

**Selected Recommendations of the
OPTN/UNOS Policy Oversight Committee to the
Board of Directors
November 12-13, 2012
St. Louis, MO**

Summary

I. Action Items For Board Consideration

- The Board is asked to approve the rewrite of Policy 9 (Release of Data) (Item 1, Page 2)
- The Board is asked to approve a POC resolution regarding geography (Item 2, Page 16)

II. Other Significant Items

- None

**Selected Recommendations of the
OPTN/UNOS Policy Oversight Committee to the
Board of Directors
November 12-13, 2012
St. Louis, MO**

**Carl Berg, MD, Chair
Yolanda Becker, MD, Vice Chair**

The following report represents the selected recommendations of the Policy Oversight Committee to the Board of Directors.

1. Proposal to Rewrite the Data Release Policies.

The OPTN¹ Contractor has initiated a plain language rewrite of the OPTN policies and bylaws. The rewrite project is currently consolidating, reorganizing, and simplifying the language of the policies and bylaws. During the evaluation of the policies, it was noted that the data release policies contain outdated elements that require substantive changes. Since substantive changes are outside the scope of the plain language rewrite project, this proposal was distributed separately from the rewrite project. The current Policy 9 (Release of Information to the Public) and Policy 10 (Access to Data) were combined into one policy as outlined in this report. Below are several of the larger changes that are in the proposed policy language that was released for public comment. Several of these provisions were changed as a result of public comment.

- The proposed policy allows the OPTN Contractor to release more data than is currently released, but does not require its release in every case. In cases where there is disagreement between the OPTN Contractor and a requestor about whether data should be released, the Executive Director will make the final decision about release of confidential and personnel data, and the Policy Oversight Committee (POC) will make the decision about release of other OPTN data.
- The proposal sets requirements for the release of confidential information. These requirements are meant to protect confidential information and allow the release only in limited situations. Additionally, the policy defines confidential information (e.g., financial and personnel information).
- Under current policy, the OPTN Contractor may release by institution only the data elements specifically approved by the now-defunct OPTN Data Advisory Committee. Many of these fields are currently found on the OPTN website. The proposed language will allow the POC to maintain the list of data elements outside of policy.
- The proposal eliminates from policy language lists of data elements that can be released in special circumstances. Several lists of specific data elements that can be released under the current policy are not included in the new policy language because the language is being broadened, and future lists of releasable data elements will be

¹ Organ Procurement and Transplantation Network

approved by the POC. This approach will give the OPTN greater flexibility to modify the lists of releasable elements in the future.

- The process for release of person-identified data does not change. Person-identified OPTN data are given to researchers for bona fide research purposes, but the OPTN Contractor only fulfills requests that are *approved by HRSA* because the OPTN does not have the authority to release person-identified data to researchers.

This proposal was released for public comment between March 15, 2012, and June 15, 2012. The POC considered all public comments received on the proposal at its October 10, 2012, meeting. There was considerable concern about the potential misuse of OPTN data (e.g., use of center-level data for marketing efforts or by insurance companies) and potential risk to patient confidentiality (i.e., patients may be more easily identified if more institution-identified data are available to a wider audience). To address the concerns raised in the public comments, the POC considered each of the following issues:

- *Institution identifiers in patient-level data sets* – This is the information currently released in STAR (Standard Transplant Analysis and Research) files that contains center and OPO identifiers in the data sets only for research purposes. Currently, researchers are required to submit a concept paper stating why they need these data and sign a data use agreement promising not to publish in a way that identifies those institutions. The original proposal would eliminate these restrictions with the intent to allow for greater transparency and access to data. The institution identified data would be available to the public, not just to researchers, and the restriction on publishing by institution could be lifted. The restriction is currently in the data use agreement, but not in OPTN policy. Following discussion, the POC agreed to maintain the current process and allow an avenue for appeals as outlined in the proposed language. Additionally, if a researcher requests institution identified data, then the requester should provide a justification. The UNOS Research Department will periodically update the POC on the number of requests that are approved and denied.
- *OPTN data requests for summary information (e.g., listings, tables, etc.) by institution* – The OPTN receives many requests for summary data each month. These are analyses such as the number of patients with a certain diagnosis by OPTN region. Current policy allows the OPTN to release by institution only certain data elements that are on an approved list. For example, if a requester wants to know the diagnosis by transplant center that would be acceptable, but receiving information about which transplant center performs the most transplants on HIV positive patients would not be allowed under current policy. The original proposed policy change would remove such restrictions and allow the OPTN to release any data field by institution. The SRTR² noted that they also receive data requests and are not restricted by the list, so data are available through two mechanisms where one has restrictions and the other does not. HRSA noted that this proposal is a step in the right direction by reducing restrictions and that discussion with the SRTR regarding their process for releasing data should be reviewed in the future. Following public comment, there was agreement that a list of data fields that the OPTN Contractor may release as institution level summary data would be maintained by the POC.

