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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  
Date: May 9, 2007

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The attached document summarizes bylaw changes and policy changes approved at the March 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.

To help you review this information quickly and easily, we have developed a new format for communicating policy changes. First of all, rather than sending out individual notices throughout the year, we will send only one batched notice after every board meeting. This notice will allow you to quickly identify which transplant professionals need to know about each policy change. A simple, three-column format summarizes the policy as it currently stands, describes how the policy has changed, and pinpoints any specific action required of you or your center as a result of this change. After reading the summaries, you can access the modified policy language by clicking on the provided link.

We hope you find this new format helpful. We welcome your feedback as we work to fine tune the way that we communicate bylaw and policy changes. If you have any questions about a particular policy change, please contact your regional administrator at (804) 782-4800.

## Overview of Policy Modifications and Affected Professionals

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Who should review and be aware of the policy change?

Policy/Bylaw Change	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
1 Inclusion of Current and Change in PCO2 in Determining a Candidate's Lung Allocation Score (LAS) <i>Thoracic Organ Transplantation Committee</i>									x	x	x	x		x	x	x
2 Modifications to Transplant Recipient Follow-up (TRF) Form Data Elements on UNet <i>Policy Oversight Committee</i>									x	x	x			x		
3 Model Elements To Include in DCD Protocols <i>OPO Committee</i>	x				x	x		x	x			x				x
4 Onsite Coverage <i>Membership and Professional Standards Committee</i>									x	x		x		x		x
5 Notice of UNOS Bylaw Changes <i>Membership and Professional Standards Committee</i>									x			x		x		x

**Notice of Policy Change** — Thoracic Organ Transplantation Committee – Inclusion of Current and Change in PCO<sub>2</sub> in Determining a Candidate’s Lung Allocation Score (LAS) [Policy 3.7.6.1]

**Action Required:** Review Only

**Estimated Effective Date:** TBD

**Professional Groups Affected by the change:**

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

<b>Current Issue/Policy</b>	<b>Proposed Change or Addition</b>	<b>What You Need to Do</b>
<p>Data analyses show that lung transplant candidates who experience elevations in their current or change in PCO<sub>2</sub> values are more likely to die on the waiting list.</p> <p>Currently in UNet<sup>SM</sup>, transplant centers may enter candidate values for arterial, venous, or capillary PCO<sub>2</sub> – the entry of these values is optional, not required. These values have not been factors in calculating the LAS.</p>	<p>Policy 3.7.6.1 will now require transplant centers to report a candidate’s venous, capillary, or arterial PCO<sub>2</sub> value for inclusion in the lung allocation score. An increase in the value of current PCO<sub>2</sub> or change in PCO<sub>2</sub> (where the change is 15 percent or higher in the previous six months) or both can contribute to an increase in a candidate’s Lung Allocation Score. This policy affects the allocation of lungs to registered lung transplant candidates of ages 12 years and older.</p> <p>NOTE: If a transplant center does not enter a PCO<sub>2</sub> value for a candidate, UNet<sup>SM</sup> will assign a default, normal clinical value of 40 mm Hg. This normal clinical value will not be used to calculate the change in PCO<sub>2</sub>.</p>	<p>Transplant professionals should familiarize themselves with this policy and either continue or begin entering PCO<sub>2</sub> values (arterial, venous and capillary) for lung transplant candidates in UNet<sup>SM</sup>. Once the policy is programmed, transplant professionals will receive a UNet<sup>SM</sup> implementation notice with additional education on this policy, and an implementation date.</p>

To view the modified policy language please visit [www.optn.org/policiesAndBylaws/policies.asp](http://www.optn.org/policiesAndBylaws/policies.asp)

**Notice of Board Action** — Modifications to Transplant Recipient Follow-up (TRF) Form Data Elements on UNet<sup>SM</sup>

**Action Required:** Review Only

**Estimated Effective Date:** TBD

**Professional Groups Affected by the change:**

Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Data Coordinators

<b>Current Issue/Policy</b>	<b>Proposed Change or Addition</b>	<b>What You Need to Do</b>
Members are required to follow transplant recipients until death or retransplantation. The current TRF collects the same data elements for every year the patient is followed.	This will significantly reduce the number of data elements that transplant centers will be required to submit on the Transplant Recipient Follow-up (TRF) form after 5 years post-transplant (see Table 1).	Some centers will need to update their computer programs to accommodate this change.

Table 1. List of Data Elements That Would be Retained on the TRF After 5 years

<p><b>Follow-up Elements Common to All Organs</b></p> <p><u>Demographics:</u> Zip code and State  <u>Provider/Donor Information:</u> Follow-up center (for logistical purposes only)  <u>Patient Status:</u> Date last seen, or retransplanted, died, primary cause of death  <u>Other Information:</u> Graft status, Date of graft failure, Most recent serum creatinine  <u>Post-Transplant Malignancy Data<sup>1</sup>:</u> Tumor Type, Site, and Date</p> <p><b>Follow-up Elements: Liver</b>            Contributory causes of graft failure</p> <p><b>Follow-up Elements: Intestine</b>            Primary cause of graft failure</p> <p><b>Follow-up Elements: Kidney</b>            Primary cause of graft failure</p> <p><b>Follow-up Elements: Kidney-Pancreas</b>            Primary cause of graft failure</p>
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1 The requirement to submit malignancy data is being reviewed by the OPTN/UNOS Policy Oversight Committee.

Contributory causes of graft failure (pancreas)

**Follow-up Elements: Pancreas**

Contributory causes of graft failure

**Follow-up Elements: Thoracic**

Bronchiolitis Obliterans Syndrome (Lung forms only)

Coronary Artery Disease (Heart forms only)

Renal dysfunction (Yes/No) (All Thoracic forms)

**Affected Policy Language: None**

**Notice of Policy Change—Model Elements Required for DCD Protocols—OPO Committee**

**Action Required:**        **Review and Implement by July 1, 2007**

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

**Professional Groups Affected by the change:**

OPO Executive Directors, Transplant Physicians and Surgeons, Directors of Organ Procurement, Procurement Coordinators, Transplant Administrators, Transplant Coordinators

<b>Current Issue/Policy</b>	<b>Proposed Change or Addition</b>	<b>What You Need to Do</b>
<p>OPOs and transplant hospitals are required to have a protocol for Donation after Cardiac Death (DCD) and all protocols must include the model elements.</p>	<p>All OPOs and transplant hospitals must include model elements in the areas of:</p> <ul style="list-style-type: none"> <li>--Suitable Candidate Selection</li> <li>--Consent/Approval</li> <li>--Withdrawal of Life Sustaining Measures/Patient Management</li> <li>--Pronouncement of Death</li> <li>--Organ Recovery</li> <li>--Financial Considerations</li> </ul> <p>These model elements will help OPO and transplant hospitals develop, review, and improve their DCD protocols.</p>	<p>OPOs and transplant hospitals need to review existing protocols and ensure that their DCD protocols address the model elements by July 1, 2007.</p>

To view the modified policy language please visit:  
[www.optn.org/policiesAndBylaws/policies.asp](http://www.optn.org/policiesAndBylaws/policies.asp)



**Notice of Bylaw Changes —On Site Coverage—Membership and Professional Standards Committee**

**Action Required:** Review Only

**Estimated Effective Date:** Upon notice

**Professional Groups Affected by the change:** Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians

Current Issue/Policy	Proposed Changes or Additions	What You Need to Do
<p>Presently, the Bylaws require that qualified physicians and surgeons be “on site” at the transplant center, and that “100% surgical and medical coverage is provided by individuals credentialed by the institution to provide transplant service.”</p>	<p>The program director, in conjunction with the primary transplant surgeon and primary transplant physician, must submit a Program Coverage Plan to the OPTN Contractor. This plan will document how individuals credentialed by the institution will provide the transplant service with 100% surgical and medical coverage.</p> <p>These changes are refinements to criteria presently used to review program and key personnel applications for membership in the OPTN, as well as the surveys utilized by the Data Subcommittee to evaluate program performance.</p> <p>The goals of these changes are to:</p> <ul style="list-style-type: none"> <li>• make existing criteria clearer and more specific,</li> <li>• ensure timely organ acceptance, and</li> <li>• prevent delays in organ procurement after acceptance.</li> </ul>	<p>UNOS will implement the submission of the initial Program Coverage Plans on a rolling basis (such as by region). UNOS will contact centers in the next few months and give them additional information regarding the expected Plan content plus deadlines for its submission .</p> <p>Once centers have submitted their plans, they will be responsible for notifying their patients at the time of listing and UNOS if any substantive changes in the program or personnel occur.</p> <p>A request for the Program Coverage Plan will also be added to the application materials and survey tools as appropriate.</p> <p>During site surveys of transplant centers, DEQ staff will verify that each program has a Program Coverage Plan.</p>

		<p>Programs should begin sending this summary out to candidates within 3 months of the implementation date. This information could be included in the patient notification letter.</p> <p>During site surveys of transplant centers, DEQ staff will verify that candidates are notified of the Program Coverage Plan at the time of listing.</p>
		<p>UNOS will contact each transplant center and request that the program director(s) provide an update to the information already on file that defines which surgeons and physicians in the program meet the criteria for “additional” and which ones do not.</p>

To view the modified policy language please visit [www.optn.org/policiesAndBylaws/policies.asp](http://www.optn.org/policiesAndBylaws/policies.asp)

**Notice of UNOS Bylaw Changes – Membership and Professional Standards Committee (MPSC)**

- **Appendix A – 2.06A – MPSC Action**  
Requires centers under “Probation” or “Member Not in Good Standing” to investigate its personnel.
- **Appendix A – 1.03A – Application and Hearing Procedures for Members and Designated Transplant Programs – *Procedures upon Application for Membership***  
Requires centers to submit a plan for continuing policy compliance.
- **Appendix B – Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership – *II.D. Transplant Hospitals: Investigation of Personnel***  
Requires transplant hospitals to conduct and report investigations of its personnel in a manner consistent with its own peer review process.
- **Attachment I to Appendix B – *IV. Investigation of Personnel; and, VII. Transplant Surgeon and Physician***  
Requires centers to submit a plan for sustaining policy compliance.
- **Appendix B, Attachment I, Section XII(C)**  
Requires new program applications to include additional character assessments of its physicians and surgeons.

