donor and transplant candidate's ABO.

6. Detailed guidance on policy compliance

- Two source documents for ABO verification need to be present in the medical record.

1. Policy title Time Waiting for Thoracic Organ Candidates	**2. Policy number** 3.7.9 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Specify exactly how waiting time is accrued for thoracic organs. Waiting time is not accrued while a transplant candidate is inactive on the waiting list. Waiting time accrued by a candidate for a single thoracic organ (heart or single lung) while waiting on the waiting list may be transferred to the waiting list for a multiple thoracic organ transplant. Conversely, waiting time accrued by a candidate for a multiple thoracic organ (heart-lung or double lung) transplant while waiting on the waiting list may be transferred to the waiting list for a single thoracic organ transplant.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

No specific action is required of members.

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies Members of modifications to system through the use of system notices and documentation updates. UNOS staff also monitors and analyzes the total accumulated time at Status 1A on a monthly basis.

1. Policy title Waiting Time Accrual for Heart Candidates	**2. Policy number** 3.7.9.1 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Specify how waiting time will be accrued within each heart status. Waiting time accrued at a Status 1A, 1B or 2 is counted within each status separately. Waiting time accrued at a lower status will not be applied toward heart allocation if the candidate is upgraded to a higher status.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

No specific action is required of members.

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies Members of modifications to system through the use of system notices and documentation updates. UNOS staff also monitors and analyzes the total accumulated time at Status 1A on a monthly basis.

1. Policy title Waiting Time Accrual for Lung Candidates Age 12 and Older	**2. Policy number** 3.7.9.2 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Establish how waiting time will be utilized in determining priority in lung allocation among lung candidates with a Lung Allocation Score

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

No specific action is required of members.

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates.

1. Policy title Sequence of Adult Heart Allocation	**2. Policy number** 3.7.10 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Specify the sequence by which hearts recovered from donors 18 years of age and older are allocated

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOS are expected to:

- Allocate all thoracic organs in accordance with the donor match run

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor thoracic match runs to determine if the organs were allocated according to the match run sequence as established by thoracic allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy.

1. Policy title Sequence of Adult Donor Lung Allocation	**2. Policy number** 3.7.11 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Specify the sequence by which lungs from adult donors (age 18 years and older) are allocated. For allocation purposes, a candidate awaiting a single lung transplant is grouped with those awaiting a double lung transplant. Candidates age 12 and over will be grouped together for adult donor lung allocation, and lungs from adult donors will first be offered to candidates aged 12 and older.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOS are expected to:

- Allocate all thoracic organs in accordance with the donor match run

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to the system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor thoracic match runs to determine if the organs were allocated according to the match run sequence as established by thoracic allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy.

1. Policy title Sequence of Pediatric Donor Lung Allocation	**2. Policy number** 3.7.11.1 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Specify the sequence by which lungs from pediatric donors (age 0-17 years) are allocated. For allocation purposes, a candidate awaiting a single lung transplant is grouped with those awaiting a double lung transplant. Candidates aged 12-17 will be grouped together for pediatric donor lung allocation. Lungs from donors age 0-11 will first be offered to candidates aged 0-11, then to candidates age 12-17.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOS are expected to:

- Allocate all thoracic organs in accordance with the donor match run

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to the system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor thoracic match runs to determine if the organs were allocated according to the match run sequence as established by thoracic allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy.

1. Policy title Minimum Information for Thoracic Organ Offers, Subsection 3.7.12.1 - Essential Information	**2. Policy number** 3.7.12 **Subsections** 3.7.12.1

3. Purpose of policy

The purpose of the policy is to:

- Specify the minimum information that OPOs must provide to recipient centers with each thoracic offer

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOS are expected to:

- Educate organ recovery and placement staff with the requirements for heart offers
- Provide transplant center personnel with the minimum information required when making heart offers
- Maintain documentation of the minimum information required and provide such documentation, upon request, for review
- Maintain a complete record of all organ offers

5. How OPTN/UNOS will evaluate member compliance with this policy

During on-site reviews, UNOS staff reviews a sample of donor records based on the number of donors the OPO had in the previous year and determines whether the OPO documented the minimum information for thoracic offers. UNOS also examines any complaints or potential policy violations and refers them to the appropriate OPTN/UNOS Committee.

1. **Policy title** Desirable Information for Heart Offers	2. **Policy number** 3.7.12.2 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Identify information that the OPO is encouraged to provide the recipient center with each heart offer

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOS are expected to:

- Educate organ recovery and placement staff with the requirements for heart offers
- Provide transplant center personnel with the desired information for heart offers whenever possible
- Maintain documentation of this information and provide such documentation, upon request, for review
- Maintain a complete record of all organ offers

5. How OPTN/UNOS will evaluate member compliance with this policy

During on-site reviews, UNOS staff reviews a sample of donor records based on the number of donors the OPO had in the previous year and determines whether the OPO documented the minimum information for thoracic offers. UNOS also examines any complaints or potential policy violations and refers them to the appropriate OPTN/UNOS Committee.

1. Policy title Essential Information for Lung Offers	**2. Policy number** 3.7.12.3 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Specify the minimum information that OPOs must provide to recipient centers with each lung organ offer, in addition to the essential information required for thoracic offers defined by policy 3.7.12.1

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOS are expected to:

- Educate organ recovery and placement staff with the requirements for lung offers
- Provide transplant center personnel with the minimum information required when making lung offers
- Maintain documentation of the minimum information required and provide such documentation, upon request, for review
- Maintain a complete record of all organ offers

5. How OPTN/UNOS will evaluate member compliance with this policy

During on-site reviews, UNOS staff reviews a sample of donor records based on the number of donors the OPO had in the previous year and determines whether the OPO documented the minimum information for lung offers. UNOS also examines any complaints or potential policy violations and refers them to the appropriate OPTN/UNOS Committee.

1. **Policy title** Desirable Information for Lung Offers	2. **Policy number** 3.7.12.4 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Identify information that the OPO is encouraged to provide to the recipient center with each lung offer

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOS are expected to:

- Educate organ recovery and placement staff with the requirements for lung offers
- Provide transplant program personnel with the desired information for lung offers whenever possible
- Maintain documentation of this information and provide such documentation, upon request, for review
- Maintain a complete record of all organ offers

5. How OPTN/UNOS will evaluate member compliance with this policy

During on-site reviews, UNOS staff reviews a sample of donor records based on the number of donors the OPO had in the previous year and determines whether the OPO documented the minimum information for lung offers. UNOS also examines any complaints or potential policy violations and refers them to the appropriate OPTN/UNOS Committee.

1. Policy title Status 1 Listing Verification	**2. Policy number** 3.7.13 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Randomly audit transplant centers that have demonstrated non-compliance with Status 1 listing policies

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List all candidates at the appropriate heart status and to maintain medical record documentation in support of each status listing
- Complete the appropriate Status Justification Form in UNet^{SM} at the time of candidate listing or status extension
- Adjust a candidate's status if the medical criterion for listing changes pursuant to policy
- Provide, upon request, medical record documentation in support of listing criteria for review

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS staff facilitates and monitors thoracic listings with the RRB process by communicating with transplant centers and appropriate OPTN/UNOS Committees regarding RRB decisions. UNOS also informs transplant centers of pending downgrades in status due to the expiration of a listing term.

UNOS reviews all Status Justification Forms daily for completeness and monitors the percentage of Status 1A listings by criterion on a monthly basis. Through on-site reviews, staff verifies a recipient's status indicated in UNet^{SM} and on Status Justification Forms with actual patient medical record documentation.

1. Policy title Removal of Thoracic Organ Transplant Candidates from Thoracic Waiting Lists when Transplanted or Deceased	**2. Policy number** 3.7.14 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Maximize the efficiency of the organ allocation system by requiring that candidates who receive a transplant or die be immediately removed from the waiting list

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Remove candidates from the waiting list within 24 hours of transplant or death

5. How OPTN/UNOS will evaluate member compliance with this policy

During routine site surveys, UNOS staff reviews a sample of records to verify that candidates were removed from the waiting list within 24 hours of transplant or death.

6. Detailed guidance on policy compliance

- If you learn of a candidate's death more than 24 hours after the death, document in the candidate's record the date you become aware of the death. Remove the candidate from the waiting list within 24 hours of learning of the candidate's death. Include documentation in the candidate's record to support the date of death, if available.

1. Policy title Local Conflicts Involving Thoracic Organ Allocation	**2. Policy number** 3.7.15 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Provide a platform where local conflicts may be submitted for review and resolution

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs and transplant centers are expected to:

- Report any conflicts or irresolvable inequities to the appropriate OPTN/UNOS Committee for review

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS examines any reported conflicts to determine if a policy violation has occurred and facilitates review by the appropriate OPTN/UNOS Committee and the OPTN/UNOS Board of Directors. The facilitation includes the use of the alternate dispute resolution, which encourages both parties to discuss their issues with each other or an impartial subcommittee of the MPSC.

1. Policy title Allocation of Domino Donor Hearts	**2. Policy number** 3.7.16 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Define a domino heart transplant
- Specify how domino donor hearts should be allocated

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:
- Allocate all thoracic organs in accordance with the donor match run

Transplant centers are expected to:
- Allocate organs in accordance with current policy

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor thoracic match runs to determine if the organs were allocated according to the match run sequence as established by thoracic allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. Staff refers any instances of potential policy violations to the appropriate OPTN/UNOS Committee.

1. Policy title Crossmatching for Thoracic Organs	**2. Policy number** 3.7.17 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Ensure that all thoracic transplant programs and their histocompatibility laboratories have a joint written policy on when a crossmatch is necessary

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:
- Collaborate with histocompatibility labs to create a joint policy on crossmatching
- Provide, upon request, documentation of this policy

5. How OPTN/UNOS will evaluate member compliance with this policy

During on-site reviews, UNOS staff verifies the existence of a written policy on crossmatching.

6. Detailed guidance on policy compliance

- Review policy Appendix 3D, "Guidelines for the Development of Joint Written Agreements Between Histocompatibility Laboratories and Transplant Programs" http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_109.pdf

1. Policy title Pancreas Organ Allocation	**2. Policy number** 3.8 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Establish specific requirements, allocation sequence, etc. for pancreas allocation

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs and transplant centers are expected to:

- Comply with these policies for pancreas allocation

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to the system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor match runs to determine if the organs were allocated according to the match run sequence as established by organ allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy.

During on-site reviews, staff selects a sample of donor records and reviews the donor file documentation to determine whether pancreata were allocated in accordance with the match runs.

1. Policy title Pancreas Organ Allocation	**2. Policy number** 3.8.1 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Specifically define how isolated pancreas, combined kidney-pancreas or combined solid organ-islet transplants are to be allocated
- Define how zero antigen mismatch pancreas organs are to be allocated

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate organs according to the match run
- Maintain documentation of all organ offers and provide such documentation upon request for review

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs of modifications to the system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor match runs to determine if the organs were allocated according to the match run sequence as established by organ allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy.

During on-site reviews, staff selects a sample of donor records and reviews the donor file documentation to determine whether pancreata were allocated in accordance with the match runs.

1. **Policy title** Local Whole Pancreas Allocation, Regional Whole Pancreas Allocation and National Whole Pancreas Allocation	2. **Policy number** 3.8.1.1 3.8.1.2 3.8.1.3 **Subsections** N/A

3. Purpose of policy

The purpose of these policies is to:

- Define the specific geographic allocation of pancreata

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate organs according to the match run
- Maintain documentation of all organ offers and provide such documentation upon request for review

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs of modifications to the system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor match runs to determine if the organs were allocated according to the match run sequence as established by organ allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy.

During on-site reviews, staff selects a sample of donor records and reviews the donor file documentation to determine whether pancreata were allocated in accordance with the match runs.

1. Policy title Facilitated Pancreas Allocation	**2. Policy number** 3.8.1.4 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Expedite the placement of pancreata and therefore minimize ischemia time

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Use the Organ Center for expedited placement of pancreata

Transplant centers are expected to:

- Notify UNOS in writing if they are willing to participate in this system

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to the system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor match runs to determine if the organs were allocated according to the match run sequence as established by organ allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy.

During on-site reviews, staff selects a sample of donor records and reviews the donor file documentation to determine whether pancreata were allocated in accordance with the match runs.

1. Policy title Islet Transplantation	**2. Policy number** 3.8.1.5 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Define the allocation sequence for pancreatic islet cell transplantation

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate all organs according to the match run
- Maintain documentation of all organ offers and provide such documentation upon request for review

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs of modifications to the system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor match runs to determine if the organs were allocated according to the match run sequence as established by organ allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy.

1. **Policy title** Islet Allocation Protocol	2. **Policy number** 3.8.1.6 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Establish a protocol for the allocation and reallocation of pancreata for islet cell transplantation
- Define how waiting time is accrued for islet cell transplant candidates
- Define medical suitability of an islet preparation
- Define active and inactive candidate status
- Establish a protocol for updating candidate status and removal from the waiting list

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate islet cells according to this policy
- Maintain documentation of all organ offers and provide such documentation upon request for review

Transplant centers are expected to:

- Allocate islet cells according to this policy
- Document whether the islet preparation is medically suitable or medically unsuitable for the candidate for whom the center accepted the islets, and the reasons why the islets are medically unsuitable
- Update candidate status in UNet^{SM} within 72 hours of a transplant center's knowledge of a clinical change and provide such documentation upon request for review
- Remove a candidate from the waiting list within 24 hours of the candidate receiving his/her third islet infusion
- Maintain and submit documentation upon request

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to the system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor match runs to determine if the organs were allocated according to the match run sequence as established by organ allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy.

1. **Policy title** Mandatory Sharing of Zero Antigen Mismatch Pancreata	2. **Policy number** 3.8.1.7 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Define the mandatory sharing requirements for pancreas allocation

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:
- Allocate all pancreata according to the match run
- Maintain documentation of all organ offers and provide such documentation upon request for review

Transplant centers are expected to:
- List all pancreas candidates with accurate information

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to the system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor match runs to determine if the organs were allocated according to the match run sequence as established by organ allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy.

During on-site reviews, staff selects a sample of donor records and reviews the donor file documentation to determine whether pancreata were allocated in accordance with the match runs.

1. Policy title Organ Offer Limit	**2. Policy number** 3.8.1.7.1

3. Purpose of policy

The purpose of the policy is to:

- Define requirements for offering zero antigen mismatch pancreata
- Promote efficiency in placement of zero antigen mismatch pancreata

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Offer zero antigen mismatched pancreata according to the match run sequence, either through the Organ Center or through DonorNet®
- Make offers for at least the first 10 zero antigen mismatched potential recipients on the match run. If fewer than 10 zero mismatched potential recipients appear on the match run, offers must be made for all potential recipients on the match run.
- Make offers within eight hours after organ procurement
- Maintain documentation of all organ offers and provide such documentation upon request for review

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet℠ system according to current approved policies and notifies OPOs of modifications to system through the use of system notices and documentation updates. UNOS staff monitors all deceased donor pancreas and kidney/pancreas match runs to ensure:

- organs were allocated according to the match run sequence, and
- mandatory shares were offered according to policy.

When insufficient information is provided by the OPO, UNOS staff makes a written inquiry into any allocations that do not follow the match run sequence. During on-site surveys of organ procurement organizations, staff reviews a sample of kidney allocations and validates data entered into DonorNet® and Tiedi® for donors in the review sample. UNOS staff forwards potential policy violations to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review.

6. Detailed guidance on policy compliance

- Organ Center telephone: (800) 292-9537
- The Host OPO **will** be entitled to a kidney payback if the kidney/pancreas combination is accepted for any potential recipient who is located outside the host OPO's local service area. This includes potential recipients who are beyond the 10th potential recipient on the match run.
- To receive a payback credit, OPOs must:
    - Fax a completed Kidney Payback Sheet to the Organ Center within 5 business days of organ recovery
    - Enter the final acceptance in DonorNet®
    - Enter the cross-clamp date/time in DonorNet®

1. Policy title Waiting Time Adjustment	**2. Policy number** 3.8.2 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Specify when waiting time accrued by a transplant candidate for one or more organs shall be transferred if it is determined that the candidate requires another organ or organ combination

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Comply with this policy for waiting time accrual

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to the system through the use of system notices and documentation updates. The Organ Center manages any requests for waiting time transfers and adjustments and refers any potential policy violations to the appropriate department.

1. Policy title Inclusion of HLA Data	**2. Policy number** 3.8.3 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Require recipient HLA information at the time of listing for a pancreas or combined kidney-pancreas transplant

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- To provide recipient HLA information at the time of listing for a pancreas or combined kidney-pancreas transplant

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to the system through the use of system notices and documentation updates.

1. **Policy title** Regional or National Allocation to Alternate Recipients	2. **Policy number** 3.8.5 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Require that for pancreata shared regionally or nationally, the Organ Center will advise the OPO for the recipient transplant center to seek alternate backup candidates on the OPO local waiting list

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:
- Facilitate local backup for all imported organs
- Maintain documentation of all organ offers and provide such documentation upon request for review

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs of modifications to the system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor match runs to determine if the organs were allocated according to the match run sequence as established by organ allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy.

During on-site reviews, staff selects a sample of donor records and reviews the donor file documentation to determine whether pancreata were allocated in accordance with the match runs.

1. **Policy title** Minimum Information for Pancreas Offers, Essential Information Category	2. **Policy number** 3.8.6 **Subsections** 3.8.5.1

3. Purpose of policy

The purpose of the policy is to:

- Specify the essential information that OPOs must provide to potential recipient centers with each pancreas offer

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Educate organ recovery and placement staff with the requirements for pancreas offers
- Provide transplant center personnel with the minimum information required when making pancreas offers
- Maintain documentation of the essential information required and provide such documentation, upon request, for review
- Maintain a complete record of all organ offers

5. How OPTN/UNOS will evaluate member compliance with this policy

During on-site reviews, UNOS staff reviews a sample of donor records based on the number of donors the OPO had in the previous year and determines whether the OPO documented the minimum information for thoracic offers. UNOS also examines any complaints or potential policy violations and refers them to the appropriate OPTN/UNOS Committee.

1. Policy title Removal of Pancreas Transplant Candidates from Pancreas Waiting Lists when Transplanted or Deceased	**2. Policy number** 3.8.7 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Maximize the efficiency of the organ allocation system by requiring that candidates who receive a pancreas transplant or who die while awaiting a transplant be immediately removed from the waiting list

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Remove all candidates from the waiting list within 24 hours of transplant or death

5. How OPTN/UNOS will evaluate member compliance with this policy

During routine site surveys, UNOS staff reviews a sample of records to verify that candidates were removed from the waiting list within 24 hours of transplant or death.