² Scientific Registry of Transplant Recipients

- *Publication by institution* – The current data use agreement restricts requesters from publishing or presenting data that in any way identifies an institution. Currently the OPTN has no way of preventing the misuse of data and the only recourse is preventing offenders from having future access to data. There was a question raised about what constitutes a “publication.” Most medical professionals think of publication as peer-review literature where there is a step in the review process by journal experts. It was noted that currently the data use agreement states that the requester will not present or publish by institution. This is interpreted by UNOS staff as releasing the information outside the requester’s research group. Following additional discussion, the POC agreed to add policy language specifying that requesters provide an explanation for why they need institutional identifiers and agree not to publish or present in a way that identifies an institution.
- *Institutional Review Board (IRB) requirements* – The current policy does not require IRB approval to receive patient-level data sets. IRB approval is required for patient-identified data sets, which are covered by federal law. University researchers are usually required by their institution to have IRB approval for patient-level data, so this requirement should not cause a burden for those individuals. It could, however, be a burden to the public because they may not have access to an IRB. Additionally, some data for “quality or process improvement” might not require IRB approval because it is not being used for research purposes. There was a question about the process the OPTN Contractor uses to determine if a request is reasonable. Currently requests are reviewed by UNOS research staff before the data sets are released. It was noted that the proposed policy language does include an appeals process if requests are denied. It was noted that tracking the approval and denial of requests would be useful information for the POC to have in the future. Following discussion, the POC agreed that proof of IRB approval should be required for researchers, and anyone else requesting patient-level data will be required to submit a concept paper explaining the reasons for the request. Additionally, if an institution is requesting data for quality or process improvement, which some IRBs may not need to approve, then a concept paper is required. If there are concerns about a particular request, the POC will have the authority to make a decision. A subgroup of the POC be created for this purpose.
- *Cell size limits* – During public comment, concerns were raised about patient confidentiality, and several commenters expressed a desire for cell size limits in publications. It was noted that even with patient-level data by institution there might be a way, especially for certain small subgroups of patients, for individual patients to be identified. The current OPTN policy does not restrict cell size in publications. It was noted that USRDS³ and CMS⁴ have cell size limits of ten, which might be acceptable for those data sets but not OPTN data. While cell limits could decrease the chances of patients being identified, it would also reduce the usefulness of the OPTN data to both researchers and the public. This includes certain data requests fulfilled by the OPTN as well as the data on the OPTN website. The POC agreed that placing limits on the cell size would not be the best way to address potential patient confidentiality issues. It was

³ United States Renal Data System (USRDS)

⁴ Centers for Medicare and Medicaid Services

also noted that there are no cell size limits in the program-specific reports (PSRs), so maintaining consistency would be important.

HRSA noted that the data collected by the OPTN are essential to its function. The data are used for policy development and other vital functions. The OPTN also needs to ensure the transparency and availability of the data so that the public can have trust in the system. The Final Rule clearly states that the data should be available to researchers and the public for a variety of reasons, including assessing individual transplant program performance. HRSA noted that this proposal supports what is outlined in the Final Rule. If an individual seeks information about what transplant center has the most experience dealing with certain disease processes, then they should be able to get that information. As currently written, the policy does not allow the OPTN to provide that information. It was noted that the PSRs are a different issue than what this proposal addresses and are being addressed through a separate process. It was also noted that the PSRs are generated by a group of experts using comprehensive data without institutional bias, while wide-open access to data may lead to analyses that could be misleading for a variety of reasons.

While there was considerable concern about increasing the availability of data in the public comments, the POC agreed that modifications to the existing Data Use Agreement, requirements to submit a concept paper, and added IRB and publication requirements adequately address these concerns. All comments and responses are included in the briefing paper. **(Exhibit A)**. The Resource Assessment and Impact Statement for this proposal can be found in **(Exhibit B)**.

The Committee approved the final version to be considered by the Board. Committee vote: 15 in favor, 1 opposed, and 0 abstentions.