**Action Required:** Review Only

**Estimated Effective Date:** Upon notice

**Professional Groups Affected by the change:** Transplant Administrators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians

Current Issue/Policy	Proposed Change or Addition	What You Need to Do
Current policy does not prevent physicians or surgeons involved in non-compliant activity at one institution from continuing that or similar activity at the same or another institution.	Modification to 2.06A requires a center that is under “Probation” or determined a “Member not in Good Standing” to investigate its personnel.	A center placed under “Probation” or determined a “Member not in Good Standing” must conduct an investigation of its personnel.
	The modifications to 1.03A require new programs to submit a “Plan for Continuing Policy Compliance” in their application process.	A center’s named primary surgeon and/or physician must assess the center’s surgeons or physicians regarding prior transgressions. If the center surgeons or physicians have prior transgressions, the named primary surgeon and/or physician must submit a plan that ensures the elimination of improper conduct.

	The modifications to Appendix B (II.D) allows MPSC to request a transplant hospital to investigate its personnel and report its final determination, to the MPSC, in a manner consistent with and that protects the hospital’s own peer review process.	If requested by the MPSC, a transplant hospital must conduct an investigation of its personnel and report its final determination to the MPSC. This report must be consistent with and protect the hospital’s own peer review process.
	<u>The modifications to Appendix B, Attachment I</u> require new programs to submit a “Plan for Continuing Policy Compliance” in their application process.	A center’s named primary surgeon and/or physician must assess the center’s surgeons or physicians regarding prior transgressions. If the center surgeons or physicians have prior transgressions, the named primary surgeon and/or physician must submit a plan that ensures the elimination of improper conduct.
Currently, letters of reference are only required to respond to the transplant physician or surgeon’s training and experience.	<u>The modifications to Appendix B, Attachment I (Section XII(C))</u> require an additional letter of reference for each organ program, and surgeon and physician pathways. This new letter must attest to the physician’s or surgeon’s personal integrity, honesty, and familiarity with and experience in adhering to the OPTN requirements and compliance protocols.  This new requirement will prevent an individual physician or surgeon involved in non-compliant activity at one institution from continuing that or similar activity at the same or another institution.	Centers submitting new program applications or key personnel applications must now also address these new physician or surgeon elements. Centers may submit a single letter that addresses both training and experience, as well as these new elements.

To view the modified policy language please visit [www.optn.org/policiesAndBylaws/policies.asp](http://www.optn.org/policiesAndBylaws/policies.asp)

**Notice of Policy Change** — Thoracic Organ Transplantation Committee – Inclusion of Current and Change in PCO<sub>2</sub> in Determining a Candidate’s Lung Allocation Score (LAS) [Policy 3.7.6.1]

**Affected Policy Language:**

**3.7.6 Lung Allocation.** Candidates are assigned priority in lung allocation as follows:

**3.7.6.1 Candidates Age 12 and Older.** Candidates age 12 and older are assigned priority for lung offers based upon Lung Allocation Score, which is calculated using the following measures: (i) waitlist urgency measure (expected number of days lived without a transplant during an additional year on the waitlist), (ii) post-transplant survival measure (expected number of days lived during the first year post-transplant), and (iii) transplant benefit measure (post-transplant survival measure minus waitlist urgency measure). Waitlist urgency measure and post-transplant survival measure (used in the calculation of transplant benefit measure) are developed using Cox proportional hazards models. Factors determined to be important predictors of waitlist mortality and post-transplant survival are listed below in Tables 1 and 23. **Table 2 describes the calculation of current PCO<sub>2</sub> and change in PCO<sub>2</sub> in the Lung Allocation Score.** It is expected that these factors will change over time as new data are available and added to the models. The Thoracic Organ Transplantation Committee will review these data in regular intervals of approximately six months and will propose changes to **Tables 1, and 2 and 3** as appropriate.

**Table 1**

<b>Factors Used to Predict Risk of Death on the Lung Transplant Waitlist</b>	
1.	Forced vital capacity (FVC)
2.	Pulmonary artery (PA) systolic (Group A, C, D <sup>1</sup> )
3.	O <sub>2</sub> required at rest (A, C, D <sup>1</sup> )
4.	Age
5.	Body mass index (BMI)
6.	Diabetes
7.	Functional status (New York Heart Association (NYHA) class)
8.	Six-minute walk distance
9.	Continuous mechanical ventilation
10.	Diagnosis
<u>11.</u>	<u>PCO<sub>2</sub></u>

<sup>1</sup>Group A includes candidates with obstructive lung disease, including without limitation, chronic obstructive pulmonary disease (COPD), alpha-1-antitrypsin deficiency, emphysema, lymphangioliomyomatosis, bronchiectasis, and sarcoidosis with mean pulmonary artery (PA) pressure ≤ 30 mmHg.

Group B includes candidates with pulmonary vascular disease, including without limitation, primary pulmonary hypertension (PPH), Eisenmenger’s syndrome, and other uncommon pulmonary vascular diseases.

Group C includes, without limitation, candidates with cystic fibrosis (CF) and immunodeficiency disorders such as hypogammaglobulinemia.

Group D includes candidates with restrictive lung diseases, including without limitation, idiopathic pulmonary fibrosis (IPF), pulmonary fibrosis (other causes), sarcoidosis with mean PA pressure > 30 mmHg, and obliterative bronchiolitis (non-re-transplant).

**Table 2**  
**PCO<sub>2</sub> Used in the LAS Calculation**

<b><u>Value of current PCO<sub>2</sub><sup>1</sup></u></b>	<b><u>Value of prior PCO<sub>2</sub><sup>1</sup></u></b>	<b><u>PCO<sub>2</sub> used in LAS calculation<sup>1</sup></u></b>	<b><u>Change in PCO<sub>2</sub> used in LAS calculation<sup>1</sup></u></b>
Not missing or expired	Not missing or expired; within 6 months of current PCO <sub>2</sub>	Current PCO <sub>2</sub>	Change in PCO <sub>2</sub> (i.e., highest – lowest/lowest) <sup>2</sup>
Not missing or expired	Missing or expired or is not within 6 months prior to current value	Current PCO <sub>2</sub>	No Change <sup>3</sup>
Missing or expired	(any value, expired or not)	Normal Clinical Value (40 mmHg) <sup>4</sup>	No Change <sup>3</sup>

**<sup>1</sup>A center may enter a PCO<sub>2</sub> from an arterial, venous, or capillary blood gas into UNet<sup>SM</sup> to count towards a candidate’s lung allocation score. A center must enter the value into UNet<sup>SM</sup> exactly as reported by the laboratory. Ideally, the arterial blood gas value will be used to calculate the lung allocation score. If venous and capillary blood gas values are entered, these values will be used to estimate an arterial value as follows: a capillary value will be equal to an arterial value; a venous value will have 6 mm Hg subtracted from it to produce an equivalent arterial value.**

**<sup>2</sup>Both numbers must be actual, candidate blood gas values, and must be within 6 months of each other. Also, the lowest value must come temporally before the highest. A transplant candidate will receive a benefit from this parameter if the PCO<sub>2</sub> change is greater than or equal to 15%.**

**<sup>3</sup>Change must be calculated using two actual, candidate blood gas values. Therefore, if the equation contains a prior blood gas value that is missing, expired, or outdated, then change cannot be computed. The result is no change.**

**<sup>4</sup>The default value will be the normal clinical value of 40 mmHg.**

**Table 23**

<b>Factors That Predict Survival After Lung Transplant</b>	
1.	FVC (Group B, D <sup>1</sup> )
2.	PCW pressure $\geq$ 20 (Group D <sup>1</sup> )
3.	Continuous mechanical ventilation
4.	Age
5.	Serum Creatinine
6.	Functional Status (NYHA class)
7.	Diagnosis

The calculations define the difference between transplant benefit and waitlist urgency: Raw Allocation Score = Transplant Benefit Measure – Waitlist Urgency Measure.

Raw allocation scores range from –730 days up to +365 days, and are normalized to a continuous scale from 0 – 100 to determine Lung Allocation Scores. The higher the score, the higher the priority for receiving lung offers. Lung Allocation Scores are calculated to sufficient decimal places to avoid assigning the same score to multiple candidates.

	<b>Candidate X</b>	<b>Candidate Y</b>
<b>a. Post-transplant survival (days)</b>	<b>286.3</b>	<b>262.9</b>
<b>b. Waitlist survival (days)</b>	<b>101.1</b>	<b>69.2</b>
<b>c. Transplant benefit (a-b)</b>	<b>185.2</b>	<b>193.7</b>
<b>d. Raw allocation score (c-b)</b>	<b>84.1</b>	<b>124.5</b>
<b>e. Lung Allocation Score</b>	<b>74.3</b>	<b>78.0</b>

As an example, assume that a donor lung is available, and both Candidate X and Candidate Y are on the Waiting List. Taking into account all diagnostic and prognostic factors, Candidate X is expected to live 101.1 days during the following year without transplant. Also using available predictive factors, Candidate X is expected to live 286.3 days during the following year if transplanted today. On the other hand, Candidate Y is expected to live 69.2 days during the following year on the waitlist and 262.9 days post-transplant during the following year if transplanted today. Computationally, the proposed system would prioritize candidates based on the difference between each candidate’s transplant benefit measure and the waitlist urgency as measured by the expected days of life lived during the next year.

In the example here, Candidate X's raw allocation score would be 84.1 and Candidate Y's raw allocation score would be 124.5.

Similar to the mathematical conversion of temperature from Fahrenheit to Centigrade, once the raw score is computed, it will be normalized to a continuous scale from 0-100 for easier interpretation by candidates and caregivers (see formula above). A higher score on this scale indicates a higher priority for a lung offer. Conversely, a lower score on this scale indicates a lower priority for organ offers. Therefore, in the example above, Candidate X's raw allocation score of 84.1 normalizes to a Lung Allocation Score of 74.3. Candidate Y's raw score of 124.5 normalizes to a Lung Allocation Score of 78.0. As in the example of raw allocation scores, Candidate Y has a higher Lung Allocation Score and will therefore receive a higher priority for a lung offer than Candidate X.

## Notice of Policy Change—Model Elements Required for DCD Protocols

### Affected Policy Language and Relevant Resources:

**\*\*RESOLVED**, that the modifications to Attachment III to Appendix B of the OPTN Bylaws, (amended DCD protocol model elements), set forth below shall be approved effective July 1, 2007.

