Proposal to Revise OPTN/UNOS Data Release Policies

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Proposal to Revise OPTN/UNOS Data Release Policies

Summary

Current OPTN/UNOS policy restricts the release of organ procurement organization (OPO)- and hospital-identified data, even though the OPTN Final Rule (the Final Rule) requires the OPTN to release data in response to “reasonable requests from the public for data needed for bona fide research or analysis purposes” and “reasonable requests from the public for data needed to assess the performance of the OPTN or Scientific Registry, to assess individual transplant programs, or for other purposes.”¹ The Health Resources and Services Administration (HRSA) clarified that this portion of the Final Rule applies to release of data that is identified by transplant hospital or OPO, and therefore OPTN/UNOS policy is not consistent with the Final Rule. The OPTN/UNOS Data Advisory Committee (DAC) is proposing changes in response to this interpretation of the Final Rule.

This proposal revises the OPTN/UNOS Data Release policy to better align with the Final Rule by removing restrictions on the release of OPTN data. This will allow the OPTN contractor to release more data than are currently released, including any non-confidential data by institution (e.g., data identifiable by transplant hospital, histocompatibility lab, or OPO). As allowed in the Final Rule, UNOS staff will still evaluate data requests for reasonableness, but the process for doing so will not reside in OPTN policy.

Is the sponsoring Committee requesting specific feedback or input about this proposal?

DAC requests that reviewers comment on the following issues, as well as any comments on the overall document.

1. Is the proposed policy language consistent with the requirements of the Final Rule?
2. Are the proposed Standard Operating Procedures for Review of OPTN Data Requests (Exhibit A), which will not reside in OPTN/UNOS policy, sufficient for the needs of the OPTN’s constituents and appropriately transparent?

¹ Organ Procurement and Transplantation Network Final Rule, 42 CFR §121.11. 
Proposal to Revise OPTN/UNOS Data Release Policies


Sponsoring Committee: OPTN/UNOS Data Advisory Committee

Public Comment Period: August 14 – October 14, 2015

What problem will this proposal solve?
Current OPTN/UNOS policy restricts the release of organ procurement organization (OPO)- and hospital-identified data, even though the OPTN Final Rule (the Final Rule) requires the OPTN to release data in response to “reasonable requests from the public for data needed for bona fide research or analysis purposes” and “reasonable requests from the public for data needed to assess the performance of the OPTN or Scientific Registry, to assess individual transplant programs, or for other purposes.” The Health Resources and Services Administration (HRSA) clarified that this portion of the Final Rule applies to release of data that is identified by transplant hospital or OPO, and therefore OPTN policy is not consistent with the Final Rule. The OPTN/UNOS Data Advisory Committee (DAC) is proposing changes in response to this interpretation of the Final Rule. This policy change would allow the OPTN to release data, such as the number of HIV-positive recipients transplanted at each transplant program, by institution, and it could allow patients to make informed decisions about their care based on information about a particular program’s experience or outcomes. The OPTN will evaluate the reasonableness of all requests for data.

Why should you support this proposal?
The proposed solution ensures that OPTN policies and processes remain consistent with the Final Rule, and permits the OPTN to release data that will allow the public to perform research and independently evaluate OPTN members.

How was this proposal developed?
The OPTN/UNOS Policy Oversight Committee initially sought to revise the OPTN/UNOS Data Release Policy in 2012, but the proposal was not completed due to a lack of consensus in the community. During the February 10, 2015 DAC meeting, HRSA explained that the current OPTN/UNOS Data Release policy is not consistent with the Final Rule because it imposes more restrictions on the release of hospital-, and OPO-identifiable data than is allowed by the Final Rule, and it must be revised. In response, UNOS staff, DAC members, the Scientific Registry of Transplant Recipients (SRTR) Contractor, and HRSA reviewed

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3 http://optn.transplant.hrsa.gov/PublicComment/pubcommentPropSub_310.pdf
the current OPTN/UNOS data release policy to identify areas that are inconsistent with the requirements of the Final Rule. DAC’s Data Release Policy Subcommittee met multiple times by phone during the spring of 2015 to achieve consensus on the areas of the policy that needed to be revised.

