

Proposed Modifications to UNOS Policy 9.0 (Release of Information to the Public)

Summary

The proposed policy changes are made in part as a result of new regulatory and contractual requirements and in part as an ongoing review process of relevant policies by the Data Advisory Committee. The proposed policy changes would allow the release of information and data that had not previously been published and made available to the public.

Background

Policy 9.0 addresses information and data collected by UNOS as the OPTN contractor which can be released to the public. This includes information and data in the following areas: Mailing Lists, OPTN Data, Organ Center Data, Sharing Arrangements, Center and OPO Activity, Review of Institution Specific Data, and Recipient Outcomes Data.

Policy Proposal

The major modifications are in Policy 9.6 (Public Release of Center and OPO Activity). Previously this Policy allowed the release of information if these data were part of a current or previously published UNOS report which is available to the public. This restriction has been removed from the proposed Policy.

In May 2001 the Data Advisory Committee, by unanimous vote, approved the following motion, which was discussed and approved by the Board of Directors at the June 2001 Board meeting:

RESOLVED, that Policy 9.0 (Release of Information to the Public), as amended, shall be approved effective June 29, 2001, and submitted for public comment, concurrently.

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 UNOS 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) UNOS receives an executed agreement restricting the use of the information for the permitted purpose.

9.2 OPTN 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, ~~sex~~gender, and age.

9.2.2 The number of patients on the UNOS Patient Waiting List according to organ type, race, ABO blood group, ~~sex~~gender, and age.

9.2.3 The number and disposition of organs retrieved.

9.3 ORGAN CENTER DATA. Composite UNOS Organ Center information such as the following may be released:

9.3.1 The number of organs allocated through the UNOS Organ Center.

9.3.2 Data reflecting UNOS Organ Center Activity (See Policy 9.6).

9.3.3 The number and final destination of kidneys placed internationally through the UNOS Organ

Center.

9.3.4 The number of historic "UNOS/STAT" designations.

9.4 SHARING ARRANGEMENTS. The names of institutions participating in interregional or intraregional sharing arrangements approved by the UNOS Board of Directors may be released.

9.5 OPTN MEMBERS. Listings of OPTN member institutions (including names of personnel) may be released.

9.6 PUBLIC RELEASE OF CENTER AND OPO ACTIVITY. Without obtaining permission from each member, UNOS may release ~~reports~~ analysis results containing the following data:

~~9.6.1 Updated Center validated transplant volumes as validated by the member through UNetsm, by organ type, stratified by demographic and medical factors as determined appropriate by the UNOS Scientific Advisory Committee. These data may be presented on a calendar year basis and for such portions of a calendar year as determined by the UNOS Scientific Advisory Committee. These data may be released in whole or as part of a current or previously published UNOS report which is available to the public.~~

9.6.1.2 Updated Center-specific waiting list activity, by organ type, including the number of patients on the waiting list at the initiation of a period; the number of patients added to the list; and the number of patients 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 UNOS Scientific Data Advisory Committee. These data may be presented on a calendar year basis and for such portions of a calendar year as determined by the UNOS Scientific Data Advisory Committee. Updated Center-specific waiting list size, by organ type, stratified by demographic and medical factors as determined appropriate by the Scientific Data Advisory Committee. ~~These data may be released in whole or as part of a current or previously published UNOS report which is available to the public.~~

~~9.6.23~~ Updated Center-specific or OPO-specific waiting time information, by organ type, stratified by demographic and medical variables as determined appropriate by the UNOS Scientific Data Advisory Committee, and the probability of receiving a transplant within a specific period of time stratified by demographic and medical factors as determined appropriate by the UNOS Scientific Data Advisory Committee. ~~These data may be released in whole or as part of a current or previously published UNOS report which is available to the public.~~

~~9.6.34~~ Updated Center-specific ~~one and/or six month and one year, three or five year~~ risk adjusted survival rate information, along with percentage of transplants with follow-up information, using ~~data validated data that may be validated~~ by the member through UNetsm, by organ type, assessing transplants performed during a period that allows UNOS Research Staff sufficient time to collect the data and compute the rates as determined by the UNOS Scientific Data Advisory Committee. 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 Scientific Data Advisory Committee. ~~These data may be released in whole or as part of a current or previously published UNOS report which is available to the public.~~

~~9.6.45~~ Center specific transplant volume, by organ type, not time related, for recipients of a particular age. Updated Center-validated transplant volumes as validated by the member through UNetsm, by organ type, stratified by demographic and medical factors as determined appropriate by the Data Advisory Committee. These data may be presented on a calendar year basis and for such portions of the calendar year as determined by the Data Advisory