## ATTACHMENT III TO APPENDIX B OF THE OPTN BYLAWS

### Model Elements for Controlled DCD Recovery Protocols

*Introduction:* Donation after Cardiac Death (DCD) has been accepted by the Institute of Medicine and the transplant community as an ethically and medically acceptable option for patients and families making end of life decisions.

The intent of developing model elements for OPO and transplant hospital DCD recovery protocols is to establish model elements for OPOs and transplant hospitals to meet in developing, reviewing and improving their respective DCD recovery protocols. This outline is intended to set standards of what must be addressed in a DCD recovery protocol by OPOs and hospitals without being prescriptive regarding practice; each hospital and each DSA is specific in its practice, culture, and resources. The continuing collaboration between OPOs and transplant hospitals is encouraged to allow for the constant development of DCD best practices. The joint OPO Committee/MPSC Working Group is available as a continuing resource for OPTN member hospitals that experience delay or difficulty in adopting a DCD recovery protocol.

### Controlled\* Donation after Cardiac Death Recovery Protocol Model Elements

#### A. Suitable Candidate Selection:

1. A patient (aged newborn to DSA's defined upper age limit if applicable) who has a non-recoverable and irreversible neurological injury resulting in ventilator dependency but not fulfilling brain death criteria may be a suitable candidate for DCD.
2. Other conditions that may lead to consideration of DCD eligibility include end stage musculoskeletal disease, pulmonary disease, and high spinal cord injury.
3. The decision to withdraw life sustaining measures must be made by the hospital's patient care team and legal next of kin, and documented in the patient chart.

4. The assessment for DCD candidate suitability should be conducted in collaboration with the local OPO and the patient's primary health care team. OPO determination of donor suitability may include consultation from the OPO Medical Director and Transplant Center teams that may be considering donor organs for transplantation.
5. An assessment should be made as to whether death is likely to occur (after the withdrawal of life-sustaining measures) within a time frame that allows for organ donation.

## **B. Consent/Approval**

1. The legal next of kin may elect to consent to procedures or drug administration for the purposes of organ donation (e.g. heparin, regitine, femoral line placement, lymph node excision, ECMO, and bronchoscopy). No donor related medications shall be administered or donation related procedures performed without consent.
2. Clearance from medical examiner/coroner must be obtained when applicable.
3. There should be a plan for patient care if death does not occur within the established timeframe after the withdrawal of life sustaining measures. This plan should include logistics and provisions for continued end of life care, including immediate notification of the family.
4. For purposes of these model elements, "legal next of kin" shall also include the patient, a designated health care representative, legal next of kin, or appropriate surrogate.

## **C. Withdrawal of Life Sustaining Measures/ Patient Management**

1. A timeout is recommended prior to the initiation of the withdrawal of life sustaining measures. The intent of the timeout is to verify patient identification, roles and the respective roles and responsibilities of the patient care team, OPO staff, and organ recovery team personnel.
2. No member of the transplant team shall be present for the withdrawal of life-sustaining measures.

3. No member of the organ recovery team or OPO staff may participate in the guidance or administration of palliative care, or the declaration of death.
4. There must be a determination of the location and process for withdrawal of life sustaining measures (e.g. ETT removal, termination of blood pressure support medications) as a component of the patient management.
5. If applicable, placement of femoral cannulas and administration of pharmacologic agents (e.g. regitine, heparin) for the sole purpose of donor organ function must be detailed in the consent process.

**D. Pronouncement of Death**

1. The patient care team member that is authorized to declare death must not be a member of the OPO or organ recovery team.
2. The method of declaring cardiac death must comply in all respects with the legal definition of death by an irreversible cessation of circulatory and respiratory functions **before** the pronouncement of death. \*\* / \*\*\*

**E. Organ Recovery**

1. Following the declaration of death by the hospital patient care team, the organ recovery may be initiated.

**F. Financial Considerations**

1. OPO policy shall ensure that no donation related charges are passed to the donor family.

**\* Maastricht Classification – Definition of Controlled DCD Donors**

DCD donors are grouped by the Maastricht classification (1995; amended 2003):

- I Dead on arrival to hospital
- II Unsuccessful resuscitation
- III Awaiting cardiac arrest – In-Patient (w/d of support)
- IV Cardiac arrest after brain-stem death
- V Cardiac arrest in a hospital inpatient

Controlled DCD donors would include those outlined in classification III of the Maastricht criteria.

**\*\* The Uniform Determination of Death Act:**

The National Conference of Commissioners on Uniform State Laws in 1980 formulated the Uniform Determination of Death Act (UDDA).

The UDDA states that: "An individual who has sustained either

(1) irreversible cessation of circulatory and respiratory functions, or

(2) irreversible cessation of all functions of the entire brain, including the brain stem is dead.

A determination of death must be made in accordance with accepted medical standards. This definition was approved by the American Medical Association in 1980 and by the American Bar Association in 1981. Today all fifty states and the District of Columbia follow the UDDA as a legal standard of death.

**Sources:**

- President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Defining Death: A Report on the Medical, Legal and Ethical Issues in the Determination of Death* (Washington: Government Printing Office, 1981), p. 73.
- Uniform Determination of Death Act. 12 Uniform Laws Annotated 320 (1990 Supp).

### **How is irreversibility defined?**

From the Report of a National Conference on Donation after Cardiac Death.  
Am J Transplant. 2006 Feb; 6 (2):281-91.

*Irreversibility* is recognized by persistent cessation of function during an appropriate period of observation. Based on a cardiopulmonary criterion, DCD donor death occurs when respiration and circulation have ceased and cardiopulmonary function *will not resume spontaneously*. This meaning of “irreversibility” also has been called the “permanent” cessation of respiration and circulation.

If data show that auto-resuscitation (spontaneous resumption of circulation) cannot occur and if there is no attempt at artificial resuscitation, it can be concluded that respiration and circulation have ceased permanently.

In clinical situations in which death is expected, once respiration and circulation cease (irrespective of electrical cardiac activity), the period of observation necessary to determine that circulation will not recur spontaneously (auto-resuscitation) may be only a few minutes. Current data on auto-resuscitation indicate that the relevant event is cessation of circulation, not cessation of electrical activity.

When life-sustaining therapy is withdrawn, based on the limited data available (presented by Michael Devita at the National Conference), spontaneous circulation does not return after 2 minutes of cessation of circulation.

### **How is the permanent absence of circulation determined?**

From the Report of a National Conference on Donation after Cardiac Death.

***Cessation of functions*** is recognized by an appropriate clinical examination that reveals the absence of responsiveness, heart sounds, pulse and respiratory effort.

In applying the circulatory criterion of death in non-DCD circumstances, clinical examination alone may be sufficient to determine cessation of circulatory and respiratory functions. However, the urgent time

constraints of DCD may require more definitive proof of cessation of these functions by the use of confirmatory tests.

Confirmatory tests (e.g. intra-arterial monitoring or Doppler study) should be performed in accordance with the hospital protocol to assure the family and the hospital professional staff that the patient is dead.

**\*\*\* Other Important Determination of Death Resources**

1. Recommendations for non-heart-beating organ donation, A Position Paper by the Ethics Committee, American College of Critical Care Medicine, Society of Critical Care Medicine, ***Critical Care Medicine 2001 Vol. 29, No. 9***, pp. 1826-1831.
2. Non-Heart-Beating Organ Transplantation: Medical and Ethical Issues in Procurement, Institute of Medicine, December 1997.
3. Non-Heart-Beating Organ Transplantation: Practice and Protocols, Institute of Medicine, 2000.

## Notice of Bylaw Changes —On Site Coverage—Membership and Professional Standards Committee

### Affected Policy Language:

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.

### Proposed Modifications to the Appendix B, Attachment 1 of the UNOS and OPTN Bylaws

**Note: Double underline/Double Strikeouts are changes recommended by the MPSC post public comment.**

#### Appendix B, Attachment 1 of the OPTN Bylaws

VI. Transplant Surgeon and Physician. The transplant program must identify a qualified primary surgeon and primary physician, the requirements for whom are specified below, as well as the program director.

A. The program director, in conjunction with the primary transplant surgeon and primary transplant physician, must submit to the OPTN Contractor in writing ~~written~~ a Program Coverage Plan, which documents how that 100% surgical and medical coverage is provided by individuals credentialed by the institution to provide transplant service for the program. The Program Coverage Plan must address the following requirements:

- (1) All transplant programs ~~should~~ must have transplant surgeon(s) and transplant physician(s) available 365 days a year, 24 hours a day, 7 days a week, to provide program coverage. ~~If such coverage cannot be provided, unless an written explanation must be is provided that justifies the current level of coverage to the satisfaction of the Membership and Professional Standards Committee (MPSC). All~~ ~~A~~ transplant programs shall should provide patients with a written summary of the Program Coverage Plan at the time of listing or when there are any substantial changes in program or personnel. ~~served by a single transplant surgeon or transplant physician or unable to provide transplant surgeon/physician coverage 365 days a year, 24 hours a day, 7 days a week shall inform its patients of this fact in writing and explain the potential unavailability of one or both of these individuals, as applicable, during the year.~~
- (2) When “on call” a ~~surgeon/physician must be available and able to be on the hospital premises within one hour ground transportation time.~~ transplant surgeon and transplant physician may not be on call at two transplant programs more than 30 miles apart unless the specific circumstances of that coverage have been reviewed and approved by the Membership and Professional Standards Committee.

- (3) A transplant surgeon or transplant physician must be readily available in a timely manner to facilitate organ acceptance, procurement, and implantation, and to address urgent patient issues.
- (3 4) Unless exempted by the MPSC for specific causal reasons, the primary transplant surgeon or ≠ primary transplant physician cannot be designated as the primary transplant surgeon/primary transplant physician at more than one transplant center unless there are “additional” transplant surgeons/transplant physicians at each of those facilities.
- (i) Additional Transplant Surgeons must be credentialed by the institution to provide transplant services and be able to independently manage the care of transplant patients including performing the transplant operation and procurement procedures.
- (ii) Additional Transplant Physicians must be credentialed by the institution to provide transplant services and be able to independently manage the care of the transplant patients immunosuppression.
- B. The primary surgeon and primary physician, collectively, are further responsible for ensuring the ongoing operation of the program in compliance with the criteria set forth in this Appendix B, Attachment I, and notification to the OPTN Contractor if at any time the program deviates from such criteria.