**** RESOLVED, that Policy 9 (Release of Data) are hereby approved as set forth below, effective February 1, 2013:**

9. Release of Data

The OPTN Contractor will not release confidential information unless specifically allowed under a subsection of Policy 9.

9.1 Requests for Data

The OPTN Contractor may provide data upon request except as restricted by Policy 9, federal or state laws, or the OPTN contract. Regardless of any restrictions in Policy 9, the OPTN Contractor will release any data required by federal or state laws or the OPTN contract.

The OPTN Contractor may prescribe specific administrative requirements necessary to protect confidential information, patient welfare, or patient privacy.

If a requestor does not comply with any requirements of Policy 9, then the OPTN Contractor may withhold additional data from future data requests.

9.2 Requests for Confidential Information

The OPTN Contractor may release confidential information if *all* of the following occur:

1. The request is necessary to perform a function on behalf of the OPTN
2. The requestor is one of the following:
 - a. A person bound by a fiduciary responsibility to the OPTN or a contractual obligation to the OPTN Contractor to maintain the confidentiality of such information;
 - b. A person acting on behalf of the Board of Directors
 - c. A person acting on behalf of a permanent standing or ad hoc committee
3. The request is approved by the Executive Director.

The release of confidential information does not convey any ownership rights in recipients of confidential information.

9.3 Requests for Person Identified Data

Any person may receive, or authorize another person to receive, any data pertaining to that person.

The OPTN Contractor may release person identified data according to Table 9-1.

If the requestor is...	Then the OPTN Contractor may release the following person identified data:
Authorized to receive confidential information according to Policy 9.2	Confidential information according to Policy 9.2
Laboratory	HLA information of deceased donors and recipients typed by that Laboratory when discrepant HLA information is reported to the OPTN Contractor
Member	Data previously submitted by the Member to the OPTN Contractor
Member	Data that are necessary for the Member to prepare a report required by the OPTN Contractor
OPO	Recipient characteristics and outcomes data for each transplanted organ that was recovered by the OPO
Transplant Program	Recipient characteristics and outcomes for each organ offer received by the Transplant Program
Transplant Program	Whether the Transplant Program's candidate is multiply listed, but not where the candidate is multiply listed
Transplant Program and its affiliated Laboratory	Prior donor's HLA information for any recipients under the Transplant Program's care

Table 9-1: Requests for Person Identified Data

If the OPTN Contractor does not approve a request for person identified data, then the requestor may appeal the request to the Policy Oversight Committee (POC).

9.4 Requests for Personnel Data

The OPTN Contractor may not release contact information for personnel at Member institutions unless the Executive Director approves the request. Requestors must submit a signed Data Use Agreement (DUA) before receiving personnel data. The requestor must maintain a copy of this DUA and provide it to the OPTN Contractor upon request.

9.5 Requests for Person Level Data

Requestors must fulfill *all* of the following requirements before receiving person level data from the OPTN Contractor:

1. Submit a signed Data Use Agreement (DUA) before receiving the data. The requestor must maintain a copy of this DUA and provide it to the OPTN Contractor upon request.
2. Agree not to use the data for any purpose that could have a negative impact on patient welfare
3. Agree to neither attempt nor permit others to attempt to learn the identity of any person whose information is contained in the data
4. Agree to include the following disclaimer in any publication using the released data: *The data reported here have been supplied by [name of the OPTN Contractor] as the Organ Procurement and Transplantation Network. The interpretation and reporting of these data are the responsibility of the author and in no way should be seen as an official policy of or interpretation by the OPTN or the U.S. Government.*
5. Agree to include the source and date of the data in any publication or graphic presentation using the released data
6. Obtain approval or exemption for a specific research project from an Institutional Review Board (IRB) or submit a concept paper to the OPTN Contractor for a specific research project.

If the OPTN Contractor does not approve a request for person-level data, then the requestor may appeal the request to the Policy Oversight Committee (POC).

9.6 Requests for Institution Level or Institution Identified Data

The Policy Oversight Committee (POC) will maintain a list of data fields that the OPTN Contractor may release as institution level data with institution identifiers but without patient level data.

In addition to the requirements in Policy 9.5 *Requests for Person Level Data*, requestors must also fulfill *both* of the following requirements before receiving person level data that has institution identifiers from the OPTN Contractor:

1. Submit to the OPTN Contractor a concept paper for a specific research project and explain the need for institution identifiers
2. Agree to neither publish nor publicly present OPTN data in a way that allows identification of an institution

9.7 Definitions

The following definitions apply to Policy 9.

