

At-a-Glance

- **Proposal to Update Data Release Policies**
- **Affected Policies:** Policy 9 (Release of Information to the Public) and Policy 10 (Access to Data)
- **Policy Oversight Committee (POC)**

The proposed revisions to the OPTN Data Release Policies will combine Policy 9 and Policy 10 into a single policy (Policy 9 – Release of Data). The proposed changes will:

- Allow the OPTN Contractor to release more data than is currently released
- Provide an appeals process if the OPTN denies a data request
- Set requirements for the release of confidential information
- Allow the OPTN Contractor to release non-confidential data by institution to *any* requester
- Eliminate the list of data elements that can be released in special circumstances out of policy to allow for greater flexibility in data release.
- The process for release of person-identified data will not change.

During the evaluation of the policies as part of the Plain Language Rewrite Project, it was noted that the data release policies contained outdated elements that required substantive changes. The proposed revisions align these policies with current practice and present the information in a simpler format.

- **Affected group**

The proposed changes will affect any individual or institution that requests data from the OPTN Contractor

- **Number of Potential Candidates Affected**

No expected impact to candidates or recipients.

- **Compliance with OPTN Strategic Goals and Final Rule**

This proposal allows the OPTN Contractor to better comply with the directive in the Final Rule to “respond to reasonable requests from the public for data needed for bona fide research or analysis purposes, to the extent that the OPTN’s or Scientific Registry’s resources permit, or as directed by the Secretary.”

- **Specific Requests for Comment**

Does this proposal meet the needs of the public and transplant community for access to OPTN data?

Proposal to Update Data Release Policies

Affected Policies: Policy 9 (Release of Information to the Public) and Policy 10 (Access to Data)

Policy Oversight Committee

Summary and Goals of the Proposal:

The proposed revisions will combine Policy 9 and Policy 10 into a single policy (Policy 9 – Release of Data). The proposed changes will also:

- Allow the OPTN Contractor to release more data than is currently released
- Provide an appeals process if the OPTN Contractor denies a data request
- Set requirements for the release of confidential information
- Allow the OPTN Contractor to release non-confidential data by institution to *any* requester
- Eliminate the list of data elements that can be released in special circumstances to allow greater flexibility in data release
- The process for release of person-identified data will not change

During the evaluation of the policies as part of the Plain Language Rewrite Project, it was noted that the data release policies contained outdated elements that required substantive changes. The proposed revisions align these policies with current practice and present the information in a simpler format.

Background and Significance of the Proposal:

The OPTN 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 is being distributed separately from the rewrite project. Below are several of the larger changes that are in the proposed policy language:

- The proposed policy allows the OPTN Contractor to release more data than is currently released, but doesn't 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 of the OPTN Contractor 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 new policy would allow the OPTN to release any non-confidential data element by institution.* For example, under current policy, the OPTN Contractor is unable to release the number of HIV positive recipients by transplant center. Under the proposed language, the OPTN Contractor would be able to release these data by

institution to *any* requester, including the media, and OPTN policy would not restrict publication of data by institution.

- 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 approved by the POC. The current list is included as **Exhibit A** and will be made available on the OPTN website. This approach will give us 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 identified data to researchers.

Description of intended and unintended consequences:

The proposed changes allow the OPTN Contractor to release more data while maintaining patient confidentiality protections. However, allowing the release of data by institution to researchers and members of the press without restrictions could result in publication of analyses, whose quality will be beyond the control of the OPTN, that reflect poorly on transplant centers and OPOs.

Expected Impact on Living Donors or Living Donation:

Not applicable

Expected Impact on Specific Patient Population

There is no expected impact to candidates or recipients.

Expected Impact on Program Goals, Strategic Plan, and Adherence to OPTN Final Rule:

This proposal allows the OPTN Contractor to better comply with the directive in the Final Rule to “respond to reasonable requests from the public for data needed for bona fide research or analysis purposes, to the extent that the OPTN's or Scientific Registry's resources permit, or as directed by the Secretary.”

Additional Data Collection:

This proposal does not require additional data collection.

Expected Implementation Plan:

This proposal will not require programming in UNetSM.

Communication and Education Activities:

If the Board of Directors approves the proposed modifications, standard communication methods will be used to inform members.

Communication Activities			
Type of Communication	Audience(s)	Deliver Method(s)	Timeframe
Policy Notice following Board Approval (informs community that the proposed policy was approved by the OPTN/UNOS Board of Directors)	OPTN Members	E-mail	Distributed 30 days after Board approval
UNet SM System Notice upon implementation (informs the community about an automated solution to an approved policy)	OPTN Members	E-mail, UNet SM notice	Four weeks before the update to the UNet SM help documentation, and on the date of the update.

Compliance Monitoring:

UNOS staff will investigate any reports of noncompliance with policy or agreements.

Policy Proposal:

For the convenience of the reader, the proposed policy language for Policy 9 (Release of Data) is presented below without underlines as the entire section is new. The original policies can be found in **Exhibit B**.

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 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.