~~A transplant program served by a single surgeon or physician shall inform its patients of this fact and potential unavailability of one or both of these individuals, as applicable, during the year.~~ (relocated to Section (1) above)

Sections VII – XI - No Changes

**Attachment I, Section XII to Appendix B of the UNOS Bylaws -Designated Transplant Program Criteria**

**XII. Transplant Programs.**

- A. No Change
- B. No Change.
- C. To qualify for membership in UNOS, a transplant program must have a clinical service which meets the following criteria. Each transplant program must identify a UNOS qualified primary surgeon and physician, the requirements for whom are described below, as well as the program director.

The program director, in conjunction with the primary transplant surgeon and primary transplant physician, must submit to UNOS in writing provide written a Program Coverage Plan, which documents ation how that 100% medical and surgical coverage is provided by individuals credentialed by the institution to provide transplant service for the program. The Program Coverage Plan must address the following requirements:

- (1) All transplant programs ~~should~~ must have transplant surgeon(s) and physician(s) available 365 days a year, 24 hours a day, 7 days a week, to provide program coverage. ~~If such coverage cannot be provided, unless an written explanation must be is provided that justifies the current level of coverage to the satisfaction of the MPSC. All A~~ transplant programs ~~should~~ shall provide patients with a written summary of the Program Coverage Plan, at the time of listing ~~or~~ and when there are any substantial changes in program or personnel. ~~served by a single surgeon or physician or unable to provide transplant surgeon/physician coverage 365 days a year, 24 hours a day, 7 days a week shall inform its patients of this fact in writing and explain the potential unavailability of one or both of these individuals, as applicable, during the year.~~
- (2) ~~When “on call” a~~ A surgeon/physician must be available and able to be on the hospital premises within one-hour ground transportation time to address urgent patient issues.
- (3) A transplant surgeon must be readily available in a timely manner to facilitate organ acceptance, procurement, and implantation.
- (4) ~~(3)~~ Unless exempted by the MPSC for specific causal reasons, the primary transplant surgeon/primary transplant physician cannot be designated as the primary surgeon/primary transplant physician at more than one transplant center unless there are “additional” transplant surgeons/transplant physicians at each of those facilities.
  - (i) Additional Transplant Surgeons must be credentialed by the institution to provide transplant services and be able to independently manage the care of transplant patients including performing the transplant operation and procurement procedures.
  - (ii) Additional Transplant Physicians must be credentialed by the institution to provide transplant services and be able to independently manage the care of transplant patients immunosuppression.

A transplant center applying as a new member or for a key personnel change must include for the proposed primary transplant surgeon and/or physician a report from their hospital credentialing committee that the committee has reviewed the said individual’s state licensing, board certification, training, and transplant CME’s and affirm that they are “currently” a member in good standing.

**Notice of UNOS Bylaw Changes – Membership and Professional Standards Committee (MPSC)  
Affected Bylaw Language:**

**Final Proposal**

**Appendix A to the OPTN and UNOS Bylaws  
Application and Hearing Procedures for Members and Designated Transplant Programs**

**1.01A Nature of Membership/Designated Transplant Program Status** [No changes]

**1.02A Duration of Membership** [No changes]

**1.03A Procedures upon Application for Membership**

- (1) **General Procedure:** The Membership and Professional Standards Committee shall investigate and consider under confidential medical peer review each application for membership and designation as a transplant program and shall adopt and transmit recommendations thereon to the Board of Directors.
- (2) **Application Form :** Each application for membership and designation as a transplant program shall be in writing, submitted on the prescribed form approved by the Membership and Professional Standards Committee, signed by the applicant.
- (3) **Content:** The application form shall include:
  - (a) **Acknowledgment and Agreement:** A statement that the applicant has received and read the current Articles of Incorporation, Bylaws, and Policies and that the applicant agrees: (i) to be bound by the terms thereof, as amended, if the applicant is granted membership and/or designated transplant program status and (ii) to be bound by the terms thereof in all matters relating to consideration of the application without regard to whether or not the applicant is granted membership or designated transplant program status.
  - (b) **Qualifications:** Detailed information and supporting documentation, as may be specified by the Membership and Professional Standards Committee (MPSC) from time to time and described in the application form, concerning the applicant’s qualifications, including information in satisfaction of the basic qualifications specified in Article 1 of the Bylaws and the Criteria for Membership (Appendix B) regarding applicable membership requirements. This shall include, by way of example and without in any way limiting information that may be required in the application, submission of a:
    - (1) Plan for Continuing Policy Compliance that reports results from an assessment by the named primary physician and/or surgeon for transplant programs designated to perform organ transplants regarding involvement of any of the program’s physicians or surgeons in prior transgressions of UNOS requirements and plans to ensure that the improper conduct is not continued.
  - (c) **Information on Liability Insurance Coverage:** [No Change]
  - (d) **Administrative Remedies:** [No Change]
  - (e) **Release of Information to HHS:** [No Change]

**1.04A - Processing the Application** [No Change]

**1.05A - Effect of Membership and Professional Standards Committee Action** [No Change]

**1.06A - Time Periods for Processing** [No Change]

**1.07A - Reapplication after Adverse Decision** [No Change]

#### **Appendix A of the OPTN Bylaws**

#### **Application and Hearing Procedures for Members and Designated Transplant Programs**

**2.01A - 2.05A** [No changes]

#### **2.06A - Membership and Professional Standards Committee Action**

- (a) **Category I, II, and III Potential Violations.** Matters referred to the MPSC, MPSC-PCSC, or a MPSC ad hoc subcommittee will be defined initially by decision of the MPSC Chairperson (with advice from the Executive Director and President) as Category I potential violations according to the process outlined in Section 2.05 above, or by the MPSC, MPSC-PCSC, or MPSC ad hoc subcommittee as either Category II or Category III potential violations. For Category I potential violations, the MPSC-PCSC or ad hoc subcommittee shall report its determination in writing to the Executive Committee and full MPSC.

Category II potential violations generally are of the type described in Section 2.05(2)(c) above, while Category III potential violations generally are of the type described in Section 2.05(2)(a-b) above. Category II and III potential violations are further distinguished by the expectation that Category II potential violations will proceed to formal Hearings and, perhaps, Appellate Reviews. Upon determination of a Category II potential violation, the MPSC shall consider a timeline for review and action to assist in timely resolution of the matter.

- (b) For Category II and III potential violations, the MPSC-PCSC shall report its action in writing to the full MPSC. The MPSC shall report its action in writing to the Board of Directors.

Category I, II, and III potential violations are generally defined as follows. Individual cases may vary depending upon the unique circumstances, and cases may move among the categories as circumstances may change.

- Category I = potential violation of OPTN requirements posing substantial, time sensitive threat to patient health or public safety,
- Category II = material breach of OPTN requirements, and
- Category III = dialogue with MPSC expected to correct any noncompliant behavior and lead to ongoing future compliance.

Actions available for all categories of potential violations may include, without limitation (see Figures A-2a and A2b for a general overview of these actions), the following. Sanctions listed under numbers (1) and (2) below may be imposed directly by action of either the MPSC-PCSC or MPSC. Sanctions listed under numbers (3) – (7) below must be recommended by the MPSC to the Board of Directors and imposed by the Board, or may be imposed by the Executive Committee or the Board without recommendation of the MSPC. Unless specifically noted, the sanctions listed below may be taken in cases of : (i) noncompliance with policies or behavior posing risk to patient health or public safety covered by Section 1138 of the Social Security Act, 42 U.S.C. § 1320-b8, by virtue of (a) recommendation by the OPTN to be mandatory and designation by the Secretary of HHS for coverage, (b) determination by the Secretary of HHS to be mandatory under the OPTN Final Rule, or (c) determination of risk to the health of patients or to the public safety, which is confirmed by the Secretary of HHS, and (ii) noncompliance with all other OPTN requirements. Policies and behavior posing risk to patient health or public safety described under

category (i) above are hereinafter referred to collectively as “policies covered by Section 1138 of the Social Security Act,” or individually as “policy covered by Section 1138 of the Social Security Act.”

The MPSC-PCSC or the MPSC may impose the following sanctions without referral to the Board of Directors for approval:

- (1) **Reject Request for Corrective Action.** The MPSC-PCSC or the MPSC may reject the request for corrective action, notice of which shall be provided to the Board of Directors;
- (2) **Notice of Uncontested Violation, Letter of Warning or Letter of Reprimand.** The MPSC-PCSC or the MPSC may issue a Notice of Uncontested Violation, Letter of Warning or a Letter of Reprimand, any of which is not an adverse action under the Bylaws but is meant to inform the Member of the need for the Member to ensure continuing compliance with OPTN requirements. The Board of Directors and the Secretary of HHS shall be notified of final decisions to issue a Notice of Uncontested Violation, Letter of Warning or a Letter of Reprimand. These categories of non-adverse actions are appropriate under the following circumstances:
  - (a) **Notice of Uncontested Violation** – There has been a violation of OPTN requirements with no substantial evidence of mitigating factors based on medical judgment, and there is believed to be no likelihood of recurrence. The Member is not entitled to an interview.
  - (b) **Letter of Warning** – There has been an apparent violation of OPTN requirements under circumstances in which medical judgment is credibly put forth as a partial mitigating factor and there is believed to be no likelihood of recurrence. The Member is not entitled to an interview.
  - (c) **Letter of Reprimand** – There has been an apparent violation of OPTN requirements under circumstances where medical judgment is not a credible mitigating factor and there is believed to be no likelihood of recurrence. The Member shall be entitled to an interview under the procedures described in Section 3.01A prior to any issuance of a Letter of Reprimand by the MPSC/PCSC or the MPSC.

The MPSC may make recommendations to the Board of Directors for the imposition of the following adverse sanctions or the Board of Directors or the Executive Committee may take such action without recommendation by the MPSC:

- (3) **Probation.** 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 place the Member on probation, which would be an adverse action under the Bylaws and would first entitle the Member to procedural rights as provided in Section 3.01A – 3.03A 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 Board of Directors or the Executive Committee and notice to the Secretary of HHS of the final decision to place the Member on probation. Probation may include one or more of the following or other actions deemed appropriate by the MPSC-PCSC/MPSC, Executive Committee, or the Board of Directors and will include notice to all Members.
  - (a) Required submission of a compliance action plan or plan of correction developed to specifications as may be defined by the MPSC-PCSC/MPSC, with demonstration to the MPSC-PCSC/MPSC of adherence to the plan and correction of any non-compliant activity within some period of time.
  - (b) Unscheduled on-site audit(s) throughout the period of probation, to be performed by OPTN Contractor audit staff at the sole reasonable cost and expense of the Member. Such costs and expenses shall include, but not be limited to, travel and lodging expenses of OPTN Contractor staff.

