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### IMPORTANT POLICY NOTICE

To: Transplant Professionals

From: Karl J. McCleary, Ph.D., M.P.H  
UNOS Director of Policy, Membership and Regional Administration

RE: Recently Approved Policy Modifications and Board Actions

Date: August 7, 2007

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The attached documentation summarizes bylaw changes, policy changes and other actions approved at the June 2007 OPTN/UNOS Board of Directors meeting. As always, our goal is to keep you fully informed of these changes and also of any action required on your part.

Based on your positive feedback, we are again communicating all individual notices in one batch, using the three-column format and grid outlining transplant professionals affected to help you review this information quickly and easily. After reading the summaries, you can access modified policy language by clicking on the link provided. Page numbering is included for those who prefer to use a paper copy.

Thank you in advance for your careful review. We welcome your feedback as we continue to improve the way that we communicate bylaw and policy changes as well as other Board actions. If you have any questions about a particular notice within this document, please contact your regional administrator at (804) 782-4800.

# Overview of Policy Modifications/Board Actions and Affected Professionals

## Page 1 of 2

Who should be aware of these actions? Please review the **13** notices included on the grid below and share with other colleagues as appropriate.

	Directors of Organ Procurement	Lab Directors	Lab Supervisors	OPO Data Coordinators	OPO Executive Directors	OPO Medical Directors	OPO PR/Public Education Staff	OPO Procurement Coordinators	Transplant Administrators	Transplant Coordinators	Transplant Data Coordinators	Transplant Physicians	Transplant PR/Public Education Staff	Transplant Program Directors	Transplant Social Workers	Transplant Surgeons	Page #
1	Changes to Living Donor Registration (LDR) and Living Donor Follow-up (LDR) Forms <i>Living Donor Committee</i>								X	X	X	X		X	X	X	4
2	Modifications to Data Elements for Pediatric Candidates and Recipients on UNet <sup>SM</sup> Transplant Candidate Registration (TCR), Transplant Recipient Registration (TRR), and Transplant Recipient Follow-up (TRF) Forms <i>Pediatric Transplantation Committee</i>	X	X	X	X				X	X	X	X	X	X	X	X	6
3	Modifications to Deceased Donor Registration (DDR) Form Data Elements on UNet <sup>SM</sup> <i>Organ Availability Committee</i>	X		X	X	X		X									8
4	Modifications to OPTN/UNOS Policy 3.1 (Organ Distribution: Definitions) <i>Operations Committee</i>	X			X			X	X	X		X	X	X		X	10
5	Modifications to OPTN and UNOS Bylaws, Appendix A2-1, Section 2.06A, (b), (3) "Probation," (4) "Member Not in Good Standing," (5) "Suspension of Member Privileges," (6) "Termination of Membership or Designated Transplant Program Status," (7) "Action Specified in OPTN Final Rule." <i>Patient Affairs Committee</i>								X	X	X	X	X	X	X	X	11
6	Modifications to Policy 3.3.6 (Center Acceptance of Organ Offers) Requiring the Re-Allocation of Organs when the Donation after Cardiac Death (DCD) Donor Converts to Brain Death. <i>Transplant Coordinators Committee</i>	X		X	X	X	X	X	X	X	X	X	X	X	X	X	13

# Overview of Policy Modifications/Board Actions and Affected Professionals

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	Policy/Bylaw Change or Board Action	Directors of Organ Procurement	Lab Directors	Lab Supervisors	OPO Data Coordinators	OPO Executive Directors	OPO Medical Directors	OPO PR/Public Education Staff	OPO Procurement Coordinators	Transplant Administrators	Transplant Coordinators	Transplant Data Coordinators	Transplant Physicians	Transplant PR/Public Education Staff	Transplant Program Directors	Transplant Social Workers	Transplant Surgeons	Page #
7	Modifications to OPTN/UNOS Policy 5.0 (Standard Packaging and Transporting of Organs and Tissue Typing Materials) <i>Operations Committee</i>	X				X	X		X	X	X		X		X		X	15
8	Modifications to Policies 7.1 (Reporting Definitions) and 7.3 (Submission of Organ-Specific Transplant Recipient Registration (TRR) Forms and Submission of Living Donor Registration (LDR) Forms) that Extend Living Donor Follow-up to Two Years <i>Living Donor Committee</i>									X	X	X	X		X	X	X	16
9	Modifications to Policies 7.1.7 (Imminent Neurological Death) and 7.1.8 (Eligible Death) Definitions <i>OPO Committee</i>	X			X	X	X		X									17
10	Modifications to Policy 7.3.3 (Submission of Organ-Specific Transplant Recipient Registration (TRR) Forms and Submission of Living Donor Registration (LDR) Forms) <i>Living Donor Committee</i>									X	X	X	X		X	X	X	18
11	Modifications to Policy 7.7 (Submission of Death Notification Information), Changing Due Date for Submission of Death Notification Data <i>OPO Committee</i>	X			X	X	X		X									19
12	Recommendations Regarding Release of Recipient Information to Donor Families as a Best Practice <i>Transplant Coordinators Committee</i>	X			X	X	X	X	X	X	X	X	X	X	X	X	X	20
13	Modifications to Policy 3.2.4 (Match System Access) Regarding ABO Verification <i>OPO Committee</i> <b><i>This proposal was passed by the Board in September 2006</i></b>	X	X	X	X	X	X		X	X	X				X		X	21

**Notice of Board Action**— Changes to Living Donor Registration (LDR) and Living Donor Follow-up (LDF) Forms (Living Donor Committee)

**Action Required:** Review

**Estimated Effective Date:** September 1, 2007

**Professional Groups Affected by the change:**

Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Social Workers, Transplant Data Coordinators

Current Issue/Policy	Proposed Change or Addition	What You Need to Do
<p>The current LDF form allows transplant professionals to describe living donors in only four ways:</p> <ul style="list-style-type: none"> <li>• Living</li> <li>• Dead</li> <li>• Lost</li> <li>• Not seen</li> </ul> <p>Additional data collection follows the OPTN Principle of Data Collection to “ensure patient safety when no alternative sources of data exist.” There are currently no other sources of data for living donors that would allow the OPTN to meet this contractual requirement.</p>	<p>Changes add one new data element to the Living Donor Follow-Up (LDF) form and three new data elements to the Living Donor Registration Form (LDR)</p> <p>Changes to the LDF form will increase reporting options to include:</p> <ul style="list-style-type: none"> <li>• Living               <ul style="list-style-type: none"> <li>➤ Donor seen at transplant center</li> <li>➤ Donor status updated by verbal or written communication between transplant center and donor</li> <li>➤ Donor status updated by other health care facility</li> <li>➤ Donor status updated by transplant recipient</li> <li>➤ Donor contacted, declined follow up with transplant center</li> </ul> </li> <li>• Dead</li> <li>• Lost               <ul style="list-style-type: none"> <li>➤ No attempt to contact donor</li> <li>➤ Unable to contact donor (document)</li> </ul> </li> </ul> <p>Changes to the Living Donor Registration (LDR) form include:</p>	<p>For each living donor, submit the LDR within 60 days from date of generation.</p> <p>For each living donor, submit a LDF at six months, one year, and two years from the date of donation.</p>

	<ul style="list-style-type: none"><li>• The date of and the living donor's status during the most recent contact between the donor and the recipient transplant center</li><li>• Whether living donor organ recovery and transplant of that organ occurred at the same center.</li></ul>	
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[Click Here to View the Modified Policy Language](#)

**Notice of Board Action** —Modifications to Data Elements for Pediatric Candidates and Recipients on UNet<sup>SM</sup> Transplant Candidate Registration (TCR), Transplant Recipient Registration (TRR), and Transplant Recipient Follow-up (TRF) Forms (Pediatric Transplantation Committee)

**Action Required:** Review

**Estimated Effective Date:** September 1, 2007

**Professional Groups Affected by the change:** OPO Executive Directors, OPO Data Coordinators, Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Social Workers, Transplant Data Coordinators, Lab Directors, Lab Supervisors, Transplant PR/Public Education staff

Current Issue/Policy	Proposed Change or Addition	What You Need to Do
<p>The National Organ Transplant Act of 1984 requires that the OPTN "Collect, analyze, and publish data concerning organ donation and transplants." This activity is carried out through a series of data collection forms that OPTN members are required to complete and submit to the OPTN. Currently, forms are submitted through UNet<sup>SM</sup>, a secure web-based data collection system.</p> <p>In 2005, the OPTN began to focus on reducing the data burden on the transplant programs. The result of this process was the Policy Oversight Committee's (POC's) successful proposal to reduce the number of required data fields for adult candidates and recipients registered in UNet<sup>SM</sup>.</p>	<p>Changes to the UNet<sup>SM</sup> TCR, TRR and TRF data collection forms will complement the recently approved deletions to the adult OPTN data collection forms.</p> <p>Changes to the pediatric forms will:</p> <ul style="list-style-type: none"> <li>• Streamline data collection and reduce the data collection burden on the transplant centers</li> <li>• Complement the recently approved deletions to the adult OPTN data collection forms without sacrificing data integrity and long term follow-up essential in providing care to children as they transition into adulthood</li> <li>• Develop several new data fields to capture information regarding growth and development that are critical indicators of a child's progress both pre- and post-transplant.</li> </ul> <p>The OPTN will now follow pediatric recipients using the pediatric TRF forms for five years after transplant. Beyond five</p>	<p>Transplant professionals should familiarize themselves with the pending changes to the current TCR, TRR and TRF forms.</p> <p>UNOS will send a UNet<sup>SM</sup> implementation notice to remind members of the upcoming changes to these forms prior to the anticipated effective date, September 1, 2007.</p>

	<p>years after transplant and until the pediatric recipients reach 25 years of age, they will be followed using TRF forms with limited data elements similar to those recommended by the OPTN/UNOS organ specific committees for adults, but also including specific data elements pertinent to pediatric issues, especially growth and development, for all organs. When pediatric recipients become 26 years old, they will be followed using the adult TRF forms with limited data elements.</p>	
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[Click Here to View the Modified Policy Language](#)

**Policy Notice**

**Notice of Board Action**— Modifications to Deceased Donor Registration (DDR) Form Data Elements on UNet<sup>SM</sup> (Organ Availability Committee)

**Action Required:** Review

**Estimated Effective Date:** September 1, 2007

**Professional Groups Affected by the change:** OPO Executive Directors, Directors of Organ Procurement, OPO Procurement Coordinators, OPO Data Coordinators, OPO Medical Directors

Current Issue/Policy	Proposed Change or Addition	What You Need to Do
<p>Currently, the DDR form requires OPO coordinators to answer the following questions about DCD donors:</p> <p>Was this a DCD donor? If so:</p> <ol style="list-style-type: none"> <li>1) Was it controlled?</li> <li>2) Was core cooling used?</li> <li>3) What was the estimated warm ischemic time (WIT); and</li> <li>4) Has there been any instance(s) of cardiac arrest since neurological event that led to declaration of brain death?</li> </ol> <p>Collecting additional details on the recovery process for individual DCD donors will help the transplant community develop transplant, donation and allocation policies, one of the OPTN guiding principles for future data management.</p>	<p>The following data elements will be added to the DDR under the Organ Recovery Section:</p> <ul style="list-style-type: none"> <li>• Withdrawal of Support (Date/Time)</li> <li>• Agonal Phase Begins, SBP and/or O2 sat drops below 80 (Date/Time)</li> <li>• Cardiac Death (Date/Time)</li> <li>• Abdominal Aortic Cannulation (Date/Time)</li> <li>• Thoracic Aorta Cannulation (Date/Time)</li> <li>• Portal Vein Cannulation (Date/Time)</li> <li>• Pulmonary Artery Cannulation (Date/Time)</li> <li>• For each organ type recovered, the Date/Time each organ at the back table</li> <li>• Between Withdrawal of Support and Cardiac Death, collect available serial data [every 15 min between withdrawal of support and start of agonal phase and every 5 min between start of agonal phase and cardiac death] on the following during OR recovery phase:               <ul style="list-style-type: none"> <li>Systolic, Diastolic, and Mean Arterial Pressure and</li> </ul> </li> </ul>	<p>The coordinator will need to enter additional information for <u>DCD donors only</u> and confirm that a center’s computer system can accommodate this change.</p>