6. Detailed guidance on policy compliance

- If you learn of a candidate's death more than 24 hours after the death, document in the candidate's record the date you become aware of the death. Remove the candidate from the waiting list within 24 hours of learning of the candidate's death. Include documentation in the candidate's record to support the date of death, if available.

1. **Policy title** Waiting Time Reinstatement for Pancreas Recipients	2. **Policy number** 3.8.8 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Define the requirements and procedures for reinstating previously accrued waiting time to pancreas transplant candidates following graft failure

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Submit a completed Pancreas Waiting Time Reinstatement Form to the Organ Center
- Maintain documentation to support the information submitted on the Pancreas Waiting Time Reinstatement Form, including documentation of radiographic evidence indicating that the transplanted pancreas has failed
- Submit supporting medical record documentation to UNOS upon request

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to the system through the use of system notices and documentation updates. The Organ Center manages any requests for waiting time transfers and adjustments and refers any potential policy violations to the appropriate department.

6. Detailed guidance on policy compliance

- A partial pancreatectomy performed in the first two weeks of transplant should be treated as a "removal of the organ" for the purposes of Policy 3.8.7.
- Link to Pancreas Waiting Time Reinstatement Form

1. Policy title Prospective Crossmatching	**2. Policy number** 3.8.9 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Provide an exception for omission of prospective crossmatching warranted by clinical circumstances

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers and histocompatibility laboratories are required to:

- Develop a joint written policy concerning clinical circumstances which substantiate the omission of prospective crossmatching

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs of modifications to the system through the use of system notices and documentation updates. Documentation of joint policy is subject to review by UNOS staff.

6. Detailed guidance on policy compliance

- Review policy Appendix 3D, "Guidelines for the Development of Joint Written Agreements Between Histocompatibility Laboratories and Transplant Programs" http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_109.pdf

1. Policy title Allocation System for Organs Not Specifically Addressed	**2. Policy number** 3.9 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Assign a point system for allocation of organs not specifically addressed in other organ specific policies

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List all candidates at the appropriate status and to maintain medical record documentation in support of each status listing
- Provide, upon request, medical record documentation in support of listing criteria for review

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to system through the use of system notices and documentation updates.

1. Policy title Degree of Medical Urgency	**2. Policy number** 3.9.1 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Assign a status code or mortality risk score that corresponds to the medical urgency of the candidate

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List all candidates at the appropriate status and to maintain medical record documentation in support of each status listing
- Provide, upon request, medical record documentation in support of listing criteria for review

5. How OPTN/UNOS will evaluate member compliance with this policy

During an on-site or desk audit, UNOS reviews the assigned status code or mortality risk score and verifies it with the medical documentation.

1. Policy title Distance Criteria	**2. Policy number** 3.9.2 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Define the geographic sequence of allocation for organs not specifically addressed in policy

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate all organs in accordance with this policy

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS programs the UNet^{SM} system and notifies OPOs of system modifications through the use of system notices and documentation updates.

1. **Policy title** Organ Allocation to Multiple Organ Transplant Candidates	2. **Policy number** 3.9.3 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Specify that candidates needing multiple organs must be registered on each organ list for the organ that they need
- Specify that allocation of additional organs for those listed for a heart and/or lung and/or liver is mandatory when the donor is located within the same local organ distribution unit as the candidate. If the multiple organ candidate is on a waiting list outside the local organ distribution unit where the donor is located, voluntary sharing of the second organ is recommended.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- OPOs are expected to allocate organs according to the match run

Transplant centers are expected to:

- List all candidates at the appropriate status and to maintain medical record documentation in support of each status listing
- Provide, upon request, medical record documentation in support of listing criteria for review

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor organ match runs to determine if the organs were allocated according to the match run sequence as established by organ allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. During on-site reviews, staff verifies donor organ allocation.

6. Detailed guidance on policy compliance

- To receive a payback credit for sharing a kidney with a non-renal organ to a multiple organ candidate located outside the local organ distribution unit, OPOs must fax a completed Kidney Payback Sheet to the Organ Center
- Organ Center telephone: (800) 292-9537
- For instruction on heart-lung allocation, review Policy 3.7.7
- For instruction on liver-intestine allocation, review Policy 3.11.4 and Policy 3.6.4.8

1. Policy title Local Conflicts	**2. Policy number** 3.9.4 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Provide a platform where local conflicts may be submitted for review and resolution

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs and transplant centers are expected to:

- Report any conflicts or irresolvable inequities to the appropriate OPTN/UNOS Committee for review

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS examines any reported conflicts to determine if a policy violation has occurred and facilitates review by the appropriate OPTN/UNOS Committee and the OPTN/UNOS Board of Directors. The facilitation includes the use of the alternate dispute resolution, which encourages both parties to discuss their issues with each other or an impartial subcommittee of the MPSC.

1. Policy title Back-up for Inactive Transplant Programs	**2. Policy number** 3.10 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Specify that each transplant center should address the issue of providing services for transplant centers that are temporarily inoperative

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Notify candidates on their center's waiting list when they are temporarily inactive and will not be accepting organs for transplant
- Assist candidates on their waiting list in finding other transplant program coverage while their program is inoperative

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS monitors activity of transplant centers and verifies that an inactive center has contacted its candidates on the waiting list about the program's status. UNOS also examines any reported conflicts to determine if a policy violation has occurred and facilitates review by the appropriate OPTN/UNOS Committee.

1. Policy title Intestinal Organ Allocation	**2. Policy number** 3.11 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Define how intestinal organs will be allocated. Intestinal organs may include the stomach, small and/or large intestine and any portion of the gastro-intestinal tract.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Follow this policy when listing candidates or allocating intestinal organs and to maintain medical records in support of both

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews daily all deceased donor match runs to determine if the organs were allocated according to the match run sequence as established by organ allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy.

1. Policy title Degree of Medical Urgency	**2. Policy number** 3.11.1 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Outline the Status candidates may be assigned according to the medical condition of the candidate

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List all candidates at the appropriate intestinal organ status and maintain medical record documentation in support of each status listing
- Accurately complete the appropriate information and Justification Form in UNet^{SM} at the time of candidate listing
- Adjust a candidate's status if the medical criterion for listing changes

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates.

1. **Policy title** Geographic Sequence for Intestinal Organ Allocation	2. **Policy number** 3.11.2 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Define the way in which intestinal organs will be allocated. Intestinal organs are allocated first to size compatible and blood type identical candidates and followed by candidates who have a blood type that is compatible to the organ donor. Allocation is based upon length of time waiting and in accordance with the sequence: To local Status 1 first then Local Status 2; Status 1 candidates in the Host OPO's region; Status 2 candidates in the Host OPO's region; Status 1 candidates in all other regions; and Status 2 candidates in all other regions.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:
- Comply with this policy when executing a match run and contacting possible recipients

Transplant centers are expected to:
- List all candidates at the appropriate intestinal organ status and to maintain medical record documentation in support of each status listing
- Accurately complete the appropriate information and justification form in UNet^{SM} at the time of candidate listing. Transplant centers are also expected to adjust a candidate's status if the medical criterion for listing changes

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to the system through the use of system notices and documentation updates. UNOS reviews all deceased donor match runs to determine if the organs were allocated according to the match run sequence as established by organ allocation policy and programmed into the UNet^{SM} system.

When insufficient information is provided by the OPO, UNOS staff makes a written inquiry into any allocations that do not follow the match run sequence. During on-site surveys of organ procurement organizations, staff reviews a sample of allocations and validates data entered into DonorNet® and Tiedi® for donors in the review sample. UNOS staff forwards potential policy violations to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for confidential medical peer review.

1. Policy title Justification Form	**2. Policy number** 3.11.3 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Inform the transplant center of the requirement to complete a Justification Form in order to list a candidate on the intestinal organ waiting list. This requirement is for any Status 1 listing or renewal.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List Status 1 candidates in the UNet^{SM} system utilizing the Justification Form provided in an electronic format
- List candidates appropriately according to policy and medical urgency and maintain medical records supporting the listing

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates.

1. **Policy title** Combined Intestine-Liver Organ Candidates	2. **Policy number** 3.11.4 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Define the allocation sequence for combined intestine-liver grafts

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Make liver offers sequentially according to the liver match run (including all MELD/PELD potential recipients) through national Status 1A and 1B potential recipients **before** making offers to combined liver-intestine potential recipients sequentially according to the intestine match run

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to the system through the use of system notices and documentation updates. UNOS reviews all liver and intestine match runs to verify that the organs were allocated according to the match run sequence as established by policy and programmed into the UNet^{SM} system.

When insufficient information is provided by the OPO, UNOS staff makes a written inquiry into any allocations that do not follow the match run sequence. During on-site surveys of organ procurement organizations, staff reviews a sample of allocations and validates data entered into DonorNet® and Tiedi® for donors in the review sample. UNOS staff forwards potential policy violations to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for confidential medical peer review.

1. Policy title Waiting Time Accrual for Combined Liver-Intestinal Organ Candidates	**2. Policy number** 3.11.4.1 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Define how waiting time accrued by a candidate for an isolated intestinal organ transplant while waiting on the waiting list also may be accrued for a combined liver-intestinal organ transplant when it has been determined that the candidate requires multiple organs

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List candidates appropriately according to policy and medical urgency and maintain medical records supporting the listing

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS, through the Organ Center, facilitates waiting time transfers and adjustments and reports any potential policy violations to the appropriate department.

2. Policy title Combined Liver-Intestinal Organs from Donors 0-10 years of age	**2. Policy number** 3.11.4.2 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Increase the availability of liver/intestine grafts for pediatric candidates awaiting liver/intestine transplant by changing the allocation priority that displays on the liver match run for liver/intestine donors between the ages of 0 and 10

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Allocate combined liver-intestine organs from donors aged 0-10 according to the liver match runs generated by DonorNet® and according to policies 3.11.4 and 3.11.4.2

5. How OPTN/UNOS will evaluate member compliance with this policy

Staff monitors all liver and intestinal organ allocations and makes a written inquiry into any allocations that do not follow the match run sequence. During on-site surveys of organ procurement organizations, staff reviews a sample of liver and intestinal organ allocations. The OPTN/UNOS Membership and Professional Standards Committee (MPSC) reviews instances of allocations that do not follow the match run sequence and the responses to the written inquiries.

6. Detailed guidance on policy compliance

- Implementation date June 20, 2007

1. Policy title Removal of Intestinal Transplant Candidates from Intestine Waiting Lists when Transplanted or Deceased	**2. Policy number** 3.11.5 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Maximize the efficiency of the organ allocation system by requiring that candidates who receive an intestinal transplant or who die while awaiting a transplant be immediately removed from the waiting list.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Remove candidates from the waiting list within 24 hours of transplant or death

5. How OPTN/UNOS will evaluate member compliance with this policy

During routine site surveys, UNOS staff reviews a sample of records to verify that candidates were removed from the waiting list within 24 hours of transplant or death.

6. Detailed guidance on policy compliance

- If you learn of a candidate's death more than 24 hours after the death, document in the candidate's record the date you become aware of the death. Remove the candidate from the waiting list within 24 hours of learning of the candidate's death. Include documentation in the candidate's record to support the date of death, if available.

1. **Policy title** Waiting Time Reinstatement for Intestinal Organ Transplant Recipients	2. **Policy number** 3.11.5.1 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Define the circumstances that would allow a candidate to continue to accrue additional time and maintain their previously accrued time on the waiting list when they may need to be re-listed after transplant for immediate and permanent non-function
- Further define for the transplant centers that immediate and permanent non-function means an intestinal organ graft failure resulting in the removal of the organ within the first seven days following transplantation

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Re-list candidates only under the circumstances defined in this policy for the purpose of requesting reinstatement of previously accrued time
- Complete and submit all reinstatement requests to the Organ Center on the proper form with documentation including, but not limited to, the operative report

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS, through the Organ Center may facilitate waiting time reinstatement upon a center's request and reports any instances of potential policy violations to the appropriate department.

1. **Policy title** Waiting Time for Intestinal Organ Transplant Candidates in an Inactive Status	2. **Policy number** 3.11.6 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Define the parameters in which a candidate who has been made inactive on the waiting list may still continue to accrue an aggregate of 30 days inactive status waiting time. The waiting time is calculated on a cumulative basis.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Ensure that a candidate's status on the waiting list accurately reflects the current medical urgency or condition

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. The system counts the total number of days at inactive time and is programmed according to policy.

1. Policy title Acquired Immune Deficiency Syndrome (AIDS), Human Pituitary Derived Growth Hormone (HPDGH) and Reporting of Potential Recipient Diseases or Medical Conditions, Including Malignancies, or Donor Origin	**2. Policy number** 4.0 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Establish guidelines that apply to the pre-transplant consideration of potential organ donors and/or potential organ recipients

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs and transplant centers are expected to:

- Comply with these policies for donor and recipient screening
- Maintain documentation of donor/recipient screening and provide such documentation upon request for review

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS examines any reported instances for a potential policy violation and will refer any instances of potential policy violations to the appropriate committee.

1. Policy title Screening Potential Organ Donors for HIV	**2. Policy number** 4.1 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Specify the testing requirements for HIV screening of all potential donors
- Outline OPO responsibilities in reporting these results to recipient centers with respect to pre- and post-transfusion testing samples

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Comply with the HIV testing and reporting requirement for all donors
- Maintain documentation of donor/recipient screening and provide such documentation upon request for review

5. How OPTN/UNOS will evaluate member compliance with this policy

During on-site reviews, staff selects a sample of donor records and reviews the on-site documentation to determine whether the OPO was compliant with this policy.

1. **Policy title** Communication of Donor History	2. **Policy number** 4.1.1 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Ensure the Host OPO will obtain a history on each donor and determine whether the donor is in a "high risk" group
- Include in OPTN Policy a reference to the Centers for Disease Control and Prevention (CDC) criteria for a "high risk" donor. These criteria are defined in the Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs (CDC Guidelines)[1]
- Require the OPO to communicate high risk donor history to every transplant center that receives an organ from the donor
- Require the transplant center to obtain informed consent from the recipient prior to implantation of an organ from a "high risk" donor*

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Obtain a donor history for each potential donor
- Evaluate each donor's history to determine if the donor is "high risk" according to the criteria identified by the Centers for Disease Control and Prevention (CDC)
- Inform the transplant center of the donor's specific behaviors or history that places the donor in a "high risk" group according to the CDC criteria defined in the CDC Guidelines
- Indicate in DonorNet® that the donor meets the CDC definition of high risk
- Maintain documentation that the donor's history has been communicated to the transplant center

Transplant centers are expected to:

- Be familiar with the criterion(a) defined by the CDC that places a donor in a high risk group for transmitting HIV through transplantation
- Inform the potential recipient, legal next of kin, designated healthcare representative, or appropriate surrogate of the donor's specific behaviors or history that places the donor in a "high risk" group, as defined by the CDC, prior to implantation of the organ
- Obtain and document informed consent from the potential recipient, legal next of kin, designated healthcare representative, or appropriate surrogate prior to implantation when the organ is from a donor who meets the CDC definition of "high risk"
- Maintain all documentation pertaining to communication of donor history and informed consent, and make this documentation available upon request

5. How OPTN/UNOS will evaluate member compliance with this policy

[1] Rogers MF, Simonds RJ, Lawton KE, et al. Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs. CDC MMWR Recommendations and Reports. 1994;May 20/ 43(RR-8):1-17.

UNOS staff will request documentation from OPOs and Transplant Centers for donors who meet the criteria defined by the Centers for Disease Control and Prevention as "high risk" and included in OPTN Policy 4.1.1. UNOS staff will review the documentation to ensure:

- the OPO communicated the donor's history to all transplant centers that received organs from that donor; and
- the transplant center obtained informed consent from the recipient, legal next of kin, designated healthcare representative, or appropriate surrogate prior to implantation of the organ.

UNOS staff will forward any potential policy violations to the OPTN/UNOS Membership and Professional Standards Committee for review and potential action.

6. Detailed guidance on policy compliance

- Review "CDC Guidelines for High Risk Behavior" and "CDC Guidelines for Preventing Transmission of Human Immunodeficiency Virus through Transplantation of Human Tissue and Organs"
- *These changes to Policy 4.1.1 were effective January 18, 2008

1. Policy title Organ Sharing	**2. Policy number** 4.1.2 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Prohibit the sharing and transplantation of organs from donors who are HIV positive

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:
- Screen all donors for HIV
- Defer organ donation for donors who test positive HIV

5. How OPTN/UNOS will evaluate member compliance with this policy

During on-site reviews, staff selects a sample of donor records and reviews the on-site documentation to determine whether the OPO was compliant with this policy. Any time a donor is reported as being HIV positive, UNOS Department of Evaluation and Quality will review the issue and the results will be reviewed by the OPTN/UNOS Membership and Professional Standards Committee.

1. Policy title Exceptions	**2. Policy number** 4.1.3 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Define that in extreme medical emergencies the transplantation of an organ from a donor who has not been tested for HIV is permitted
- Obligate the transplant surgeon to obtain informed consent from the recipient or next of kin

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Obtain informed consent of the recipient prior to the transplantation of organs from donors who have not been tested for HIV
- Maintain documentation of informed consent and provide such documentation upon request for review

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS examines any reported instances for a potential policy violation and will refer any instances of potential policy violations to the appropriate OPTN/UNOS Committee.

1. Policy title Donor Consent Forms	**2. Policy number** 4.1.4 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Suggest to OPOs that each donor consent form includes a notice that all potential donors will be screened for medical acceptability for organ donation and results of such tests may be the basis for not using the organ in transplantation

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Consider the suggestion to include notification on donor consent forms

5. How OPTN/UNOS will evaluate member compliance with this policy

No monitoring efforts are required.

1. Policy title Screening Potential Transplant Recipients for HIV	**2. Policy number** 4.2 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Require that all potential transplant recipients be tested for HIV as a condition of candidacy for organ transplantation, except in cases where such testing would violate state or federal laws or regulations

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:
- Test all potential transplant recipients for HIV
- Maintain documentation of testing and provide such documentation upon request for review

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS examines any reported instances for a potential policy violation and will refer any instances of potential policy violations to the appropriate OPTN/UNOS Committee.