DAC developed language that removed the restrictions for releasing transplant hospital- and OPO-identifiable data. It also included a detailed table explaining when it is appropriate to release person-identifiable data, and to whom it could be released. Other provisions included restrictions on the release of confidential information.

Based on feedback provided by HRSA, DAC elected to propose an amended policy that simply confirms that the OPTN will release OPTN data according to the Final Rule and other applicable laws and regulations. The remainder of the language developed by DAC will be maintained in standard operating procedures for data release outside OPTN policy (Exhibit A). DAC discussed and voted on the final proposed policy language on its June 17, 2015 conference call and voted to send the proposal for public comment. DAC also voiced their opinion that the standard operating procedures for data release be made publicly available for transparency.

How well does this proposal address the problem statement?
This proposal revises the OPTN/UNOS Data Release Policy to remove restrictions that are not permitted by the Final Rule. This will allow the OPTN contractor to release more data than are currently released, including any non-confidential data by institution. Examples of data that currently are not releasable under current policy, but would be releasable under the proposed policy, include the number of HIV positive liver recipients by transplant hospital, and de-identified patient-level Standard Analysis and Research (STAR) files that include transplant hospital and OPO identifiers.4

HRSA representatives and the U.S. Department of Health and Human Services (DHHS) legal counsel reviewed the proposed policy language and determined that the proposed changes make the OPTN/UNOS data release policy consistent with the requirements of the Final Rule. Furthermore, the protections for person-identified and person-identifiable data remain intact, as other laws, such as the Health Insurance Portability and Accountability Act (HIPAA)5 and the Privacy Act6, impose restrictions on the OPTN’s ability to release such data. Therefore, including such restrictions in policy is redundant and unnecessary.

As allowed by the Final Rule, UNOS staff will still evaluate data requests for reasonableness, but the process for doing so will not reside in OPTN policy. For transparency, the OPTN will make this process publicly available. The process for release of person-identified data (e.g., patient name or Social Security Number) will not change. Person-identified OPTN data are permitted to be given to researchers for bona fide research purposes, but the OPTN contractor fulfills only requests for these data that are approved by HRSA. This is permitted by the Final Rule, which states, “Patient-identified data may be made available to bona fide researchers upon a showing that the research design requires such data for matching or other purposes, and that appropriate confidentiality protections, including destruction of patient identifiers upon completion of matching, will be followed.”7

The Final Rule also requires the OPTN contractor to “Respond to reasonable requests from the public for data needed to assess the performance of the OPTN or Scientific Registry, to assess individual transplant programs, or for other purposes.”8 The new policy would also allow the OPTN to release any non-confidential data element by hospital or OPO. For example, under current policy, the OPTN contractor is unable to release the number of HIV positive recipients by transplant hospital. Under the proposed

4 For more information on STAR files, visit http://optn.transplant.hrsa.gov/converge/data/request_main.asp?refer=true
7 Final Rule 121.11(b)(v)
8 Final Rule 121.11(b)(vi)
language, the OPTN contractor would be able to release these data by transplant hospital to any requester, and OPTN policy would not restrict publication of data by institution.

Allowing the release of data by institution could result in publication of analyses that reflect poorly on transplant hospitals and OPOs and whose quality will be beyond the control of the OPTN. While this is a concern to some members, providing this type of protection to institutions is not under the purview of the OPTN. Conversely, releasing this information may result in research that provides a great benefit to patients, OPTN members, and policy-makers.

Removing restrictions on the release of hospital- and OPO-identified OPTN data could also have the unintended effect of making patient-level datasets (e.g., STAR files) more easily identifiable for certain small populations, such as pediatric patients or intestinal transplant recipients. This concern is mitigated by the requirement in the OPTN’s standard operating procedures for data release that all persons who receive patient-level data sign a data use agreement in which they promise not to attempt to identify patients in the dataset. The OPTN is permitted to require requestors to sign a data use agreement, as the Final Rule states that “Patient-identified data may be made available to bona fide researchers upon a showing that the research design requires such data for matching or other purposes, and that appropriate confidentiality protections, including destruction of patient identifiers upon completion of matching, will be followed.”