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

(d) Required investigation of personnel as provided for in Section 1.03A of Appendix A of the Bylaws and Sections IV and VII of Attachment I to Appendix B of the Bylaws .

(4) **Member Not in Good Standing.** The MPSC may recommend that the Board of Directors or Executive Committee, or either the Executive Committee or the Board of Directors on its own accord, may declare the Member a Member Not in Good Standing, which would be an adverse action under the Bylaws and would first entitle the Member to procedural rights as provided in Section 3.01A – 3.03A followed in the case of an initial recommendation by the MSPC by a final recommendation to, and in any event, final action by the Board of Directors or Executive Committee and notice to the Secretary of HHS of the final decisions to declare the Member a Member Not in Good Standing. 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:

(a) Withdrawal of voting privileges in OPTN affairs.

(b) Suspension 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) Formal notification, along with subsequent changes in such status, to the entire OPTN Membership as well as to the Chief Executive Officer of Institutional Members

(d) 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) Notice, within reasonable limits and means, to patients and the general public in the area of the Member. 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.

(f) Required investigation of personnel as provided for in Section 1.03A of Appendix A of the Bylaws and Sections IV and VII Attachment I to Appendix B of the Bylaws.

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

(5) **Suspension of Member Privileges.** 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 to suspend the Member's 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 followed in the case of an initial recommendation by the MSPC 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. Suspension of membership privileges may include one or more of the

following or other actions deemed appropriate by the MPSC-PCSC/MPSC, the Executive Committee, or the Board of Directors:

- (a) Suspension of the privilege to hold office and/or sit on OPTN Board of Directors or Committees.
- (b) Suspension of voting privileges in OPTN affairs.
- (c) Suspension of the privilege to receive all organ offers or offers of particular organ types for transplantation and related services.
- (d) Suspension of the privilege to list all patients or patients in need of particular organ types on the Patient Waiting List.
- (e) Required investigation of personnel as provided for in Section 1.03A of Appendix A of the Bylaws and Sections IV and VII Attachment I to Appendix B of the Bylaws.
- (f) ~~(e)~~ The actions listed for a Member on probation and the actions listed for a Member Not in Good Standing.

(6) **Termination of Membership or Designated Transplant Program Status.** 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 to terminate membership or designated transplant program status for one or more organs, which are adverse actions under the Bylaws and would first entitle the Member to procedural rights as provided in Section 3.01A – 3.03A 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; and

(7) **Action Specified in OPTN Final Rule.** 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 recommend to the Secretary of HHS any action specifically identified in Section 121.10(c) of the OPTN Final Rule, 42 CFR § 121.10(c), which would be an adverse action under the Bylaws and would first entitle the Member to procedural rights as provided in Section 3.01A – 3.03A 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.

## Appendix A to the UNOS Bylaws

### Corrective Action and Enforcement of UNOS Requirements OPO, Transplant Hospital, and Histocompatibility Laboratory Members

2.01A - 2.05A [No changes]

#### 2.06A Membership And Professional Standards Committee Action

- (a) **Category I, II, and III Potential Violations.** Matters referred to the MPSC, MPSC-PCSC, or a MPSC ad hoc subcommittee will be defined initially by decision of the MPSC Chairperson (with advice from the Executive Director and President) as Category I potential violations according to the process outlined in Section 2.05 above, or by the MPSC, MPSC-PCSC, or MPSC ad hoc subcommittee as either Category II or Category III potential violations. For Category I potential violations, the MPSC-PCSC or ad hoc subcommittee shall report its determination in writing to the Executive Committee and full MPSC.

Category II potential violations generally are of the type described in Section 2.05(2)(c) above, while Category III potential violations generally are of the type described in Section 2.05(2)(a-b) above. Category II and III potential violations are further distinguished by the expectation that Category II potential violations will proceed to formal Hearings and, perhaps, Appellate Reviews. Upon determination of a Category II potential violation, the MPSC shall consider a timeline for review and action to assist in timely resolution of the matter; and

- (b) For Category II and III potential violations, the MPSC-PCSC shall report its action in writing to the full MPSC. The MPSC shall report its action in writing to the Board of Directors.

Category I, II, and III potential violations are generally defined as follows. Individual cases may vary depending upon the unique circumstances, and cases may move among the categories as circumstances may change.

- Category I = potential violation of UNOS requirements posing substantial, time sensitive threat to patient health or public safety,
- Category II = material breach of UNOS requirements, and
- Category III = dialogue with MPSC expected to correct any noncompliant behavior and lead to ongoing future compliance.

Actions available for all categories of potential violations may include, without limitation (see Figures A-2a and A2b for a general overview of these actions), the following. Sanctions listed under numbers (1) and (2) below may be imposed directly by action of either the MPSC-PCSC or MPSC. Sanctions listed under numbers (3) – (7) below must be recommended by the MPSC to the Board of Directors and imposed by the Board, or may be imposed by the Executive Committee or the Board without recommendation of the MPSC. Unless specifically noted, the sanctions listed below may be taken in cases of : (i) noncompliance with policies or behavior posing risk to patient health or public safety covered by Section 1138 of the Social Security Act, 42 U.S.C. § 1320-b8, by virtue of (a) recommendation by the OPTN to be mandatory and designation by the Secretary of HHS for coverage, (b) determination by the Secretary of HHS to be mandatory under the OPTN Final Rule, or (c) determination of risk to the health of patients or to the public safety, which is confirmed by the Secretary of HHS, and (ii) noncompliance with all other UNOS requirements. Policies and behavior posing risk to patient health or public safety described under category (i) above are hereinafter referred to collectively as “policies covered by Section 1138 of the Social Security Act,” or individually as “policy covered by Section 1138 of the Social Security Act.”

The MPSC-PCSC or the MPSC may impose the following sanctions without referral to the Board of Directors for approval:

- (1) **Reject Request for Corrective Action.** The MPSC-PCSC or the MPSC may reject the request for corrective action notice of which shall be provided to the Board of Directors; and
- (2) **Notice of Uncontested Violation, Letter of Warning or Letter of Reprimand.** The MPSC-PCSC or the MPSC may issue a Notice of Uncontested Violation, Letter of Warning or a Letter of Reprimand, any of which is not an adverse action under the Bylaws but is meant to inform the Member of the need for the Member to ensure continuing compliance with UNOS requirements. These categories of non-adverse actions are appropriate under the following circumstance.
  - (a) **Notice of Uncontested Violation** –There has been a violation of UNOS requirements with no substantial evidence of mitigating factors based on medical judgment, and there is believed to be no likelihood of recurrence. The Member is not entitled to an interview;
  - (b) **Letter of Warning** – There has been an apparent violation of UNOS requirements under circumstances in which medical judgment is credibly put forth as a partial mitigating factor and there is believed to be no likelihood of recurrence. The Member is not entitled to an interview; and
  - (c) **Letter of Reprimand** – There has been an apparent violation of UNOS requirements under circumstances where medical judgment is not a credible mitigating factor and there is believed to be no likelihood of recurrence. The Member shall be entitled to an interview under the procedures described in Section 3.01A prior to any issuance of a Letter of Reprimand by the MPSC/PCSC or the MPSC.

The MPSC may make recommendations to the Board of Directors for the imposition of the following adverse sanctions or the Board of Directors or the Executive Committee may take such action without recommendation by the MSPC:

- (3) **Probation.** 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 place the Member on probation, which would be an adverse action under the Bylaws and would first entitle the Member to procedural rights as provided in Section 3.01A – 3.03A 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 Board of Directors or the Executive Committee of the final decision to place the Member on probation. Probation may include one or more of the following or other actions deemed appropriate by the MPSC-PCSC/MPSC, Executive Committee, or the Board of Directors and will include notice to all Members.
  - (a) Required submission of a compliance action plan or plan of correction developed to specifications as may be defined by the MPSC-PCSC/MPSC, with demonstration to the MPSC-PCSC/MPSC of adherence to the plan and correction of any non-compliant activity within some period of time;
  - (b) Unscheduled on-site audit(s) throughout the period of probation, to be performed by UNOS audit staff at the sole reasonable cost and expense of the Member. Such costs and expenses shall include, but not be limited to, travel and lodging expenses of UNOS staff; and
  - (c) Required submission of reports, data, or other evidence to UNOS documenting correction of the non-compliant activity throughout the period of probation.
  - (d) Required investigation of personnel as provided for in Section 1.03A of Appendix A of the Bylaws and Sections IV and VII of Attachment I to Appendix B of the Bylaws.

(4) **Member Not in Good Standing.** The MPSC may recommend that the Board of Directors or Executive Committee, or either the Executive Committee or the Board of Directors on its own accord, may declare the Member a Member “Not in Good Standing” which would be an adverse action under the Bylaws and would first entitle the Member to procedural rights as provided in Section 3.01A – 3.03A 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 Executive Committee of the Final decision to declare the Member a Member Not in Good Standing. 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 the Executive Committee:

- (a) Withdrawal of voting privileges in UNOS affairs;
- (b) Suspension of the ability for any personnel named in the UNOS 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) Formal notification, along with subsequent changes in such status, to the entire UNOS Membership as well as to the Chief Executive Officer of Institution Members;
- (d) 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) Notice, within reasonable limits and means, to patients and the general public in the area of the Member. Such notice may include, but is not limited to, communication using the UNOS website and/or as prescribed by the Board of Directors for distribution by the Member; and
- (f) Required investigation of personnel as provided for in Section 1.03A of Appendix A of the Bylaws and Sections IV and VII Attachment I to Appendix B of the Bylaws.