1. Policy title HIV Positive Transplant Candidates	**2. Policy number** 4.2.1 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Address the appropriateness of listing candidates who test positive for HIV. This policy states that these candidates should not be automatically excluded from candidacy for organ transplantation. Transplant centers should inform potential recipients of the increased risk in morbidity and mortality.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Inform potential recipients of the increased risk of transplantation due to their HIV status and immunosuppressive therapy

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS examines any reported instances for a potential policy violation and will refer any instances of potential policy violations to the appropriate OPTN/UNOS Committee.

1. Policy title Informing Personnel	**2. Policy number** 4.2.2 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Specify that healthcare personnel caring for donors, potential donors, candidates, potential candidates, and recipients who test positive for HIV should be informed of HIV status

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Inform healthcare personnel regarding a candidate's HIV status

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS examines any reported instances for a potential policy violation and will refer any instances of potential policy violations to the appropriate OPTN/UNOS Committee.

1. Policy title Candidate and Recipient Treatment	**2. Policy number** 4.2.3 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Administration of treatment to candidates and recipients who test positive for HIV should not be optional or discretionary for healthcare personnel

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Follow the policies for all candidates and recipients

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS examines any reported instances for a potential policy violation and will refer any instances of potential policy violations to the appropriate OPTN/UNOS Committee.

1. Policy title Disclosure of Information about HIV Status	**2. Policy number** 4.3 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Assure that OPOs and transplant centers comply with state and federal statutes and regulations applicable to the disclosure of personalized data on actual or potential organ donors, candidates or recipients

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs and transplant centers are expected to:

- Comply with state and federal regulations

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS examines any reported instances for a potential policy violation and will refer any instances of potential policy violations to the appropriate OPTN/UNOS Committee.

1. Policy title General Recommendations	**2. Policy number** 4.4 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Encourage member institutions (OPOs, transplant centers, and histocompatibility laboratories) to adopt healthcare policies addressing HIV-related issues with regard to transplant candidates and recipients

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs, transplant centers, and histocompatibility labs are requested to:

- Adopt healthcare policy for HIV-related issues

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS examines any reported instances for a potential policy violation and will refer any instances of potential policy violations to the appropriate OPTN/UNOS Committee.

1. Policy title Human Pituitary Derived Growth Hormone	**2. Policy number** 4.5 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Define that people who have received Human Pituitary Derived Growth Hormone (HPDGH) from human tissue (not recombinant) shall be evaluated as organ donors with potential organs used at the discretion of the accepting transplant center and with informed consent from the transplant recipient
- State that the use of recombinant HPDGH carries no additional risk of transmissible disease

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:
- Evaluate potential organ donors who have received HPDGH (not recombinant)
- Maintain documentation of informed consent and provide such documentation upon request for review

Transplant centers are expected to:
- Obtain informed consent from transplant recipients or next of kin
- who receive organ transplants from donors who have received HPDGH
- Maintain documentation of informed consent and provide such documentation upon request for review

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS examines any reported instances for a potential policy violation and will refer any instances of potential policy violations to the appropriate OPTN/UNOS Committee.

1. **Policy title** Screening Potential Organ Donors for Transmission of Diseases or Medical Conditions, Including Malignancies	2. **Policy number** 4.6 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Specify the testing requirements for screening all potential donors for transmissible diseases and malignancies
- Outline OPO responsibilities in reporting any suspected or confirmed transmissible disease to the recipient centers and the OPTN

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Comply with screening and reporting requirements for all donors
- Maintain documentation of donor/recipient screening and provide such documentation upon request for review

5. How OPTN/UNOS will evaluate member compliance with this policy

During on-site reviews, UNOS staff selects a sample of donor records and reviews the on-site documentation to determine if donors were screened for these conditions. Upon notification of the transmission of a disease or medical condition by an organ donor by the procuring OPO, UNOS will assist in identifying all recipients of those organs. UNOS will monitor the notification process by the procuring OPO to the affected transplant centers. UNOS will forward a copy of the investigation conducted by the procuring OPO to the affected transplant centers and to the Division of Organ Transplantation of the Health Resources and Services Administration.

6. Detailed guidance on policy compliance

As of August 18, 2008, serologic diagnostic tests may be used in place of screening tests to detect hepatitis, EBV, RPR/VDRL, HTLV, and CMV. Diagnostic tests may be FDA licensed, approved, or cleared. (Policy 4.1 still requires FDA licensed screening tests to be used for detecting HIV I/II.)

1. Policy title Donor History	**2. Policy number** 4.6.1 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Require that the Host OPO will obtain a history on each donor and determine whether the donor is in a "high risk" group
- Require the Host OPO to communicate the donor history to all potential recipient institutions

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Obtain a history on each potential donor and determine if the donor is in a "high risk" group as defined by the CDC
- Communicate the complete donor history to all potential recipient institutions
- Maintain documentation of donor screening and provide such documentation upon request for review
- Educate OPO staff about the CDC high risk definition and this requirement

5. How OPTN/UNOS will evaluate member compliance with this policy

During on-site reviews, staff selects a sample of donor records and reviews the on-site documentation to determine whether the OPO was compliant with this policy.

6. Detailed guidance on policy compliance

- Review "CDC Guidelines for High Risk Behavior"
- Review "CDC Guidelines for Preventing Transmission of Human Immunodeficiency Virus through Transplantation of Human Tissue and Organs"

1. Policy title Reporting	**2. Policy number** 4.6.2 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Specify known conditions that must be communicated to the transplant centers

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Communicate known conditions that may be transmitted by the donor organs to transplant centers

5. How OPTN/UNOS will evaluate member compliance with this policy

During on-site reviews, UNOS staff selects a sample of donor records and reviews the on-site documentation to determine if known conditions were communicated to all recipient transplant centers.

1. Policy title Exceptions	**2. Policy number** 4.6.3 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Define that organs from donors with medical conditions that may be transmitted to a recipient, except HIV, may be transplanted at the discretion of the transplant center with the informed consent of the transplant recipient

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Obtain informed consent prior to the transplantation of organs from donors that may have medical conditions that could be transmitted from the transplanted organs
- Maintain documentation of informed consent and provide such documentation upon request for review

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS examines any reported instances for a potential policy violation and will refer any instances of potential policy violations to the appropriate committee.

1. Policy title Donor Consent Forms	**2. Policy number** 4.6.4 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Suggest to OPOs that each donor consent form include a notice that all potential donors will be screened for medical acceptability for organ donation and results of such tests may be the basis for not using the organ in transplantation

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Consider including such notification on donor consent forms

5. How OPTN/UNOS will evaluate member compliance with this policy

No monitoring efforts are required.

1. **Policy title** Post-Transplant Reporting of Potential Transmission of Disease or Medical Conditions, Including Malignancies	2. **Policy number** 4.7 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Set forth a procedure for reporting to the transplant center, OPO and OPTN, any potential transmission of a disease or medical condition from a donor organ as quickly as possible

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Report any potential or confirmed cases of disease transmission from an organ donor to an organ recipient to the procuring OPO within one working day and/or,
- Report any potential or confirmed cases of disease transmission from an organ donor to an organ recipient to the OPTN through the Patient Safety System in Secure Enterprise^{SM} as soon as possible
- Maintain documentation related to the potential or confirmed disease transmission and provide it upon request to the procuring OPO, OPTN and other OPTN members as appropriate

OPOs are expected to:

- Communicate the test results and diagnosis of a potentially transmissible disease in an organ donor, to any transplant center and tissue bank that received an organ or tissue from that donor, as soon as possible
    - Notify the OPTN of the event through the Patient Safety System in Secure Enterprise^{SM} as soon as possible
    - Submit a final written report to the OPTN as specified in policy

Transplant centers and OPOs are expected to:

- Comply with all requirements outlined in this policy

5. How OPTN/UNOS will evaluate member compliance with this policy

Upon notification by the procuring OPO of the potential or confirmed transmission of a disease or medical condition by an organ donor, UNOS will assist in identifying all recipients of those organs. UNOS will monitor the notification process by the procuring OPO to the affected transplant centers. UNOS will forward a copy of the investigation conducted by the procuring OPO to the affected transplant centers and to the Division of Organ Transplantation of the Health Resources and Services Administration.

6. Detailed guidance on policy compliance

- Initial OPTN notification can occur 24/7 through the Patient Safety System located in UNet^{SM}

- Initial report forms will be provided to the procuring OPO by designated UNOS staff members
- The final report is required 45 days after the initial report is received. Currently, the report format is at the procuring OPO's discretion.
- Patient Safety/Disease Transmission Reporting training is to be held at least quarterly.
- To view a Live Meeting® tutorial about patient safety:
    - Go to Secure Enterprise
    - On the top toolbar, mouse over "Help"
    - Select "Online Help"
    - Follow the instructions to view the "Improving Patient Safety" recording dated December 8, 2006

1. **Policy title** Standardized Packaging and Transporting of Organs and Tissue Typing Materials	2. **Policy number** 5.0 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- As of September 1, 2007, add requirements for live donor organ ABO verification, packaging, and transport
- Define expectations for standardized packaging of live and deceased donor organs and tissue typing materials
- Ensure that two different persons verify all data required by policies 5.0 and its subsections, and maintain documentation of this verification

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Host OPOs are expected to:

- Have an internal policy and procedure describing how the requirements of OPTN Policy 5.0 are met for both documentation and maintenance of those records
- Retain documentation of the double verification of the donor's ABO on the shipping labels and within the donor's record
- Include in the donor file or other location documentation that a second person (can be non-OPO staff) verified accuracy of shipping container labels
- Include compliance with documentation requirements in OPO's routine quality assurance process

Transplant centers are expected to:

- Verify the accuracy of the donor ABO, recipient ABO, and UNOS Donor ID after receipt of a live or deceased donor organ and prior to its implantation

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS reviews and verifies transplant center and OPO policies and procedures, and verifies the presence and accuracy of the documentation for a sample of records during site surveys.

6. Detailed guidance on policy compliance

- Refer to OPTN Policy 3.1.2 for ABO and UNOS Donor ID number verification requirements after receipt of an organ and prior to its implantation

1. Policy title Specimen Collection and Storage	**2. Policy number** 5.1 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Ensure that each OPO has a documented policy and procedure for standardized safe specimen collection and storage

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Host OPOs are expected to:

- Have a written policy available for review during an audit that includes specific descriptions of the type of specimen and medium, in addition to the shipping requirements of the specimen

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS reviews and verifies OPOs' written policies for specific descriptions of the type of specimen, medium, and shipping requirements, as approved by ASHI or UNOS, during an on-site review.

6. Detailed guidance on policy compliance

- Link to "Specimens for Histocompatibility Testing Guidelines for OPOs"
- Review the OPTN's Recommended Histocompatibility Guidelines: http://optn.transplant.hrsa.gov/SharedContentDocuments/Histocompatibility_Guidelines.pdf

1. **Policy title** Standard Labeling Specifications	2. **Policy number** 5.2 **Subsections** 5.2.1 5.2.2 5.2.3

3. Purpose of policy

The purpose of the policy is to:

- Ensure safe and efficient shipment of organs by applying standard UNOS labeling to the outermost surface of the transport box containing organs and/or tissue typing specimen containers
- Define a transport container to include a corrugated wax coated disposable box, cooler, or mechanical preservation cassette or machine
- Provide requirements to address deceased or live donor organs that remain in the same operating room suite as the intended recipient(s)

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Host OPOs are expected to:

- Label the outermost surface of the transport container with the secure label, provided by UNOS, that contains and clearly states all data specified in Policy 5.2
- Label the outer bag or rigid container with a secure label which clearly states the contents, ABO type and donor I.D. Tissue typing specimens must also have a secure label clearly stating the same information mentioned above, and the date and time recovered.

Transplant centers are expected to:

- Develop, implement, and comply with a procedure to ensure identification of the correct donor organ for the correct recipient for any deceased or live donor organs that remain in the same operating room suite as the intended recipient(s). The transplant center must document in the recipient's chart that this identification procedure occurred, and make the documentation available upon request.
- Ensure that the packaging of live donor organs that travel outside the recovery facility is consistent with the requirements of OPTN policy 5.2 and its subsections.

5. How OPTN/UNOS will evaluate member compliance with this policy

During site surveys of OPOs, Department of Evaluation and Quality (DEQ) staff reviews packaging requirements with each OPO and requests a corrective action plan if the OPO's policies and procedures do not comply with the requirements of OPTN Policy 5.2 and its subsections. DEQ staff forward the results of site surveys to the Membership and Professional Standards Committee (MPSC) for review.

During site surveys of transplant centers, DEQ staff reviews documentation that the transplant center verified the donor and recipient ABO, and UNOS Donor ID, after receipt of an organ and prior to its implantation. DEQ staff will verify that the transplant center has a procedure to ensure identification of the correct donor organ for the correct recipient for any deceased or live donor organs that remain in the same operating room suite as the intended recipient(s). DEQ staff will request a corrective action plan if the center does not have a procedure to comply with the requirements of OPTN Policies 3.1.2 and 5.0, and will forward the results of site surveys to the MPSC for review.

6. Detailed guidance on policy compliance

- Use the UNOS-issued organ shipping container labels.
- Members can purchase organ shipping container labels from UNOS by calling (800) 292-9548 during normal business hours, or by visiting the UNOS online store at: http://store.unos.org/UNOS-catalog/ or by navigating to the UNOS website (www.UNOS.org), selecting Resources, and then clicking on Online Store.
- New UNOS organ container shipping labels contain all required information on one external label. The new labels will be available July 1, 2008. Members can use the previous labels until September 30, 2008. **As of October 1, 2008, all Members must use the revised organ container shipping labels.**
- Link to PDFs of the UNOS-issued shipping container labels:

  Revised shipping labels – available for use as of 7/1/08, **required for use as of 10/1/08**
- If labels from UNOS are not available when the OPO requests them, the OPO should maintain documentation of efforts to obtain labels and present this documentation upon request.

1. Policy title Documentation	**2. Policy number** 5.3 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Ensure that all information pertaining to the organ donor and the condition of donor organs, as outlined in OPTN Policy 2.5.7.1, is included in each organ transport container when transported to the recipient institution

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Host OPOs and Transplant centers are expected to:

- Provide paperwork of complete donor information as described in Policy 2.5.7.1 in all circumstances during which an organ is transported

5. How OPTN/UNOS will evaluate member compliance with this policy

At OPOs, UNOS reviews donor records, including information submitted to DonorNet®, for evidence of all required donor information, as specified in the policy during an on-site review. UNOS also reviews and examines any instances when insufficient or erroneous documentation are reported by members.

At transplant centers, UNOS verifies the center has a documented organ packaging procedure, that is consistent with policy requirements, for live donor organs that travel outside the facility.

6. Detailed guidance on policy compliance

- Include an organ-specific checklist of items to be packaged inside each organ shipping container
- ABO documentation should include a copy of the primary source document

1. Policy title Packaging	**2. Policy number** 5.4 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Clarify that the Host OPO is responsible for the proper packaging, labeling and handling of the organ in a manner which ensures safe arrival and maintains the integrity of the organ

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs and Transplant centers are expected to:

- Properly pack and label the organ in accordance with the specifications listed throughout Policy 5.0

5. How OPTN/UNOS will evaluate member compliance with this policy

At OPOs, UNOS verifies that an OPO properly packs and labels a transport container, provides appropriate tissue typing materials, and includes all pertinent donor information when preparing the transport container for shipment. UNOS investigates all reports of improper labeling reported by members and refers instances of non-compliance to the Membership and Professional Standards Committee.

At transplant centers, UNOS verifies the center has a documented organ packaging procedure that is consistent with policy requirements, for live donor organs that travel outside the facility.

6. Detailed guidance on policy compliance

- Best practice suggestion: Some OPO's include a quality assurance feedback form with the organ to obtain feedback from the transplant center
- As of April 21, 2008, OPOs and Transplant centers must use a red plastic biohazard bag when packaging organs in disposable transport boxes. Policy 5.5.2 was modified, effective August 18, 2008, to clarify that a red plastic biohazard bag must be placed between the outer container used to transport the organ and the inner polystyrene insulated container.
- As of April 21, 2008, policy requires that universal precautions be used when packaging organs on the donor's back table.

1. Policy title Standard Organ Package Specifications	**2. Policy number** 5.5 **Subsections** 5.5.1 5.5.2 5.5.3 5.5.3.1 5.5.4 5.5.5 5.5.6

3. Purpose of policy

The purpose of the policy is to:

- Outline the requirements and use of organ transport containers

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs and Transplant centers are expected to:

- Package organs only in transport containers that meet the requirements specified in Policy 5.5 and its subsections

5. How OPTN/UNOS will evaluate member compliance with this policy

At OPOs, UNOS staff reviews and verifies that an OPO properly packs and labels a transport container, including all pertinent donor information and adequate tissue typing material, during an on-site review. UNOS investigates all reports of shipping container reuse by members and refers instances of non-compliance to the Membership and Professional Standards Committee.

At transplant centers, UNOS verifies the center has a documented organ packaging procedure, that is consistent with policy requirements, for live donor organs that travel outside the facility.

6. Detailed guidance on policy compliance

Policy 5.5.2 was modified, effective August 18, 2008, to clarify that a red plastic biohazard bag must be placed between the outer container used to transport the organ and the inner polystyrene insulated container.

The OPO Committee has determined that 6-piece insulation panels that serve as the inner liner of a shipping box can be considered a container, as required in OPTN policy 5.5.2, when assembled and as long as the “R” value is appropriate.