After reviewing the Final Rule and all applicable laws and regulations, the DAC is confident that the proposed changes will align OPTN policies with the Final Rule, make data more readily available to the public and to researchers, and maintain confidentiality protections.

Which populations are impacted by this proposal?
This proposal affects the release of all OPTN data and therefore affects all candidates, recipients, donors, and OPTN members whose data reside in the OPTN database.

How does this proposal support the OPTN Strategic Plan?
*Increase the number of transplants:* There is no impact to this goal.

*Improve equity in access to transplants:* There is no impact to this goal.

*Improve waitlisted patient, living donor, and transplant recipient outcomes:* There is no impact to this goal.

*Promote living donor and transplant recipient safety:* There is no impact to this goal.

*Promote the efficient management of the OPTN:* This proposal makes OPTN policy consistent with the requirements of the Final Rule.

How will the sponsoring Committee evaluate whether this proposal was successful post implementation?
OPTN staff will provide DAC regular updates on whether the revised policy language and standard operating procedures for OPTN data requests have been sufficient for processing all requests for OPTN data that were received by the OPTN.

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9 Final Rule 121.11(b)(v)
How will members implement this proposal?
Members will not need to do anything to comply with this policy. Both members and the public will have access to more OPTN data. The process for requesting institution-identified OPTN data will be publicly available.

Will this proposal require members to submit additional data?
This proposal does not require additional data collection.

How will the OPTN implement this proposal?
The OPTN will work with HRSA and the SRTR contractor to develop standard operating procedures for responding to OPTN data requests to guide the implementation of the proposal. This proposal will not require programming in UNet\textsuperscript{SM}.

How will members be evaluated for compliance with this proposal?
Members will not need to do anything to comply with this policy and will not be evaluated for compliance with the policy.
Policy 19: Data Release

The OPTN Contractor will release OPTN data according to the Final Rule and other applicable federal and state laws and regulations. The OPTN Contractor will release all OPTN data requested by the Secretary of the Department of Health and Human Services (HHS).

19.1 Mailing Lists

Lists showing members' or program directors' names with addresses or telephone numbers may be released, only if both of the following requirements are met:

1. The Executive Director deems the request to be for a legitimate, non-commercial purpose furthering the objectives of the OPTN.
2. The OPTN Contractor receives an executed agreement restricting the use of the information for the permitted purpose.

19.2 Composite Demographic Data

The OPTN Contractor may release to the public any composite demographic national, regional, or state data that is provided to HRSA through the OPTN Contract, such as the following:

- The number of transplant recipients, according to organ type, ethnicity, blood type, gender, and age...
The number of candidates on the Waiting List according to organ type, ethnicity, blood type, gender, and age.
The number and outcome of organs recovered.

19.3 Organ Center Data

The OPTN Contractor may release to the public composite Organ Center information such as the following:
The number of organs allocated through the Organ Center.
Data reflecting Organ Center activity.
The number and final destination of kidneys placed internationally through the Organ Center.

19.4 Sharing Arrangements

The OPTN Contractor may release to the public the names of members participating in sharing arrangements approved by the Board of Directors.

19.5 Members

The OPTN Contractor may release to the public listings of members (including names of personnel).

19.6 Public Release of Transplant Hospital and OPO Activity

The OPTN Contractor may release to the public, without obtaining permission from each member, the analysis results containing the following data:

1. Updated transplant hospital-specific waiting list activity, by organ type, including but not limited to 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.

2. Updated transplant hospital-specific waiting list size, by organ type, stratified by demographic and medical factors as determined appropriate by the POC.

3. Updated transplant hospital-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.

4. Updated transplant hospital-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 the OPTN Contractor, 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, transplant hospital-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.

5. Updated transplant hospital-validated transplant volumes as may be validated by the member through the OPTN Contractor, 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 OPTN Contractor may release the following transplant hospital volume information:
Transplant hospital-specific transplant volume, by year, by organ type, using data that may be validated by the member through the OPTN Contractor, for recipients of a particular age.

Transplant hospital-specific transplant volume, by year, by organ type, using data that may be validated by the member through the OPTN Contractor, for recipients with a particular diagnosis.

Transplant hospital-specific transplant volume, by year, by organ type, using data that may be validated by the member through the OPTN Contractor, by deceased and living donor transplant.