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

(5) **Suspension of Member Privileges.** 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 to suspend the Member’s ability to list patients on the waiting list, the Member’s eligibility to receive organ offers for transplant 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 followed 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. Suspension of membership privileges may include one or more of the following or other actions deemed appropriate by the MPSC-PCSC/MPSC, the Executive Committee, or the Board of Directors:

- (a) Suspension of the privilege to hold office and/or sit on the UNOS Board of Directors or Committees;
- (b) Suspension of voting privileges in UNOS affairs;

- (c) Suspension of the privilege to receive all organ offers or offers of particular organ types for transplantation and related services;
  - (d) Suspension of the privilege to list all patients or patients in need of particular organ types on the Waiting List; and
  - (e) Required investigation of personnel as provided for in Section 1.03A of Appendix A of the Bylaws and Sections IV and VII Attachment I to Appendix B of the Bylaws.
  - (f) ~~(e)~~ The actions listed for a Member on probation and the actions listed for a Member Not in Good Standing.
- (6) **Termination of Membership or Designated Transplant Program Status.** 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 terminate membership or designated transplant program status for one or more organs, which are adverse actions under the Bylaws and would first entitle the Member procedural rights as provided in Section 3.01A – 3.03A 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.
- (7) **Action Specified in OPTN Final Rule.** 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 recommend to the any action specifically identified in Section 121.10(c) of the OPTN Final Rule, 42 CFR § 121.10(c), which would be an adverse action under the Bylaws and would first entitle the Member to procedural rights as provided in Section 3.01A – 3.03A 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.

- 2.07A **Medical Peer Review** [No changes]
- 2.08A **Enforcement Period** [No changes]
- 2.09A **Restoration of Membership Privileges** [No changes]
- 2.10A **Notice** [No changes]
- 2.11A **Procedural Rights** [No changes]
- 2.12A **Time Period For Action** [No changes]

**Appendix B to Bylaws - OPTN  
Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership**

**I. Organ Procurement Organizations.**

[No Change]

**II. Transplant Hospitals.**

**A. General.** [No further changes]

**B. Survival Rates.** [No further changes]

**C. Inactive Membership Status.** [No further changes]

**D. Investigation of Personnel.** At the request of the MPSC, the Transplant Hospital must conduct an investigation, ~~including~~ of personnel identified by the MPSC, who are associated with one or more of the Transplant Hospital's designated transplant programs (as defined below) qualified as a transplant program by other than the requirements set forth in Attachment I and sub-attachments to Appendix B, and report to the MPSC upon initiation and conclusion of the inquiry that it has conducted the investigation in accordance with the terms of this provision. The purpose of the investigation would be to examine the individual's or individuals' role(s) in a matter under review or reviewed by the MPSC and would be explained to the Transplant Hospital. The Hospital's investigation must be conducted ~~include peer review~~ pursuant to the institution's standard peer review process for conducting inquiries of potential professional misconduct and conclude with appropriate action consistent with this process. Failure to comply with this provision shall result in recommendation to the Board of Directors that the Board so notify the Secretary, and/or take appropriate action in accordance with Appendix A of these Bylaws.

**E. Patient Notification.** [No further changes]

**F. Clinical Transplant Coordinator.** [No further changes]

**G. Financial Coordinator.** [No further changes]

**H. Routine Referral Procedures.** [No further changes]

**I. Designated Transplant Program Status.** [No further changes]

**III. Histocompatibility Laboratories.** [No Change]

**Appendix B to the UNOS Bylaws**

**Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership**

**I. Organ Procurement Organizations.**

**II. Transplant Hospitals.**

**A. General.** [No further changes]

**B. Survival Rates.** [No further changes]

**C. Inactive Membership Status.**

**D. Investigation of Personnel.** At the request of the MPSC, the Transplant Hospital must conduct an investigation, including of personnel identified by the MPSC, who are associated with one or more of the Transplant Hospital's designated transplant programs (as defined below) qualified as a transplant program by other than the requirements set forth in Attachment I and sub-attachments to Appendix B, and report to the MPSC upon initiation and conclusion of the inquiry that it has conducted the investigation in accordance with the terms of this provision. The purpose of the investigation would be to examine the individual's or individuals' role(s) in a matter under review or reviewed by the MPSC and would be explained to the Transplant Hospital. The Hospital's investigation must be conducted include peer review pursuant to the institution's standard peer review process for conducting inquiries of potential professional misconduct and conclude with appropriate action consistent with this process. Failure to comply with this provision shall result in recommendation to the Board of Directors that the Board take appropriate action in accordance with Appendix A of these Bylaws.

**E. Key Personnel.** [No further changes]

**F. Patient Notification.** [No further changes]

**G. Clinical Transplant Coordinator.** [No further changes]

**H. Financial Coordinator.** [No further changes]

**I. Routine Referral Procedures.** [No further changes]

**J. Designated Transplant Program Status.** [No further changes]

**Attachment I to Appendix B of the OPTN Bylaws**

**I. Facilities and Resources.** [No Change]

**II. Inactive Program Status.** [No Change]

**III. Reporting Changes in Key Personnel.** [No Change]

**IV. Investigation of Personnel.** At the request of the MPSC, the designated transplant program must conduct an investigation of personnel identified by the MPSC, who are associated with the program, and report to the MPSC upon initiation and conclusion of the inquiry that it has conducted the investigation in accordance with the terms of this provision. The purpose of the investigation would be to examine the individual's or individuals' role(s) in a matter under review or reviewed by the MPSC and would be explained to the designated transplant program. The program's investigation must be conducted include peer review pursuant to the program's institutional standard peer review process for conducting inquiries of potential professional misconduct and conclude with appropriate action consistent with this process. Failure to comply with this provision shall result in appropriate action in accordance with Appendix A of these Bylaws.

**IV. OPO Affiliation.** The transplant program must have letters of agreement or contracts with an OPO as defined in Article 1.2 of the Bylaws.

**VI. Histocompatibility Laboratory Affiliation.** The transplant program must use, for its histocompatibility testing, a laboratory that meets the standards for histocompatibility testing, as described in these Bylaws, Appendix B, Attachment II, and is approved by the Board of Directors as meeting these standards.

**VII. Transplant Surgeon and Physician.** The transplant program must identify a qualified primary surgeon and primary physician, the requirements for whom are specified below, as well as the program director. The program director, in conjunction with the primary surgeon and primary physician, must submit written documentation that 100% surgical and medical coverage is provided by individuals credentialed by the institution to provide transplant service for the program. The primary surgeon and primary physician, collectively, are further responsible for ensuring the ongoing operation of the program in compliance with the criteria set forth in this Appendix B, Attachment I, and notification to the OPTN Contractor if at any time the program deviates from such criteria.

Upon applying to serve as Each primary surgeon or primary physician, listed on the application as a part of the plan for continuing policy compliance, shall submit an assessment, subject to medical peer review confidentiality requirements and which follows guidelines provided in the application and is satisfactory to the MPSC, of all physicians and surgeons participating in the program regarding their involvement in prior transgressions of OPTN requirements and plans to ensure that the improper conduct is not continued. A transplant program served by a single surgeon or physician shall inform its patients of this fact and potential unavailability of one or both of these individuals, as applicable, during the year.

**A. Renal Transplantation** [No Change]

**B. Liver Transplantation** [No Change]

**C. Pancreas Transplantation** [No Change]

**D. Pancreatic Islet Transplantation** [No Change]

**E. Heart Transplantation** [No Change]

**F. Lung Transplantation** [No Change]

**G. Heart/Lung Transplantation** [No Change]

**VIII. Collaborative Support.** [No further Change]

**VIXH. Ancillary Services.** [No further Change]

**IX. Blood Bank Support.** [No further Change]

**XI. Transplant Mental Health and Social Support Services.** [No further Change]

**XII. Additional Requirements for Pancreatic Islet Transplantation.** [No further Change]

### **Attachment I, to Appendix B of the UNOS Bylaws Designated Transplant Program Criteria**

A transplant program that meets the following criteria shall be qualified as a designated transplant program to receive organs for transplantation:

**IV. Facilities and Resources.** [No changes]

**II. Inactive Program Status.** [No changes]

**III. Reporting Changes in Key Personnel.** [No changes]

**IV. Investigation of Personnel:** At the request of the MPSC, the designated transplant program must conduct an investigation of personnel identified by the MPSC, who are associated with the program, and report to the MPSC upon initiation and conclusion of the inquiry that it has conducted the investigation in accordance with the terms of this provision. The purpose of the investigation would be to examine the individual's or individuals' role(s) in a matter under review or reviewed by the MPSC and would be explained to the designated transplant program. The program's investigation must be conducted ~~include peer review~~ pursuant to the program's institutional standard peer review process for conducting inquiries of potential professional misconduct and conclude with appropriate action consistent with this process. Failure to comply with this provision shall result in appropriate action in accordance with Appendix A of these Bylaws.

**IV. OPO Affiliation.** [No further changes].

**VI. Histocompatibility Laboratory Affiliation.** [No further changes]

**VII. Transplant Surgeon and Physician.** The transplant program must identify a qualified primary surgeon and primary physician, the requirements for whom are specified below, as well as the program director. The program director, in conjunction with the primary surgeon and primary physician, must submit written documentation that 100% surgical and medical coverage is provided by individuals credentialed by the institution to provide transplant service for the program. The primary surgeon and primary physician, collectively, are further responsible for ensuring the ongoing operation of the program in compliance with the criteria set forth in this Appendix B, ~~Attachment I~~, and notification to the OPTN Contractor if at any time the program deviates from such criteria.

Each primary surgeon or primary physician, listed on the application as a part of the plan for who shares coverage responsibility, shall submit an assessment, subject to medical peer review confidentiality requirements and which follows guidelines provided in the application and is satisfactory to the MPSC, of all physicians and surgeons participating in the program regarding their involvement in prior transgressions of UNOS requirements and plans to ensure that the improper conduct is not continued. A transplant program served by a single surgeon or physician shall inform its patients of this fact and potential unavailability of one or both of these individuals, as applicable, during the year.