Committee. At a minimum, the following center volume information will be releasable:

- 9.6.45.1 Center-specific transplant volume, by year, by organ type, using data that may be validated by the member through UNetsm, not time related, for recipients of a particular age for a particular diagnosis.
- 9.6.45.2 Center-specific transplant volume, by year, by organ type, using data that may be validated by the member through UNetsm, not time related, by cadaveric and living donor transplant, for recipients with a particular diagnosis.
- 9.6.45.3 Center-specific transplant volume, by year, by organ type, using data that may be validated by the member through UNetsm, by cadaveric and living donor transplant.
- 9.6.45.4 Center-specific multi-organ transplant volume, by year, by organ type, using data that may be validated by the member through UNetsm.
- 9.6.45.5 Center-specific non-resident alien transplant volume, by year, by organ type, using data that may be validated by the member through UNetsm, by cadaveric and living donor transplant.
- 9.6.45.6 Center-specific waiting list size on any given day, by organ type, according to the UNOS Patient Waiting List.
- 9.6.45.7 Center- and OPO-specific data submission compliance rates.
- 9.6.45.8 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.
- 9.6.59 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 Scientific Data Advisory Committee. These data may be released in whole or as part of a current or previously published UNOS report which is available to the public.
- 9.6.610 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 UNOS Scientific Data Advisory Committee. OPO-specific organ transplant volume and size of patient 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 UNOS Scientific Data Advisory Committee. These data may be released in whole or as part of a current or previously published UNOS report which is available to the public.
- 9.6.711 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 UNOS Scientific Data Advisory Committee.

NOTE: New Policy 9.6.7 shall be implemented following programming modifications to the UNOS computer system.

- ~~9.6.811~~ Center, OPO, or other organization-specific data as approved by the UNOS Executive Committee, which UNOS 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.** UNOS may release to OPO members such center specific data as are required for the OPOs to prepare reports or other documents required by UNOS for the purposes of assessing the impact of variances, alternative local units and sharing agreements on organ allocation.
- ~~9.8 REPORT OF CENTER SPECIFIC GRAFT AND PATIENT SURVIVAL RATES.~~ UNOS may release the bi annual report of verified, appropriately stratified, center specific transplant data as determined by the Scientific Advisory Committee. This Report shall include center specific non-resident alien transplant data and OPO specific data on the number of non U. S citizen organ donors.
- ~~9.9 RELEASE OF OPO SPECIFIC DATA.~~ UNOS may release to the public a report of verified and appropriately stratified OPO specific data as determined by the Scientific Advisory Committee.
- 9.810 REVIEW OF INSTITUTION SPECIFIC DATA.** During the data validation process, UNOS may release to institutional members for their review such primary data as may be needed for institution-specific UNOS 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 UNOS by original institution submitters). Conversely, for these purposes, laboratories and OPOs may receive relevant data submitted to UNOS by transplant centers. The institutions that receive the data will not publish or publicly disseminate outcomes of specific patients, physicians or institutions.
- 9.911 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 be used to publish or publicly disseminate outcomes of specific patients, physicians or institutions. These data fields are located on the UNOS Transplant Recipient Registration Forms and include:
- 9.911.1 Patient 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)
- 9.911.2 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 patient 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?
- 9.911.3 Graft Status at Discharge (kidney, liver and pancreas only)**
- Functioning or failed
 - If failed, date and cause
- 9.911.4 Preservation Information (all organs)**

9.1012—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.

Proposed Modifications to UNOS Policy 10.0 (Access to Data)

Summary

Some of the proposed policy changes are made as a result of new regulatory and contractual requirements. Others are the result of routine periodic review of the policy language, which continues as an ongoing process by the Data Advisory Committee.

Background

Policy 10.0 addresses the types of data that are available to the public and who has access to this data. The issues addressed in this Policy are: Access to the Database, Transfer of Information, Specific Projects, Public Use Presentations and Publications, and Committee Access to Data.

Policy Proposal

In May 2001 the Data Advisory Committee, by unanimous vote, approved the following motion, which was discussed and approved by the Board of Directors at the June 2001 Board meeting:

RESOLVED, that Policy 10.0 (Access to Data), as amended, shall be approved effective June 29, 2001, and submitted for public comment, concurrently.