	<p style="text-align: center;">O<sub>2</sub> Saturation</p> <ul style="list-style-type: none"><li>• Total Urine Output</li><li>• Was this a Consented DCD donor that deteriorated to brain death? Yes/No</li></ul>	
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**Notice of Policy Change**— Modifications to OPTN/UNOS Policy 3.1 (Organ Distribution: Definitions) Requiring UNOS Donor ID Verification (Operations Committee)

**Action Required:** Review

**Estimated Effective Date:** September 1, 2007

**Professional Groups Affected by the change:** Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant PR/Public Education staff, OPO Executive Directors, Directors of Organ Procurement, OPO Procurement Coordinators

Current Issue/Policy	Proposed Change or Addition	What You Need to Do
<p>Currently transplant centers are required to verify the recorded donor ABO upon receipt of an organ, and to verify the recorded donor ABO and the ABO of the intended recipient prior to implantation.</p>	<p>Transplant Centers must now verify the <b>UNOS Donor ID number</b> and ABO upon receipt of an organ, and prior to implantation.</p> <p>This change should minimize the risks associated with incorrectly matching candidates and donors with incompatible blood types and thus increase patient safety.</p>	<p>Upon receipt of an organ, prior to implantation, transplant centers are responsible for verifying the recorded donor ABO, the recorded ABO of the intended recipient, <u>and</u> <b>UNOS Donor ID number</b>.</p> <p>Transplant centers must document these actions and this documentation may be reviewed during audits.</p>

[Click Here to View the Modified Policy Language](#)

**Notice of Bylaws Modification** — Modifications to OPTN and UNOS Bylaws, Appendix A2-1, Section 2.06A, (b), (3) “Probation,” (4) “Member Not in Good Standing,” (5) “Suspension of Member Privileges,” (6) “Termination of Membership or Designated Transplant Program Status,” (7) “Action Specified in OPTN Final Rule.” (Patient Affairs Committee)

**Action Required:** Review Urgently

**Estimated Effective Date:** August 1, 2007 and pending notice to the membership

**Professional Groups Affected by the change:** Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Social Workers, Transplant Data Coordinators, Transplant PR/Public Education staff

Current Issue/Policy	Proposed Change or Addition	What You Need to Do
<p>If a transplant center is voted Member Not in Good Standing, it must notify all of its patients about this action.</p>	<p>Now transplant centers must notify its patients if it receives any of the following adverse actions: probation, member not in good standing, suspension of member privileges, termination of membership or designated transplant program status, and action specified in the OPTN Final Rule.</p> <p>If any of these adverse actions occur, transplant centers must notify the following individuals within 30 days of the adverse action:</p> <ul style="list-style-type: none"> <li>• patients in the evaluation process</li> <li>• candidates</li> <li>• candidates added to the national waiting list throughout the duration of the adverse action</li> <li>• recipients receiving follow-up services</li> </ul> <p>In probation cases, transplant centers only need to notify patients, candidates, and recipients of the <b>cited transplant program</b>.</p>	<p>Familiarize yourself with this bylaws change and discuss with your staff how you would handle this notification requirement in the event of an adverse action.</p>

	<p><b>In cases of the remaining four adverse actions, transplant centers must notify <u>patients, candidates, and recipients of the entire transplant center.</u></b></p> <p>The Member Transplant Center must provide this notification in writing, in each patient’s spoken language, for the duration of the adverse action, and as prescribed by the Executive Committee or Board of Directors.</p>	
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[Click Here to View the Modified Policy Language](#)

**Notice of Policy Change** —Modifications to Policy 3.3.6 (Center Acceptance of Organ Offers) requiring the re-allocation of organs when the Donation after Cardiac Death (DCD) donor converts to brain death. (Transplant Coordinators Committee)

**Action Required:** Review Urgently

**Estimated Effective Date:** August 1, 2007 and pending notice to the membership

**Professional Groups Affected by the change:**

OPO Executive Directors, Directors of Organ Procurement, OPO Procurement Coordinators, OPO Data Coordinators, OPO Medical Directors, Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Social Workers, Transplant Data Coordinators, OPO PR/Public Education staff, Transplant PR/Public Education staff

Current Issue/Policy	Proposed Change or Addition	What You Need to Do
<p>Currently, the OPO may decide whether or not to reallocate organs if a DCD donor converts to brain death.</p>	<p>If a DCD donor converts to brain death, the OPO must re-allocate organs unless the following circumstances occur:</p> <ol style="list-style-type: none"> <li>1) Lack of donor family approval and consent;</li> <li>2) Donor instability; or</li> <li>3) Other extraordinary circumstances.</li> </ol> <p>This change will ensure that organs are allocated to the sickest patients and encourage the transplantation of more organs per donor.</p>	<p>The OPO should re-allocate the organs from the DCD donor who converts to brain death.</p> <p>After the donor converts to brain death, it is the OPO’s responsibility to notify the center and close the DCD match run. The DonorNet® application will not automatically close any open match prior to the new match run.</p> <p>If a transplant center has accepted an offer and OPTN/UNOS Policy 3.3.6.1.1 (Exception for DCD Donor who Converts to Brain Death After an Organ Offer has been Made) does not apply, the OPO needs to contact the transplant center and close the DCD match, and they must also modify the PTR information in DonorNet®.</p> <p>The match may still be closed if a transplant center has selected a 'provisional yes' for the offer. At this time, there are no plans to add an additional status code. Because the center is not really refusing the offer, it may</p>

		not make sense to list the offer as refused. However, an enhancement has been added to the list to indicate why a match run was closed when no organs were allocated.
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[Click Here to View the Modified Policy Language](#)

**Notice of Policy Change**— Modifications to OPTN/UNOS Policy 5.0 (Standardized Packaging and Transporting of Organs and Tissue Typing Materials) (Operations Committee)

**Action Required:** Review

**Estimated Effective Date:** September 1, 2007

**Professional Groups Affected by the change:** OPO Executive Directors, Directors of Organ Procurement, OPO Procurement Coordinators, OPO Medical Directors, Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians,

Current Issue/Policy	Proposed Change or Addition	What You Need to Do
<p>Policy 5.0 addresses standardized packaging and transporting of organs and typing materials for deceased donor organs.</p> <p>There is currently insufficient guidance within policy related to packaging and transporting living donor organs, as well as deceased donor organs that fall outside the parameters of current policy. The Quality Management Subcommittee proposed modifications to Policy 5.0 that would standardize the packaging and transporting of both living and deceased donor organs not addressed in current policy.</p>	<p>New guidance for packaging and transporting living donor organs includes the following:</p> <ul style="list-style-type: none"> <li>• Any organ traveling outside the recovery facility will need to be packaged and transported according to this policy.</li> <li>• Two or more organs remaining in the recovery facility for transplant will need to comply with new policy.</li> <li>• Transplant centers’ living donor organ responsibilities are outlined in this policy.</li> <li>• The new definition of a transport container includes a mechanical preservation cassette or machine.</li> </ul> <p>The basic tenets of the modifications note that when any organ leaves the operating room suite it must be packaged and transported properly; however if an organ does not leave the operating room suite, a second tier of practice must be implemented.</p>	<p>OPO and Transplant Center personnel should review the policy and familiarize themselves with these changes.</p>

[Click Here to View the Modified Policy Language](#)

**Notice of Policy Change**— Modifications to Policies 7.1 (Reporting Definitions) and 7.3 (Submission of Organ-Specific Transplant Recipient Registration Forms and Submission of Living Donor Registration Forms) that Extend Living Donor follow-up to Two Years (Living Donor Committee)

**Action Required:** Review

**Estimated Effective Date:** September 1, 2007

**Professional Groups Affected by the change:**

Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Social Workers, Transplant Data Coordinators

Current Issue/Policy	Proposed Change or Addition	What You Need to Do
<p>Transplant centers are required to report follow-up data on their living donors for one year.</p>	<p>The recipient transplant center will now be required to report follow-up data on living donors for a period of two years.</p> <p>This longer follow-up period will provide valuable information on the experience, safety, and health implications for living donors. Transplant center compliance with living donor follow-up is especially important since no alternative source of data exists.</p>	<p>For each living donor, submit the LDR <b>within 60 days</b> from date of generation.</p> <p>Transplant centers must submit the Living Donor Registration Form (LDR) to the OPTN within 60 days of the generation date.</p> <p>Recipient transplant centers must submit Living Donor Follow-up Forms (LDF) for each living donor at six months, one year, and two years from the date of donation.</p>

[Click Here to View the Modified Policy Language](#)

**Notice of Policy Change** — Modifications to Policies 7.1.7 (Imminent Neurological Death) and 7.1.8 (Eligible Death) Definitions (OPO Committee)

**Action Required:** Review

**Estimated Effective Date:** September 30, 2007

**Professional Groups Affected by the change:** OPO Executive Directors, Directors of Organ Procurement, OPO Procurement Coordinators, OPO Data Coordinators, OPO Medical Directors

<b>Current Issue/Policy</b>	<b>Proposed Change or Addition</b>	<b>What You Need to Do</b>
<p>OPOs currently do not have standard imminent neurological death and eligible death definitions that are used consistently to collect data nationally.</p> <p>The OPTN is tasked under contract to collect patient level data on all imminent and eligible deaths. Standardized definitions are necessary to ensure consistency of data collection and data integrity.</p>	<p>The revised imminent neurological death definition no longer includes the Glasgow Coma Scale as one of the criteria for determining imminent death status.</p>	<p>When collecting specific data on imminent and eligible deaths, OPOs should use the newly approved definitions in policy and enter this data into DonorNet®.</p>

[Click Here to View the Modified Policy Language](#)

**Notice of Policy Change**— Modifications to Policy 7.3.3 (Submission of Organ-Specific Transplant Recipient Registration Forms and Submission of Living Donor Registration Forms) (Living Donor Committee)

**Action Required:** Review Urgently

**Estimated Effective Date:** July 1, 2007 and pending notice to the membership

**Professional Groups Affected by the change:**

Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Social Workers, Transplant Data Coordinators

Current Issue/Policy	Proposed Change or Addition	What You Need to Do
<p>When aware, transplant centers are required to report all cases of living donor death and failure of the living donor’s native organ failure within 72 hours.</p> <p>Centers have been required to report these events indefinitely.</p>	<p>Centers are now required to report these events using the patient safety system. Reporting under this policy is now limited to two years from the date of donation.</p> <p>The policy also clarifies the definition of native organ failure.</p>	<p>If you become aware of the death or the loss of native organ function in a living donor, who donated less than two years ago, report this information <b>within 72 hours</b> using the patient safety system.</p>

[Click Here to View the Modified Policy Language](#)

**Policy Notice**

**Notice of Policy Change** — Modifications to Policy 7.7 (Submission of Death Notification Information), Changing Due Date for Submission of Death Notification Data (OPO Committee)

**Action Required:** Review

**Estimated Effective Date:** September 30, 2007

**Professional Groups Affected by the change:** OPO Executive Directors, Directors of Organ Procurement, OPO Procurement Coordinators, OPO Data Coordinators, OPO Medical Directors

Current Issue/Policy	Proposed Change or Addition	What You Need to Do
<p>Current policy requires OPOs to report imminent neurological and eligible death data within 30 days of the date of the death notification.</p> <p>OPOs currently collect data on all imminent neurological and eligible deaths in hospitals. However, some hospitals may not refer all deaths to the OPO, and these cases are only found during a DRR. Many OPOs do not conduct DRRs every month, so they would not be able to report the data during the required time frame. Some OPOs may only conduct a DRR every 6 months at certain hospitals.</p>	<p>This policy change defines the time requirements for the reporting of data collected on imminent and eligible deaths. Data are to be reported within 30 days from the end of the month in which a death was referred to the OPO, <u>or</u> within 30 days from the end of the month in which the death was identified by the OPO through a DRR.</p>	<p>Once implemented, the OPO must report all data on imminent and eligible deaths within the designated time frame. Use the approved definitions from Policy 7.1.7 and 7.1.8.</p>

[Click Here to View the Modified Policy Language](#)

**Notice of Board Action** —Recommendations Regarding Release of Recipient Information Brochure to Donor Families as a Best Practice (Transplant Coordinators Committee)

**Action Required:** Review

**Estimated Effective Date:** N/A

**Professional Groups Affected by the change:**

OPO Executive Directors, Directors of Organ Procurement, OPO Procurement Coordinators, OPO Data Coordinators, OPO Medical Directors, Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Social Workers, Transplant Data Coordinators, OPO PR/Public Education staff, Transplant PR/Public Education staff

<b>Current Issue/Policy</b>	<b>Proposed Change or Addition</b>	<b>What You Need to Do</b>
Currently, OPOs have difficulty securing recipient information from transplant centers to provide to donor families.	The Board of Directors strongly encourages transplant centers to share recipient information with OPOs.	Discuss effective methods for sharing pertinent information within your DSA and also formulate strategies for sharing this information with other OPOs outside of your DSA, as appropriate, in the case of imported organs.