- *Confidential information* - Includes, but is not limited to, all of the following:
 - Financial data and information of the OPTN Contractor
 - Confidential medical peer review information and related materials
 - Data and information subject to federal or state confidentiality statutes and regulations
 - Proprietary information of the OPTN Contractor
 - Health information regarding any person
 - Any person-level or institution-level data regarding patient safety incidents that are submitted to the OPTN Contractor.
- *Confidential Medical peer review information* – All documents or statements initiated, created or generated by or at the request of the OPTN or the OPTN Contractor as part of its peer review function.
- *Data* – Information submitted by Members to the OPTN Contractor about candidates, recipients, potential donors, and donors and information derived from such data.
- *Data Use Agreement* – An agreement between a data requestor and the OPTN Contractor stating the permissible use of data received from the OPTN Contractor.
- *Institution level data* – Data about a Member or Transplant Program.
- *Institution Identifiers* – Data that identifies a specific Member or Transplant Program
- *Person identified data* – Person level data that contain personally identifiable information.
- *Person level data* – Data about an individual candidate, recipient, donor, or potential donor that does not contain personally identifiable information.
- *Proprietary information* – Information including business practices, programming code, trade secrets, internal procedures and any other proprietary information that is not public knowledge.

~~9.0 — RELEASE OF INFORMATION TO THE PUBLIC.~~

~~The following policies address information which the Executive Director and his or her staff are permitted to release to the public:~~

- ~~9.1 MAILING LISTS. Lists showing members' or Program Directors' names and addresses, and/or telephone numbers may be released, ONLY if (a) the Executive Director deems the request to be for a legitimate, non-commercial purpose furthering the objectives of the OPTN, and (b) the OPTN contractor receives an executed agreement restricting the use of the information for the permitted purpose.~~
- ~~9.2 DATA. Composite demographic national, regional or state data currently provided to HRSA through the OPTN Contract such as the following may be released:~~
- ~~9.2.1 The number of transplant recipients, according to organ type, race, ABO blood group, gender, and age.~~
- ~~9.2.2 The number of candidates on the Waiting List according to organ type, race, ABO blood group, gender, and age.~~
- ~~9.2.3 The number and disposition of organs retrieved.~~
- ~~9.3 ORGAN CENTER DATA. Composite Organ Center information such as the following may be released:~~
- ~~9.3.1 The number of organs allocated through the Organ Center.~~
- ~~9.3.2 Data reflecting Organ Center Activity (See Policy 9.6).~~
- ~~9.3.3 The number and final destination of kidneys placed internationally through the Organ Center.~~
- ~~9.4 SHARING ARRANGEMENTS. The names of institutions participating in interregional or intraregional sharing arrangements approved by the Board of Directors may be released.~~
- ~~9.5 MEMBERS. Listings of member institutions (including names of personnel) may be released.~~
- ~~9.6 PUBLIC RELEASE OF CENTER AND OPO ACTIVITY. Without obtaining permission from each member, the OPTN may release analysis results containing the following data:~~
- ~~9.6.1. Updated Center-specific waiting list activity, by organ type, including the number of candidates on the waiting list at the initiation of a period; the number of candidates added to the list; and the number of candidates removed from the list for death, transplant, and other reasons and, to the extent relevant to the organ type, the probability of survival on the waiting list within a specific period of time stratified by demographic and medical factors as determined appropriate by the Policy Oversight Committee (POC). These data may be presented on a calendar year basis and for~~

such portions of a calendar year as determined by the POC. Updated Center-specific waiting list size, by organ type, stratified by demographic and medical factors as determined appropriate by the POC.