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 Extraordinary Data Requests

If a requestor requests an extraordinary volume of data or makes a request that requires an extraordinarily lengthy programming time or any statistical analysis by the OPTN Contractor, then the requestor must submit a written concept paper to the OPTN Contractor. The OPTN Contractor will review each request; approve or deny the request; and prioritize approved requests based on importance to the OPTN, scientific or clinical merit, and the potential ability to address the question.

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.
- *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.

The following are lists of data elements that will be releasable to a Member other than the Member that submitted the data.

These lists will be sent out for public comment with Policy 9, but will NOT be included in the actual policy language. Future changes to these lists will be approved by the POC.

ROOT Report: The report is available to any center that received an organ offer for an organ that was eventually transplanted. The report is posted monthly in the Secure Enterprise report section. It includes a rolling 5-year cohort.

DSA Report: This report is available to all OPOs that have had at least one organ transplanted in the time period (i.e., all active OPOs). The report is posted monthly in the Secure Enterprise report section. It includes a rolling 5-year cohort.

Listed below are recipient, donor, and match data elements that may be released to OPOs for each deceased donor organ recovered by the OPO and/or to transplant centers for each deceased donor organ offer received by the center.

Unless denoted by an asterisk, each element could appear in either the DSA Report or the ROOT Report.

Donor elements:

ABO
Age (years)
Bilirubin
BMI (categorized)
COD
Diabetes
ECD DCD / KDRI
Final creatinine for donor
Gender
Height (cm)
Hist of malignancy
Hypertension
PHS high risk
Serology results
Social history
Sodium
Weight (kg)
Donor ID
DSA
Dual Kidney recipient
Match date
Match ID
Match run list type (organ)
Number of candidates refused per refusal reason given
Number of centers after last offer*
Number of centers before first offer*
Offer accepted (Y/N)?
Organ transplanted?
Reason organ refused
Recovered in local DSA?***
Sequence Number (acceptor)

Recipient pre-transplant or transplant elements (if the organ was transplanted elsewhere this would be information about the actual recipient and would be provided in the ROOT Report to other centers that refused the organ (includes listing center code):

ABO
Age (category)
Diagnosis (category)
Ejection fraction
Gender
Ischemia time
LAS
Wait list status at transplant
Listing center
Own center accepted organ for transplant?*
Transplanted at own center?*

Post-transplant elements:

ALT at discharge
Cause of graft failure
Cause of death
Creatinine at 1 and 3 years
Dialysis in first week
EF at 1 yr
Graft status
Graft survival (days)
LFT at discharge
Patient status
Patient survival (days)
Require insulin after transplant?
Tbili at 6 mo and 1 yr

*DSA Report only

**ROOT Report only

OPO Report (in UNet) This report is available to Organ Procurement Organizations through the Tiedi® application. The report provides, for donors that the OPO recovered, current patient and graft status for organs that were transplanted. It also includes information on ischemia times and early kidney function for kidney transplants.

1. Donor Ctr
2. Donor Id/Name
3. Expanded Criteria Donor
4. RecovDt
5. TxCenter
6. Tx Date
7. Recipient name
8. CurrPxStat
9. CurrPxStatDt
10. CauseofDeath(COD) - recipient
11. Organ
12. GrftFunction? (failed or not?)
13. GrftFailDt
14. GrftFailCause
15. Isch/Preservation (R/L)-Thor(min)IN,PA(hrs)
16. Isch time (R/L)-KI/LI Cold (hrs)
17. Isch Time(R/L)-KI/LI Warm (mins)
18. 1stWkDialysis
19. Urine24Hrs
20. PreTxCreat
21. DischCreat
22. CreatDecline24Hrs

Discrepant HLA typings reports. These reports are designed to show the HLA data of deceased donors and recipients typed by the Laboratory when discrepant HLA information is reported to the OPTN and collect reasons for discrepancies. Reports are available to Histocompatibility Laboratories through the Tiedi® application. By OPTN policy, Laboratories are required to resolve HLA discrepancies. The discrepancy remains unresolved until reasons for discrepancies are provided by all involved Laboratories. Reports show information for unresolved discrepancies only.

Donor report for unresolved discrepancies:

HLA information of deceased kidney, pancreas, and kidney-pancreas donors typed by the laboratory when discrepant HLA information is reported to the OPTN. Discrepancies are identified by comparing donor HLA on the donor and recipient histocompatibility forms:

1. Donor ID
2. Laboratory
3. Place where HLA was entered (donor or recipient histocompatibility form)
4. Date of HLA typing
5. HLA typing method
6. HLA antigens (HLA-A, B, Bw4, Bw6, DR antigens)
7. The reasons for discrepancy provided by laboratories

Recipient report for unresolved discrepancies:

HLA information of kidney, pancreas, and kidney-pancreas deceased donor transplant recipients typed by the laboratory when discrepant HLA information is reported to the OPTN. Discrepancies are identified by comparing recipient HLA at the time of removal from the waiting list with HLA on the recipient histocompatibility form :

1. Recipient SSN
2. Laboratory
3. Place where HLA was entered (waiting list or recipient histocompatibility form)
4. Date of HLA typing
5. HLA typing method
6. HLA antigens (HLA-A, B, Bw4, Bw6, DR antigens)
7. The reasons for discrepancy provided by laboratory

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 consent, 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.