## Policy Notice

### Notice of Policy Change — Policy 3.2.4 Match System Access (OPO Committee)

**Action Required:** Review

**\*\*Date of Board Approval:** September 20, 2006

*\*\*This policy change was approved during the **September 2006** Board of Directors meeting. A policy notice was not circulated at that time.*

**Professional Groups Affected by the change:** OPO Executive Directors, Directors of Organ Procurement, OPO Procurement Coordinators, OPO Data Coordinators, OPO Medical Directors, Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Lab Directors, Lab Supervisors

Current Issue/Policy	Proposed Change or Addition	What You Need to Do
<p>Current policy:</p> <ul style="list-style-type: none"> <li>• allows OPOs to send one sample to two labs for donor ABO determination;</li> <li>• requires OPOs to maintain documentation that the on-line ABO verification was performed by two separate individuals even though DonorNet® captures this information; and</li> <li>• does not specify that the on-line ABO verification must be performed using the ABO source documents.</li> </ul>	<p>The OPO will be responsible for sending two separate determinations of donor ABO type by sending either: two samples sent to two labs, <u>OR</u> two samples from separate draws to the same lab. The OPO is responsible for maintaining documentation of the ABO determination and making this documentation available upon audit.</p> <p>The OPO is no longer required to maintain documentation of the separate individuals who performed the ABO verification online. The online ABO verification must be performed using the ABO source documents.</p>	<p>Review the procedures for donor ABO determination and verification to ensure that the procedures reflect current OPTN policy.</p>

[Click Here to View the Modified Policy Language](#)

**Notice of Board Action**— Changes to Living Donor Registration (LDR) and Living Donor Follow-up (LDF) Forms (Living Donor Committee)

**Affected Policy Language:**

Options for living donor status on the **LDF form** will be:

- (1) Living: Donor seen at transplant center;
- (2) Living: Donor status updated by verbal or written communication between transplant center and donor;
- (3) Living: Donor status updated by other health care facility;
- (4) Living: Donor status updated by transplant recipient
- (5) Living: Donor contacted, declined follow up with transplant center;
- (6) Dead;
- (7) Lost: No attempt to contact donor; and
- (8) Lost: Unable to contact donor (document)

If item 8 (Lost: Unable to contact donor) is selected, the transplant center will be asked to document their efforts to contact the donor.

Changes to the **LDR form** will provide:

- (1) the date of and the living donor's status during the most recent contact between the donor and the recipient transplant center; and
- (2) whether living donor organ recovery and transplant of that organ occurred at the same center.

To read the complete policy language visit [www.unos.org](http://www.unos.org) or [www.optn.org](http://www.optn.org). From the UNOS Web site, select Resources from the main menu, then select policies. From the OPTN Web site, select Policies from the main menu.

**Appendix A** **Exhibit 2**  
**List of Deletions on Transplant Candidate Registration (TCR) for Pediatrics**  
**Pediatric Data Revision Subcommittee**  
**February 9, 2007**

	<b>Comments</b>
<b>TCR - Data Elements Common to all Organs (N=13)</b>	
Angina:	
Drug Treated COPD:	
Drug Treated Systemic Hypertension:	
Dialysis:	Delete for all but Heart (HR)
Is Patient waiting in permanent ZIP code:	
Medical Condition://Medical Condition at time of listing:	
Most Recent Serum Creatinine:	Delete for all but HR
Peptic Ulcer:	
Physical Capacity:	Replace with cognitive and motor development
Previous pancreas islet infusion	Not common in pediatrics
Source of Payment//Secondary:	
Symptomatic Cerebrovascular Disease:	Delete for all but HR
Symptomatic Peripheral Vascular Disease:	
<b>TCR - Kidney, Pancreas, Kidney-Pancreas (N=0)</b>	
<b>TCR – Liver (N=3)</b>	
Drug Treated COPD:	
Pulmonary Embolism:	
Variceal Bleeding within Last Two Weeks:	
<b>TCR – Intestine (N=7)</b>	
Drug Treated COPD:	
History of TIPSS:	
Intestine Neoplasm:	
Liver Dysfunction	Replace with total bilirubin
Pulmonary Embolism:	
Secondary Diagnosis:	
Total Serum Albumin:	

**Appendix A** **Exhibit 2**  
**List of Deletions on Transplant Candidate Registration (TCR) for Pediatrics**  
**Pediatric Data Revision Subcommittee**  
**February 9, 2007**

	<b>Comment</b>
<b>TCR – Thoracic (HR=Heart; LU=Lung; HL=Heart-Lung) (N=18)</b>	
Amiodarone:	Apply to HR, HL
Antiarrhythmics:	Apply to HR, HL
Any Previous Transfusions:	Apply to HR
Corticosteroid Dependency >= 5mg/day:	Apply to LU, HL
Drug Treated COPD:	Apply to HR, HL
FeV1(L)/FVC(L):	Apply to LU, HL; already collected on waiting list
FeV1:	Apply to LU, HL; already collected on waiting list
FVC:	Apply to LU, HL; already collected on waiting list
History of Cigarette Use//If Yes, Check # pack years:	
Infection Requiring IV Drug Therapy within 2 wks prior to listing:	
IV Treated Pulmonary Sepsis Episode >= 2 in last 12 months:	Apply to LU, HL
O2 Requirement at Rest:	Apply to LU, HL already collected on waiting list
Other Tobacco Use:	
pCO2:	Apply to LU, HL already collected on waiting list
Prior Cardiac Surgery (non-transplant): Y/N/U question and type	Replace with prior thoracic surgery
Prior Lung Surgery (non-transplant): Y/N/U question and type	Replace with prior thoracic surgery
Pulmonary Embolism:	Apply to HR, HL
Six minute walk distance:	Apply to LU, HL already collected on waiting list
<b>Total number of TCR deletions: 41</b>	

**Appendix A** **Exhibit 2**  
**List of Deletions on Transplant Recipient Registration (TRR) for Pediatrics**  
**Pediatric Data Revision Subcommittee**  
**February 9, 2007**

	<b>Comment</b>
<b>TRR - Data Elements Common to all Organs (N=27)</b>	
Biological or Anti-viral Therapy:	
CMV: Culture//Culture:	
CMV: Nucleic Acid Testing//Nucleic Acid Testing:	
CMV: Was there clinical disease//Was there clinical disease:	
Did the patient participate in any clinical research protocol for immunosuppressive medications:	
EBV: EBV DNA//EBV DNA:	
EBV: IgG//IgG:	
EBV: IgM//IgM:	
EBV: Was there clinical disease//Was there clinical disease:	
HBV: HBV DNA//HBV DNA:	
HBV: Liver Histology//Liver Histology:	
HBV: Was there clinical disease//Was there clinical disease:	
HCV: Antibody//Antibody:	
HCV: HCV RNA//HCV RNA:	
HCV: Liver Histology//Liver Histology:	
HCV: RIBA//RIBA:	
HCV: Was there clinical disease//Was there clinical disease:	
HIV: Antibody//Antibody:	
HIV: RNA//RNA:	
HIV: Was there clinical disease//Was there clinical disease (ARC, AIDS):	
If Anti-viral, check all that apply//If Yes, check all that apply:	
If other therapies, check all that apply//If Yes, check all that apply:	
Other therapies:	
Physical Capacity:	Replace with cognitive and motor development
Secondary Source of Payment//Secondary:	
Was biopsy done to confirm acute rejection:	
Was patient hospitalized during the last 90 days prior to the transplant admission:	
<b>TRR – Kidney (N=19)</b>	
Any tolerance induction technique used:	
Contributory Cause of Graft Failure// Acute Rejection:	
Contributory Cause of Graft Failure// Graft Thrombosis:	
Contributory Cause of Graft Failure// Infection:	
Contributory Cause of Graft Failure// Recurrent Disease:	
Contributory Cause of Graft Failure// Surgical Complications:	
Contributory Cause of Graft Failure// Urological Complications:	
Creatinine decline by 25% or more in first 24 hours on 2 separate samples:	
Dialysis Center Name://Provider Name:	
Dialysis Provider Number//Provider #:	
Final flow rate at transplant:	
If yes, specify tumor type:	

**Appendix A** **Exhibit 2**  
**List of Deletions on Transplant Recipient Registration (TRR) for Pediatrics**  
**Pediatric Data Revision Subcommittee**  
**February 9, 2007**

	<b>Comment</b>
Incidental Tumor found at time of Transplant:	
Kidney Produced > 40ml of Urine in First 24 Hours:	
Previous Pregnancies	
Tumor type other//Specify:	
TWI Left KI//Warm ischemia Time: (include Anastomotic time)	
TWI Right KI//Warm ischemia Time Right KI (OR EN-BLOC): (include Anastomotic time)	
Was preimplantation kidney biopsy performed at the transplant center:	
<b>TRR – Pancreas (N=4)</b>	
Date Pancreas Graft Removed:	
If a simultaneous Tx with another organ, was the Pancreas revascularized before or after other organs:	
Pancreas Graft Removed:	
Surgical Incision:	
<b>TRR - Kidney-Pancreas (N=23)</b>	
Any tolerance induction technique used:	
Contributory Cause of Graft Failure// Kidney Acute Rejection:	
Contributory Cause of Graft Failure// Kidney Graft Thrombosis:	
Contributory Cause of Graft Failure// Kidney Infection:	
Contributory Cause of Graft Failure// Recurrent Disease:	
Contributory Cause of Graft Failure// Surgical Complications:	
Contributory Cause of Graft Failure// Urological Complications:	
Creatinine Decline by 25% or More in First 24 Hours on 2 separate samples:	
Dialysis Center Name://Provider Name:	
Dialysis Provider Number//Provider #:	
Pancreas Graft Removed:	
If Yes, Date Pancreas Graft Removed:	
Incidental Tumor found at time of Transplant:	
If yes, specify tumor type:	
Tumor type other//Specify:	
Kidney Produced > 40ml of Urine in First 24 Hours:	
Pancreas Secondary Source of Payment//Secondary: *	
Previous Pregnancies	
Surgical Incision:	
TCI Right KI//Total Warm Ischemia Time Right KI (OR EN-BLOC): (Include Anastomotic time):	
Total Warm ischemia Time Left KI (Include Anastomotic time):	
Was preimplantation kidney biopsy performed at the transplant center:	
Was the Pancreas revascularized before or after other organs:	

Note: \* Kidney Secondary Source of Payment//Secondary deletion is included in deletions for elements common to all organs.