2. Policy title Vessel Recovery, Storage, and Transplant	**2. Policy number** 5.7 **Subsections** 5.7.1 – 5.7.7

3. Purpose of policy

The purpose of the policy is to:

- Outline the requirements for vessel recovery, storage, and transplant

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs and Transplant centers are expected to:
- Recover and store vessels only to be used for implanting or modifying a solid organ transplant
- Handle recovered vessels that are not immediately used according to policies governing packaging, labeling, storage, storage medium and temperature, location, and duration of storage

Transplant centers are expected to:
- Only use recovered vessels for the implantation or modification of a solid organ transplant
- Document sharing of vessels with other transplant centers and provide notice about the sharing of vessels to the OPO and the OPTN according to policy
- Notify the recovering OPO and the OPTN when vessels are stored and then subsequently used for the intended recipient or for another transplant recipient
- Provide a detailed explanation for the Membership and Professional Standards Committee (MSPC) if vascular conduits with positive serology for hepatitis are subsequently used in a recipient other than the intended recipient
- Maintain all documentation of vessel storage, usage, and destruction

OPOs are expected to:
- Include language in consent forms to indicate that vessels will be used for transplant

5. How OPTN/UNOS will evaluate member compliance with this policy

During on-site reviews at OPOs, site surveyors will evaluate compliance with this policy through interviews and obtaining copies of the following:
- Copy of the OPOs policy and procedures for handing vessels
- Copy of the consent form used by the OPO that must include language indicating that vessels will be used for transplant
- Copy of the packaging label to verify that it contains the recovery date, ABO, serology, container contents, and the Donor ID number. Also, the label should clearly state for use in organ transplant only

At transplant centers, site surveyors will interview the designated staff who monitor and maintain the extra vessels and obtain a copy of the center's policy and procedure for handing vessels.
The vessel monitoring log will be reviewed to verify the following:
- Vessels are stored for a maximum of 14 days from their original recovery date

- Daily monitoring of vessels includes: documented security checks, and recorded daily temperature checks (note: policy requires vessels to be stored between 2 and 8 degrees Celsius)

6. Detailed guidance on policy compliance

- This policy was implemented on April 29, 2006
- To report the use of stored vessels transplanted into an intended or different recipient or to report discarded vessels to the OPTN, complete the Vessel Transplantation/Destruction Information Sheet and fax it to the UNOS Research Department/Data Quality at (804) 782-4809. Alternatively, you may submit vessel data to the UNOS Research Department/Data Quality via email at dataquality@unos.org.
- Transplant centers must designate a person to monitor all aspects of vessel usage and storage.
- Transplant centers must provide the transplant surgeon with 24 hour access to donor information so that he/she can review this information before using the vessels in a recipient other than the recipient who received an organ from the same donor.
- If transplant programs share vessels, the implanting transplant program must provide a justification to the OPTN/UNOS Membership and Professional Standards Committee (MPSC). You should submit this justification in writing to the UNOS Department of Evaluation and Quality, via email to: evaluationandquality@unos.org or via fax to (804) 782- 4660, Attention: Allocation Analysis.
- If a transplant program uses vessels from a donor with positive hepatitis serologies in a recipient who did not also receive an organ(s) from that donor, the transplant program must provide a justification to the MPSC. You should submit this justification in writing to the UNOS Department of Evaluation and Quality, via email to: evaluationandquality@unos.org or via fax to (804) 782- 4660, Attention: Allocation Analysis.
- Document ***all*** donor serology results on the vessel container label. This includes all negative results.
- Best practice suggestion: some recovering OPOs include their name and phone number on the vessel label. This makes it easier for the transplant program to contact the recovering OPO to report vessel disposition.

1. Policy title Nondiscrimination/Organ Allocation	**2. Policy number** 6.2.1 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Outline how transplant centers should operate and manage when allocating an organ to a non-resident alien transplant candidate

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Abide by the guidelines set forth in Policy 6.2 if they agree to list non-resident aliens

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS verifies that candidates are listed appropriately, including non-resident aliens, during surveys of transplant centers. UNOS staff reviews organ allocations and makes an inquiry if an organ was not allocated according to the match run sequence. UNOS forwards potential policy violation to the Membership and Professional Standards Committee (MPSC) for review.

1. Policy title Transplant Centers	**2. Policy number** 6.2.2 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Outline the types of transplant centers that should be utilized in wait listing non-resident aliens

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Have an historical pattern of international referral and a reputation for the treatment and care of patients being listed and transplanted at their center if they list non-resident aliens

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates.

1. Policy title Fees	**2. Policy number** 6.2.3 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Reiterate that the transplantation of a non-resident alien is done for humanitarian reasons
- Require that the waitlist fee for the non-resident alien is the same as for domestic patients

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Charge the same waitlist fee as they do domestic patients if they list non-resident aliens

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS examines any reported instances for a potential policy violation and will refer any instances of potential policy violations to the appropriate committee.

1. Policy title Referrals	**2. Policy number** 6.2.4 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Prohibit OPTN Members from entering into formal contractual agreements for the transplantation of non-resident aliens

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Refrain from entering into any type of formal contractual agreement with foreign agencies or governments if they list and transplant non-resident aliens

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS examines any reported instances for a potential policy violation and will refer any instances of potential policy violations to the appropriate committee.

1. Policy title Community Participation	**2. Policy number** 6.2.5 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Promote greater transparency and trust of the transplant system by recommending that transplant centers which list non-resident aliens establish methods for community participation in reviewing candidate acceptance criteria

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Develop methods for community participation in reviewing their candidate acceptance criteria if they list and transplant non-resident aliens

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates.

1. Policy title Training Programs	**2. Policy number** 6.2.6 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Enhance transplantation in underserved nations by encouraging development of education and training programs

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are encouraged to:

- Develop education and training programs for physicians and services from underserved nations if they list and transplant non-resident aliens

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates.

1. Policy title Audit	**2. Policy number** 6.3 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Ensure that programs that transplant more than five percent non-resident aliens get audited

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Be aware that there is a five percent threshold triggering an audit of all activities pertaining to transplantation of non-resident aliens when more than five percent of transplant recipients for any deceased organ are non-resident aliens
- Be aware that if a transplant center fails to respond to inquires or consistently has more than five percent recipients constitute non-resident aliens without justification or explanation, the matter will be referred to the Membership and Professional Standards Committee

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS generates a report for the Ad Hoc International Relations Committee that lists the centers that go above the five percent threshold. UNOS generates the report for every Ad Hoc Committee meeting. The Committee meets as needed two to four times per year. The Committee examines cases and follows up with centers for explanation or justification. Transplant centers that persistently go over the five percent threshold and do not have justification or explanation or fail to respond to inquiries are referred to the Membership and Professional Standards Committee.

1. **Policy title** Exportation and Importation of Organs-Developmental Status	2. **Policy number** 6.4 **Subsections** 6.4.1 6.4.2

3. Purpose of policy

The purpose of the policy is to:

- Prohibit the exportation of organs from the United States and/or territories unless a documented and verifiable effort to allocate the organ to a recipient on the waiting list, coordinated through the UNOS Organ Center has failed and staff has determined there is no suitable recipient on the waiting list
- Require that all foreign organ exchanges are reported to the Organ Center within 72 hours
- Outline the process for OPTN members to enter into formal organ exchange arrangements with a foreign transplant program

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- First make a verifiable and well-documented effort, coordinated through the UNOS Organ Center, to find a suitable recipient from the waiting list and receive a determination from staff that no suitable recipient is on the waiting list before exporting organs outside of the United States

OPOs and transplant centers are expected to:

- Enter into formal organ exchange arrangements with foreign transplant programs that do not exceed two years, only after receiving approval from the OPTN
- Propose and submit protocols describing the basis of the arrangement, the expected benefits to participants, credentials of the foreign source, number and type of anticipated organs involved, and plans for allocation and reporting, when entering into such an arrangement is desired
- Submit these protocols to the Ad Hoc International Relations Committee for review and recommendation to the Board of Directors
- Ensure that the foreign source for importing an organ is a transplant center or OPO that the foreign national government or appropriate agency recognizes as such

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS reviews daily all deceased donor match runs to determine if the organs were allocated according to the match run sequence as established by allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy.

6. Detailed guidance on policy compliance

Organ Center telephone (800) 292-9537

1. **Policy title** Ad Hoc Organ Exchange	2. **Policy number** 6.4.3 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Require that all offers of organs for transplantation from foreign sources be made through the UNOS Organ Center. Six exchanges are allowed on an ad hoc basis. Additional exchanges require an international organ exchange agreement outlined in Policy 6.4.2 and approval of such agreement by the Ad Hoc International Relations Committee and Board of Directors. Finally, to also ensure consistent ethical and patient safety safeguards, the policy also requires all organs imported by OPOs to also contain documentation which certifies death, informed consent of the donor or the donor's legal representative and the donors ABO.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:
- Contact the UNOS Organ Center upon receipt of an organ offer from a foreign source
- Be aware that they are allowed six organ exchanges on an ad hoc basis
- Be aware that OPOs that make more than six exchanges must enter into a formal organ exchange protocol, which must be submitted to the appropriate OPTN/UNOS Committee for approval
- Be aware that the agreement must include protocols describing the basis of the agreement
- Be aware that the Ad Hoc International Relations Committee reviews the agreement and protocols and makes a recommendation to the Board of Directors
- Obtain and maintain documentation which certifies death, informed consent of the donor or legal representative and verifies the donors ABO

Transplant centers are expected to:
- Contact the UNOS Organ Center upon receipt of an organ offer from a foreign source
- Be aware that they are allowed six organ exchanges on an ad hoc basis
- Be aware that transplant centers that make more than six exchanges must enter into a formal organ exchange protocol, which must be submitted to the appropriate OPTN/UNOS Committee for approval
- Be aware that the agreement must include protocols describing the basis of the agreement
- Be aware that the Ad Hoc International Relations Committee reviews the agreement and protocols and makes a recommendation to the Board of Directors

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS reviews daily all deceased donor match runs to determine if the organs were allocated according to the match run sequence as established by allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. Finally, UNOS reviews and verifies each donor's medical records and verifies that each chart contains documentation which certifies death, informed consent of the donor or legal representative and verifies the donors ABO.

6. Detailed guidance on policy compliance • Organ Center telephone (800) 292-9537

1. Policy title Ethical Practices and Importation	**2. Policy number** 6.4.4 6.4.5 **Subsections** N/A

3. Purpose of policy

The purpose of these policies is to:

- Require that OPOs and transplant centers accepting organs for importation engage in the same ethical practices of the transplant community of the United States
- Define an imported organ as an organ that is procured outside of the United States or its territories

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs and transplant centers must:

- Abide by the same ethical standards common in the transplant community when dealing with organ imports
- Maintain documentation that organs were voluntarily donated from deceased donors

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS reviews and examines any complaints of an OPO or transplant center acting unethically and forwards the complaints to the appropriate OPTN/UNOS Committee for review.

1. Policy title Violation of Policies	**2. Policy number** 6.5 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Give notice to OPOs and transplant centers that violations of policies in Policy 6.0 may be reported to the Membership and Professional Standards Committee and may result in the Board of Directors suspending the Member

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs and transplant centers are expected to:

- Be aware that violations of Policy 6.0 may be reported to the Membership and Professional Standards Committee and may result in the Board of Directors suspending the Member

5. How OPTN/UNOS will evaluate member compliance with this policy

The OPTN/UNOS Ad Hoc International Relations Committee reviews ad hoc organ exchanges once a year. UNOS reports any cases of organ exportation for review and follow-up and forwards any cases with potential policy violations to the appropriate OPTN/UNOS Committee.

1. **Policy title** Data Submission Requirements	2. **Policy number** 7.0 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Require all OPOs, transplant centers and histocompatibility labs to submit data to the OPTN through standardized data collection screens in UNet^{SM}
- Require online submission of data as of January 1, 2003
- As of January 1, 2008, require OPOs to submit patient-level data for all consented donors, consent not recovered potential donors, imminent neurological and eligible deaths in its DSA. The purpose of this new requirement is:
  - to help increase knowledge about donor potential,
  - identify the prevalence of cases in which clinical brain death parameters are met but brain death is not declared, and
  - to improve the standardization and validity of reported donor data.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs, transplant centers, and histocompatibility laboratories are expected to:

- Submit their respective online forms in a timely fashion according to data submission policies established within Policy 7.0

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS Department of Evaluation and Quality (DEQ) staff monitors data submission compliance rates on a quarterly basis and contacts members who have outstanding forms that are more than six months overdue. If a member fails to submit the overdue forms in a timely manner, DEQ staff refers the member to the OPTN/UNOS Membership and Professional Standards Committee. DEQ staff also reviews each member's data submission compliance rates with the member during the site survey process.

6. Detailed guidance on policy compliance

- UNet^{SM} was modified on January 9th, 2008 to allow OPOs to submit patient-level data for all imminent or eligible deaths; however, the requirement for reporting this information applies to all deaths referred or identified on January 1, 2008 and beyond to ensure complete data collection.
- Link to Imminent and Eligible Data Collection Training Presentation
  http://www.donornet2007.net/training/Imminent%20and%20Eligible%20Death%20Data%20Collection.htm
- Link to Importing and Exporting Death Notification Registration Records Training Presentation
  http://www.donornet2007.net/training/DNR%20Import-Export.htm
- Link to Imminent and Eligible Donation Data Report Changes Presentation
  http://www.donornet2007.net/training/Donation%20Data%20Report.htm

1. Policy title Follow-up Period for Transplant Recipients	**2. Policy number** 7.1.3 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Define expectations that a transplant center will follow up with transplant recipients until the recipient's death or re-transplantation.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Meet the requirement to report follow-up information on transplant recipients until graft failure

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS programs the UNet^{SM} system and notifies transplant centers of system modifications through the use of system notices and documentation updates. UNOS staff monitors and evaluates transplant centers' data submission compliance on a routine basis and assists them with submitting forms by consistent contact regarding overdue online forms. Staff could refer non-compliant transplant centers to the OPTN/UNOS Membership and Professional Standards Committee for further review and action. UNOS staff also reviews data submission standards with transplant centers during on-site reviews.

6. Detailed guidance on policy compliance

- If a multi-organ recipient experiences graft failure, each organ must be followed until failure. For example, if a liver-kidney recipient begins dialysis, liver follow-up forms must be submitted until the liver fails.

1. **Policy title** Definition of the Length of the Follow-up Period for Living Donors	2. **Policy number** 7.1.5 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Require transplant centers to submit to Tiedi® follow-up information about living donors for two years after donation

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are required to:

- Submit follow-up information about living donors to Tiedi® at six months, one year, and two years following donation on the appropriate Living Donor Follow-up (LDF) form
- Accurately enter all data required on the LDF forms
- Maintain documentation to support all data entered on the LDF forms, including documentation of the attempts to contact the living donor for follow-up information
- Submit all forms within the timeframes required by Policy 7.3.2

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS Department of Evaluation and Quality (DEQ) staff monitors data submission compliance rates on a quarterly basis and contacts members who have outstanding forms that are more than six months overdue. If a member fails to submit the overdue forms in a timely manner, DEQ staff refers the member to the OPTN/UNOS Membership and Professional Standards Committee. DEQ staff also reviews each member's data submission compliance rates with the member during the site survey process.

6. Detailed guidance on policy compliance

- The policy change to require living donor follow-up information for two years post donation was implemented on March 1, 2008. The two year follow-up requirement applies to all living donation transplant events that occur on March 1, 2008 and beyond.

1. Policy title Definition of Timely Data	**2. Policy number** 7.1.6 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Define and provide examples of how timely data should be when reporting follow-up information on transplant recipients or living donors

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are required to:

- Collect follow-up data for transplant recipients and living donors for reporting purposes to UNOS as close as possible to the specified transplant event anniversary

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS programs the UNet^{SM} system and notifies transplant centers of system modifications through the use of system notices and documentation updates. UNOS staff monitors and evaluates transplant centers' data submission compliance on a monthly basis and assists them with submitting forms by consistent contact regarding overdue online forms. UNOS staff also reviews data submission standards with transplant centers during on-site reviews.

1. Policy title Definition of Imminent Neurological Death	**2. Policy number** 7.1.7 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Define imminent neurological death
- Provide direction for reporting purposes:
  - state **when** the OPO should apply the definition to the referral to determine if the referral should be reported as an imminent neurological death
  - state what conditions would **exclude** the referral from meeting the definition of an imminent neurological death

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are required to:

- Report patient level data for all imminent neurological deaths referred each month
- Apply the policy definition to the referral at the time of OPO disposition
- Be familiar with the list of conditions in Policy 7.1.8 and not report any persons with those conditions, who would otherwise meet the definition, as an imminent neurological death

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS Department of Evaluation and Quality (DEQ) staff review death referral information reported to the OPTN during OPO site surveys. DEQ staff verify that OPO staff are using the definitions in policy to report death referral information to the OPTN.

1. Policy title General Submission of OPTN Forms	**2. Policy number** 7.2 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Establish the requirement that all OPOs, transplant centers and histocompatibility labs respectively submit Transplant Candidate Registration, Deceased Donor Registration, Living Donor Follow-up, Recipient Histocompatibility, Donor Histocompatibility, and Recipient Malignancy online forms to UNOS within 30 days of the generation date

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs, transplant centers, and histocompatibility laboratories are expected to:

- Submit Transplant Candidate Registration, Deceased Donor Registration, Living Donor Follow-up, Recipient Histocompatibility, Donor Histocompatibility, and Recipient Malignancy online forms to UNOS within 30 days of the generation date

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS programs the UNet^{SM} system and notifies OPOs, transplant centers and histocompatibility labs of system modifications through the use of system notices and documentation updates. UNOS staff monitors and evaluates OPOs', transplant centers' and histocompatibility labs' data submission compliance on a routine basis and assists them with submitting forms by consistent contact regarding overdue online forms.

1. Policy title Submission of Organ-Specific Transplant Recipient Registration Forms	**2. Policy number** 7.3.1 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Establish the requirement of all transplant centers to submit organ-specific Transplant Recipient Registration online forms within 60 days of the generation date
- Establish the time frame for data reported on the Transplant Recipient Registration online form

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Submit organ-specific Transplant Recipient Registration online forms within 60 days of the generation date

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS programs the UNet^{SM} system and notifies transplant centers of system modifications through the use of system notices and documentation updates. UNOS staff monitors and evaluates transplant centers' data submission compliance on a routine basis and assists them with submitting forms by consistent contact regarding overdue online forms.

1. **Policy title** Submission of Living Donor Registration Forms	2. **Policy number** 7.3.2 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Require the recipient transplant center to report information about living donors at:
  - discharge from the hospital post donation or six weeks post donation (whichever occurs first);
  - six months after donation;
  - one year after donation; and
  - two years after donation.
- Require the recipient transplant center to submit information about living donors to Tiedi® using the Living Donor Registration (LDR) and Living Donor Follow-up (LDF) forms
- Require the recipient transplant center to submit the LDR within 60 days of the form's generation

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Accurately enter all data required on the Living Donor Registration (LDR) Form and the Living Donor Follow-up (LDF) Forms
- Maintain documentation to support all information entered on the LDR and LDF forms, including documentation of efforts made to contact living donors
- Submit LDR forms within 60 days of the form's generation
- Submit LDF forms within 30 days of the form's generation

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS Department of Evaluation and Quality (DEQ) staff monitors data submission compliance rates on a quarterly basis and contacts members who have outstanding forms that are more than six months overdue. If a member fails to submit the overdue forms in a timely manner, DEQ staff refers the member to the OPTN/UNOS Membership and Professional Standards Committee. DEQ staff also reviews each member's data submission compliance rates with the member during the site survey process.