Transplant hospital-specific multi-organ transplant volume, by year, by organ type, using data that may be validated by the member through the OPTN Contractor.

Transplant hospital-specific non-resident alien transplant volume, by year, by organ type, using data that may be validated by the member through the OPTN Contractor, by deceased and living donor transplant.

Transplant hospital-specific waiting list size on any given day, by organ type, according to the waiting list.

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 the OPTN Contractor.

Transplant hospital- and OPO-specific data submission compliance rates.

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

Updated OPO-specific organ transplant volume, using data validated by the member through the OPTN Contractor, 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 the OPTN Contractor, by organ type, stratified by demographic and medical factors for such period(s) as determined appropriate by the POC.

Transplant hospital, 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 deems appropriate to assist readers in understanding the data.

19.7 Release of Transplant Hospital Specific Data

The OPTN Contractor may release to OPO members such transplant hospital 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.

19.8 Review of Member Specific Data

During the data validation process, the OPTN Contractor may release to members for their review such primary data as may be needed for member specific reports for public release. For example, donor and histocompatibility data about transplants performed at a transplant hospital may be sent to that transplant hospital for review (but not for modification without instruction to the OPTN Contractor by the original institution submitters). Conversely, for these purposes, laboratories and OPOs may receive relevant data submitted to the OPTN Contractor by transplant hospitals. The members that receive the data will not publish or publicly disseminate outcomes of specific recipients, physicians, or institutions.

19.9 Access to Recipient Outcomes Data

OPOs may receive recipient outcomes data, without permission from the transplant hospital, for each deceased donor organ transplanted. This information would be used in determining the appropriateness
of deceased donor selection and management techniques as well as quality assurance of the
procurement process. The data would be accessed and downloaded through the OPTN Contractor. The
members 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 all of the following:

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)

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?

Transplanted kidney, liver or pancreas status at discharge

- Functioning or failed
- If failed, date and cause
- Preservation Information (all organs)

19.10 Information Brought before the Board of Directors

The OPTN Contractor may release to the public any information brought before the Board of Directors in
public sessions.

19.11 Release of Human Leukocyte Antigen (HLA) Type of a
Recipient’s Prior Donor

The OPTN Contractor may release a recipient’s prior donor’s HLA type to a transplant hospital if the
recipient is under that transplant hospital’s care, or to the laboratory that provides services to that
transplant hospital, without obtaining permission from the transplant hospital that performed the original
transplant or the laboratory that performed the donor’s typing.

19.12 Release of HLA Type of Donors and Recipients with
Laboratory Name and Identifier

The OPTN Contractor may release, without obtaining permission from each member laboratory, 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 Policy 4.4: Resolving Discrepant Donor and Recipient HLA Typing Results.

19.13 Access to Database

Only OPTN Contractor staff, or individuals engaged by or adjunct to Contractor staff who are bound by
contracts that prohibit competing interests and breaches of confidentiality, will be permitted to program or
have direct access to data within the OPTN computer match program, or waiting list, or maintained in any
other form. 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. Unless
permitted elsewhere in policy, 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.

49.14 Transfer of Information

All requests for data should be made through the Data Request System. Requests involving twenty hours or more of programming time or any statistical analyses that are considered to be extensive may be subject to the additional requirements in Policy 19.15: Specific Projects.

Unless permitted by this Policy, data will be provided with the deletion of all candidate, recipient and transplant hospital specific identifying information. Comprehensive datasets with transplant hospital and candidate and recipient identifying information encrypted may be given out for research purposes with the approval of the POC.

Under some circumstances, transplant hospital-specific data (standard analysis files) not otherwise releasable may be provided to bona fide researchers, subject to the approval of the POC using as guidance the Agreement for Release of Data, as approved by the POC. 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 must meet the requirements of Policy 19.16: Public Use, Presentations, and Publications.

As required by the OPTN contract, the OPTN Contractor may release records which are identifiable as to candidate, recipient, transplant hospital 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.

19.15 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 POC. The POC (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. Transplant hospital 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, as required by Policy 19.16: Public Use, Presentations, and Publications.
19.16 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.

19.16.A 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 POC 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 that 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 POC for informational purposes as soon as practicable.