10.0 ACCESS TO DATA

10.1 ACCESS TO DATABASE. Only UNOS administrative staff or individuals engaged by or adjunct to UNOS staff who are bound by contracts which prohibit competing interests and breaches of confidentiality will be permitted to program the UNOS computer or have direct access to data within the UNOS computer or maintained in any other form. UNOS members requesting access to data regarding their own patients will be provided access to that information when practicable as determined by the Organ Procurement and Transplantation Network (OPTN) Project Director Scientific Registry Contract Project Director. Except as provided for in Policy 9.0~~40~~ and this Policy ~~10.1~~ 10.2 and Policy 10.3, neither individuals nor UNOS members will be given access to individual patient or member-specific information other than that from their own organization, without prior written approval from those patients or members identified. Patient-identified and institution-identified UNOS data will be made available to the Scientific Registry for Transplant Recipients (SRTR) Contractor.

10.2 TRANSFER OF INFORMATION. ~~Other than requests by UNOS members for data regarding their own patients and requests pursuant to UNOS federal government contracts, a~~ All requests for raw UNOS data from the Scientific Registry should be made through the UNOS Data Request System and the associated UNOS Data Information System must be approved by the UNOS Scientific Advisory Committee and are subject to approval by the Board of Directors. Routinely available data will comprise the following:

- Data provided in regularly updated UNOS Standard Reports;
- Data requested by UNOS members regarding their own institution and/or patients;
- 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).

~~Such~~ Unless they are releasable according to Policy 9.0 or Policy 10.2, data will be provided with the deletion of all patient-specific and patient- and center-specific identifying information. Comprehensive datasets with center and patient identifying information encrypted may be given out for research purposes with the

approval of the Data Advisory 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 Data Advisory Committee using as guidance the UNOS Agreement for Release of Data, as approved by the Data Advisory 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 will may be provided on a cost reimbursement basis. With the understanding that public use of such information would require prior written approval by the UNOS Scientific Advisory Committee and Board of Directors. 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 being from "Data Information System, United Network for Organ Sharing." As contractually required, UNOS may release records which are identifiable as to patient, 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 using the Scientific Registry data or the associated Data Information System by the UNOS administrative staff may be asked to must submit a written concept paper request to the UNOS Scientific Data Advisory Committee. The Scientific Data Advisory 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 UNOS or 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 UNOS staff member(s) assigned to complete the request. The submitting individual must indicate to the assigned staff member(s) 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 patient-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 UNOS utilizing the UNOS Scientific Registry data collected for the OPTN or the Data Information System must adhere to the following specific requirements regarding approval, content, confidentiality, and authorship:

10.4.1 **Approval for Levels I and II Data, Public Use or Presentation of Specific Projects or Studies.** The scientific and analytical content of all abstracts or manuscripts using Levels I and II data developed from customized data requests, comprehensive encrypted datasets, or standard analysis files must be approved by the UNOS Scientific Data Advisory Committee and any ad hoc work group appointed by that Committee prior to their public presentation or publication. For the purpose of performing the subject analysis. The submission for publication of an abstract or manuscript must be approved by the UNOS Scientific Advisory Committee. Requests to UNOS for public presentation of data must be approved by the UNOS Scientific Advisory Committee and directed to the ad hoc work group as described above performing the study which in turn shall be responsible for determining who shall present the data and for reviewing the scientific accuracy and content of information to be presented. If the analysis has not been provided prior to release by the investigator or institution, UNOS cannot assume responsibility for the correctness of the findings or interpretations. Failure to include UNOS in pre-release preparation may be an adverse consideration in subsequent applications by the investigator or institution for additional data. Any UNOS staff member who makes a significant intellectual contribution to a study abstract, presentation, or manuscript should be offered the opportunity to be included as an author. UNOS staff may not be listed as

study authors without obtaining written permission from the appropriate staff member(s). A copy of all published abstracts, manuscripts, or news releases should be submitted to UNOS administrative staff and/or the Data Advisory Committee for informational purposes as soon as practicable.

10.4.2 ~~Approval for Level III Data.~~Data Obtained Through the Data Request System.

Abstracts and manuscripts prepared using routinely available Level III data obtained through the data request system do not require approval by the UNOS Scientific Data Advisory Committee. However, the source and date of the data obtained must be acknowledged in text and/or graphic presentations (e.g., "Based on UNOS data as of January 1, 2000"), but must contain the following statement: "a portion of the data obtained for this study was acquired through contract with the United Network for Organ Sharing." A copy of each all published abstracts, manuscripts, or news releases or contacts with the media involving Level III studies must should be submitted to the UNOS administrative staff and/or the Data Scientific Advisory Committee for informational purposes as soon as practicable. Publications that use UNOS data collected for the OPTN shall include the following notice: *The data reported here have been supplied by UNOS. 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.*

10.4.3 ~~Center Specific Data Report.~~

As part of the Center Specific Data Report, the identification of center specific activity and results will be given on a stratified basis. Each center will have the opportunity to comment on its own results, which will be incorporated into an accompanying narrative that will also present the qualifications for interpreting these results. Following review and approval of this narrative by the UNOS Scientific Advisory Committee, the report with center specific results and the accompanying narrative will be made available to non UNOS members upon request. This policy is not intended to limit the release of information described in Policy 9.6 (Public Release of Center and OPO Activity). Information in the Center Specific Data Report may be available to supplement the information provided under Policy 9.6.