- ~~9.6.2~~ Updated Center-specific or OPO-specific waiting time information, by organ type, stratified by demographic and medical variables as determined appropriate by the POC, and the probability of receiving a transplant within a specific period of time stratified by demographic and medical factors as determined appropriate by the POC.
- ~~9.6.3~~ Updated Center-specific risk-adjusted survival rate information, along with percentage of transplants with follow-up information, using data that may be validated by the member through UNetSM, by organ type, assessing transplants performed during a period that allows the OPTN contractor sufficient time to collect the data and compute the rates as determined by the POC. The adjusted, center-specific survival rate information may include, to the extent relevant to the organ type, the probability of survival pre-transplant, post-transplant and the probability of survival with or without a transplant. An appropriate period of analysis also will be determined by the POC.
- ~~9.6.4~~ Updated Center-validated transplant volumes as may be validated by the member through UNetSM, by organ type, stratified by demographic and medical factors as determined appropriate by the POC. These data may be presented on a calendar year basis and for such portions of the calendar year as determined by the POC. At a minimum, the following center volume information will be releasable:
 - ~~9.6.4.1~~ Center-specific transplant volume, by year, by organ type, using data that may be validated by the member through UNetSM, for recipients of a particular age.
 - ~~9.6.4.2~~ Center-specific transplant volume, by year, by organ type, using data that may be validated by the member through UNetSM, for recipients with a particular diagnosis.
 - ~~9.6.4.3~~ Center-specific transplant volume, by year, by organ type, using data that may be validated by the member through UNetSM, by deceased and living donor transplant.
 - ~~9.6.4.4~~ Center-specific multi-organ transplant volume, by year, by organ type, using data that may be validated by the member through UNetSM.
 - ~~9.6.4.5~~ Center-specific non-resident alien transplant volume, by year, by organ type, using data that may be validated by the member through UNetSM, by deceased and living donor transplant.

~~9.6.4.6 Center specific waiting list size on any given day, by organ type, according to the waiting list.~~

~~9.6.4.7 OPO specific data on the number of non-U.S. citizen organ donors, by year and by organ type, using data that may be validated by the members through UNetsm.~~

~~9.6.5 Center and OPO specific data submission compliance rates.~~

~~9.6.6 Updated OPO specific donor procurement volumes, using data validated by the member through UNetsm, including organ-specific authorization, procurement, and utilization volumes, by OPO; and numbers of donors by OPO, using data validated by the member through UNetsm, stratified by demographic and medical factors for such period(s) as determined appropriate by the POC.~~

~~9.6.7 Updated OPO specific organ transplant volume, using data validated by the member through UNetsm, showing number of organs procured, number of organs imported into the OPO, and number of organs exported from the OPO. These data may be presented on a calendar year basis and for such portions of a calendar year as determined by the POC. OPO specific organ transplant volume and size of waiting list, using data validated by the member through UNetsm, by organ type, stratified by demographic and medical factors for such period(s) as determined appropriate by the POC.~~

~~9.6.8 Updated OPO specific kidney payback debt and credit volumes, including number of short term payback debts, long term payback debts, and thresholds for reducing long term debt (please see Policy 3.5.4.2 (Kidney Payback Debt Limit) for definitions of “short term debt” and “long term debt”), for such period(s) as determined appropriate by the POC.~~

~~9.6.9 Center, OPO, or other organization specific data as approved by the Executive Committee, which the OPTN anticipates will be otherwise duly released by the Department of Health and Human Services (HHS) to the public, together with such explanatory or other text or material as the Executive Committee shall deem appropriate to assist readers in understanding the data.~~

~~9.7 **RELEASE OF CENTER SPECIFIC DATA.** The OPTN may release to OPO members such center specific data as are required for the OPOs to prepare reports or other documents required by the OPTN for the purposes of assessing the impact of variances, alternative local units and sharing agreements on organ allocation.~~

~~9.8 **REVIEW OF INSTITUTION SPECIFIC DATA.** During the data validation process, the OPTN may release to institutional members for their review such primary data as may be needed for institution specific reports for public release.~~

For example, donor and histocompatibility data about transplants performed at a center may be sent to that center for review (but not for modification without instruction to the OPTN contractor by original institution submitters). Conversely, for these purposes, laboratories and OPOs may receive relevant data submitted to the OPTN by transplant centers. The institutions that receive the data will not publish or publicly disseminate outcomes of specific recipients, physicians or institutions.

9.9 ACCESS TO RECIPIENT OUTCOMES DATA. OPOs may receive recipient outcomes data, without permission from the transplant center, for each donor organ transplanted. This information would be used in determining the appropriateness of donor selection and management techniques as well as quality assurance of the procurement process. The data would be accessed and downloaded through the UNetsm system. The institutions that receive the data will not publish or publicly disseminate outcomes of specific recipients, physicians or institutions. These data fields are located on the Transplant Recipient Registration Forms and include:

9.9.1 Recipient Status (all organs)

- Living — date of hospital report
- Dead — date and cause of death
- Re-transplanted prior to hospital discharge — date
- Cause of retransplant (thoracic only)

9.9.2 Clinical Information at Discharge (kidneys only)

- Most recent serum creatinine prior to discharge
- Did kidney produce >40 ml of urine in first 24 hours?
- Did recipient need dialysis within first week?
- Did creatinine decline by 25% or more in first 24 hours on two separate serum samples taken within first 24 hours?