**Appendix A** **Exhibit 2**  
**List of Deletions on Transplant Recipient Registration (TRR) for Pediatrics**  
**Pediatric Data Revision Subcommittee**  
**February 9, 2007**

	<b>Comment</b>
<b>TRR – Liver (N=18)</b>	
Any tolerance induction technique used:	
Did Patient receive 5 or more units of packed red blood cells within 48 hours prior to transplantation due to spontaneous portal hypertensive bleeding:	
Discharge Lab Date:	
HBV: E Antigen//E Antigen:	
HBV: HDV (Delta Virus)//HDV (Delta Virus):	
HBV: Surface Antibody//Surface Antibody:	
If yes, specify tumor type//If yes, specify tumor type:	
Incidental Tumor found at time of Transplant:	
INR:	
Pretransplant Lab Date:	
Serum Albumin:	
Serum Creatinine:	
SGPT/ALT:	
SGPT/ALT:	
Spontaneous Bacterial Peritonitis:	
Surgical Procedure:	
Total Bilirubin:	
Warm Ischemia Time (include anastomotic time):	
<b>TRR – Intestine (N=2)</b>	
Liver Dysfunction:	
Number Previous Abdominal Surgeries:	
<b>TRR – Thoracic (HR=Heart; HL=Heart-Lung; LU=Lung) (N=13)</b>	
Any Drug Treated Infection:	
Cardiac Re-Operation:	
Cerebrovascular Event:	
Chest drain >2 weeks:	
If yes, specify tumor type//If yes, specify tumor type:	Apply to HL, LU
Implantable Defibrillator:	
Incidental Tumor found at time of Transplant:	Apply to HL, LU
Other Surgical Procedures:	
Oxygen Requirement at Rest:	Apply to HL, LU
Previous Pregnancies:	
Pulmonary Embolism:	Apply to HR, HL
Time on inotropes other than Isoproterenol (Isuprel):	Apply to HR, HL
Was this a retransplant due to failure of a previous thoracic graft:	
<b>Total number of TRR deletions: 106</b>	

**Appendix A** **Exhibit 2**  
**List of Deletions on Transplant Recipient Follow-up (TRF) for Pediatrics**  
**Pediatric Data Revision Subcommittee**  
**February 9, 2007**

	<b>Comment</b>
<b>TRF - Data Elements Common to All Forms (N=35)</b>	
Antibody:	
Biological or Anti-viral therapy:	
CMV//Culture:	
CMV/Was there clinical disease:	
CMV: Nucleic Acid Testing:	
Did the patient participate in any clinical research protocol for immunosuppressive medications:	
Did the physician discontinue all maintenance immunosuppressive medications:	
EBV	
EBV DNA:	
EBV: Was there clinical disease:	
HBV	
HBV DNA:	
HBV Surface Antigen:	
HBV//Liver Histology:	
HBV/Was there clinical disease:	
HBV: Core Antibody:	
HCV	
HCV Antibody:	
HCV Liver Histology:	
HCV RIBA:	
HCV RNA:	
HCV: Was there clinical disease:	
HIV	
If Anti-viral, check all that apply//If Yes, check all that apply:	
If No, Not Working Due To:	
If Yes (Working):	
Number of Hospitalizations:	
Other therapies//If Yes, check all that apply:	
Other therapies:	
Physical Capacity:	Replace with cognitive and motor development
RNA:	
Was biopsy done to confirm acute rejection:	
Was there clinical disease (ARC,AIDS):	
Was there evidence of noncompliance with immunosuppression medication during this follow-up period that compromised the patient's recovery:	
Were any of the following viruses diagnosed for onset or recurrence during this follow-up period:(HIV, CMV, HBV, HCV, EBV)	

**Appendix A** **Exhibit 2**  
**List of Deletions on Transplant Recipient Follow-up (TRF) for Pediatrics**  
**Pediatric Data Revision Subcommittee**  
**February 9, 2007**

	<b>Comment</b>
<b>TRF – Kidney (N=18)</b>	
BK	
BK/DNA(PCR) Testing:	
BK/Kidney Histology:	
BK/Treatment for BK (polyoma) virus:	
BK/Urine Cytology:	
BK/Was there clinical disease:	
Contributory Cause of Graft Failure//Acute Rejection	
Contributory Cause of Graft Failure//BK (Polyoma) Virus	
Contributory Cause of Graft Failure//Chronic Rejection	
Contributory Cause of Graft Failure//Graft Thrombosis	
Contributory Cause of Graft Failure//Infection	
Contributory Cause of Graft Failure//Patient Noncompliance	
Contributory Cause of Graft Failure//Recurrent Disease	
Contributory Cause of Graft Failure//Urological Complications	
Provider #:	
Provider Name:	
Treatment for BK (polyoma) virus//If Yes, check all that apply:	
Urine Protein Found By Any Method:	
<b>TRF – Pancreas (N=3)</b>	
Date Pancreas Removed:	
Pancreas Graft Removed:	
Serum Amylase:	
<b>TRF - Kidney-Pancreas (N=21)</b>	
BK	
BK/DNA(PCR) Testing:	
BK/Kidney Histology:	
BK/Treatment for BK (polyoma) virus:	
BK/Urine Cytology:	
BK/Was there clinical disease:	
KI Contributory Cause of Graft Failure//BK (Polyoma) Virus	
KI Contributory Cause of Graft Failure//Kidney Acute Rejection	
KI Contributory Cause of Graft Failure//Kidney Chronic Rejection	
KI Contributory Cause of Graft Failure//Kidney Graft Thrombosis	
KI Contributory Cause of Graft Failure//Kidney Infection	
KI Contributory Cause of Graft Failure//Patient Noncompliance	
KI Contributory Cause of Graft Failure//Recurrent Disease:	
KI Contributory Cause of Graft Failure//Urological Complications	
Date Pancreas Removed:	
Pancreas Graft Removed:	

**Appendix A** **Exhibit 2**  
**List of Deletions on Transplant Recipient Follow-up (TRF) for Pediatrics**  
**Pediatric Data Revision Subcommittee**  
**February 9, 2007**

	<b>Comment</b>
Provider #:	
Provider Name:	
Serum Amylase:	
Treatment for BK (polyoma) virus//If Yes, check all that apply:	
Urine Protein Found By Any Method:	
<b>TRF – Liver (N=5)</b>	
HDV:	
INR:	
Patient Noncompliance:	
Serum Albumin:	
SGPT/ALT:	
<b>TRF – Intestine (N=2)</b>	
Serum Albumin:	
Total Bilirubin:	
<b>TRF – Thoracic (N=7)</b>	
Bone Disease (Symptomatic):	
Cataracts:	
Chronic Liver Disease:	
Clinically Significant Events: (Under Coronary Artery Disease)	
Drug Treated Hyperlipidemia:	
Drug Treated Hypertension:	
Stroke:	
<b>Total number of TRF deletions: 91</b>	

**Appendix B  
Pediatric Data Revision Subcommittee  
Suggested Modifications and Additions to the OPTN Data Collection Forms**

**Data Collection Principles:** A) Develop transplant, donation and allocation policies; B) Determine if Institutional Members are complying with policy; C) Determine Member-specific performance; D) Ensure patient safety when no alternative sources of data exist; E) Fulfill the requirements of the OPTN Final Rule.

TCR = Transplant Candidate Registration; TRR = Transplant Recipient Registration; TRF = Transplant Recipient Follow-up  
KI=Kidney; PA=Pancreas; KP=Kidney-Pancreas; LI=Liver; IN=Intestine; TH=Thoracic; HR=Heart

ALL ORGANS				
Form Type	Section	Proposed Changes for Pediatrics	Principle to support data collection	Comments
<b>MODIFICATIONS TO LOOK-UP/DROP DOWN OR ADDING POP-UP BOX</b>				
TCR, TRR, TRF	Physical Capacity	Add a pop-up box for Failure to Thrive defined as less than 5% for height or weight as compared to the CDC growth charts based on month of age currently used within UNet system. If the patient falls below 5% on the CDC chart for either height or weight, a pop-up could be created to notify the user that this patient qualifies as exhibiting a failure to thrive by the definitions built into the system. If the user disagrees, the candidate's height and weight could be re-checked and changed in the system if necessary.	N/A	No data field needs to be added. Only needs pop-up.
TRR, TRF	Investigational Immunosuppressive Medications	Add "other" field		Other text field is already there; revise lay-out
<b>ADDITIONS: 3 (TCR, TRR, TRF)</b>				
TCR, TRR, TRF	Clinical Information	Add a question for the date of height and weight measurements	A	
TCR, TRR, TRF	Physical Capacity	Replace with a question to assess Cognitive Development: 1. Definite Cognitive delay/impairment (verified by IQ score <70 or unambiguous behavioral observation) 2. Probable Cognitive delay/impairment (not verified or unambiguous but more likely than not, based on behavioral observation or other evidence) 3. Questionable Cognitive delay/impairment (not judged to be more likely than not, but with some indication of cognitive delay/impairment such as expressive/receptive language and/or learning difficulties) 4- No Cognitive delay/impairment (no obvious indicators of cognitive delay/impairment) 5- Not Assessed	A	

**Appendix B  
Pediatric Data Revision Subcommittee  
Suggested Modifications and Additions to the OPTN Data Collection Forms**

**Data Collection Principles:** A) Develop transplant, donation and allocation policies; B) Determine if Institutional Members are complying with policy; C) Determine Member-specific performance; D) Ensure patient safety when no alternative sources of data exist; E) Fulfill the requirements of the OPTN Final Rule.

TCR = Transplant Candidate Registration; TRR = Transplant Recipient Registration; TRF = Transplant Recipient Follow-up  
 KI=Kidney; PA=Pancreas; KP=Kidney-Pancreas; LI=Liver; IN=Intestine; TH=Thoracic; HR=Heart

ALL ORGANS				
Form Type	Section	Proposed Changes for Pediatrics	Principle to support data collection	Comments
TCR, TRR, TRF	Physical Capacity	Replace with a question to assess Motor Development 1- Definite Motor delay/impairment (verified by physical exam or unambiguous behavioral observation) 2- Probable Motor delay/impairment (not verified or unambiguous but more likely than not, based on behavioral observation or other evidence) 3- Questionable Motor delay/impairment (not judged to be more likely than not, but with some indications of motor delay/impairment) 4- No Motor delay/impairment (no obvious indicators of motor delay/impairment) 5- Not Assessed	A	

**Appendix B  
Pediatric Data Revision Subcommittee  
Suggested Modifications and Additions to the OPTN Data Collection Forms**

**Data Collection Principles:** A) Develop transplant, donation and allocation policies; B) Determine if Institutional Members are complying with policy; C) Determine Member-specific performance; D) Ensure patient safety when no alternative sources of data exist; E) Fulfill the requirements of the OPTN Final Rule. TCR = Transplant Candidate Registration; TRR = Transplant Recipient Registration; TRF = Transplant Recipient Follow-up; KI=Kidney; PA=Pancreas; KP=Kidney-Pancreas

ORGAN	Form Type	Section	Proposed Changes	Principle to support data collection	Comments
<b>MODIFICATIONS TO LOOK-UP OR EXISTING FIELD</b>					
KI, KP	TCR, TRR	Academic Activity Level	Add "unable to participate regularly in academics due to dialysis"		
<b>KI &amp; KP ADDITIONS: 6 (TCR, TRR, TRF)</b>					
KI, KP	TCR, TRR, TRF	Clinical Information	Add a question for growth hormone therapy as a marker for growth delay: Yes/ No	A	
KI, KP	TCR, TRR, TRF	General Medical Factor	Bone Disease (check all that apply) - Fracture in the past year (or since last follow-up): Yes/No/Unknown Specify Location and number of fractures: 1) spine-compression fracture # _____ 2) extremity # _____ 3) other # _____ - AVN (avascular necrosis): Yes/No/Unknown	A A A A A	

**Appendix B  
Pediatric Data Revision Subcommittee  
Suggested Modifications and Additions to the OPTN Data Collection Forms**