10.4.4 ~~Special Center Specific Reports.~~

As part of a special center specific report approved by the Board of Directors, the identification of center specific activity, results or characteristics will be given on a stratified basis and/or risk adjusted basis, as appropriate. Prior to public release of the report, each center will receive its center specific report along with aggregate or blinded results for other centers. Each center will be given a reasonable opportunity to prepare for comment on its own results prior to public release of the report.

10.4.5 ~~OPO Specific Data Report.~~

As part of the OPO Specific Report, approved by the Board of Directors, the identification of OPO activity and waiting times will be provided on a stratified basis. In addition, transplant program activity including the number of active patients on the waiting list at the initiation of the study, the number of patients added to the waiting list, and the number of patients removed for transplant, death and other reasons will be included. Each OPO will have the opportunity to review and comment on its own data, which will be incorporated into the accompanying narrative that will also present the qualifications for interpreting these results. Following review and approval of this narrative by the UNOS Scientific Advisory Committee, the report with OPO specific data and the accompanying narrative will be made available to non UNOS members upon request. This policy is not intended to limit the release of information described in Policy 9.6 (Public Release of Center and OPO Activity). Information in the OPO Specific Report may be available to supplement the information provided under Policy 9.6.

10.4.6 ~~Authorship.~~

All publications involving analyses of Levels I and II data from the Scientific Registry or the UNOS Data Information System will list as co-author(s) those members of the

~~work group who wrote the manuscript and performed the analyses of the data. UNOS will be identified as the primary institutional affiliation for such publications. Other institutional affiliations for co-author(s) may be listed in a footnote. To provide accountability for analysis and scientific content, the co-author(s) shall include the statistical consultant as well as any individuals approved by the Scientific Advisory Committee to specifically work on the manuscript. In the case of a presentation to be made by one individual for UNOS, the listing on the program or abstract will be given as the name of that individual and other members of the project work group with the primary institutional identification being the United Network for Organ Sharing.~~

~~10.4.7 **Acknowledgments.** Each publication shall include an acknowledgment of the input of individual centers and UNOS staff. Support by contractor(s) and other sources will also be acknowledged.~~

~~10.5 **REPORTING DATA TO THE SCIENTIFIC ADVISORY COMMITTEE.**~~

~~10.5.1 All transplant recipients will be followed until death or retransplantation. Following graft failure, every reasonable effort should be made to follow patients for a minimum of two years.~~

~~10.5.2 Data will be collected on all patients anesthetized for transplant surgery whether or not the transplant actually occurs.~~

~~10.5.3 Renal graft failure shall be defined as having occurred when any of the following occurs: (1) death of the patient, (2) the patient returns to chronic dialysis, (3) the patient is retransplanted, (4) there is a transplant nephrectomy, or (5) if any of the first four conditions do not apply, the transplant center determines graft failure has occurred based on that center's definition of graft failure.~~

~~10.5.4 An intraoperative transplant related death is defined as having occurred when all of the following three (3) conditions have been met: 1) a viable donor organ has been matched for the prospective recipient; 2) no medical contraindications to transplant are identified during the course of the operation; and 3) the patient dies after anesthesia has been induced. Death resulting from conditions requiring transplantation that occur prior to the induction of anesthesia will not be considered transplant deaths.~~

~~10.5.5 A solid organ transplant has occurred when an organ has been implanted and vascularized or when a patient dies due to transplant related death (Policy 10.5.4) during the intended transplant. Extracorporeal transplants and transplantation of islet cells are not considered solid organ transplants for the purposes of this definition.~~

10.56 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 UNOS Confidential Information will be limited to members of the UNOS Board of Directors, members of UNOS permanent standing or ad hoc committees, UNOS administrative staff and individuals engaged as an adjunct to UNOS staff. Access will be limited to the above described individuals, provided that these individuals are performing functions on behalf of UNOS and are either bound by a fiduciary responsibility to UNOS or a contractual obligation to UNOS 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 UNOS 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 UNOS. All such data and information together with business practices and procedures of UNOS will be referred to collectively as "Confidential Information."

At such time as it becomes necessary to present or review patient 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 UNOS administrative 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 UNOS administrative 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 UNOS and foster the trust of those who are associated with or who have dealings with UNOS.