9.9.3 Graft Status at Discharge (kidney, liver and pancreas only)

- Functioning or failed
- If failed, date and cause

9.9.4 Preservation Information (all organs)

9.10 OTHER INFORMATION. Information brought before the Board of Directors in public sessions may be released. Any requests for more detailed information or data will be processed according to the guidelines set forth in Policy 10.0.

9.11 RELEASE OF HLA TYPE OF A RECIPIENT'S PRIOR DONOR. The OPTN contractor may release a recipient's prior donor's HLA type to a transplant center if the recipient is under that center's care, or to the laboratory that provides services to that transplant center, without obtaining permission from the transplant center that performed the original transplant or the laboratory that performed the donor's typing.

9.12 RELEASE OF HLA TYPE OF DONORS AND RECIPIENTS WITH

~~**LABORATORY NAME AND IDENTIFIER.** The OPTN may release the HLA type of deceased donors and recipients with the name and identifier of the laboratory that performed the typing to member laboratories for the purpose of resolving discrepant donor and recipient HLA typing results as set out in Appendix C to Policy 3.0 without obtaining permission from each member laboratory.~~

~~10.0 ACCESS TO DATA~~

~~**10.1 ACCESS TO DATABASE.** Only OPTN contractor staff, or individuals engaged by or adjunct to contractor staff who are bound by contracts which prohibit competing interests and breaches of confidentiality, will be permitted to program UNetSM or have direct access to data within UNetSM or maintained in any other form. OPTN members requesting access to data regarding their own candidates and recipients will be provided access to that information when practicable as determined by the OPTN Project Director. Except as provided for in Policy 9.0 and this Policy 10.2 and Policy 10.3, neither individuals nor members will be given access to individual candidate, recipient or member specific information other than that from their own organization, without prior written approval from those individuals or members identified. Candidate, recipient and institution-identified data will be made available to the Scientific Registry for Transplant Recipients (SRTR) Contractor.~~

~~**10.2 TRANSFER OF INFORMATION.** All requests for data should be made through the Data Request System. Routinely available data will comprise the following:~~

- ~~• Data provided in regularly updated Standard Reports;~~
- ~~• Data requested by OPTN members regarding their own institution and/or candidates and recipients;~~
- ~~• Data requested by the Department of Health and Human Services.~~

~~Requests involving twenty hours or more of programming time or any statistical analyses that are considered to be extensive may be subject to additional requirements (see Policy 10.3, Specific Projects).~~

~~Unless they are releasable according to Policy 9.0 or Policy 10.2, data will be provided with the deletion of all candidate, recipient and center specific identifying information. Comprehensive datasets with center and candidate and recipient identifying information encrypted may be given out for research purposes with the approval of the Policy Oversight Committee (its chair plus representative committee members). Under some circumstances, center specific data (standard analysis files) not otherwise releasable may be provided to bona fide researchers, subject to the approval of the Policy Oversight Committee using as guidance the Agreement for Release of Data, as approved by that Committee. In order to obtain these data, the submitting individual must meet the conditions for their release and sign an Agreement for Release of Data, which sets forth confidentiality and security stipulations for the data's release and use. Such data may be provided on a cost reimbursement basis. Use of such data will require written acknowledgment of the source of the data and the date it was provided~~

~~(see Policy 10.4). As contractually required, the OPTN contractor may release records which are identifiable as to candidate, recipient, transplant center or OPO without a signed Agreement for Release of Data only pursuant to official requests for data from the Department of Health and Human Services in accordance with federal or state laws and regulations.~~

~~**10.3 SPECIFIC PROJECTS.** Any individual or group requesting data requiring twenty or more hours of programming time and/or any statistical analysis of a specific question by the OPTN contractor staff may be asked to submit a written concept paper to the Policy Oversight Committee. The Policy Oversight Committee (its chair plus representative committee members) will vote to approve or disapprove each request, and may also prioritize approved requests, based on scientific or clinical merit, importance to the OPTN, and the potential ability to address the question. The approval and priority status of each request will be provided to the submitting individual. Upon approval, the submitting individual will be notified of the OPTN contractor staff assigned to complete the request. The submitting individual must indicate to the assigned staff whether he/she wishes to be directly involved in the analysis and the project work group.~~