**Data Collection Principles:** A) Develop transplant, donation and allocation policies; B) Determine if Institutional Members are complying with policy; C) Determine Member-specific performance; D) Ensure patient safety when no alternative sources of data exist; E) Fulfill the requirements of the OPTN Final Rule. TCR = Transplant Candidate Registration; TRR = Transplant Recipient Registration; TRF = Transplant Recipient Follow-up; LI=Liver; IN=Intestine

ORGAN	Form Type	Section	Proposed Changes for Pediatrics	Principle to support data collection	Comments
<b>MODIFICATIONS TO LOOK-UP/DROP DOWN OR EXISTING FIELD</b>					
LI, IN	TCR, TRR	Any previous malignancies	Add hepatoblastoma and hepatocellular cancer to the list	N/A	
LI	TRR	Split Type	Left lobe in situ (segments 2, 3 and 4) Left lobe on the bench (segments 2, 3 and 4) Left lobe with caudate in situ (segments 1, 2, 3 and 4) Left lobe with caudate on the bench (segments 1, 2, 3 and 4) Left lateral segment in situ (segments 2 and 3) Left lateral segment on the bench (segments 2 and 3) Right lobe without middle hepatic vein in situ (segments 5, 6, 7 and 8) Right lobe without middle hepatic vein on the bench (segments 5, 6, 7 and 8) Right lobe with middle hepatic vein in situ (segments 4, 5, 6, 7 and 8) Right lobe with middle hepatic vein on the bench (segments 4, 5, 6, 7 and 8)	N/A	
LI	TRR	Partial Type	Right lobe without middle hepatic vein (segments 5, 6, 7 and 8) Right lobe with middle hepatic vein (segments 4, 5, 6, 7 and 8) Left lobe (segments 2, 3 and 4) Left lateral segment (segments 2 and 3)	N/A	
IN	TCR	Intestine Medical Factors	Exhausted Vascular Access: Yes, No, Unknown	N/A	Add a definition as loss of two or more vascular access sites.
IN	TCR	Intestine Medical Factors	Italics fonts indicate modification to the current label History of Portal <b>Portomesenteric</b> Vein Thrombosis: Yes, No, Unknown	N/A	
IN	TRR, TRF	Primary Cause of graft failure	Add GVHD and ischemia/NEC (Necrotizing Enterocolitis) like Syndrome as an option	N/A	

**Appendix B  
Pediatric Data Revision Subcommittee  
Suggested Modifications and Additions to the OPTN Data Collection Forms**

**Data Collection Principles:** A) Develop transplant, donation and allocation policies; B) Determine if Institutional Members are complying with policy; C) Determine Member-specific performance; D) Ensure patient safety when no alternative sources of data exist; E) Fulfill the requirements of the OPTN Final Rule.  
TCR = Transplant Candidate Registration; TRR = Transplant Recipient Registration; TRF = Transplant Recipient Follow-up; LI=Liver; IN=Intestine

ORGAN	Form Type	Section	Proposed Changes for Pediatrics	Principle to support data collection	Comments
<b>LI ADDITIONS: 3 (TRR, TRF)</b>					
LI	TRR, TRF	Graft Status	Add the following if vascular thrombosis is selected as a graft loss cause: - Hepatic arterial thrombosis :Yes/No/Unknown - Hepatic outflow obstruction: Yes/No/Unknown - Portal vein thrombosis :Yes/No/Unknown	A A A	
<b>IN ADDITIONS: 5 (TCR); 1 (TCR, TRR, TRF)</b>					
IN	TCR	Intestine Medical Factors	Variceal Bleeding in the Last 2 Weeks: Yes, No, Unknown Recurrent Sepsis: Yes, No, Unknown Fungal Sepsis: Yes, No, Unknown Unmanageable Fluid-Electrolyte Losses: Yes, No, Unknown "Non-Reconstructible" GI Tract: Yes, No, Unknown	A A A A A	
IN	TCR, TRR, TRF	General Medical Factors; labs section	Total Bilirubin	A	

**Appendix B  
Pediatric Data Revision Subcommittee  
Suggested Modifications and Additions to the OPTN Data Collection Forms**

**Data Collection Principles:** A) Develop transplant, donation and allocation policies; B) Determine if Institutional Members are complying with policy;

C) Determine Member-specific performance; D) Ensure patient safety when no alternative sources of data exist; E) Fulfill the requirements of the OPTN Final Rule.  
TCR = Transplant Candidate Registration; TRR = Transplant Recipient Registration; TRF = Transplant Recipient Follow-up; TH=Thoracic; HR=Heart; HL=Heart-Lung; LU=Lung

ORGAN	Form Type	Section	Proposed Changes	Principle to support data collection	Comments
<b>MODIFICATIONS TO LOOK-UP OR EXISTING FIELD; ADDING DEFINITIONS</b>					
HR, LU, HL	TCR	Heart Medical Factors	Add a pop-up definitions within this category (sudden death)	N/A	Subcommittee recommended to keep this field on Ped and Adult
HR	TRR, TRF	Clinical Information: Post Transplant	Modify lookup to add "other" under primary cause of graft failure, and add other specify text field	N/A	
HR, LU, HL	TRR	Most Recent Hemodynamic	Add Cardiac Index for peds	N/A	Can be computed from cardiac output and BSA and displayed.
HR, LU, HL	TRF	Post-Transplant Events	Recommended a definition pop-up for Chronic Liver Disease and Renal Dysfunction.		
<b>TH ADDITIONS: 6 (TCR - HR, LU, HL); 1 (TCR &amp; TRR - LU, HL)</b>					
HR, LU, HL	TCR	General Medical Factors	Add "Pulmonary Insufficiency"	A	Need definition
HR, LU, HL	TCR	Prior Cardiac Surgery (non-transplant)	Any prior thoracic surgery other than previous transplant: Yes/No/Unkn - If yes, number of prior sternotomies: ____ - If yes, number of prior thoracotomies: ____	A & C A & C A & C	This is in agreement with Thoracic Committee recommendation.
HR, LU, HL	TCR	Prior Cardiac Surgery (non-transplant)	If received prior Congenital cardiac surgery - Palliative surgery: Yes, No - Corrective surgery: Yes, No	A & C A & C	
LU, HL	TCR, TRR	Patient on Life support	Add "inotropes"	A	

Appendix C - Proposed Viral Detection Section

On TRRs

Options: Positive, Negative, Not Done, Unknown/Cannot Disclose

**Viral Detection:**

HIV Serostatus:	<input type="text"/>
CMV IgG:	<input type="text"/>
CMV IgM:	<input type="text"/>
HBV Core Antibody:	<input type="text"/>
HBV Surface Antigen:	<input type="text"/>
HCV Serostatus:	<input type="text"/>
EBV Serostatus:	<input type="text"/>

On Kidney and Kidney-Pancreas TRFs (at One and Two Years)

Options: Positive, Negative, Not Done, Unknown/Cannot Disclose

**Viral Detection:**

CMV IgG:	<input type="text"/>
CMV IgM:	<input type="text"/>

**Appendix D****POC Proposal – Adult Data Elements to be Collected Beyond 5 Years**

## Elements Common to All Organs:

- Demographics: Zip code; State
- Provider/Donor Information: Follow-up center
- Patient Status: Date last seen, died or re-transplanted; primary cause of death
- Graft status; date of graft failure
- Serum creatinine

## Follow-up Elements: Kidney

- Primary cause of graft failure

## Follow-up Elements: Kidney-Pancreas

- Primary cause of graft failure
- Contributory causes of graft failure (for pancreas graft)

## Follow-up Elements: Pancreas

- Primary cause of graft failure
- Contributory causes of graft failure

## Follow-up Elements: Liver

- Contributory causes of graft failure (Note: Liver has no primary cause)
- Presence and type of post-transplant malignancies

## Follow-up Elements: Intestine

- Primary cause of graft failure (Note: Intestine has no contributory causes)

## Follow-up Elements: All Thoracic

- Primary cause of graft failure
- Bronchiolitis obliterans syndrome (lung only)
- Coronary artery disease (heart only)
- Renal dysfunction (Yes, No, Unknown) (for all thoracic organs)  
If yes:
  - Chronic dialysis?
  - Renal tx since thoracic tx

**Notice of Policy Change—** Modifications to OPTN/UNOS Policy 3.1 (Organ Distribution: Definitions) Requiring UNOS Donor ID Verification (Operations Committee)

**Affected Policy Language:**

**3.1.2 Transplant Center.** A transplant center is a hospital that is a Member in which transplant are performed. A transplant center may also be called a transplant hospital. It is the responsibility of the transplanting surgeon at the transplant center receiving the organ offer for the surgeon's candidate to ensure medical suitability of donor organs for transplantation into the potential recipient, including compatibility of donor and candidate by ABO blood type. Upon receipt of an organ, prior to implantation, the transplant center is responsible for verifying the recorded donor ABO with the recorded ABO of the intended recipient and UNOS Donor ID number. ~~This action~~ These actions must be documented and ~~is~~ are subject to review upon audit.

To read the complete policy language visit [www.unos.org](http://www.unos.org) or [www.optn.org](http://www.optn.org). From the UNOS Web site, select Resources from the main menu, then select policies. From the OPTN Web site, select Policies from the main menu.

**Notice of Bylaws Modification** — Modifications to OPTN and UNOS Bylaws, Appendix A2-1, Section 2.06A, (b), (3) “Probation,” (4) “Member Not in Good Standing,” (5) “Suspension of Member Privileges,” (6) “Termination of Membership or Designated Transplant Program Status,” (7) “Action Specified in OPTN Final Rule.” (Patient Affairs Committee)

**Affected Bylaws Language:**

2.06A Membership and Professional Standards Committee Action

(a) [no changes]

(b) [no changes]

(1) Reject Request for Corrective Action. [no changes]

(2) Notice of Uncontested Violation, Letter of Warning or Letter of Reprimand. [no changes]

(a) Notice of Uncontested Violation – [no changes]

(b) Letter of Warning – [no changes]

(c) Letter of Reprimand – [no changes]

(3) Probation.

a. Adverse Action. The MPSC may recommend that the Board of Directors or the Executive Committee place the Member on Probation, or either the Executive Committee or the Board of Directors may do so on its own accord. ~~may place the Member on probation, which~~ Such action would be an adverse action under the Bylaws. This adverse action ~~and~~ would first entitle the Member to procedural rights as provided in Section 3.01A – 3.03A. The Member is entitled to the procedural rights described in that Section in the case of a recommendation of Probation by the MPSC. ~~followed, in the case of initial recommendation by the MPSC, by a final recommendation by the MPSC to and, in any event, final action by~~ The Member is also entitled to those same rights by a final decision of the Board of Directors or the Executive Committee to place the Member on Probation and give ~~and~~ notice of that final action to the Secretary of HHS ~~of the final decision to place the Member on probation.~~

b. General Requirements. The OPTN will give notice to all Members that a Member has been placed on Probation. Probation may include one or more of the following or other actions specified ~~deemed appropriate~~ by the MPSC-PCSC, the MPSC, the Executive Committee, or the Board of Directors ~~and will include notice to all Members.:~~

~~(a)~~(1) Required submission of a compliance action plan or plan of correction developed to specifications ~~as may be defined by the MPSC-PCSC, the MPSC, the Executive Committee, or the Board of Directors.~~ The Member must demonstrate to such specifying body that it has adhered with demonstration to the MPSC-PCSC/MPSC of adherence to the plan and that it has corrected ~~correction of~~ any non-compliant activity within a ~~some~~ period of time as specified.

~~b)(2)~~ Unscheduled on-site audit(s) performed by the OPTN Contractor audit staff throughout the period of Probation. The Member shall be responsible for reimbursing the, to be performed by OPTN Contractor audit staff at the sole reasonable costs and expenses of the audit(s). Member. Such costs and expenses shall include, but not be limited to personal salaries and benefits, administrative overhead, and, travel and lodging expenses of OPTN Contractor staff.