- H. **Renal Transplantation** [No Change]
- I. **Liver Transplantation** [No Change]
- J. **Pancreas Transplantation** [No Change]
- K. **Pancreatic Islet Transplantation** [No Change]
- L. **Heart Transplantation** [No Change]
- M. **Lung Transplantation** [No Change]
- N. **Heart/Lung Transplantation** [No Change]
- ~~VIII.~~ **Collaborative Support.** [No Change]
- ~~VIX.~~ **Ancillary Services.** [No Change]
- ~~IX.~~ **Blood Bank Support.** [No Change]
- ~~XI.~~ **Transplant Mental Health and Social Support Services.** [No Change]
- ~~XII.~~ **Additional Requirements for Pancreatic Islet Transplantation.** [No Change]

**Proposed Changes to Language for Letters of Recommendation  
Appendix B, Attachment I, Section XII (C) of the UNOS Bylaws  
Designated Transplant Program Criteria,**

**XII. Transplant Programs.**

A – B [No Changes]

**XII. Transplant Programs.**

- C. To qualify for membership in UNOS, a transplant program must have a clinical service which meets the following criteria. Each transplant program must identify a UNOS qualified primary surgeon and physician, the requirements for whom are described below. The program director, in conjunction with the primary surgeon and physician, must provide written documentation that 100% medical and surgical coverage is provided by individuals credentialed by the institution to provide transplant service for the program. A transplant program served by a single surgeon or physician shall inform its patients of this fact and potential unavailability of one or both of these individuals, as applicable, during the year.

A transplant center applying as a new member or for a key personnel change must include for the proposed primary transplant surgeon and/or physician a report from their hospital credentialing committee that the committee has reviewed the said individual's state licensing, board certification status, training and affirm that they are "currently" a member in good standing.

**(1) Kidney Transplantation**

Transplant Surgeon - Each transplant center must have on site a qualified kidney transplant surgeon. A kidney transplant surgeon shall be a physician with an M.D. or

D.O. degree or equivalent degree from another country who is licensed to practice medicine in his/her state or political jurisdiction and has been accepted onto the medical staff of the applicant hospital. Such a surgeon must complete a two year formal transplant fellowship at a transplant program meeting UNOS membership criteria in renal transplantation. In lieu of a two year formal transplant fellowship, two years of experience with a transplant program meeting the criteria for acceptance into UNOS will suffice.

The surgeon shall have current certification by either the American Board of Surgery, the American Board of Urology, the American Board of Osteopathic Surgery, or their foreign equivalent. If board certification in Urology is pending (as in the case of one just finished training) conditional approval may be granted for a 12-month period, with the possibility of its being renewed for an additional 12-month period to allow time for the completion of certification. The individual shall provide a letter from the applicant hospital's credentialing committee stating that the surgeon continues to meet all requirements to be in good standing.

A formal training program for kidney transplant surgeons requires that formal training must occur in a training program approved by the Membership and Professional Standards Committee of UNOS. The criteria for approval of such a program are as follows:

**(aa) – (bb) [No Changes]**

To qualify as a kidney transplant surgeon, the training/experience requirements will be met if the following conditions of either (cc), (dd), or (ee) are met.

(cc) Training during the applicant's transplant fellowship. For kidney transplantation the training requirements for the transplant surgeon can be met during a two-year transplant fellowship if the following conditions are met:

(i) - (iv) [No Changes]

(v) The individual has a letter, sent directly to UNOS from the director of that training program and chairman of the department or credentialing committee, verifying that the fellow has met the above requirements, and that the fellow is qualified to direct a kidney transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary surgeon, and the transplant program director at the fellowship training program attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(vi) [No Changes]

(dd) For kidney transplantation, if the transplant surgeon requirements have not been met, as outlined above, in a transplant fellowship, the

requirements can be met by acquired clinical experience if the following conditions are met:

(i) – (iii) [No Changes]

(iv) The surgeon has a letter, sent directly to UNOS, from the director of this transplant program and chairman of the department or credentialing committee, verifying that the surgeon has met the above requirements, and is qualified to direct a kidney transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary surgeon, and the transplant program director at the transplant program last served by the individual, attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) [No Changes]

(ee) In the event that a surgeon cannot qualify under the requirements of any of the other criteria for primary kidney transplant surgeon, transplant programs serving predominantly pediatric patients may petition the OPTN/UNOS Membership and Professional Standards Committee for and receive approval of the surgeon to function as the primary kidney transplant surgeon provided that the surgeon can demonstrate to the satisfaction of the Membership and Professional Standards Committee and OPTN/UNOS Board of Directors that his/her training and/or experience in performing kidney transplantation is equivalent to that described in the above requirements. Additionally, the surgeon must demonstrate satisfactorily that he/she has maintained a current working knowledge (direct involvement in kidney transplant patient care within the last two years) of all aspects of kidney transplantation and patient care.

Furthermore, the individual has a letter of recommendation from the person(s) named as primary surgeon, and the transplant program director at the fellowship training program or transplant program last served by the individual attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

A preliminary interview before the Committee shall be required as a part of the petition. This option for qualification as the primary kidney

transplant surgeon is temporary only and shall cease to exist for applications for primary kidney transplant surgeon received after more specific criteria for primary transplant surgeons serving predominantly pediatric patients are incorporated into these By-Laws and implemented. The MPSC or an Ad Hoc Subcommittee of at least four committee members appointed by the Chairperson of the MPSC at his/her discretion is authorized to conduct the preliminary interview and make an interim determination. Such determinations shall be advisory to the MPSC and/or Board of Directors, which is the body responsible for final decisions with respect to membership and transplant designation applications, and shall be effective on an interim basis pending final decisions by the MPSC and/or Board, or action as may be directed through due process.

(ff) [No Changes].

- (b) Transplant Physician - Each kidney transplant program must have on site a qualified transplant physician. A kidney transplant physician shall be a physician with an M.D. or D.O. degree or equivalent degree from another country who is licensed to practice medicine in his/her state or political jurisdiction and has been accepted onto the medical staff of the applicant hospital.

The kidney transplant physician shall have current board certification in nephrology by the American Board of Internal Medicine, the American Board of Pediatrics, or the foreign equivalent. The individual shall provide a letter from the applicant hospital's credentialing committee stating that the physician continues to meet all requirements to be in good standing.

A formal training program for kidney transplant physicians requires that formal training must occur in a training program approved by the MPSC of UNOS. The criteria for approval of such a program follows:

(aa) – (bb) [No Changes]

To qualify as a kidney transplant physician, the training/experience requirement will be met if the following conditions of either (cc), (dd), (ee), (ii), or (jj) are met. For a pediatrician to qualify as a kidney transplant physician, the training/experience requirements will be met if the following conditions of either (ee), (ff), (gg), (hh), (ii), or (jj) are met:

- (cc) The training requirements for the kidney transplant physician can be met during the applicant's nephrology fellowship if the following conditions are met:

(i) – (v) [No Changes]

- (vi) That the individual has a letter sent directly to UNOS from the director of the individual fellowship training program as well as the supervising qualified kidney transplant physician verifying that the fellow has satisfactorily met the above requirements and that he/she is qualified to become a medical director of a kidney transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary physician, and the transplant program director at the

fellowship training program attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(vii) – (ix) [No Changes]

(dd) The training requirements for the kidney transplant physician can be met during a separate 12-month transplant nephrology fellowship if the following conditions are met

(i) – (v) [No Changes]

(vi) That the individual has a letter sent directly to UNOS from the director of the individual fellowship training program as well as the supervising qualified kidney transplant physician verifying that the fellow has satisfactorily met the above requirements and that he/she is qualified to become a medical director of a kidney transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary physician, and the transplant program director at the fellowship training program attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(vii) [No Changes]

(ee) If a board certified or eligible nephrologist has not met the above requirements in a nephrology fellowship or transplantation medicine fellowship the training/experience requirements for the kidney transplant physician can be met by acquired clinical experience if the following conditions are met:

(i) – (iv) [No Changes]

(v) That the individual has written a detailed letter to UNOS outlining his/her experience in a kidney transplant program and in addition that supporting letters documenting the experience and competence of the individual from the qualified transplant physician and/or the kidney transplant surgeon who has been directly involved with the individual, have been sent to UNOS.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary physician, and the transplant program director at the transplant program last served by the individual attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

- (ff) The training/experience requirements for a kidney transplant physician can be met by completion of 3 years of pediatric nephrology as mandated by the American Board of Pediatrics in a training program accredited by the Residency Review Committee for Pediatrics (RRC-Ped) of the ACGME, if during that 3 year program, there has been an aggregate of 6 months of clinical care for transplant patients and the following conditions are met:

(i) – (iii) [No Changes]

- (iv) The individual must have had a letter sent directly to UNOS from the program director of the pediatric nephrology training program, as well as from the qualified kidney transplant physician and the qualified kidney transplant surgeon verifying that the fellow has met the above requirements, that he/she is qualified to become a kidney transplant physician, and a medical director of a renal transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary physician, and the transplant program director at the fellowship training program attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) – (vi) [No Changes]

- (gg) The training/experience requirements for the kidney transplant physician can be met during a separate transplantation fellowship if the following conditions are met, and the individual is a certified pediatric nephrologist, or is approved by the American Board of Pediatrics to take the certifying examination.

(i) – (iii) [No Changes]

- (iv) The individual must have had a letter sent directly to UNOS from the program director of the pediatric nephrology training program, as well as from the qualified kidney transplant physician and the qualified kidney transplant surgeon verifying that the fellow has met the above requirements, that he/she is qualified to become a kidney transplant physician, and a medical director of a kidney transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary physician, and the transplant program director at the fellowship training program attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) - (vi) [No Changes]

- (hh) If a certified pediatric nephrologist, or a pediatric nephrologist approved by the American Board of Pediatrics to take the certifying examination, has not met requirements (ff)(i) - (ff) (iv) or (gg)(i) – (gg)(iv), he/she can meet the training/ experience requirements to qualify as a kidney transplant physician if the following conditions are met:

(i) [No Changes]

- (ii) That supporting letters documenting the experience and competence of the individual from the qualified kidney transplant physician and the qualified kidney transplant surgeon who has been directly involved with the individual, have been sent to UNOS.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary physician, and the transplant program director at the fellowship training program attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(iii) - (vi) [No Changes]

- (ii) In the event that a physician cannot qualify under the requirements of any of the other criteria for primary kidney transplant physician, transplant programs serving predominantly pediatric patients may

petition the OPTN/UNOS Membership and Professional Standards Committee for and receive approval of the physician to function as the primary kidney transplant physician provided that the physician can demonstrate to the satisfaction of the Membership and Professional Standards Committee and OPTN/UNOS Board of Directors that his/her training and/or experience in the care of kidney transplant patients is equivalent to that described in the above requirements. Additionally, the physician must demonstrate satisfactorily that he/she has maintained a current working knowledge (direct involvement in kidney transplant patient care within the last two years) of all aspects of kidney transplantation and patient care.