6. Detailed guidance on policy compliance

Form	Time Frames for Form Generation	Time Frames for Form Completion	Time Frames for Form Submission
LDR	Upon completion of living donor feedback in Tiedi®	At discharge or 6 weeks post donation	Within 60 days of generation
LDF	6 months, 1 year, and 2 years post donation	Between last required submission and current required submission (e.g. information provided on the 6-month LDF should be from the period between discharge and 6 months post-donation)	Within 30 days of generation

1. **Policy title** Submission of Living Donor Death and Organ Failure Data	2. **Policy number** 7.3.3 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Define "native organ failure" in a patient who has been a living kidney donor or living liver segment donor. This policy defines kidney failure in a patient who has donated a kidney as the initiation of dialysis. This policy defines liver failure in a patient who has donated a liver segment as being placed on the waiting list for a liver transplant.
- Specify that transplant centers must use the Patient Safety System in UNet^{sm} to report adverse events in living donors.
- Require transplant centers to report adverse events in living donors for a period of two years after the date of donation.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Report information about adverse events in living donors through the Patient Safety System in UNet^{sm} within 72 hours of the center's knowledge of the event
- Report information about adverse events in living donors through the Patient Safety System in UNet^{sm} for up to two years after the donation
- Submit accurate information about living donors to UNet^{sm}

5. How OPTN/UNOS will evaluate member compliance with this policy

Transplant centers report adverse events in living donors to UNOS through the Patient Safety System in UNet^{sm}. UNOS staff reviews this information for compliance with the policy requirements and refers the adverse event information to a subcommittee of the Membership and Professional Standards Committee (MPSC) for review. The subcommittee's recommendation is presented to the full MPSC for review and the MPSC's decision is reported to the Board.

6. Detailed guidance on policy compliance

- To view a Live Meeting® tutorial about the Patient Safety System:
  - Go to Secure Enterprise
  - On the top toolbar, mouse over "Help"
  - Select "Online Help"
  - Follow the instructions to view the "Improving Patient Safety" recording dated December 8, 2006

1. Policy title Submission of Organ-Specific Transplant Recipient Follow-up Forms	**2. Policy number** 7.4 **Subsections** 7.4.1 7.4.2

3. Purpose of policy

The purpose of the policy is to:

- Establish the requirement of all transplant centers to submit organ-specific Transplant Recipient Follow-up online forms within 14 days of the recipient's death or graft failure

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Submit organ-specific Transplant Recipient Follow-up online forms reporting death or graft failure within 14 days of the event

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS programs the UNet^{SM} system and notifies transplant centers of system modifications through the use of system notices and documentation updates. UNOS staff monitors and evaluates transplant centers' data submission compliance on a routine basis and assists them with submitting forms by consistent contact regarding overdue online forms.

1. Policy title Submission of Donor Information	**2. Policy number** 7.5 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Require OPOs to submit information for Deceased Donor Feedback within five working days of the procurement date
- Require transplant centers to register all living donors with UNOS via Living Donor Feedback prior to surgery

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Submit Deceased Donor Feedback information within five working days of the procurement date

Transplant centers are expected to:

- Register all living donors with UNOS via Living Donor Feedback prior to surgery

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS programs the UNet^{SM} system and notifies OPOs and transplant centers of system modifications through the use of system notices and documentation updates. UNOS staff monitors and evaluates OPOs' and transplant centers' data submission compliance on a routine basis and assists them with submitting forms by consistent contact regarding overdue online forms. Staff could refer non-compliant OPOs and transplant centers to the OPTN/UNOS Membership and Professional Standards Committee for further review and action. UNOS staff also reviews data submission standards with OPOs and transplant centers during on-site reviews.

1. **Policy title** Submission of Potential Transplant Recipient Forms	2. **Policy number** 7.6 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Require OPOs to submit Potential Transplant Recipient (PTR) data to the OPTN within 30 days of the match run date for each deceased donor organ that is offered to a potential recipient
- Establish the requirement that PTR refusal codes must be obtained directly from the physician, surgeon or designee involved with the potential recipient

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Submit Potential Transplant Recipient information within 30 days of the match run date
- Obtain this information directly from the physician, surgeon or designee involved with the potential recipient

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS programs the UNet^{SM} system and notifies OPOs of system modifications through the use of system notices and documentation updates. UNOS staff monitors and evaluates OPOs' data submission compliance on a monthly basis and assists them with submitting forms by consistent contact regarding overdue online forms. Staff could refer non-compliant OPOs to the OPTN/UNOS Membership and Professional Standards Committee for further review and action. UNOS staff also reviews data submission standards with OPOs during on-site reviews.

6. Detailed guidance on policy compliance

- Link to a tutorial on how to enter PTR information into DonorNet®
  http://www.donornet2007.net/training/Complete%20PTR%20Close%20Match.htm

- Link to www.donornet2007.net for additional information

1. Policy title Entry and Validation of Offers	**2. Policy number** 7.6.1.1 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Establish that the donor OPO and transplant center considering an offer have a shared responsibility to enter patient-specific refusal reasons for all organ offers
- Require the donor OPO to ensure acceptance or refusal reasons are documented for each organ offer
- Require all transplant centers to validate candidate-specific potential recipient refusal reasons for all offers using the online procedure available in UNet^{SM}

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Enter candidate-specific refusal reasons for all offers within 30 days of the match run date using the online procedure available in UNet^{SM}

Transplant centers are expected to:

- Validate the refusal reasons using the online procedure available in UNet^{SM} within 15 days of the OPO entering the refusal code. The system will automatically validate the OPOs' entered refusal code after 15 days if the transplant center has failed to validate the code.

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS programs the UNet^{SM} system and notifies OPOs and transplant centers of system modifications through the use of system notices and documentation updates.

1. Policy title Recording and Reporting of the Outcomes of Organ Offers	**2. Policy number** 7.6.2 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Require OPOs and transplant centers to cooperate when recording and reporting refusal reasons

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs and transplant centers are expected to:

- Cooperate when recording and reporting refusal reasons

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS monitors and reviews PTR code usage on a daily basis. UNOS staff refers any disparities in PTR code use to the OPTN/UNOS Membership and Professional Standards Committee for further review and action.

1. **Policy title** PTR Validation and Dispute Resolution	2. **Policy number** 7.6.2.1 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Require OPOs and transplant centers to be familiar with the current refusal reasons and use the correct reasons during the offer/refusal transaction
- Require transplant centers to validate PTRs within 15 days following the recording of the offer by the OPO. If the transplant center does not verify the refusal reasons, the reason entered by the OPO will be considered accurate and validated.
- Establish that if there is a dispute between the OPO and the transplant center, the transplant center's record will take precedence and will be reported to UNOS

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:
- Be familiar with the current refusal reasons and refer to them explicitly during the offer/refusal transaction
- Submit PTRs within 30 days of the match run

Transplant centers are expected to:
- Be familiar with the current refusal reasons and refer to them explicitly during the offer/refusal transaction.
- Validate PTRs within 15 days following the recording of the offer by the OPO

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS programs the UNet^{SM} system and notifies OPOs and transplant centers of system modifications through the use of system notices and documentation updates. UNOS staff monitors and evaluates OPOs' and transplant centers' data submission compliance on a routine basis and assists them with submitting forms by consistent contact regarding overdue online forms. Staff could refer non-compliant OPOs and transplant centers to the OPTN/UNOS Membership and Professional Standards Committee for further review and action. UNOS staff also reviews data submission standards with OPOs during on-site reviews.

6. Detailed guidance on policy compliance

- To review PTR refusal codes:
    - Go to Secure Enterprise
    - Click on Waitlist^{SM}
    - On the top toolbar, click on Resources
    - On the left sidebar, click on File Layouts
    - Under Exports/Imports, click PTR offer
    - Click Primary Refusal Code

1. Policy title Cooperation in Reviewing and Verifying Organ Offer Data	**2. Policy number** 7.6.2.2 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Require transplant centers to cooperate with OPOs in the review and verification of the data on all offers of organs for transplantation

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Cooperate with OPOs when reviewing and verifying data on all organ offers for transplantation

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS reviews daily all match runs and conducts analysis on disparities in data or reported conflicts between OPOs and transplant centers. UNOS staff could refer any potential policy violations to the appropriate OPTN/UNOS Committee.

1. Policy title Submission of Death Notification Information	**2. Policy number** 7.7 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Establish the timeframe requirements for OPOs to submit death notification information to the OPTN

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Submit patient level data for each consented donor, consent not recovered potential donor, imminent neurological death, and eligible death in its DSA by completing a Death Notification Registration in DonorNet®
- Submit the total number of deaths reported by each hospital, or identified during death record review, monthly using the Donation Data Report in DonorNet®
- Submit the information identified during the current month by the end of the next calendar month

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS Department of Evaluation and Quality (DEQ) staff monitors data submission compliance rates on a quarterly basis and contacts members who have outstanding forms that are more than six months overdue. If a member fails to submit the overdue forms in a timely manner, DEQ staff refers the member to the OPTN/UNOS Membership and Professional Standards Committee. DEQ staff also reviews each member's data submission compliance rates with the member during the site survey process.

6. Detailed guidance on policy compliance

Link to Imminent and Eligible Donation Data Report Changes Presentation
http://www.donornet2007.net/training/Donation%20Data%20Report.htm

1. **Policy title** Deadlines and Thresholds for Submitting Data	2. **Policy number** 7.8.1 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Require all OPOs, transplant centers and histocompatibility labs to meet data submission deadlines and submission thresholds

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs, transplant centers, and histocompatibility laboratories are expected to:

- Submit their respective online forms in a timely fashion according to the data submission standards established in Policy 7.8.1
- Ensure that data submission standards are met: 95 percent of data collected on online forms must be complete within three months of the due date and 100 percent complete within six months of the due date
- Ensure that recipient refusal code standards are met: Potential recipient refusal codes must be 100 percent complete within 30 days of the match run date

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS programs the UNet^{SM} system and notifies OPOs, transplant centers and histocompatibility labs of system modifications through the use of system notices and documentation updates. UNOS staff monitors and evaluates OPOs', transplant centers' and histocompatibility labs' data submission compliance on a routine basis and assists them with submitting forms by consistent contact regarding overdue online forms. Staff could refer non-compliant Members to the OPTN/UNOS Membership and Professional Standards Committee for further review and action. UNOS staff also reviews data submission standards with these Members during on-site reviews.

6. Detailed guidance on policy compliance

As of October 29, 2008, a new data submission compliance report is available to members. This report uses the same methodology that UNOS uses when providing this information to the Centers for Medicare and Medicaid Services (CMS). This new report is based on the completion of 95% of expected records within 90 days of the due date. To access this report, select **CMS Compliance Report** from the **Reports** menu in Tiedi®.

1. Policy title Feedback Submission Standards	**2. Policy number** 7.8.2 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Establish deadlines for OPOs and transplant centers when submitting feedback information

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs and transplant centers are expected to:

- Submit feedback information within 30 days of the transplant date

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS programs the UNet^{SM} system and notifies OPOs and transplant centers of system modifications through the use of system notices and documentation updates. UNOS staff monitors and evaluates OPOs' and transplant centers' data submission compliance on a routine basis and assists them with submitting forms by consistent contact regarding overdue online forms. Staff could refer non-compliant OPOs and transplant centers to the OPTN/UNOS Membership and Professional Standards Committee for further review and action. UNOS staff also reviews data submission standards with OPOs and transplant centers during on-site reviews.

1. Policy title Data Submission Non-compliance	**2. Policy number** 7.9 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Require OPOs, transplant centers and histocompatibility labs to comply with the data submission standards established in OPTN Policy 7.8.1 by submitting their data in a timely fashion according to those standards. Members that fail to submit their data after repeated attempts by UNOS to assist the Member in submitting all overdue data and after a hearing by the Membership and Professional Standards Committee resulting in a determination of Member non-compliance, the MPSC can recommend an on-site audit to retrieve the missing data at the Member's expense.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs, transplant centers, and histocompatibility laboratories are expected to:

- Comply with the data submission standards established in OPTN Policy 7.8.1 by submitting their data in a timely fashion according to those standards

5. How OPTN/UNOS will evaluate member compliance with this policy

UNOS programs the UNet^{SM} system and notifies OPOs, transplant centers and histocompatibility labs of system modifications through the use of system notices and documentation updates. UNOS staff monitors and evaluates OPOs', transplant centers' and histocompatibility labs' data submission compliance on a routine basis and assists them with submitting forms by consistent contact regarding overdue online forms. Staff could refer non-compliant Members to the OPTN/UNOS Membership and Professional Standards Committee for further review and action. UNOS staff also reviews data submission standards with these Members during on-site reviews.

1. Policy title Registration Fee	**2. Policy number** 11.0 **Subsections** N/A

3. Purpose of policy

The purpose of the policy is to:

- Establish the registration fee (provided for in Article I, Section 1.13 of the By-Laws) for the mandatory listing of all candidates who are potential recipients on the waiting list, as required by Policy 3.2.1. The fee structure is two-fold comprising a Candidate Registration Fee and the UNOS Computer Registration Fee.

4. How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Pay all registration fees within 30 days of invoice from UNOS

5. How OPTN/UNOS will evaluate member compliance with this policy

For billing purposes, a center's listing activity is reviewed in 30-day increments. The invoice UNOS sends to centers includes all candidates added to the waiting list during a 30-day period. The invoices are detailed and include each candidate's name and the organ(s) for which each candidate was listed. Staff monitors accounts receivables on a monthly basis and attempts to collect payment on delinquent accounts.

VIII. CORRECTIVE ACTIONS FOR VIOLATIONS OF POLICY*

The primary focus of the Membership and Professional Standard Committee's (MPSC's) medical peer review processes is to bring about voluntary compliance by the Member with applicable OPTN Policies and regulations without the use of sanctions.

a. Referral to MPSC

Upon receipt of information about a potential violation, the Executive Director, or his Designee, will communicate with the member requesting clarification or explanation of the potential violation. At the same, he will make an initial determination of the seriousness or time sensitivity of the matter. The most serious violations require further consultation among the Executive Director, Chair of the MPSC and the President.

The most serious category of noncompliance is a Category I violation. They are potential policy or rule violations posing substantial, time sensitive threats to patient health or public safety. The next most serious type of violation is a Category II violation, one that is a material breach of OPTN requirements. The last type of violation is a Category III violation, one in which a dialogue with the MPSC is expected to correct noncompliant behavior.

Category III matters include normal MPSC tasks, such as application reviews and program outcome or inactivity review in which the program is, for example, addressing a lack of offers or acting on a plan of action for volume enhancements. The goal of this process is to assist programs in improvement. Programs remain in Category III if there are no policy compliance issues, the program continues to act in good faith, and/or there is involvement from institutional leadership and demonstrable improvement.

Category II matters involve suspected policy or rule noncompliance where it is expected that more than informal dialogue with the MPSC will be needed to bring about long-term compliance, there is a lack of progress in improvement or addressing MPSC concerns, and/or there is a lack of institutional involvement. The issues are more serious than in a Category III matter, but less serious or time sensitive than a Category I matter. These issues may result in adverse recommendations from the MPSC and require formal due process proceedings.

Category I matters pose the most substantial or serious, time sensitive threat to patient health or public safety. Time is of the essence in addressing these issues. For this reason, a rapid response procedure has been established.

- Preliminary determination of Category I by the MPSC chairperson.
- Notice to the Secretary of the Department of Health and Human Services.
- Start of fact-finding by UNOS staff. This investigation is conducted within 14 days.
- Referral to MPSC subcommittee for review and determination to continue the matter in Category I or move to another category.
- In the event that the matter continues as Category I, determination of time sensitive threat to patient health or public safety would result in immediate referral to the Executive Committee. There is no right to an interview.

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* In an effort to assist readers easily identify updates to the Evaluation Plan within the "Corrective Actions for Violations" section, updates to the section will be highlighted in blue. Information that no longer applies will be removed from the section and will not appear in any form.

- A hearing and any appellate review would commence together or would follow rather than precede the Executive Committee or Board of Directors' decision regarding the MPSC subcommittee's recommendation.
- The timeline for the hearing and appellate review is expedited.

It is expected that the process from the notice of Category I matter through an appellate review would take between 100-133 days.

b. Potential MPSC Determinations

Upon notice of a potential infraction of these requirements by a Transplant Hospital, OPO, or Histocompatibility Laboratory, the Member is first requested to clarify and/or explain the matter. At this point, sanctions may be required to achieve compliance with applicable policies and regulations. Consideration by the MPSC (or subcommittee of the MPSC) may result in one of the following determinations:

- That no further investigation is warranted because no infraction occurred, any infraction was the result of mistake or lack of knowledge of relevant criteria/policies with assurances regarding future behavior satisfactory to the reviewing body, or non-compliant activity was present but has been corrected with assurances regarding future behavior satisfactory to the reviewing body. The Member is notified of the determination and any recommended actions to ensure ongoing compliance with Membership requirements. Following completion of peer review communications with the Member, the Member also would be notified that the matter is concluded and what sanction, if any, has been imposed.

- That an infraction may have occurred and that additional review and analysis is appropriate but that dialogue between the MPSC (or subcommittee of the MPSC) and the Member in accordance with principles of confidential medical peer review is expected to bring the Member into compliance.

- That a material breach of OPTN requirements, such as occurrence of a repeat violation of OPTN Policy or expectation of such an occurrence in the future based upon the Member's failure to respond and/or develop or agree to a reasonable compliance action plan, may have taken place. The MPSC (or subcommittee of the MPSC) would proceed with additional investigation, as appropriate, in accordance with principles of confidential medical peer review in order to bring the Member into compliance.

When the MPSC (or subcommittee of the MPSC) considers the use of sanctions to bring about compliance, it evaluates (i) the nature of the infraction, (ii) the length of time the infraction has continued, and (iii) any efforts by the Member to correct the infraction. Several corrective actions are then available. They may be applied individually, in combination, or in succession beginning, for example, with a less onerous sanction allowing time to demonstrate compliance and moving to more onerous sanctions if compliance is not achieved within prescribed periods. The possible actions are summarized in **Charts 4** and **5, OPTN Policy Enforcement Options (1)** and **(2),** and are listed below. Any or all of them may be taken with respect to policies recommended by the OPTN to be mandatory and designated by the Secretary of HHS as covered by Section 1138 of the Social Security Act ("mandatory policies"). The last three sanctions may be taken only in the case of non-compliance with mandatory policies and with authorization from the Secretary of HHS.