19.16.B 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 POC. Routinely available data will comprise all of the following:

1. Data provided in regularly updated standard reports
2. Data requested by OPTN members regarding their own institution or candidates and recipients
3. Data requested by the Department of Health and Human Services

However, the source and date of the data obtained must be acknowledged in text or graphic presentations. A copy of each published abstract, manuscript, or news release should be submitted to OPTN Contractor and/or the POC for informational purposes as soon as practicable. Publications that use data collected for the OPTN will 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 authors and in no way should be seen as an official Policy or interpretation of the OPTN, or the U.S. Government.

19.17 Committee Access to Data

Confidential Information, as herein defined, will 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 will have no ownership right in or to any of the Confidential Information and maintenance of the Confidential Information will 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 deceased and living 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 transplant hospital-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 will 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.
Standard Operating Procedures for Review of OPTN Data Requests

The OPTN Contractor will release OPTN data according to the Final Rule, and other applicable federal and state laws and regulations. The OPTN Contractor will release all OPTN data requested by the Secretary of the Department of Health and Human Services.

The OPTN Contractor reviews all requests for OPTN data according to the Final Rule and other applicable federal and state laws and regulations and, as allowed in the Final Rule, can impose reasonable charges for the separable costs of responding to data requests.

Requests for Person-Identified Data
The OPTN Contractor may release person-identified data according to the following Table.

<table>
<thead>
<tr>
<th>Release of Person-Identified Data by the OPTN Contractor</th>
</tr>
</thead>
<tbody>
<tr>
<td>If the requestor is…</td>
</tr>
<tr>
<td>An individual</td>
</tr>
<tr>
<td>Anyone granted authorization to receive information about an individual</td>
</tr>
</tbody>
</table>
| A member | • Data previously submitted by that member to the OPTN Contractor  
| | • Data that are necessary for that member to prepare a report required by the OPTN Contractor  
| | • Data that enable the OPTN Contractor to fulfill its obligations under the OPTN contract |
| An OPO | Recipient characteristics and outcomes data for each transplanted organ that was recovered by that OPO |
| A transplant hospital | • Recipient characteristics and outcomes for each organ offer received by that transplant program  
| | • Whether the transplant program’s candidate is registered on the waiting list at more than one transplant program, according to Policy 3.4.G: Multiple Transplant Program Registrations. |
| A transplant hospital or its affiliated histocompatibility laboratory | Prior donor’s HLA information for any recipients under that transplant program’s care |
If the requestor is… | Then the OPTN Contractor may release the following person-identified data:
---|---
A histocompatibility laboratory | HLA information of deceased donors and recipients typed by that laboratory when discrepant HLA information is reported to the OPTN Contractor
Anyone authorized to receive data, according to federal laws and regulations | Data approved by the U.S. Department of Health and Human Services (HHS), according to federal laws and regulations

Requests for Person-Level De-Identified Data (e.g., STAR files)

Before receiving person-level de-identified data from the OPTN Contractor, requestors must submit a signed data use agreement (DUA) to the OPTN Contractor. The DUA must contain both of the following agreements:

1. The requestor agrees to neither attempt, nor permit others to attempt, to learn the identity of any person whose information is contained in the data.
2. The requestor agrees to include the disclaimer in the signed DUA in any publication using the released data.

Requests for Confidential Information

The OPTN Contractor will release confidential information if the following requirements are met:

**Requirements for Release of Confidential Information**

| The requestor is at least one of the following: | And both of the following are true:
---|---
• Bound by a fiduciary responsibility to the OPTN Contractor | 1. The request is necessary to perform an OPTN function on behalf of the OPTN Board of Directors or an OPTN Committee
• Contractually obligated to the OPTN Contractor to maintain the confidentiality of the released information | 2. The OPTN Contractor approves the request
• Acting on behalf of the OPTN Board of Directors | 
• Acting on behalf of an OPTN Committee |

Requests for Personnel Information at Member Institutions

The OPTN Contractor will release contact information for personnel at member institutions only if both of the following requirements are met:

1. The requestor submits a signed data use agreement (DUA) to the OPTN Contractor
2. The OPTN Contractor approves the request