~~Data will be provided with the deletion of all candidate and recipient specific identifying information. Center identifiers may be provided to bona fide researchers who meet the conditions specified in Agreement for Release of Data, which sets forth confidentiality and security stipulations for the data's release and use. Such data may be provided on a cost reimbursement basis. Use of such data will require written acknowledgment of the source of the data and the date it was provided (see Policy 10.4).~~

~~**10.4 PUBLIC USE, PRESENTATIONS AND PUBLICATIONS.** All scientific data provided and/or analyses performed by the OPTN contractor utilizing data collected for the OPTN must adhere to the following specific requirements regarding approval, content, confidentiality, and authorship:~~

~~**10.4.1 Public Use or Presentation of Specific Projects or Studies.** The scientific and analytical content of all abstracts or manuscripts developed from customized data requests, comprehensive encrypted datasets, or standard analysis files must be approved by the Policy Oversight Committee and any ad hoc work group appointed by that Committee prior to their public presentation or publication. If the analysis has not been provided prior to release by the investigator or institution, the OPTN contractor cannot assume responsibility for the correctness of the findings or interpretations. Failure to include the OPTN contractor in pre-release preparation may be an adverse consideration in subsequent applications by the investigator or institution for additional data. Any contractor staff who makes a significant intellectual contribution to a study abstract, presentation, or manuscript should be offered the opportunity to be included as an author. Contractor staff may not be listed as study authors without obtaining written permission from the appropriate staff. A copy of all published abstracts, manuscripts, or news releases should be~~

submitted to staff and/or the Policy Oversight Committee for informational purposes as soon as practicable.

~~**10.4.2 Data Obtained Through the Data Request System.** Abstracts and manuscripts prepared using routinely available data obtained through the data request system do not require approval by the Policy Oversight Committee. However, the source and date of the data obtained must be acknowledged in text and/or graphic presentations (e.g., "Based on OPTN data as of January 1, 2000"). A copy of each published abstract, manuscript, or news release should be submitted to OPTN contractor and/or the Policy Oversight Committee for informational purposes as soon as practicable. Publications that use data collected for the OPTN shall include the following notice: *The data reported here have been supplied by [XXX], the OPTN contractor. The interpretation and reporting of these data are the responsibility of the author(s) and in no way should be seen as an official policy or interpretation of the OPTN, or the U.S. Government.*~~

~~**10.5 COMMITTEE ACCESS TO DATA.** Confidential Information, as herein defined, shall not be made available in a public meeting. In a non-public forum or meeting setting, access to Confidential Information will be limited to members of the Board of Directors, members of permanent standing or ad hoc committees, OPTN contractor staff and individuals engaged as an adjunct to contractor staff. Access will be limited to the above described individuals, provided that these individuals are performing functions on behalf of the OPTN and are either bound by a fiduciary responsibility to the OPTN or a contractual obligation to the OPTN contractor to maintain the confidentiality of such data and information. These individuals shall have no ownership right in or to any of the Confidential Information and maintenance of the Confidential Information shall be a private and confidential matter which is required for the continued success of the OPTN and its business. This Confidential Information includes but is not limited to financial data and information; data and information relating to procedural and substantive needs, problems, developments and projects; and data and information regarding organ donors and recipients and institutions and medical personnel involved in organ transplantation, which constitute sensitive medical data or information subject to federal or state confidentiality statutes and regulations, all of which constitute trade secrets or confidential information of the OPTN. All such data and information together with business practices and procedures of the OPTN will be referred to collectively as "Confidential Information."~~

~~At such time as it becomes necessary to present or review candidate and recipient specific or center specific data or other Confidential Information, such data or Confidential Information will be provided in individual packets for review at that non-public meeting only. At the conclusion of the meeting all individual packets will be collected by the administrative staff, and no such data or Confidential Information will be permitted outside the meeting room except that maintained by administrative staff and adjunct personnel. When practicable, the Confidential Information will be displayed electronically via overhead projection or~~

~~slide projection for discussion purposes thereby eliminating the need for individualized sets of the Confidential Information. Only OPTN contractor staff, or government staff pursuant to contractual requirements, will be able to retain the data or Confidential Information in written or electronic form.~~