- Notice of Uncontested Violation, Letter of Warning, or Letter of Reprimand. This action is intended to inform the Member of the need for the Member to ensure continuing compliance with policies monitored by the OPTN. This sanction is appropriate when there is no likelihood of recurrence.

- Probation. This action may include, for example, one or more of the following:

  (a) Required submission of a compliance action plan or plan of correction consistent with defined specifications, with demonstration of adherence to the plan and correction of any non-compliant activity within some period of time.
  (b) Unscheduled on-site audit(s) throughout the period of probation, to be performed by OPTN Contractor audit staff at the sole reasonable cost and expense of the Member.
  (c) Required submission of reports, data, or other evidence to the OPTN Contractor documenting correction of the non-compliant activity throughout the period of probation.

- Member Not in Good Standing. This action includes all of the following plus any other action deemed appropriate by the Board of Directors, unless specifically limited to one or more of such actions by the Board of Directors:

  (a) Withdrawal of voting privileges in OPTN affairs.
  (b) Suspension of the ability for any personnel named in the OPTN Contractor Membership database as associated with the Member - who are not otherwise eligible to serve by virtue of their association with a Member in Good Standing - to sit on any Committee, hold office, and sit on the Board of Directors.
  (c) Formal notification, along with subsequent changes in such status, of the Membership and OPOs and Histocompatibility Laboratories with whom the Member has affiliations known to the OPTN Contractor, as well as the Chief Executive Officer of those institutions.
  (d) Formal notification, along with subsequent changes in such status, to the Member's Chief Executive Officer or Administrator and to the state health commissioner or other appropriate state representative with oversight of health care institutions doing business in the Member's state.
  (e) Notice, within reasonable limits and means, to candidates and the general public in the area of the Member. Such notice may include, but is not limited to, communication using the OPTN website and/or as prescribed by the Board of Directors for distribution by the Member.

- Suspension of Member Privileges. This action includes, for example, one or more of the following:

  (a) Suspension of the privilege to hold office and/or sit on OPTN/UNOS Board of Directors or Committees.
  (b) Suspension of voting privileges in OPTN affairs.
  (c) Suspension of the privilege to receive all organ offers or offers of particular organ types for transplantation and related services.
  (d) Suspension of the privilege to list all candidates or candidates in need of particular organ types on the waiting list.

- Termination of Membership or Designated Transplant Program Status.

- Action Specified in OPTN Final Rule.

An OPO, Transplant Hospital, or Histocompatibility Laboratory Member that is placed on probation or declared a Member Not in Good Standing shall be entitled to full restoration of Membership privileges at any time prior to recommendation for expulsion, if the Member demonstrates to the Board of Directors full compliance with OPTN requirements. An OPO, Transplant Hospital, or Histocompatibility Laboratory Member that is placed on suspension shall, with prior approval from the Board and Secretary of HHS, be entitled to full restoration of Membership privileges at any time prior to recommendation for expulsion, if the Member demonstrates full compliance with OPTN requirements. After expulsion, the Member must submit a new complete application for OPTN Membership.

IX. INTERVIEWS AND HEARINGS: DUE PROCESS RIGHTS OF THE MEMBER

In the event the MPSC, subcommittee of the MPSC, or Board of Directors, recommends or takes (as applicable) one of the following adverse actions, the affected applicant or Member is entitled to various procedural rights of due process:

- Rejection of initial Membership or designation as a transplant program.
- Probation.
- Initial declaration of Membership Not in Good Standing and subsequent determinations not to restore the Member to unrestricted Membership status.
- Suspension of Membership privileges either directly or after a period of probation.
- Termination of Membership, either directly or after a period of probation.
- Any other action specified in Section 121.10(c) of the OPTN Final Rule.

These rights include notice regarding the nature of the circumstances leading to, as well as basis for, the recommendation or action and opportunity to respond. At each stage of the due process procedure described below, however, a determination by the Board of Directors based on available evidence that an alleged infraction of OPTN requirements poses a substantial and imminent threat to the quality of candidate care may result in immediate action by the Board even if the Member has not had the opportunity to complete due process. Additionally, a Board action placing a Member on probation is effective when taken or at such other time as the Board may direct, and may remain in effect during the period in which the hearing and appellate review proceedings described below are pending.

Interview. Adverse actions recommended or taken by the MPSC (or subcommittee of the MPSC) entitle the applicant/Member first to an interview before the MPSC (or a subcommittee of the MPSC). Written request to accept an interview must be received within prescribed time limits or the applicant/Member waives its rights to the procedure. **Chart 6** summarizes these and other time limits applicable to the due process procedures. Interviews are preliminary and informal. It is hoped that through open dialogue between the applicant /Member and MPSC (or subcommittee) facts and issues can be fully clarified and understood. Members are not entitled to interviews in the case of Category I potential violations.

Hearing. In the event the MPSC (or subcommittee) continues to recommend or take an adverse action following the interview, the affected applicant/Member is entitled to a hearing before the MPSC (or a Hearing Committee composed of three MPSC Members). Hearings also may be initiated by adverse actions taken by the Board of Directors contrary to a favorable recommendation by the MPSC or upon the Board's own initiative without benefit of a prior recommendation by the MPSC. Hearings resulting from Board actions are convened before a Hearing Committee composed of three Board Members. Written request to accept a hearing must be received within prescribed time limits or the applicant/Member waives its rights to the procedure (see **Chart 6**). Hearings provide each party with opportunity to call and examine witnesses, introduce exhibits, cross-examine witnesses, impeach witnesses, and rebut evidence. They are more formal than interviews but do not necessarily strictly follow rules of law regarding examination of witnesses or presentation of evidence. A record of the hearing, including exhibits admitted into evidence at the hearing and memoranda submitted to the Hearing Committee, will be kept and made available to the applicant/Member upon request. Following preparation of the hearing record, the Hearing Committee also will issue a written report of findings and recommendations, which is forwarded to the MPSC or Board of Directors (*i.e.*, the body making the adverse recommendation) and applicant/Member. The MPSC or Board, as applicable, will

then consider the hearing report and affirm, modify, or reverse the recommendation or action contained therein. Notice of this decision is provided to the applicant/Member.

Appellate Review. In the event the decision of the MPSC or Board of Directors continues to be adverse to the applicant/Member following the hearing, the affected applicant/Member is entitled to an appellate review before the Board of Directors. Written request to accept an appellate review must be received within prescribed time limits or the applicant/Member waives its rights to the procedure (see **Chart 6**). The proceedings by the Board are in the nature of an appellate review based upon the record of the hearing, the Hearing Committee report, and subsequent related results and actions, including evidence related to steps taken after the conclusion of the original hearing to bring the applicant or Member into full compliance with Membership qualifications or requirements. The Board also will consider statements submitted by or on behalf of the applicant/Member or MPSC/Board of Directors, and may, at the Board's discretion, allow the parties or their representatives to personally appear, make oral presentations in favor of their positions, and respond to questions from the Board. Introduction of other new or additional matters or evidence not raised or presented during the original hearing or in the hearing report and not otherwise reflected in the record may be introduced at the appellate review only at the discretion of the Board of Directors. Such new or additional matters or evidence may, but need not, be referred back to the Hearing Committee for additional consideration.

The Board of Directors, acting as the appellate review body, may affirm, modify, or reverse the adverse result or action taken by the MPSC or Board or, at its discretion, may refer the matter back to the Hearing Committee with instructions for further review and recommendation. Following receipt of such recommendation after any referral, the Board of Directors makes its decision, which is final. Notice of a final decision by the Board of Directors that a Member has been placed on probation is circulated to all Members. Notice of a final decision by the Board of Directors that the Member has been declared Not in Good Standing is circulated to all Members unless the Board of Directors determines such notice is not appropriate as part of the corrective action. The Membership is notified of final decisions by the Board to recommend to the Secretary of HHS suspension of Membership privileges or termination of Membership only upon approval of such recommendations by the Secretary.

Right of Appeal to the Secretary. Applicants for Membership or designation as a transplant program have the right to appeal decisions of the MPSC, MPSC subcommittees, or the Board of Directors regarding these applications to the Secretary of HHS in accordance with the OPTN Final Rule, 42 CFR Part 121. In the event an applicant exercises this right of appeal prior to exhaustion of the applicant's other procedural rights as described above, the applicant must notify the OPTN Contractor of this exercise. Upon receiving such notification, the OPTN Contractor will notify the Secretary of the status of the matter with respect to these procedures. Pending a decision on the appeal, the process defined by the procedures summarized above will continue unless the Secretary directs otherwise. In the event the appeal is denied, the process will be further continued or reinitiated, as applicable. Any other decision on the appeal by the Secretary would be submitted to the MPSC or Board of Directors as appropriate for action consistent with the Secretary's decision.

X. COMMUNICATIONS

The Evaluation Plan will be published on the OPTN web site at http://optn.transplant.hrsa.gov for access by each member Transplant Center, OPO, and Histocompatibility Laboratory, as well as by the Board of Directors and OPTN/UNOS committee members. The Evaluation Plan will be updated and republished at the end of each calendar quarter. With each publication, an electronic notification will advise the community of the availability of updated information.

XI. CHARTS

This section of the Evaluation Plan contains the charts referenced in the plan narrative:

- Chart 1 – Policy Development Process
- Chart 2 – OPTN System Modifications Procedures
- Chart 3 – Application and Hearing Procedures for Members and Designated Transplant Programs
- Chart 4 – OPTN Policy Enforcement Options (1)
- Chart 5 – OPTN Policy Enforcement Options (2)
- Chart 6 – Time Periods for Accepting/Scheduling Interviews, Hearings, and Appellate Reviews

XII. RESOURCE MATERIALS

This section of the Evaluation Plan contains the resource materials referenced in the plan narrative.

Resource Document	Section	Policy / Bylaw Reference
Link to Final Rule http://optn.transplant.hrsa.gov/SharedContentDocuments/final_rule_1.pdf	I, II, III, IV, V, VIII, IX	N/A
Chart 1 – policy development process http://optn.transplant.hrsa.gov/SharedContentDocuments/Chart_1_Policy_Development_Process.pdf	II, XI	N/A
Chart 2 OPTN System modification procedures http://optn.transplant.hrsa.gov/SharedContentDocuments/Visio-070331_Chart_2_IT_OPTN_System_Modification_Procedures-2004-03.pdf	II, XI	N/A
Link to NOTA http://optn.transplant.hrsa.gov/SharedContentDocuments/NOTA_as_amended_-_Jan_2008.pdf	III, IV, VI	N/A
Chart 3 – Application and hearing procedures http://optn.transplant.hrsa.gov/SharedContentDocuments/Chart_3_EvaluationPlanChart.pdf	IV, XI	N/A
Annual Goals for the OPTN/UNOS Committees 2008-2009 http://optn.transplant.hrsa.gov/members/committeeAnnualGoals.asp	VI	N/A
Link to Notice for Change to Patient Notification Bylaw http://optn.transplant.hrsa.gov/SharedContentDocuments/070122_Notice_for_Change_to_Patient_Notification_Bylaw.pdf	VII	Appendix B to OPTN Bylaws, section II.F
Link to Clarification of Change to Patient Notification Bylaw http://optn.transplant.hrsa.gov/SharedContentDocuments/070124_Clarification_of_Change_to_Patient_Notification_Bylaw.pdf	VII	Appendix B to OPTN Bylaws, section II.F
Link to Resources on Living Donation http://www.unos.org/living_donation.asp	VII	Bylaws
Guidelines for Histocompatibility Specimen Testing for OPOs Brochure http://optn.transplant.hrsa.gov/SharedContentDocuments/Histo_Brochure_2006.pdf	VII	2.5.5 2.6 5.1
Link to Recommended Histocompatibility Guidelines http://optn.transplant.hrsa.gov/SharedContentDocuments/Histocompatibility_Guidelines.pdf	VII	2.5.5 2.6 5.1
Link to System Notice sent June 9, 2008 regarding access to UNet℠ http://optn.transplant.hrsa.gov/SharedContentDocuments/080609_Access_to_UNet_System_Notice.pdf	VII	3.2.1.2
Patient brochure about multiple listing in Spanish http://optn.transplant.hrsa.gov/SharedContentDocuments/span_multiple_listing(1).pdf	VII	3.2.3
Patient brochure about multiple listing in English http://optn.transplant.hrsa.gov/SharedContentDocuments/multiple_listing(2).pdf	VII	3.2.3
Link to ECD brochure (English) http://www.unos.org/SharedContentDocuments/ExpandedCriteriaDonor_KidneysBrochure.pdf	VII	3.5.1
Link to ECD brochure (Spanish) http://optn.transplant.hrsa.gov/SharedContentDocuments/Answers_to_Questions-Spanish.pdf	VII	3.5.1
Link to System Notice sent May 21, 2007 announcing EC Change to KI-PA Placement	VII	3.5.6.3

Resource Document	Section	Policy / Bylaw Reference
http://optn.transplant.hrsa.gov/SharedContentDocuments/070521_System_Notice_Announcing_EC_Change_to_KI-PA_Placement.pdf		
Link to Kidney Payback Accounting Sheet http://optn.transplant.hrsa.gov/SharedContentDocuments/Kidney_Payback_Accounting_Sheet.pdf	VII	3.5.3.5 3.8.1.6.1 3.9.3
Link to System Notice sent May 29, 2007 with additional information about EC Change to KI-PA Placement http://optn.transplant.hrsa.gov/SharedContentDocuments/070529_System_Notice_for_Executive_Committee_Change_to_National_KI-PA_Placement.pdf	VII	3.5.6.3
Link to LiveMeeting recording on CPRA https://www115.livemeeting.com/cc/unos/view?id=96QQSC	VII	3.5.11.3
System Notice sent June 14, 2006 About Entering Liver Lab Values as Reported by Laboratory into UNet[sm] http://optn.transplant.hrsa.gov/SharedContentDocuments/060614_SystemNotice_LiverLabsRounding.pdf	VII	3.6.4.1 3.6.4.2
Link to MELD/PELD Calculator http://optn.transplant.hrsa.gov/resources/professionalResources.asp?index=8	VII	3.6.4.1 3.6.4.1.1 3.6.4.2
Link to all UNOS Brochures (including MELD/PELD brochures) http://www.unos.org/resources/brochures.asp	VII	3.6.4.1 3.6.4.1.1 3.6.4.2
Link to System Notice about Distance in Nautical Miles http://optn.transplant.hrsa.gov/SharedContentDocuments/System_Notice_for_Distance_in_Nautical_Miles.doc	VII	3.7.2
Link to LAS calculator and brochures http://optn.transplant.hrsa.gov/resources/professionalResources.asp?index=9	VII	3.7.6 3.7.6.3.1 3.7.6.3.2 3.7.6.4
Link to Pancreas Waiting Time Reinstatement Form http://optn.transplant.hrsa.gov/SharedContentDocuments/PANCREAS_WAITING_TIME_REINSTATEMENT_FORM.pdf	VII	3.8.7
CDC Guidelines for High Risk Behavior http://optn.transplant.hrsa.gov/SharedContentDocuments/CDC_Guidelines_for_High_Risk_Behavior.pdf	VII	4.1.1 4.6.1
CDC document – prevent spread of HIV http://optn.transplant.hrsa.gov/SharedContentDocuments/CDC_document.pdf	VII	4.1.1 4.6.1
Link to revised organ container shipping labels http://optn.transplant.hrsa.gov/SharedContentDocuments/080701_UNOS_shipping_label_system.pdf	VII	5.2
Vessel Transplantation / Destruction Sheet http://optn.transplant.hrsa.gov/SharedContentDocuments/090611_Extra_vessels_tx_destruction_fax_sheet.pdf	VII	5.7 XII-2
Donation Data Report Training Presentation http://www.donornet2007.net/training/Donation%20Data%20Report.htm	VII	7.0 7.7
Imminent and Eligible Data Collection Training Presentation http://www.donornet2007.net/training/Imminent%20and%20Eligible%20Death%20Data%20Collection.htm	VII	7.0

Resource Document	Section	Policy / Bylaw Reference
Importing and Exporting Death Notification Registration Records Training Presentation http://www.donornet2007.net/training/DNR%20Import-Export.htm	VII	7.0
Link to PTR Tutorial http://www.donornet2007.net/training/Complete%20PTR%20Close%20Match.htm	VII	7.6
Link to http://www.donornet2007.net for additional information	VII	7.6
Link to 2009 OPTN/UNOS Computer Registration Fees Memo http://optn.transplant.hrsa.gov/SharedContentDocuments/2009_OPTN_and_UNOS_Fee_Letter.pdf	VII	11.0
Chart 4 – Policy enforcement options http://optn.transplant.hrsa.gov/SharedContentDocuments/Chart_4_EvaluationPlanChartA-2a.pdf	VIII, XI	N/A
Chart 5 – Policy enforcement options (2) http://optn.transplant.hrsa.gov/SharedContentDocuments/Chart_5_EvaluationPlanChartA-2b.pdf	VIII, XI	N/A
Chart 6 – Time periods for hearings, interviews, appellate reviews http://optn.transplant.hrsa.gov/SharedContentDocuments/Chart_6_EvaluationPlanTimePeriodChart.pdf	IX, XI	N/A

Member Requirements for OPTN Notifications

Frequently Used Numbers:

UNOS Main Number	(804) 782-4800 (phone)
Organ Center	(800) 292-9537 (phone)
Allocation Analysis	(804) 782-4660 (fax)

Requirements for All OPTN Members				
OPTN Member	**Required Notification**	**Timeframe for Notifying OPTN**	**How to Notify OPTN**	**Policy / Bylaws Reference**
Members (except transplant centers, which are governed by Article II of Appendix B to the OPTN Bylaws)	Notice that a member intends to exercise its right to appeal termination of its membership by the OPTN	The Bylaws are silent as to timeframe. Recommendation is immediate notification.	Submit letter to Legal Department with copies to the Membership Department and Department of Evaluation and Quality. Send the letter registered or certified mail, return receipt requested.	OPTN Bylaws, Section 1.11