~~(c)(3)~~ Specified Required submission of reports, data, or other evidence to the OPTN Contractor documenting correction of the non-compliant activity throughout the period of pProbation.

c. Additional Notice Requirements if the Member Placed on Probation is a Transplant Center. Notice of this adverse action must be given by the Member to all Patients directly associated with the cited transplant program. For purposes of this requirement, "Patients" shall include the following individuals:

- (1) Patients undergoing the cited transplant program's evaluation process;
- (2) Candidates on the waitlist of the cited transplant program;
- (3) Candidates added to the cited transplant program's waiting list; and
- (4) Recipients being followed by the cited transplant program.

If the Member placed on Probation by the OPTN is a Transplant Center, then the Member Transplant Center must notify its patients that the Member received this adverse action. This notice to Patients must be given within 30 days of the Member receiving formal notification from the OPTN that it has been placed on Probation. The notice must be sent by the Member Transplant Center to each Patient as defined above during the time the Member is on Probation.

The notice to Patients must be provided in writing, in each Patient's spoken language, and as specified by the Executive Committee or Board of Directors.

The Member shall comply with any additional notification requirements specified by the MPSC-PCSC, MPSC, Executive Committee, or Board of Directors.

~~If the Member receiving the adverse action set forth in this section is a transplant center, then Wwithin 30 days of the Member's notification of Probation, as described herein, the Member shall provide for the transplant program being cited for the adverse action, written notice in the patient's spoken language as prescribed by the Executive Committee and/or Board of Directors to all patients in the transplant program's evaluation process, candidates associated with the transplant program, and recipients being followed by the transplant program, as prescribed by the Executive Committee and/or Board of Directors. The Member shall provide written notice to all additional patients evaluated and , as well as to all candidates added to the national waitlist by the transplant program, for the duration of the Probation, as prescribed by the Executive Committee and/or Board of Directors. Additional notification requirements shall be at the discretion of the Executive Committee and/or Board of Directors.~~

(4) Member Not in Good Standing.

a. Adverse Action. The MPSC may recommend that the Board of Directors or the Executive Committee declare the Member a “Member Not in Good Standing,” or either the Executive Committee or the Board of Directors may do so on its own accord. ~~may declare the Member a Member Not in Good Standing, which~~ Such action would be an adverse action under the Bylaws ~~and.~~ This adverse action would first entitle the Member to procedural rights as provided in Section 3.01A – 3.03A. The Member is entitled to the procedural rights described in that Section ~~followed~~ in the case of an ~~initial~~ recommendation of declaring a Member a “Member Not in Good Standing” by the MPSC. The Member is also entitled to those same rights by a final decision of the ~~by a final recommendation to, and in any event, final action by the~~ Board of Directors or the Executive Committee and notice to the Secretary of HHS of the final decisions to declare the Member a “Member Not in Good Standing” and give notice of that final action to the Secretary of HHS. ~~Member Not in Good Standing includes all of the following plus any other action deemed appropriate by the Board of Directors, unless specifically limited to one or more of such actions by the Board of Directors or Executive Committee:~~

b. General Requirements. The adverse action of Member Not in Good Standing may include one or more of the following, plus any other action, as specified by the Board of Directors or the Executive Committee:

~~(a)~~(1) Withdrawal of voting privileges in OPTN affairs.

~~(b)~~(2) During the duration of the adverse action, Ssuspension of the ability for any personnel named in the OPTN Contractor Membership database as associated with the Member ~~who are not otherwise eligible to serve by virtue of their association with a member in Good Standing~~ to sit on any Committee, hold office, and sit on the Board of Directors.

~~(c)~~(3) Formal notification, along with subsequent changes in such status, to the entire OPTN Membership, including as well as to the Chief Executive Officer of each OPTN Institutional Members

~~(d)~~(4) Formal notification, along with subsequent changes in such status, to the Member’s Chief Executive Officer or Administrator and to the state health commissioner or other appropriate state representative with oversight of health care institutions doing business in the Member’s state.

~~(e)~~(5) Notice within reasonable limits and means, ~~to patients and~~ the general public in the area of the Member as specified by the Board of Directors or the Executive Committee. Such notice may include, but is not limited to, communication using the OPTN website ~~and/or as prescribed by the Board of Directors for distribution by the Member.~~

(6) The actions listed for a Member on Probation.

c. Additional Notice Requirements for Transplant Centers Declared a Member Not in Good Standing. Notice of this adverse action must be given by the Member to all Patients directly associated with the Member Transplant Center, including Patients of all of the Member’s

transplant programs. For purposes of this requirement, "Patients" shall include the following individuals:

- (1) Patients undergoing the evaluation process at all of the Member's transplant programs;
- (2) Candidates on the waitlist of all of the Member's transplant programs;
- (3) Candidates added to all of the Member's transplant programs' waiting lists; and
- (4) Recipients being followed by all of the Member's transplant programs.

If the Member declared a Member Not in Good Standing by the OPTN is a Transplant Center, then the Member must notify its Patients that the Member received this adverse action. This notice to Patients must be given within 30 days of the Member receiving formal notification from the OPTN that it has been declared a Member Not in Good Standing. The notice must be sent by the Member to each Patient as defined above during the time the Member is a Member Not in Good Standing of the OPTN.

The notice to Patients must be provided in writing, in each Patient's spoken language, and as specified by the Executive Committee or Board of Directors.

The Member shall comply with any additional notification requirements specified by the MPSC-PCSC, MPSC, Executive Committee, or Board of Directors.

~~(f) If the Member receiving the adverse action set forth in this section is a transplant center, then Wwithin 30 days of the Member's notification of Member Not in Good Standing, as defined herein, the Member shall provide written notice in the patient's spoken language as prescribed by the Executive Committee and/or Board of Directors to all patients in the evaluation process, patients in the evaluation process, candidates and recipients associated with and recipients being followed by the Member, as prescribed by the Board of Directors. The Member shall provide written notice to all additional patients evaluated and, as well as to all candidates added to the national waitlist by the Member, for such duration as prescribed by the Board of Directors. Additional notification requirements shall be at the discretion of the Executive Committee and/or Board of Directors.~~

~~(g) (f) The actions listed for a Member on probation.~~

#### (5) Suspension of Member Privileges.

- a. Adverse Action. Only in the case of noncompliance with policies covered by Section 1138 of the Social Security Act, the MPSC may recommend that the Board of Directors or the Executive Committee, or either the Executive Committee or the Board of Directors on its own accord, may request approval from the Secretary of HHS to suspend the Member's Privileges. The Board of Directors or the Executive Committee may request such approval from the Secretary on its own accord. This adverse action ability to list patients on the waiting list, the Member's eligibility to receive organ offers for transplants and related services, and other membership privileges, any of which would be an adverse action under the Bylaws which would first entitle the Member to procedural rights as provided in Section 3.01A – 3.03A. The Member is entitled to the procedural rights described in that Section in the case of a followed in the case of an initial recommendation by the MSPC that by a final recommendation to and, in any event, final action by the Board of

Directors or the Executive Committee request approval from the Secretary to suspend the Member's Privileges. The Member is also entitled to those same rights by a final decision of the Board of Directors or the Executive Committee to request such approval from the Secretary. and, if the decision is to move the request forward, submission of the recommendation to the Secretary of HHS for consideration.

b. General Requirements. Suspension of membership privileges may include one or more of the following or other actions as specified deemed appropriate by the MPSC-PCSC, the MPSC, the Executive Committee, or the Board of Directors. The actions requested to be taken shall be included in the request for approval from the Secretary.

~~(a)~~(1) Suspension of voting privileges in OPTN affairs.

~~(b)~~(2) During the duration of the adverse action, suspension of the ability for any personnel named in the OPTN Contractor Membership database as associated with the Member privilege to hold office and/or sit on OPTN Board of Directors or Committees.

~~(c)~~(3) Suspension of the privilege to receive all organ offers or offers of particular organ types for transplantation and related services.

~~(d)~~(4) Suspension of the privilege to list all patients or patients in need of particular organ types on the OPTN Patient Waiting List.

~~(e)~~(5) The actions listed for a Member on Probation and the actions listed for a Member Not in Good Standing

c. Additional Notice Requirements if the OPTN Recommends Suspension of Member Privileges for a Transplant Center. Notice of this adverse action must be given by the Member to all Patients directly associated with the Member Transplant Center, including Patients of all of the Member's transplant programs. For purposes of this requirement, "Patients" shall include the following individuals:

- (1) Patients undergoing the evaluation process at all of the Member's transplant programs;
- (2) Candidates on the waitlist of all of the Member's transplant programs;
- (3) Candidates added to all of the Member's transplant programs' waiting lists; and
- (4) Recipients being followed by all of the Member's transplant programs.

If the Member whose Privileges are suspended is a transplant center, then the Member must notify its Patients that the Member received this adverse action. This notice to Patients must be given within 30 days of the Member receiving formal notification from the OPTN that its Privileges have been suspended. The notice must be sent by the Member to each Patient as defined above during the time the Member's Privileges are suspended.

The notice to Patients must be provided in writing, in each Patient's spoken language, and as specified by the Executive Committee or Board of Directors.

The Member shall comply with any additional notification requirements specified by the MPSC-PCSC, MPSC, Executive Committee, or Board of Directors.

If the Member receiving the adverse action set forth in this section is a transplant center, then within 30 days of the Member's notification of Suspension of Member Privileges, as defined herein, the Member shall provide written notice in the patient's spoken language as prescribed by the Executive Committee and/or Board of Directors to all patients in the evaluation process, patients in the evaluation process, candidates and recipients associated with the Member and recipients being followed by associated with the Member, as prescribed by the Board of Directors and/or the Secretary of HHS. Additional notification requirements shall be at the discretion of the Executive Committee and/or Board of Directors.

(6) Termination of Membership or Designated Transplant Program Status.

a. Adverse Action. ~~Only in the case of noncompliance with policies covered by Section 1138 of the Social Security Act, t~~ The MPSC may recommend that the Board of Directors or the Executive Committee, or either the Executive Committee or the Board of Directors on its own accord, may request approval from the Secretary of HHS to terminate membership or designated transplant program status for one or more of the Member's organs, transplant programs. The Board of Directors or the Executive Committee may request such approval from the Secretary on its own accord. which are ~~This adverse actions under the Bylaws and would first entitle the Member to procedural rights as provided in Section 3.01A – 3.03A. The Member is entitled to the procedural rights described in that Section in the case of a recommendation of the MPSC that the Board of Directors, or the Executive Committee, request approval from the Secretary to terminate membership or designated transplant program status for one or more of the Member's organ transplant programs. The Member is also entitled to those same procedural rights by a final decision of the Board of Directors or the Executive Committee to request such approval from the Secretary. followed in the case of an initial recommendation by the MPSC, by a final recommendation to and in any event, final action by the Board of Directors or the Executive Committee and, if the decision is to move the request forward, submission of the recommendation to the Secretary of HHS for consideration.~~

b. General Requirements. Termination of Membership or Designated Transplant Program Status may include one or more of the following or other actions as specified by the MPSC-PCSC, the MPSC, the Executive Committee, or the Board of Directors. The actions requested to be taken shall be included in the request for approval from the Secretary.

(1) Suspension of voting privileges in OPTN affairs.

(2) During the duration of the adverse action, s suspension of the ability for any personnel named in the OPTN Contractor Membership database as associated with the Member to hold office and/or sit on OPTN Board of Directors or Committees.

(3) Suspension of the privilege to receive all organ offers or offers of particular organ types for transplantation and related services.

(4) Suspension of the privilege to list all patients or patients in need of particular organ types on the OPTN Patient Waiting List.

(5) The actions listed for a Member on Probation, the actions listed for a Member Not in Good Standing, and/or the actions listed for Suspension of Member Privileges.

c. Additional Notice Requirements for Transplant Centers if the OPTN Recommends Termination of Membership or Designated Transplant Program Status. Notice of this adverse action must be given by the Member to all Patients directly associated with the Member Transplant Center, including Patients of all of the Member’s transplant programs. For purposes of this requirement, “Patients” shall include the following individuals:

- (1) Patients undergoing the evaluation process at all of the Member’s transplant programs;
- (2) Candidates on the waitlist of all of the Member’s transplant programs;
- (3) Candidates added to all of the Member’s transplant programs’ waiting lists; and
- (4) Recipients being followed by all of the Member’s transplant programs.