~~In no event shall any person, other than OPTN contractor staff and adjunct personnel in attendance in any non-public meeting be permitted to have access to these data or Confidential Information outside the meeting room. Cooperation and compliance with these procedures will ensure the integrity of the OPTN and foster the trust of those who are associated with or who have dealings with the OPTN.~~

2. Geographic Disparities in Organ Allocation

The issue of addressing geographic disparities in organ allocation is one of the key goals outlined in the OPTN Strategic Plan that was approved by the Board of Directors in June 2012. It was noted that this issue is currently being addressed within some of the organ allocation systems. The ultimate goal of addressing this issue is to identify and eventually come up with equitable allocation and distribution to best meets the needs of the patients. The first step could be to evaluate current allocation algorithms and determine if they are appropriate in their current format or perhaps could be enhanced to promote a broader distribution of organs in a measurable manner that is associated with an improved outcome. The POC acknowledged that each allocation system works differently and it is unlikely that one overarching set of principles will apply across all the systems. It was noted that the first step could be to endorse some broad ideas that will guide the organ-specific committees as they begin to address whether current allocation meets the desired goals or whether there needs to be some changes to the different allocation paradigms that might include broader geographic units.

Some of the comments from the POC members include:

- Remove the business aspect from the discussions and think more about how to better serve the patients. What might be best for a transplant center might not be what is best for the population as a whole, especially for those waiting for an organ. Economic factors can be a barrier to making changes that are acceptable to the transplant community.
- Consider separating OPOs from transplant centers because the recovery and distribution of organs does not have to be coupled.
- There are a number of issues to be considered including access to transplant, organ wastage, cold ischemia time, donation rates, etc.
- Impact of any change on patients throughout the country. For example the impact on patients in Montana versus those in New York City.
- The Pediatric Committee is pilot testing regional sharing for highly-sensitized patients so one approach could be to take smaller steps.
- Balancing cost versus outcomes.
- Geography is a significant concern to the Ethics Committee
- Potentially identify patient populations that are disadvantaged.
- Philosophical shift in thinking about the field of transplantation today

HRSA noted that this is an important issue to them because the issue of geography is explicitly stated in the Final Rule. It was noted that the Advisory Committee on Transplantation approved a recommendation in 2010 that states organ allocation should be evidence-based and not based on the arbitrary boundaries of DSAs or OPOs. Allocation systems should minimize this variation and HRSA is supportive of any approach to do so.

The SRTR noted that it will be very important to clearly define what will be optimized by any change. For example, reduction in waitlist deaths or lower MELD scores at transplant, increased access to organs, etc. The SRTR can then create a model that shows a system that appears to best achieve what you are trying to accomplish. The SRTR also noted that it will be important to identify what constraints you are not willing to sacrifice. For example, if you want to avoid shipping organs if it takes 8 hours or if you don't want to have worse outcomes. These are issues that can be addressed by the individual committees.

It was noted that it will be important to build in an education piece so the transplant community will be aware of what is going on and why we are doing this. It will be important to collaborate with committees and other individuals and organization as we work towards defining fairness. It was noted that this will not be an easy thing to do and it will generate considerable discussion. There was a suggestion to utilize the new education department at UNOS to assist the POC and other committees.

The POC discussed the importance of having a timeline for this important work. There was considerable discussion about the appropriate timeline with some members wanting something done within a year. It was acknowledged that this is a huge project and that the first step is to get the Board to endorse the POC recommendations and provide specific guidance. The POC also agreed that a reasonable milestone would be to have committees define fairness by June of 2013. It was noted that although the resolution directs the organ-specific committees to define fairness, they will be encouraged to seek input from other committees as they move forward in development of their recommendations.

The Committee approved the following language to be considered by the Board. Committee vote: 16 in favor, 1 opposed, and 0 abstentions. The Executive Committee met on October 19, 2012, and recommended the resolution language be changed from "access to organ transplants" to "allocation of organs for transplant." The POC leadership agreed to this recommended change. The following is recommended for consideration by the Board:

**** RESOLVED, that the Board of Directors approve the following position regarding geography in organ allocation:**

- The existing geographic disparity in allocation of organs for transplant is unacceptably high.
- The Board directs the organ-specific committees to define the measurement of fairness and any constraints for each organ system by June 30, 2013. The measurement of fairness may vary by organ type but must consider fairness based upon criteria that best represent patient outcome.
- The Board requests that optimized systems utilizing overlapping versus non-overlapping geographic boundaries be compared, including using or disregarding current DSA boundaries in allocation.