Requirements for Non-Institutional OPTN Members				
OPTN Member	**Required Notification**	**Timeframe for Notifying OPTN**	**How to Notify OPTN**	**Policy / Bylaws Reference**
Business members	The name and address of a representative, to whom all notices may be sent	This information should be submitted upon being elected into membership. Completion of the form indicates acceptance. Any time that the representation changes the OPTN should be notified as soon as possible in order to ensure a seamless transition.	Upon approval a new member is asked to complete an OPTN/UNOS Representatives Form designating these contact persons. If any of these individuals change, the member should obtain an OPTN/UNOS Representatives Change Form from the Membership Department. Forms should be returned by mail. Advance copies may be faxed.	OPTN Bylaws, Section 1.9
Individual members	The individual member's name and address to whom all notices may be sent	This information should be submitted upon being elected into membership. Completion of the form indicates acceptance.	Notice of any changes to the contact information should be submitted to the Membership Department, Attention: Administrator	OPTN Bylaws, Section 1.9

Member Requirements for OPTN Notifications

Requirements for Non-Institutional OPTN Members (continued)				
OPTN Member	**Required Notification**	**Timeframe for Notifying OPTN**	**How to Notify OPTN**	**Policy / Bylaws Reference**
Medical/Scientific members	The name and address of a representative, to whom all notices may be sent, and its alternate representative	This information should be submitted upon being elected into membership. Completion of the form indicates acceptance. Any time that the representation changes the OPTN should be notified as soon as possible in order to ensure a seamless transition.	Upon approval a new member is asked to complete an OPTN/UNOS Representatives Form designating these contact persons. If any of these individuals change, the member should obtain an OPTN/UNOS Representatives Change Form from the Membership Department. Forms should be returned by mail. Advance copies may be faxed.	OPTN Bylaws, Section 1.9
Public Organization members	The name and address of representative, to whom all notices may be sent, and alternate representative	This information should be submitted upon being elected into membership. Completion of the form indicates acceptance. Any time that the representation changes the OPTN should be notified as soon as possible in order to ensure a seamless transition	Notify the Executive Director in writing Upon approval a new member is asked to complete an OPTN/UNOS Representatives Form designating these contact persons. If any of these individuals change, the member should obtain an OPTN/UNOS Representatives Change Form from the Membership Department. Forms should be returned by mail. Advance copies may be faxed.	OPTN Bylaws, Section 1.9

Member Requirements for OPTN Notifications

Requirements for Institutional OPTN Members				
OPTN Member	**Required Notification**	**Timeframe for Notifying OPTN**	**How to Notify OPTN**	**Policy / Bylaws Reference**
All Institutional members	Name and address of representative to whom all notices may be sent, and an alternate representative. Applies to Transplant Centers, Independent OPOs, and Independent Tissue Typing Laboratories.	This information should be submitted upon being elected into membership. Completion of the form indicates acceptance. Any time that the representation changes the OPTN should be notified as soon as possible in order to ensure a seamless transition.	Upon approval a new member is asked to complete an OPTN/UNOS Representatives Form designating these contact persons. If any of these individuals change, the member should obtain an OPTN/UNOS Representatives Change Form from the Membership Department. Forms should be returned by mail. Advance copies may be faxed.	OPTN Bylaws, Section 1.9
Histocompatibility Laboratory	1) An adverse action that leads to or threatens material change in the laboratory's ability to: • perform histocompatibility testing, or • be reimbursed for the costs of such testing by Medicare or a state Medicaid program 2) any threatened or actual adverse action by a state or federal regulatory agency or its designee that would impose a significant limitation upon the laboratory's ability to perform histocompatibility testing for the benefit of transplant candidates and recipients	Within five days	Written notice to include copies of all related correspondence or reports. Notice should be submitted to the Membership Department.	OPTN Bylaws, Appendix B, Section III, General

Member Requirements for OPTN Notifications

Requirements for Institutional OPTN Members (continued)				
OPTN Member	**Required Notification**	**Timeframe for Notifying OPTN**	**How to Notify OPTN**	**Policy / Bylaws Reference**
Histocompatibility Laboratory	Reporting Changes in Key Personnel: When the laboratory learns that a key person (Director, Technical Supervisor, or Clinical Consultant) upon whose participation the laboratory's OPTN approval is based, plans to leave, the OPTN must be notified immediately. Failure to inform the OPTN Contractor of changes in key personnel may result in disciplinary action.	Immediately; at least 30 days (if possible) prior to the departure	Prior to the departure of the key person, the laboratory shall submit to the OPTN Contractor the name of the replacement key person, Curriculum Vitae, and information demonstrating and documenting compliance with OPTN criteria for designated laboratories. The effective data and plan for coverage should also be included. Submit information to the Membership Department, Attention: Membership Administrator	Attachment II to Appendix B of the OPTN Bylaws, II. Reporting Changes in Key Personnel
OPO	When a non-renal organ is offered for transplantation, the recipient center procurement team must be given the option of removing the non-renal organ unless extenuating circumstances dictate otherwise. Cases in which this option is not given to the recipient transplant team must be reported in writing by the Host OPO and recipient transplant center to the appropriate organ-specific OPTN committee. This policy also applies to non-renal organs from controlled donation after cardiac death (DCD) donors.	Notify the organ specific committees in writing when appropriate.	Prepare detailed explanation and submit to UNOS staff via email to evaluationandquality@unos.org or via fax to (804) 782 – 4660 Attn: Allocation Analysis. Written notification should include the following information: • Parties involved • Donor ID • Reason not given option • Time frame • Resolution	Policy 2.7

Member Requirements for OPTN Notifications

Requirements for Institutional OPTN Members (continued)				
OPTN Member	**Required Notification**	**Timeframe for Notifying OPTN**	**How to Notify OPTN**	**Policy / Bylaws Reference**
OPO	Computer Entry: If pre-procurement tissue typing is not initiated, the Host OPO shall provide a written explanation of the reasons to the OPTN contractor.	Recommend notification occur within 10 business days	Prepare detailed explanation and submit to UNOS staff via email to evaluationandquality@unos.org or via fax to (804) 782 – 4660 Attn: Allocation Analysis	Policy 3.5.3.2
OPO	Foreign organ exchange: 1. OPO must contact Organ Center to verify that there is no suitable recipient for the organ on the waiting list. 2. OPO must report foreign organ exchange	1. Prior to exchange 2. Within 72 hours of exchange	Complete Organ Export Form and fax to UNOS Organ Center at (804) 697-4372	Policy 6.4.2.1
OPO	Foreign organ exchange: If a member is contacted by a foreign source with an organ offer, that member must notify the Organ Center of that offer	Immediately	Call the Organ Center at (800) 292-9537	Policy 6.4.3
OPO	Imminent and eligible deaths: The OPO shall report to the OPTN all imminent neurological deaths, eligible deaths and consent not recovered death notification information	• Within 30 days from the end of the month in which a death was referred to the OPO by the hospital in which the death occurred, or • 30 days from the end of the month in which the death was identified by the OPO through a Death Record Review	Complete Death Notification Registration form in DonorNet®	Policy 7.7

Member Requirements for OPTN Notifications

Requirements for Institutional OPTN Members (continued)				
OPTN Member	**Required Notification**	**Timeframe for Notifying OPTN**	**How to Notify OPTN**	**Policy / Bylaws Reference**
OPO	Each OPO shall fully inform the OPTN Contractor when any of the following events occur: (1) an adverse action that leads to or threatens material change in the OPO's eligibility to procure organs or be reimbursed for organ procurement costs by Medicare or a state Medicaid program, including but not limited to any threatened or actual termination of Medicare designated status; and (2) any threatened or actual adverse action by a state or federal regulatory agency or its designee that would impose a significant limitation upon the OPO's ability to procure organs.	Within five days	Written notice to include copies of all related correspondence or reports. Notice should be submitted to the Membership Department.	OPTN Bylaws, Appendix B, Section I, General
OPO	Key Personnel: The OPO must identify the individual selected to serve as the OPO's Executive Director and, if the OPO maintains a position for Medical Director, the OPO must identify the individual selected to serve as Medical Director, and their respective credentials.	When the OPO learns that one or both of the Executive/Medical Directors plan(s) to leave, the OPTN Contractor must be notified immediately.	At least 30 days (if possible) prior to the departure of the individual, the OPO shall submit to the OPTN Contractor the name of the replacement Director and information documenting his/her credentials. This notification should include the effective date of the change and a current CV. Submit information to the Membership Department, Attention: Administrator.	OPTN Bylaws, Appendix B, Section I, Key Personnel

Member Requirements for OPTN Notifications

Requirements for Institutional OPTN Members (continued)				
OPTN Member	**Required Notification**	**Timeframe for Notifying OPTN**	**How to Notify OPTN**	**Policy / Bylaws Reference**
Transplant Center	When a non-renal organ is offered for transplantation, the recipient center procurement team must be given the option of removing the non-renal organ unless extenuating circumstances dictate otherwise. Cases in which this option is not given to the recipient transplant team must be reported in writing by the Host OPO and recipient transplant center to the appropriate organ-specific OPTN committee. This policy also applies to non-renal organs from controlled donation after cardiac death (DCD) donors.	Policy is silent on timeframe. Recommendation is immediate notification.	Submit letter to appropriate organ-specific OPTN committee and submit a copy to UNOS staff via email to evaluationandquality@unos.org or via fax to (804) 782 – 4660 Attn: Allocation Analysis.	Policy 2.7
Transplant Center	Candidate receives transplant or expires	24 hours of event	Remove candidate from Waitlist[SM] in UNet[SM]	Policies 3.2.4.1, 3.6.6, 3.7.14, 3.8.~~6~~7, 3.11.5
Transplant Center	Recipient confirmed positive for, or died from, transmissible disease that could have been of donor origin	Within one working day of knowledge	Notify OPO by phone within one working day of knowledge. Also notify OPTN through Patient Safety System in UNet[SM] .	Policy 4.7
Transplant Center	Sharing vessels among transplant programs	Recommend notification within 10 business days	Prepare detailed explanation for MPSC, submit to UNOS staff via email to evaluationandquality@unos.org or via fax to (804) 782 – 4660 Attn: Allocation Analysis	Policy 5.7.3

Member Requirements for OPTN Notifications

Requirements for Institutional OPTN Members (continued)				
OPTN Member	**Required Notification**	**Timeframe for Notifying OPTN**	**How to Notify OPTN**	**Policy / Bylaws Reference**
Transplant Center	If vessels are stored and subsequently used for the intended or a different transplant recipient, the OPO and the OPTN must be notified. The OPTN must also be notified of vessel disposal.	Monthly or more often	Complete the Vessel Transplantation/ Destruction Information Sheet and fax it to the UNOS Research Department/Data Quality at (804) 782-4809. Alternatively, submit vessel data to UNOS Research Department/Data Quality via email at dataquality@unos.org.	Policies 5.7.4, 5.7.6.5
Transplant Center	Using vessels from hepatitis positive donor in recipient who did not receive organ from that donor	Recommend notification within 10 business days	Prepare detailed explanation for MPSC, submit to UNOS staff via email to evaluationandquality@unos.org or via fax to (804) 782 – 4660 Attn: Allocation Analysis	Policy 5.7.7
Transplant Center	Foreign organ exchange	TXC must report foreign organ exchange within 72 hours of exchange.	Call the Organ Center at (800) 292-9537	Policy 6.4.2.1
Transplant Center	Foreign organ exchange	If a member is contacted by a foreign source with an organ offer, that member must notify the Organ Center of that offer.	Call the Organ Center at (800) 292-9537	Policy 6.4.3
Transplant Center	Living donor death / living donor organ failure	For a period of two years from the date of donation, report within 72 hours after program becomes aware of living donor death / organ failure	Submit information to Patient Safety System in UNet[SM]	Policy 7.3.3

Member Requirements for OPTN Notifications

Requirements for Institutional OPTN Members (continued)				
OPTN Member	**Required Notification**	**Timeframe for Notifying OPTN**	**How to Notify OPTN**	**Policy / Bylaws Reference**
Transplant Center	For each of its organ-specific transplant programs, a Transplant Hospital shall fully inform the OPTN Contractor when any of the following events occur: (1) an adverse action that leads to or threatens material change in the status of the program's eligibility to perform or be reimbursed for organ transplants for Medicare or state Medicaid beneficiaries, in the status of the program's eligibility to perform or be reimbursed for organ transplants for Medicare or state Medicaid beneficiaries, including but not limited to initial approval of eligibility and any threatened or actual termination of eligibility; and (2) any threatened or actual adverse action by a state or federal regulatory agency or its designee (e.g., the Joint Commission on Accreditation of Healthcare Organizations) which would impose a significant limitation upon the program's ability to serve transplant candidates or recipients.	Within five days	Written notice to include copies of all related correspondence or reports. Notice should be submitted to the Membership Department.	OPTN Bylaws, Appendix B, II.A, General

Member Requirements for OPTN Notifications

Requirements for Institutional OPTN Members (continued)				
OPTN Member	**Required Notification**	**Timeframe for Notifying OPTN**	**How to Notify OPTN**	**Policy / Bylaws Reference**
Transplant Center	Changes in Program Status: An OPTN Member Transplant Hospital that fails to remain functionally active with respect to any designated transplant program may voluntarily stop transplantation at that transplant program for a period of up to twelve months by notice to the Executive Director, or may relinquish designated transplant program status for the program. Programs that are not able to serve patients, as a group, for a period of 15 consecutive days or more are further expected to notify the OPTN Contractor.	Written notice should be submitted immediately.	A letter detailing the circumstances should be addressed to the Executive Director and submitted to the Membership Department. The letter must include at a minimum: • the effective date • reason for change in program status • steps that have been or will be taken to notify candidates on the waiting list.	OPTN Bylaws, Appendix B, II.C, Inactive Membership Status; and Attachment I to Appendix B of OPTN Bylaws, II, Inactive Program Status
Transplant Center	Key Personnel: The Transplant Hospital must identify for any designated transplant program the primary surgeon and primary physician. If a key person (such as the primary transplant surgeon or the primary transplant physician) upon whose participation the program's OPTN approval is based, plans to leave or is not substantively able to participate in the program for 15 or more consecutive days (such as military leave or temporary leave of absence)	Immediately; at least 30 days (if possible) prior to the departure of the individual	Written notice of the change should be provided immediately. Contact the regional membership coordinator to obtain the necessary forms for completing a change in key personnel application.	OPTN Bylaws, Appendix B, Section II.E, Key Personnel; and Attachment I to Appendix B of the OPTN Bylaws, III, Reporting Changes in Key Personnel

Member Requirements for OPTN Notifications

Requirements for Institutional OPTN Members (continued)				
OPTN Member	**Required Notification**	**Timeframe for Notifying OPTN**	**How to Notify OPTN**	**Policy / Bylaws Reference**
Transplant Center	Program Coverage: The primary surgeon and primary physician, collectively, are further responsible for ensuring the ongoing operation of the program in compliance with the criteria set forth in this Appendix B and notification to the OPTN Contractor if at any time the program deviates from such criteria.	Preferably prior to the change, but definitely with Key Personnel Change application submission.	Contact the regional membership coordinator to obtain any required forms.	Attachment I to Appendix B of OPTN Bylaws, VII.B, Transplant Surgeon and Physician

XIII. EVALUATION PLAN CHANGE LOG

The table below lists updates to the Evaluation Plan by publication date.

Document Reference and Description of Key Updates	Page Number	Add, Change, or Delete	Evaluation Plan Publication Date
Evaluation Plan Overview • Updated to highlight significant changes in current publication	Overview-1	Change	06/30/09
Patient Notification Bylaw • Modification to require the use of the UNOS Patient Information Letter as part of patient notification requirements	Bylaws 7-8	Change	06/30/09
Policy 2.1 Host OPO • Removed requirement for Host OPO to verify pronouncement of death • New responsibility to make reasonable attempts to obtain medical/behavioral history on the donor	2.0-1	Change	06/30/09
Policy 2.2 Evaluation of Potential Donors • Entire section re-numbered • New responsibilities regarding documentation and evaluations • Modifications to tests required for all donors, renal donors, liver donors, heart donors, pancreas donors, and lung donors	2.0-2 through 2.0-5	Change	06/30/09
Policy 2.3 Donor Maintenance • Clarification that the Host OPO must make reasonable efforts to maintain the deceased donor, document these efforts, and communicate this information to the OPO or transplant center	2.0-6	Change	06/30/09
Policy 2.5 Organ Procurement Quality • Certain subsections are renumbered and reorganized • Modification that minimum standards of quality include documentation of all items in policy section 2.2 • New requirements regarding record	2.0-8 through 2.0-11	Change	06/30/09

keeping of flush solutions and additives and donor medications administered (new number 2.5.3) • New requirement for OPOs and histocompatibility labs to define and document minimum tissue typing material requirements (new number 2.5.4) • Updates to list of documentation required to accompany each organ (new number 2.5.6) • Moves language about donor medications and flush solutions from 2.5.7 to 2.5.3 (new numbers)			
Policy 2.6 Initiating Organ Procurement and Placement • Removes statement that tissue typing is initiated only after the consent of either the donor by previous designation or the next of kin	2.0-12	Change	06/30/09
2.7.1 Multiple Abdominal Organ Procurement • Modifications to state that all authorized organs should be procured from a donor and OPOs are required to document the specific reason for non-recovery. Cooperation among all organ recovery teams is required.	2.0-14	Change	06/30/09
2.8 Organ Recovery from a DCD Donor • Sets standards for organ recovery from a DCD donor	2.0-15	Add section 2.8	06/30/09
2.9 Multi-Cultural and Diversity Issues • Renumbered (was section 2.8)	2.0-16	Numbering change	06/30/09
3.1.13 Definition of Directed Donation • Added new policy regarding allocation of an organ(s) to a specific transplant candidate named by the person who authorized the donation, unless prohibited by state law	3.1-13	Add section 3.1.13	06/30/09
3.2.4 Match System Access • Modification that transplant centers are to maintain documentation when transplanting a candidate who does not	3.2-3 and 3.2-4	Change	06/30/09

appear on the match run			
3.8.1 Pancreas Organ Allocation • Added new subsection 3.8.1.1, Local Whole Pancreas Allocation and renumbered other subsections	3.8-3	Add section 3.8.1.1	06/30/09
3.8.1.6 Islet Allocation Protocol • Modifications to define medical suitability of an islet preparation, devine active and inactive candidate status, and establish a protocol for updating candidate status and removal from the waiting list • Renumbering of policy sections	3.8-6 through 3.8-8	Change	06/30/09
3.8.5 through 3.8.9 – policy sections renumbered	3.8-11 through 3.8-15	Change	06/30/09
Policy 5.7 Vessel Recovery, Storage and Transplant • Updated link to revised Vessels Transplantation/Destruction Information Sheet	5.0-9	Change	06/30/09
Evaluation Plan Overview • Updated to highlight significant changes in current publication	Overview-1	Change	03/31/09
Patient Notification, Appendix B to OPTN Bylaws, section II.F • Language modification to clarify patient notification requirements	Bylaws-7	Change	03/31/09
Transplant Surgeon and Physician, Program Coverage Plan, Attachment I to Appendix B of OPTN Bylaws, section VII • Clarification to explain when candidates are to receive a written summary of the program coverage plan	Bylaws-8	Change	03/31/09
Policy 3.1.2, Transplant Center • Clarification to explain requirements to verify donor ABO, recipient ABO, and UNOS donor ID after receipt of an organ and prior to its implantation	3.1-2	Change	03/31/09
Policy 3.1.4, Waiting List • Clarification to highlight definition of	3.1-3	Change	03/31/09