If the Member whose Membership is terminated or whose organ transplant program’s Designated Transplant Program Status is terminated must notify its Patients that the Member received this adverse action. This notice to Patients must be given within 30 days of the Member receiving formal notification from the OPTN that its Membership or Designated Transplant Program Status has been terminated.

The notice to Patients must be provided in writing, in each Patient’s spoken language, and as specified by the Executive Committee or Board of Directors.

The Member shall comply with any additional notification requirements specified by the MPSC-PCSC, MPSC, Executive Committee, or Board of Directors.

~~If the Member receiving the adverse action set forth in this section is a transplant center, then Wwithin 30 days of the Member’s notification of Termination of Membership or Designated Transplant Program Status, as defined herein, the Member shall provide written notice in the patient’s spoken language as prescribed by the Executive Committee and/or Board of Directors to all patients in the evaluation process, patients in the evaluation process, candidates and recipients and recipients being followed by associated with the Member, as prescribed by the Executive Committee, Board of Directors and/or the Secretary of HHS. Additional notification requirements shall be at the discretion of the Executive Committee, Board of Directors and/or Secretary of HHS.~~

~~d. Transfer of Candidates on the OPTN Waiting List. If the Member’s Membership is terminated, the Member shall transfer all candidates listed by all of its transplant programs to other transplant programs. If the Member has a transplant program for which the Designated Transplant Program Status is terminated, then only the cited transplant program(s) must transfer all of the cited transplant program’s candidates to other transplant programs.~~

(7) Action Specified in OPTN Final Rule.

a. Adverse Action. Only iIn the case of noncompliance with policies covered by Section 1138 of the Social Security Act, the MPSC may recommend that the Board of Directors or the Executive Committee or either the Executive Committee or the Board of Directors on its own accord, may recommend to the Secretary of HHS any action specifically identified in Section 121.10(c) of the

~~OPTN Final Rule. The Board of Directors or the Executive Committee may make such a recommendation to the Secretary on its own accord. , 42 CFR § OPTN Bylaws, Appendix A2-6 December 14, 2006 121.10(c), which would be an This adverse action under the Bylaws and would first entitle the Member to procedural rights as provided in Section 3.01A – 3.03A. The Member is entitled to the procedural rights described in that Section in the case of a recommendation by the MPSC that the Board of Directors or the Executive Committee recommend that the Secretary take any action specifically identified in Section 121.120(c) of the OPTN Final Rule. The Member is also entitled to those same rights by a final decision of the Board of Directors or the Executive Committee to make such a recommendation to the Secretary of HHS. followed in the case of initial recommendation by the MPSC, by a final recommendation to and in any event, final action by the Board of Directors or the Executive Committee and, if the decision is to move the recommendation forward, submission of the recommendation to the Secretary of HHS for consideration.~~

b. Additional Notice Requirements if the OPTN Recommends an Action Specified in OPTN Final Rule against a Transplant Center. Notice of this adverse action must be given by the Member to all Patients directly associated with the Member Transplant Center, including Patients of all of the Member’s transplant programs. For purposes of this requirement, “Patients” shall include the following individuals:

- (1) Patients undergoing the evaluation process at all of the Member’s transplant programs;
- (2) Candidates on the waitlist of all of the Member’s transplant programs;
- (3) Candidates added to all of the Member’s transplant programs’ waiting lists; and
- (4) Recipients being followed by all of the Member’s transplant programs.

If the Member against which the adverse action is taken is a transplant center, then the Member must notify its Patients that the Member received this adverse action. This notice to Patients must be given within 30 days of the Member receiving formal notification from the OPTN that the adverse action has been taken.

The notice to Patients must be provided in writing, in each Patient’s spoken language, and as specified by the Executive Committee or Board of Directors.

The Member shall comply with any additional notification requirements specified by the MPSC-PCSC, MPSC, Executive Committee, or Board of Directors.

~~Within 30 days of the Member’s notification of the Action Specified in OPTN Final Rule, as defined herein, the Member shall provide written notice in the patient’s spoken language as prescribed by the Executive Committee and/or Board of Directors to all patients in the evaluation process patients in the evaluation process, candidates and recipients, and recipients being followed by associated with the Member, as prescribed by the Board of Directors and/or the Secretary of HHS. The Member shall provide written notice to all additional patients evaluated and as well as to all candidates added to the national waitlist by the Member, for such duration as prescribed by the Executive Committee, Board of Directors, and/or the Secretary of HHS. Additional notification requirements shall be at the discretion of the Executive Committee, Board of Directors, and/or the Secretary of HHS.~~

**Notice of Policy Change** — Modifications to Policy 3.3.6 (Center Acceptance of Organ Offers) requiring the re-allocation of organs when the Donation after Cardiac Death (DCD) donor converts to brain death. (Transplant Coordinators Committee)

**Affected Policy Language:**

**3.3.6 Center Acceptance of Organ Offers.** If an organ is offered and accepted without conditions, the Host OPO and ~~recipient~~ intended recipient's transplant center shall be bound by this transaction unless there is mutual agreement on an alternative allocation of the organ.

**3.3.6.1 Exception for DCD Donor who Converts to Brain Death After an Organ Offer has been Made.** When a DCD donor converts to brain death, the match system must be re-executed and organs must be allocated according to policies 3.5 - 3.11. Policy 3.6.5.1 does not apply when a DCD donor converts to brain death. Additionally, OPOs are encouraged to initiate allocation of organs that may have been ruled out due to the donor's DCD status (i.e. heart, lungs, pancreas).

**3.3.6.1.1** The Host OPO may choose not to re-allocate organs from a DCD donor who converts to brain death in the following circumstances: 1) lack of donor family approval and consent; 2) donor instability; or 3) other extraordinary circumstances. The Host OPO must document the reason for not re-allocating organs when a DCD donor converts to brain death and make this documentation available upon request.

To read the complete policy language visit [www.unos.org](http://www.unos.org) or [www.optn.org](http://www.optn.org). From the UNOS Web site, select Resources from the main menu, then select policies. From the OPTN Web site, select Policies from the main menu.

**Notice of Policy Change**— Modifications to OPTN/UNOS Policy 5.0 (Standardized Packaging and Transporting of Organs and Tissue Typing Materials) (Operations Committee)

**Affected Policy Language:**

**5.0 STANDARDIZED PACKAGING AND TRANSPORTING OF ORGANS AND TISSUE TYPING MATERIALS**

The following policies address standardized packaging of ~~transplant~~ live and deceased donor organs and tissue typing materials to be transported for the purposes of organ transplantation. When ~~the~~ a deceased donor organ is procured, the Host OPO shall be responsible for ensuring the accuracy of the donor's ABO on the container label and within the donor's documentation. Each OPO shall establish and implement a procedure for obtaining verification of donor ABO data by an individual other than the person initially performing the labeling and documentation requirements put forth in policy 5.2 and 5.3. The OPO shall maintain documentation that such separate verification has taken place and make such documentation available for audit.

Upon receipt of a live or deceased donor organ and prior to implantation, the Transplant Center shall be responsible for determining the accuracy and compatibility of the donor and recipient ABO and document this verification in compliance with Policy 3.1.2.

**5.1 SPECIMEN COLLECTION AND STORAGE.** Each OPO shall have a written policy established with (a) laboratory(s) approved by the American Society for Histocompatibility and Immunogenetics (ASHI) or THE OPTN. This policy should be determined by the specimen requirements of the typing laboratory and the quality assurance criteria of ASHI or UNOS. The policy shall include specific descriptions of the type of specimen, and medium, in addition to the shipping requirements of same.

**5.2 STANDARD LABELING SPECIFICATIONS.** The Host OPO or the Transplant Center, as applicable, shall be responsible for ensuring that the outermost surface of the transport box containing organs and/or tissue typing specimen containers must have a completed standardized external organ container label (provided by the OPTN contractor). Any previous labels on the transport container must be removed prior to labeling the box so that only one label exists. The OPO shall label each specimen within the package in accordance with policy. The Host OPO is responsible for ensuring that each tissue or ~~deceased~~ donor organ container that travels outside the recovery facility is labeled appropriately.

In the case of deceased or live donor organs that remain in the same operating room suite as the intended candidate(s), the Host OPO (if applicable) and Transplant Center must develop, implement, and comply with a procedure ~~a standardized approach~~ to ensure identification of the correct donor organ for the correct recipient. The Transplant Center must document that the correct

organ was identified for the correct recipient candidate prior to transplant. Some type of label must accompany the donor organ labeling and documentation must be present in both the donor and recipient the candidate charts. A "time out" prior to leaving the donor operating room and an additional "time out" upon arrival in the candidate operating room is recommended. Exception: In the case of a single donor organ/organ segment remaining in the same operating room suite as a single intended candidate for a simultaneous transplant, donor organ labeling and "time outs" are not necessary.

In the case of live donor organs that travel outside the recovery facility, the Transplant Center(s) involved shall be responsible for ensuring packaging is consistent with ~~current Policy~~ the requirements of OPTN Policies 5.2.1, and 5.2.3 and that the outermost surface of the transport box containing the organ must have a completed OPTN/UNOS standardized external organ container label (provided by UNOS). ~~Any previously used labels on the transport container must be removed prior to labeling the box for transport to ensure that only one label exists.~~ The recovering Transplant Center shall label each specimen within the package in accordance with OPTN/UNOS policy. The recovering Transplant Center is responsible for ensuring that each container that travels outside the recovery facility is labeled appropriately.

**5.2.1** The Host OPO or the Transplant Center, as applicable, is responsible for ensuring that the Donor I.D. number, donor ABO type, and a secure label identifying the specific contents (e.g., liver, right kidney, heart) are attached to the outer bag or rigid container housing the ~~deceased~~ donor organ prior to transport.

**5.2.2** Each separate specimen container of tissue typing material must have a secure label with the Donor I.D. Number, donor ABO type, date and time the sample was procured, and the type of tissue. The Host OPO or the Transplant Center, as applicable, is responsible for labeling the materials appropriately.

**5.2.3** The Host OPO or the Transplant Center, as applicable, is responsible for fixing to the transport container the standardized label completed with the Donor I.D. Number, Donor ABO type, a description of the specific contents of the box, the sender's name and telephone number, and the Organ Center telephone number. A transport container is defined as a corrugated, wax coated disposable box, cooler, or mechanical preservation cassette or machine.

**5.3** **DOCUMENTATION.** ABO results must be provided by the Host OPO or the Transplant Center, as applicable, in all circumstances during which a ~~deceased~~ donor organ is transported. Properly packaged paperwork containing complete donor information, as described in Policy 2.5.7.1, will be included with the organ transport container in all instances in which the organ is transported.

- 5.4 PACKAGING.** In all circumstances during which an ~~deceased~~ deceased donor organ is transported outside the recovery facility, the Host OPO or the Transplant Center, as applicable, is responsible for packaging, labeling, and handling the organ in a manner which ensures arrival without compromise to the organ(s). Proper insulation and temperature controlled packaging including adequate ice or refrigeration shall be used to protect the organs during transport.
- 5.5 STANDARD ORGAN PACKAGE SPECIFICATIONS.** The re-use of disposable transport boxes is prohibited. If the ~~deceased~~ deceased donor organ is to be commercially shipped, such as with a courier service, commercial airline or charter service, the ~~deceased~~ deceased donor organ must be packaged in a disposable transport box. Coolers are permitted for non-commercial transporting when the organ recovery team is taking the ~~deceased~~ deceased donor organ with them from the donor hospital to the candidate transplant center. The re-use of coolers is permitted. All labels for the previous donor organ must be removed before re-using the cooler. The standard disposable package used by members must have the following properties:
- 5.5.1** A corrugated, wax coated outer container of 200 pound burst strength, or one of equal or greater strength and moisture resistance, must be used.
- 5.5.2** Inside the moisture resistant outer-container, 1-1/2" thick, expanded polystyrene insulated container or its R-factor equivalent must be used. A closed plastic liner must be placed between the outer container and the polystyrene insulated container to encase the ice.
- 5.5.3** A closed plastic liner must also be placed inside the polystyrene container to encase the ice. Inside the insulated container, the organ must be protected by a triple sterile barrier and one rigid container which, if sterile, may be considered one of the triple barriers.
- 5.5.3.1** The rigid container is not required for livers or lungs.
- 5.5.4** The tissue typing specimen containers must be in a leak proof plastic bag and must not be imbedded in the ice.
- 5.5.5** The ~~deceased~~ donor paperwork must be in a watertight container. It may be placed in a location specifically designed for the paperwork or inside the outer container, outside of the insulated container.
- 5.5.6** Accompanying each ~~deceased~~ deceased donor organ and tissue typing material, a "red top" tube of blood, specifically for confirmation of ABO must be sent to the receiving OPO or transplant center. This tube must be labeled as described in Policy 5.2.2 and placed within the insulated container. The Host OPO or the Transplant Center, as applicable, is responsible for ensuring that the tube is appropriately labeled.

**5.6 TRANSPORTATION RESPONSIBILITY.** The Host OPO, as defined in Policy 2.1, is responsible for transportation of deceased donor kidney(s) and tissue typing material to the primary destination designated by the recipient member, (e.g., laboratory, transplant hospital, or OPO). In charter aircraft situations, before the Organ Center will arrange for this mode of transportation, the Host OPO must agree to use a charter aircraft, and it must be determined who will pay for the charter.

**5.6.1 Transportation Costs Incurred for Renal Organs.** Payment of transportation costs incurred by the OPTN contractor on behalf of a member for a ~~deceased donor~~ kidney that is unconditionally accepted by a member and subsequently forwarded to another member is the responsibility of the member that forwarded the kidney. Payment of transportation costs incurred by the OPTN contractor on behalf of a member for a ~~deceased donor~~ kidney that is conditionally accepted by a member and subsequently forwarded to another member is the responsibility of the Host OPO.

**5.6.2 Transportation Costs Incurred for Tissue Typing Material.** Payment of transportation costs incurred by the OPTN contractor on behalf of a member for tissue typing material sent to crossmatch backup recipients for a ~~deceased donor kidney organ~~ that is conditionally accepted by a member is the responsibility of the member which requested backup for the organ.

**5.6.3 Transportation Costs Incurred for Non-Renal Organs.** Payment of non-renal ~~deceased donor~~ organ transportation costs incurred by the OPTN contractor on behalf of a member is the responsibility of the member that accepts the organ. Payment of transportation costs incurred by the OPTN contractor on behalf of a member for ~~deceased donor~~ organs that have been accepted and transported, but cannot be utilized for transplantation, also is the responsibility of the member that accepted the organ. If an ~~deceased donor~~ organ is first accepted by one member and subsequently forwarded to another member, payment of transportation costs incurred by UNOS on behalf of a member in forwarding the organ is the responsibility of the member that finally accepts the organ.

**Notice of Policy Change**— Modifications to Policies 7.1 (Reporting Definitions) and 7.3 (Submission of Organ-Specific Transplant Recipient Registration Forms and Submission of Living Donor Registration Forms) that Extend Living Donor follow-up to Two Years (Living Donor Committee)

**Affected Policy Language:**

**7.1 REPORTING DEFINITIONS**

7.1.5 The follow-up period for living donors will be a minimum of ~~one~~ two years.

**7.3 SUBMISSION OF ORGAN-SPECIFIC TRANSPLANT RECIPIENT REGISTRATION FORMS AND SUBMISSION OF LIVING DONOR REGISTRATION FORMS**

**7.3.2** Living Donor Registration Forms (LDR) must be submitted to the OPTN within 60 days of the form generation date. Recipient Transplant Centers must complete the LDR form when the donor is discharged from the hospital or by six weeks following the transplant date, whichever is first. The recipient transplant center must submit LDR forms for each living donor at six months, one year and two years from the date of donation.

To read the complete policy language visit [www.unos.org](http://www.unos.org) or [www.optn.org](http://www.optn.org). From the UNOS Web site, select Resources from the main menu, then select policies. From the OPTN Web site, select Policies from the main menu.

**Notice of Policy Change** — Modifications to Policies 7.1.7 (Imminent Neurological Death) and 7.1.8 (Eligible Death) Definitions (OPO Committee)

**Affected Policy Language:**

**7.1.7 Imminent Neurological Death.** Imminent Neurological Death is defined as a patient who is 70 years old or younger with severe neurological injury and requiring ventilator support who, upon clinical evaluation documented in the OPO record or donor hospital chart, has an absence of at least three brain stem reflexes ~~or a GCS < 5~~ but does not yet meet the OPTN definition of an eligible death, specifically that the patient has not yet been legally declared brain dead according to hospital policy, and who eventually deteriorates to cardiac death (during the referred hospitalization.) Persons with any condition which would exclude them from being reported as an eligible death would also be excluded from consideration for reporting as an imminent death.

Brain Stem Reflexes:

- Pupillary reaction
- Response to iced caloric
- Gag Reflex
- Cough Reflex
- Corneal Reflex
- Doll's eyes reflex
- Response to painful stimuli
- Spontaneous breathing

**7.1.8 Eligible Death.** Although it is recognized that this definition does not include all potential donors, for reporting purposes for DSA performance assessment, an eligible death for organ donation is defined as the death of a patient 70 years old or younger who ultimately is legally declared brain dead according to hospital policy independent of family decision regarding donation or availability of next-of-kin, independent of medical examiner or coroner involvement in the case, and independent of local acceptance criteria or transplant center practice, who exhibits none of the following:

Active infections (specific diagnoses) [Exclusions to the Definition of Eligible]

Bacterial: Tuberculosis, Gangrenous bowel or perforated bowel and/or intra-abdominal sepsis, See "sepsis" below under "General"

Viral: HIV infection by serologic or molecular detection, Rabies, Reactive Hepatitis B Surface Antigen, Retroviral infections including HTLV I/II, Viral Encephalitis or Meningitis, Active Herpes simplex, varicella zoster, or cytomegalovirus viremia or pneumonia, Acute Epstein Barr Virus (mononucleosis), West Nile Virus infection, SARS

Fungal: Active infection with Cryptococcus, Aspergillus, Histoplasma, Coccidioides, Active candidemia or invasive yeast infection

Parasites: Active infection with Trypanosoma cruzi (Chagas'), Leishmania, Strongyloides, or Malaria (Plasmodium sp.)

Prion: Creutzfeldt-Jacob Disease

General [Exclusions to the Definition of Eligible]:

Aplastic Anemia, Agranulocytosis

Extreme Immaturity (<500 grams or gestational age of <32 weeks)

Current malignant neoplasms except non-melanoma skin cancers such as basal cell and squamous cell cancer and primary CNS tumors without evident metastatic disease

Previous malignant neoplasms with current evident metastatic disease

A history of melanoma

Hematologic malignancies: Leukemia, Hodgkin's Disease, Lymphoma, Multiple Myeloma

Multi-system organ failure (MSOF) due to overwhelming sepsis or MSOF without sepsis defined as 3 or more systems in simultaneous failure for a period of 24 hours or more without response to treatment or resuscitation

Active Fungal, Parasitic, Viral, or Bacterial Meningitis or Encephalitis

To read the complete policy language visit [www.unos.org](http://www.unos.org) or [www.optn.org](http://www.optn.org). From the UNOS Web site, select Resources from the main menu, then select policies. From the OPTN Web site, select Policies from the main menu.

**Notice of Policy Change**— Modifications to Policy 7.3.3 (Submission of Organ-Specific Transplant Recipient Registration Forms and Submission of Living Donor Registration Forms) (Living Donor Committee)

**Affected Policy Language:**

- 7.3.3** Submission of Living Donor Death and Organ Failure Data. Transplant programs must report all instances of live donor deaths and failure of the live donor’s native organ function within 72 hours after ~~of~~ the programs ~~knowledge~~ becomes aware of the live donor death or failure of the live donors’ native organ function. Live donors’ native organ failure is defined as listing for transplant for liver donors, and as transplant, listing for transplant or the need for dialysis in renal donors. These events will be reported to the MPSC for further review and reporting to the Board. Transplant centers must report these incidents through the UNet<sup>SM</sup> Patient Safety System for a period of two years from the date of the donation. The MPSC will review and report all adverse events to the Board.

To read the complete policy language visit [www.unos.org](http://www.unos.org) or [www.optn.org](http://www.optn.org). From the UNOS Web site, select Resources from the main menu, then select policies. From the OPTN Web site, select Policies from the main menu.

**Notice of Policy Change** — Modifications to Policy 7.7 (Submission of Death Notification Information), Changing Due Date for Submission of Death Notification Data (OPO Committee)

**Affected Policy Language:**

**7.7 SUBMISSION OF DEATH NOTIFICATION INFORMATION**

The OPO shall report to the OPTN all imminent neurological deaths, eligible deaths and consent not recovered death notification information either

- within 30 days from the end of the month in which a death was referred to the OPO by the hospital in which the death occurred, or
- 30 days from the end of the month in which the death was identified by the OPO through a Death Record Review.

To read the complete policy language visit [www.unos.org](http://www.unos.org) or [www.optn.org](http://www.optn.org). From the UNOS Web site, select Resources from the main menu, then select policies. From the OPTN Web site, select Policies from the main menu.

**Notice of Policy Change** — Modifications to Policy 3.2.4 (Match System Access) Regarding ABO Verification (OPO Committee)

**Affected Policy Language:**

**3.2.4 Match System Access.** OPOs are required to use the Match System (UNet<sup>SM</sup>) for the allocation of all deceased donor organs. The Host OPO must enter required information about the donor (Policies 3.5.7, 3.6.9, 3.7.9 and 3.8.5) and execute the Match System to determine organ allocation priorities. Such information must be entered into the Match System for all deceased donors. The OPO shall be responsible for two separate determinations (~~e.g., 1) two samples sent to two labs, or 2) one sample sent to two labs, or 3) two samples from separate draws sent to the same lab~~) of the donor's ABO type prior to incision and for ensuring the accuracy of the donor's ABO data in UNet<sup>SM</sup>. The OPO shall maintain documentation that such separate verification has taken place and make such documentation available for audit. Each OPO shall establish and implement a procedure utilizing the ABO source documents for providing on-line verification of donor ABO data by an individual other than the person initially entering the donor's ABO data in UNet<sup>SM</sup>. ~~The OPO shall maintain documentation that such separate verification has taken place and make such documentation available for audit.~~ Organs shall be allocated only to candidates who appear on a match run. In the event that an organ has not been placed after the organ has been offered for all potential recipients on the initial match run, the Host OPO may give transplant programs the opportunity to update their transplant candidates' data, and the Host OPO may re-run the match system. In any event, the organ shall be allocated only to a candidate who appears on a match run. For all deceased donor organs, the organ must be transplanted into the original designee or be released back to the Host OPO or to the Organ Center for distribution. If an organ is accepted for a candidate who ultimately is unavailable to receive the transplant at his/her listing transplant center in the organ allocation unit to which the organ is being distributed, then the organ shall be released back to the Host OPO or to the Organ Center for allocation to other transplant candidates in accordance with the organ-specific allocation policies. The Host OPO may delegate this responsibility to the Local OPO. Further allocation at the local OPO level must be done according to the match run. The final decision whether to use the organ will remain the prerogative of the transplant surgeon and/or physician responsible for the care of that candidate. This will allow physicians and surgeons to exercise judgment about the suitability of the organ being offered for the specific candidate. If an organ is declined for a candidate, a notation of the reason for the decision refusing the organ for that candidate must be made on the appropriate form and promptly submitted.

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