ABO typing on "two separate occasions"			
Policy 3.2.3, Waiting Time Transferal and Multiple Listing • Clarification to explain that certain written materials are to be provided to the candidate during the evaluation process	3.2-2	Change	03/31/09
Policy 3.5.11.3, Panel Reactive Antibody • Clarification to explain at least one unacceptable HLA antigen must be entered into UNet^{SM} for sensitized candidates to receive additional points	3.5-31	Change	03/31/09
Policy 3.7.4, Pediatric Candidate Status • Clarification to point out that OPTN policy does not require pediatric heart candidates to be admitted to the listing transplant center to be listed as status 1A	3.7-6	Change	03/31/09
Policy 3.7.6.3.2, Updating Candidate Variables • Clarification to explain how to enter information about diabetes into the LAS calculator	3.7-14	Change	03/31/09
Policy 3.7.17, Crossmatching for Thoracic Organs	3/7-34	Change	03/31/09
Policy 5.5, Standard Organ Package Specifications • Clarification from the OPO Committee that 6-piece insulation panels serving as the inner liner of a shipping box may be considered a container	5.0-7	Change	03/31/09
Policy 5.7, Vessel Recovery, Storage, and Transplant • Members are to submit Vessel Transplantation/Destruction Information Sheet to UNOS Research Department/Data Quality rather than Department of Information Management Services	5.0-9	Change	03/31/09
Section XII, Member Requirements for OPTN Notifications, OPTN Bylaws, Appendix B, Section III, General	Notifications Document-3	Change	03/31/09

• Clarification that Histocompatibility Labs need to send written notice regarding adverse actions to the UNOS Membership Department			
Section XII, Member Requirements for OPTN Notifications, OPTN Bylaws, Appendix B, Section I, General • Clarification that OPOs need to send written notice regarding adverse actions to the UNOS Membership Department	Notifications Document-6	Change	03/31/09
Section XII, Member Requirements for OPTN Notifications, OPTN Bylaws, Appendix B, Section I, General • Members are to submit Vessel Transplantation/Destruction Information Sheet to UNOS Research Department/Data Quality rather than Department of Information Management Services	Notifications Document-8	Change	03/31/09
Section XII, Member Requirements for OPTN Notifications, OPTN Bylaws, Appendix B, Section II.A, General • Clarification that Transplant Centers need to send written notice regarding adverse actions to the UNOS Membership Department	Notifications Document-9	Change	03/31/09
Evaluation Plan Overview • Updated to highlight significant changes in current publication	Overview-1	Change	12/31/08
VI. OPTN/UNOS Committee Statements on Organ Allocation Policy Goals	VI-11	Change	12/31/08
Policy 3.3.7, Acceptance and Transplant of Living Donor Organs • New section to describe requirement for accepting/transplanting living donor organs	3.3-7	Add	12/31/08
Policy 3.7.6, Lung Candidates • Included guidance on entering PCO_2 and CVP values	3.7-9 through 3.7-10	Change	12/31/08
Policy 3.7.6.3, Lung Candidate Variables in UNet^{SM}	3.7-12	Change	12/31/08

• Updated description of purpose			
Policy 3.7.6.4, Lung Candidates with Exceptional Cases • Updated guidance to explain candidates with an approved exception score will appear on lung matches according to the approved exception score	3.7-15	Change	12/31/08
Policy 7.1.3, Data Submission on Recipient Follow-up • Updated requirements to reflect recently implemented policy change	7.0-2	Change	12/31/08
Policy 7.8.1, Data Submission • Included instructions on how to access new Compliance Report	7.0-18	Change	12/31/08
Section XII, Resource Materials • Updated link to Committee Goals	XII-1	Change	12/31/08
Evaluation Plan Overview • Updated to highlight significant changes in current publication	Overview-1	Change	09/30/08
OPTN Bylaws Appendix A, 3.01A, 5.05A, 5.07A • New section to describe restoration of Membership privileges	Bylaws-3	Add	09/30/08
UNOS Bylaws Appendix B, Attachment I, Section XIII, D.(2) • Included new requirement of living donor kidney programs	Bylaws-10	Change	09/30/08
UNOS Bylaws Appendix B, Attachment I, Section XIII, D.(4) • Included new requirement of living donor liver programs	Bylaws-11	Change	09/30/08
UNOS Bylaws, Appendix B, Attachment I, Section XIII, D. (4), c. • New section to describe requirements of living donor liver programs granted conditional approval	Bylaws-13	Add	09/30/08
Policy 2.2.8, Performing Pertinent Tests for	2.0-5	Change	09/30/08

All Donors • Updated to reflect policy change regarding donor screening tests			
Policy 3.1.4, Waiting List • Updated instructions on adding and verifying a candidate's ABO in Waitlist℠	3.1-4	Change	09/30/08
Policy 3.2.1.2, Permissible Access to UNet℠ • New section to provide instructions for Institutional Members giving third parties access to UNet℠	3.2-1	Add	09/30/08
Policy 3.2.4, Match System Access • Updated instructions on how to find reason candidate does not appear on the match run	3.2-4	Change	09/30/08
Policy 3.5.3, Mandatory Sharing of Zero Antigen Mismatched Kidneys • Updated to provide reference to detailed requirements in Policy 3.5.3.5	3.5-4	Change	09/30/08
Policy 3.5.3.3.1, Zero Antigen Mismatched Kidney Allocation Sequence • Updated to reflect policy change allowing OPOs to place zero antigen mismatched kidneys without contacting Organ Center	3.5-8	Change	09/30/08
Policy 3.5.3.3.2, Zero Antigen Mismatched Kidney Allocation Sequence • Included policy reference on page 3.5-8 and deleted duplicate information	3.5-9	Delete	09/30/08
Policy 3.5.3.4, Kidney/Non-Renal Exception • Updated to provide reference to detailed requirements in Policy 3.5.3.5	3.5-9	Change	09/30/08
Policy 3.5.3.5, Organ Offer Limit • Updated to reflect policy change from number of hours to number of offers and payback accounting procedural	3.5-10	Change	09/30/08

changes			
Policy 3.5.4.1, Mandatory Sharing • Updated to provide reference to detailed requirements in Policy 3.5.3.5 and Policy 3.8.1.6.1	3.5-12	Change	09/30/08
Policy 3.6.4, Degree of Medical Urgency • Updated to give instructions about rounding laboratory values when performing data entry	3.6-7	Change	09/30/08
Policy 3.6.4.1, Adult Candidate Status • Updated to reflect policy clarification regarding CVVHD and the MELD score calculation	3.6-9	Change	09/30/08
Policy 3.6.4.8, Combined Liver-Intestine Allocation • Added to correspond with newly added policy language intended to clarify existing requirements	3.6-24	Add	09/30/08
Policy 3.7.3, Adult Candidate Status • Added clarification about entering inotrope dosages and documentation requirements	3.7-4	Change	09/30/08
Policy 3.7.4, Pediatric Candidate Status • Added clarification about entering inotrope dosages and documentation requirements	3.7-5	Change	09/30/08
Policy 3.8.1.6.1 Organ Offer Limit • Updated to reflect policy change from number of hours to number of offers and payback accounting procedural changes	3.8-8	Change	09/30/08
Policy 3.8.7 Waiting Time Reinstatement for Pancreas Recipients • Updated to reflect policy and procedural changes regarding waiting time reinstatement	3.8-14	Change	09/30/08
Policy 3.9.3, Organ Allocation to Multiple	3.9-4	Change	09/30/08

Organ Transplant Candidates • Added link to Kidney Payback Sheet and included policy references for heart-lung and liver-intestine allocation			
Policy 3.11, Intestinal Organ Allocation • Updated to include clarification regarding combined intestine-liver allocation, and updated description of monitoring efforts	3.11-3, 3.11-5, 3.11-6	Change	09/30/08
Policy 4.1.1, Communication of Donor History • Updated to include reference to guidelines document and additional information about informed consent	4.0-3 through 4.0-4	Change	09/30/08
Policy 4.6, Screening Potential Organ Donors • Updated to reflect policy change regarding donor screening tests	4.0-15	Change	09/30/08
Policy 5.2, Standard Labeling Specifications • Deleted links to labels not valid for use as of 9/30/08	5.0-4	Change	09/30/08
Policies 5.4 and 5.5.2, Organ Packaging • Updated to reflect policy change regarding red plastic biohazard bag	5.0-6, 5.0-7	Change	09/30/08
Policy 5.7, Vessel Recovery, Storage, and Transplant • Updated to include expectation that documentation is maintained	5.0-8	Change	09/30/08
Policy 11.0, Registration Fee • Updated to include latest Candidate Registration and UNOS Computer Registration Fees	11-1	Change	09/30/08
Section XII, Resource Materials • Updated to reflect additional resources linked to Evaluation Plan	XII-1 through XII-3	Change	09/30/08
Section XII, Resource Materials • New section – Member Requirements	Pages 1-11	Add	09/30/08

for OPTN Notifications			
Evaluation Plan Overview • Updated to highlight significant changes in current publication	Overview-1	Change	06/30/08
Section III. Interested and Affected Entities • Updated description of MPSC	III-3 through III-5	Change	06/30/08
Bylaws Document • Reformatted document to include description and table of contents	Bylaws-1 through Bylaws-10	Change	06/30/08
OPTN Bylaws Appendix B, II.B, Survival Rates • New section to describe OPTN/UNOS review of transplant outcomes and associated expectations of transplant centers	Bylaws-3	Add	06/30/08
OPTN Bylaws Appendix B, II.C, and OPTN Bylaws Appendix B, Attachment I, Section II., Inactive Status • New section to describe OPTN/UNOS review inactive program status and associated expectations of transplant centers	Bylaws-4 through Bylaws-5	Add	06/30/08
OPTN Bylaws Appendix B, II.F, Patient Notification • Additional clarification regarding Patient Notification requirements	Bylaws-6	Change	06/30/08
UNOS Bylaws Appendix B, Attachment I, Section XIII, D.(2), Living Donor Kidney Transplant Programs • New link to resource document	Bylaws-9	Change	06/30/08
UNOS Bylaws Appendix B, Attachment I, Section XIII, D.(4), Living Donor Liver Transplant Programs • New link to resource document	Bylaws-10	Change	06/30/08
Policy number 3.1.2 • Additional clarification regarding transplant center responsibilities	3.1-2	Change	06/30/08

Policy number 3.2.4.1, Removal of Kidney Transplant Candidates from Kidney Waiting Lists when Transplanted or Deceased • New description of how UNOS will monitor compliance • New detailed guidance section	3.2-4	Change	06/30/08
Policy 3.5.11.3, Panel Reactive Antibody • Additional clarification about how to access the Live Meeting training module	3.5-33	Change	06/30/08
Policy number 3.5.11.6, Donation Status • New detailed guidance section about requesting donation status points for a kidney candidate who is a prior living donor	3.5-37	Change	06/30/08
Policy number 3.6.4, Degree of Medical Urgency • Updated link to resource material	3.6-9 through 3.6-10, 3.6-13	Change	06/30/08
Policy numbers 3.6.4.1and 3.6.4.2, Liver Candidate Status (Adult and Pediatric) • Additional information added to detailed guidance section	3.6-9, 3.6-13	Change	06/30/08
Policy number 3.7.6, Lung Allocation • Updated link to resource material	3.7-7, 3.7-10 through 3.7-12	Change	06/30/08
Policy number 3.7.14, Removal of Thoracic Organ Transplant Candidates from Thoracic Waiting Lists when Transplanted or Deceased • New description of how UNOS will monitor compliance • New detailed guidance section	3.7-28	Change	06/30/08
Policy number 3.8.6, Removal of Pancreas Transplant Candidates from Pancreas Waiting Lists when Transplanted or Deceased • New description of how UNOS will monitor compliance	3.8-13	Change	06/30/08

• New detailed guidance section			
Policy number 3.11.5, Removal of Intestinal Transplant Candidates from Intestine Waiting Lists when Transplanted or Deceased • New description of how UNOS will monitor compliance • New detailed guidance section	3.11-8	Change	06/30/08
Policy number 5.2, Standard Labeling Specifications • New shipping labels are required as of October 1, 2008	5.0-3 through 5.0-4	Change	06/30/08
Policy number 5.7, Vessel Recovery, Storage, and Transplant • New detailed guidance section • Link to Vessel Transplantation / Destruction Information Sheet	5.0-8 through 5.0-9	Change	06/30/08
Policy numbers 7.0, 7.6, and 7.7, Data Submission • Updated links to resource material	7.0-1, 7.0-12, and 7.0-17	Change	06/30/08
Section X. Communications • Updated description of electronic communication	X-1	Change	06/30/08
Section XII. Resource Materials • Reformatted document to cross-reference linked resources to Plan sections	XII-1 through XII-3	Change	06/30/08
Evaluation Plan Overview	Overview-1	Change	03/31/08
OPTN Bylaws, Appendix B, Attachment I, Section VII	Bylaws-1	Changes	03/31/08
OPTN Bylaws, Appendix B, Attachment III	Bylaws-5	Change	03/31/08
Policy number 2.2.8.1	2.0-5	Change	03/31/08
Policy number 2.5.5	2.0-9	Change	03/31/08
Policy number 2.7.1	2.0-14	Change	03/31/08

Policy number 3.1.4.2	3.1-3, 3.1-4	Change	03/31/08
Policy number 3.5.9	3.5-27	Change	03/31/08
Policy number 3.7.6	3.7-7	Change	03/31/08
Policy number 4.1.1	4.0-3, 4.0-4	Change	03/31/08
Policy number 5.2	5.0-4	Change	03/31/08
Policy number 5.4	5.0-6	Change	03/31/08
Policy number 7.0	7.0-1	Change	03/31/08
Policy number 7.1.5	7.0-3	Change	03/31/08
Policy number 7.1.7	7.0-5	Add	03/31/08
Policy number 7.3.2	7.0-8	Change	03/31/08
Policy number 7.3.3	7.0-9	Change	03/31/08
Policy number 7.7	7.0-17	Change	03/31/08
XII. Resource Materials	XII-2	Change	03/31/08
Consolidated PDF of entire Evaluation Plan	N/A	Add	03/31/08
Evaluation Plan Overview	Overview-1	Change	12/31/07
Policy number 2.2	2.0-2 through 2.0-4	Change	12/31/07
Policy number 3.1.4.2	3.1-3, 3.1-4	Change	12/31/07
Policy number 3.2.4	3.2-2, 3.2-3	Change	12/31/07
Policy numbers 3.5.3.5, 3.5.6.3, 3.5.11.1, 3.5.11.3	3.5-11, 3.5-12, 3.5-23, 3.5-30, 3.5-33,	Change	12/31/07
Policy numbers 3.6.4.1, 3.6.4.2, 3.6.4.2.1, 3.6.6, 3.6.11	3.6-8, 3.6-9, 3.6-12 through 3.6-14, 3.6-26, 3.6-32	Change	12/31/07
Policy number 5.7	5.0-8, 5.0-9	Add	12/31/07

Bylaws – Appendix B, Attachment I, Section XIII, D.(2)	Bylaws-2	Add	12/31/07
Bylaws, Appendix B, Attachment I, Section XIII, D.(4)	Bylaws-3	Add	12/31/07
Bylaw – Appendix B, Section II.F	Bylaws-4	Change	12/31/07
III. Interested and Affected Entities	III-1	Change	12/31/07
IV. Membership Criteria and Evaluation of Applications	IV-1, IV-6,	Change	12/31/07
V. Designated Transplant Program to Receive Organs for Transplantation	V-2, V-3	Change	12/31/07
VI. OPTN/UNOS Committee Statements on Organ Allocation Policy Goals	VI-11	Change	12/31/07
XII. Resource Materials	XII-1, XII-2	Change	12/31/07
Evaluation Plan Overview	Overview-1	Change	09/30/07
Policy number 3.1.2	3.1-2	Change	09/30/07
Policy number 3.3.6	3.3-6	Change	09/30/07
Policy numbers 5.0, 5.2, 5.3, 5.4, 5.5	5.0-1, 5.0-3 through 5.0-7	Change	09/30/07
Policy number 7.3.3	7.0-8	Add	09/30/07
Bylaw – Appendix A to OPTN Bylaws, Section 2.06A	Bylaws-4	Add	09/30/07
XII. Resource Materials	XII-1	Change	09/30/07
Evaluation Plan Overview	Overview-1	Add	06/30/07
VII. Measuring Compliance – Cover Page	VII-1	Change	06/30/07
Policy number 3.5.9	3.5-27	Change	06/30/07
Policy number 3.6.2.2	3.6-5	Change	06/30/07
Policy number 3.6.4.2	3.6-12	Change	06/30/07
Policy number 3.6.4.7	3.6-22	Change	06/30/07
Policy number 3.7.2	3.7-3	Change	06/30/07

Policy number 3.11.4.2	3.11-7	Add	06/30/07
Policy number 7.6	7.0-10	Change	06/30/07
Bylaw – Attachment I to Appendix B of OPTN Bylaws, section VII	Bylaws-1	Add	06/30/07
Bylaw – Appendix B to OPTN Bylaws, section II.F	Bylaws-2	Add	06/30/07
Bylaw – Attachment III to Appendix B of OPTN Bylaws	Bylaws-3	Add	06/30/07
XII. Resource Materials	XII-1	Change	06/30/07
XIII. Evaluation Plan Change Log	XIII-1	Add	06/30/07
Evaluation Plan	All	Revised plan	03/31/07

- Policy Management
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  - Policies
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Effective March 16, 2000, the U.S. Department of Health and Human Services (HHS) implemented a Final Rule establishing a regulatory framework for the structure and operations of the OPTN. Under the terms of the Final Rule, policies intended to be binding upon OPTN members are developed through the OPTN committees and Board of Directors and then submitted to the Secretary of HHS for final approval.

View the final rule now