Furthermore, the individual has a letter of recommendation from the person(s) named as primary physician or primary physician, and the transplant program director at the fellowship training program or transplant program last served by the individual attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

A preliminary interview shall be required as part of the petition. This option for qualification as the primary kidney transplant physician is temporary only and shall cease to exist for applications for primary kidney transplant physician received after more specific criteria for primary transplant physician serving predominantly pediatric patients are incorporated into these By-Laws and implemented. The MPSC or an Ad Hoc Subcommittee of at least four committee members appointed by the Chairperson of the MPSC at his/her discretion is authorized to conduct the preliminary interview and make an interim determination. Such determinations shall be advisory to the MPSC and/or Board of Directors, which is the body responsible for final decisions with respect to membership and transplant designation applications, and shall be effective on an interim basis pending final decisions by the MPSC and/or Board, or action as may be directed through due process.

(jj) In the case of a change in the primary kidney transplant physician at a UNOS approved kidney transplant program, if items (cc) iii or (ee) i-ii are not met, the replacement physician, a nephrologist, can function as a kidney transplant physician for a maximum period of twelve months if the following conditions are met:

(i) – (vi) [No Changes]

(kk) [No Changes]

**(2) Live Donor Kidney Transplant Programs.** [No Changes]

**(3) Liver Transplantation**

- (a) Transplant Surgeon - Each transplant center must have on site a qualified liver transplant surgeon. A liver transplant surgeon shall be a physician with an M.D. or D.O. degree or equivalent degree from another country who is licensed to practice medicine in his/her state or political jurisdiction and has been accepted onto the medical staff of the applicant hospital.

The surgeon shall have current certification by either the American Board of Surgery, the American Board of Urology, the American Board of Osteopathic Surgery, or their foreign equivalent. If board certification in Urology is pending (as in the case of one just finished training) conditional approval may be granted for a 12-month period, with the possibility of its being renewed for an additional 12-month period to allow time for the completion of certification. The individual shall provide a letter from the applicant hospital's credentialing committee stating that the surgeon continues to meet all requirements to be in good standing.

A formal training program for transplant surgeons requires that formal training must occur in a training program approved by the Membership and Professional Standards Committee of UNOS. The criteria for approval of such a program are as follows:

(aa) - (bb) [No Changes]

- (cc) Training during the applicant's transplant fellowship. For liver transplantation the training requirements for the transplant surgeon can be met during a two-year transplant fellowship if the following conditions are met:

(i) - (iv) [No Changes]

- (v) The individual has a letter, sent directly to UNOS from the director of that training program verifying that the fellow has met the above requirements, and that the fellow is qualified to direct a liver transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary surgeon, and the transplant program director at the fellowship training program attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(vi) [No Changes]

- (dd) For liver transplantation, if the transplant surgeon requirements have not been met, as outlined above, in a transplant fellowship, the requirements can be met by acquired clinical experience if the following conditions are met.

(i) - (iii) [No Changes]

- (iv) The surgeon has a letter, sent directly to UNOS, from the director of this transplant program and chairman of the department or credentialing committee, verifying that the surgeon has met the above requirements, and is qualified to direct a liver transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary surgeon, and the transplant program director at the transplant program last served by the individual attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

- (v) [No Changes]

- (ee) In the event that a surgeon cannot qualify under the requirements of any of the other criteria for primary liver transplant surgeon, transplant programs serving predominantly pediatric patients may petition the OPTN/UNOS Membership and Professional Standards Committee for and receive approval of the surgeon to function as the primary liver transplant surgeon provided that the surgeon can demonstrate to the satisfaction of the Membership and Professional Standards Committee and OPTN/UNOS Board of Directors that his/her training and/or experience in performing liver transplantation is equivalent to that described in the above requirements.

Additionally, the surgeon must demonstrate satisfactorily that he/she has maintained a current working knowledge (direct involvement in liver transplant patient care within the last two years) of all aspects of liver transplantation and patient care.

Additionally, the individual has a letter of recommendation from the person(s) named as primary surgeon, and the transplant program director at the fellowship training program or transplant program last served by the individual attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

A preliminary interview before the Committee shall be required as a part of the petition. This option for qualification as the primary liver transplant surgeon is temporary only and shall cease to exist for applications for primary liver transplant surgeon received after more specific criteria for primary transplant surgeons serving predominantly pediatric patients are incorporated into these Bylaws and implemented.

The MPSC or an Ad Hoc Subcommittee of at least four committee members appointed by the Chairperson of the MPSC at his/her discretion is authorized to conduct the preliminary interview and make an interim determination. Such determinations shall be advisory to the MPSC and/or Board of Directors, which is the body responsible for final decisions with respect to membership and transplant designation applications, and shall be effective on an interim basis pending final decisions by the MPSC and/or Board, or action as may be directed through due process

(ff) [No Changes]

- (b) Transplant Physician - Each liver transplant program must have on site a qualified transplant physician. A liver transplant physician shall be a physician with an M.D. or D.O. degree or equivalent degree from another country who is licensed to practice medicine in his/her state or political jurisdiction and has been accepted onto the medical staff of the applicant hospital.

The liver transplant physician shall have current board certification in gastroenterology by the American Board of Internal Medicine, American Board of Pediatrics, or the foreign equivalent.

In general, pediatric liver transplant programs should have a board certified pediatrician (or foreign equivalent) who meets the criteria for liver transplant physician. In the absence of such an individual, a physician meeting the criteria as a liver transplant physician for adults, can function as a liver transplant physician for the pediatric program if a pediatric gastroenterologist is involved in the care of the pediatric liver transplant recipients.

The individual shall provide a letter from the applicant hospital's credentialing committee stating that the physician continues to meet all requirements to be in good standing.

To qualify as a liver transplant physician, the training/experience requirement will be met if the following conditions of either (aa), (bb), (cc), (dd), (ee) (ff), (gg), (hh), or (ii) are met:

- (aa) The training requirements for the liver transplant physician can be met during the applicant's gastroenterology fellowship if the following conditions are met:

(i) – (iv) [No Changes]

- (v) That the individual has a letter sent directly to UNOS from the director of the individual fellowship training program as well as the supervising qualified liver transplant physician verifying that the fellow has satisfactorily met the above requirements and that he/she is qualified to become a medical director of a liver transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary physician, and the transplant program director at the fellowship training program attesting to the individual's overall qualifications to act as primary physician addressing

the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(vi) – (viii) [No Changes]

- (bb) The training requirements for the liver transplant physician can be met during a separate 12 month transplant hepatology fellowship if the following conditions are met.

(i) – (v) [No Changes]

- (vi) That the individual has a letter sent directly to UNOS from the director of the individual fellowship training program as well as the supervising qualified liver transplant physician verifying that the fellow has satisfactorily met the above requirements and that he/she is qualified to become a medical director of a liver transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary physician, and the transplant program director at the fellowship training program attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(vii) [No Changes]

- (cc) If a board certified gastroenterologist has not met the above requirements in a gastroenterology, or transplant hepatology, fellowship the training/experience requirements for the liver transplant physician can be met by acquired clinical experience if the following conditions are met:

(i) – (iv) [No Changes]

- (v) That the individual has written a detailed letter to UNOS outlining his/her experience in a liver transplant program and in addition that supporting letters documenting the experience and competence of the individual from the qualified transplant physician and/or liver transplant surgeon who has been directly involved with the individual, have been sent to UNOS.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary

physician, and the transplant program director at the transplant program last served by the individual attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

- (dd) The training/experience requirements for a liver transplant physician can be met by completion of 3 years of pediatric gastroenterology fellowship training as mandated by the American Board of Pediatrics and accredited by the ACGME RRC-Ped, if during that 3 year program there has been an aggregate of 6 months of clinical care for transplant patients and the following conditions are met:

(i) – (iii) [No Changes]

- (iv) The individual must have had a letter sent directly to UNOS from the program director of the pediatric gastroenterology training program, as well as from the qualified liver transplant physician and the qualified liver transplant surgeon verifying that the fellow has met the above requirements, that he/she is qualified to become a liver transplant physician, and a medical director of a liver transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary physician, and the transplant program director at the fellowship training program attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) - (vi) [No Changes]

- (ee) The training requirements for the liver transplant physician can be met during a separate transplantation fellowship if the following conditions are met, and the individual is a board certified pediatric gastroenterologist, or is approved by the American Board of Pediatrics to take the certifying examination.

(i) – (iii) [No Changes]

- (iv) The individual must have had a letter sent directly to UNOS from the program director of the pediatric gastroenterology training program, as well as from the qualified liver transplant physician and the qualified liver transplant surgeon verifying that the fellow has met the above requirements, that he/she is

qualified to become a liver transplant physician, and a medical director of a liver transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary physician, and the transplant program director at the fellowship training program attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) - (vi)[No Changes]

(ff) If a board certified pediatric gastroenterologist, or a pediatric gastroenterologist approved by the American Board of Pediatrics to take the certifying examination, has not met requirements (dd) or (ee), he/she can meet the training/ experience requirements to qualify as a liver transplant physician if the following conditions are met:

(i) [No Changes]

(ii) That the physician has written a detailed letter to UNOS outlining his/her experience in a liver transplant program and in addition that supporting letters documenting the experience and competence of the individual from the qualified transplant physician and the qualified transplant surgeon who have been directly involved with the individual, have been sent to UNOS.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary physician, and the transplant program director at the transplant program last served by the individual attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(iii) - (v)[No Changes]

(gg) In the event that a physician cannot qualify under the requirements of any of the other criteria for primary liver transplant physician, transplant programs serving predominantly pediatric patients may petition the OPTN/UNOS Membership and Professional Standards Committee for and receive approval of the physician to function as the primary liver transplant physician provided that the physician can demonstrate to the satisfaction of the Membership and Professional

Standards Committee and OPTN/UNOS Board of Directors that his/her training and/or experience in the care of liver transplant patients is equivalent to that described in the above requirements.

Furthermore, the individual has a letter of recommendation from the person(s) named as primary physician or primary physician, and the transplant program director at the fellowship training program or transplant program last served by the individual attesting to the individual's overall qualifications to act as primary physician, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

A preliminary interview shall be required as part of the petition. This option for qualification as the primary liver transplant physician is temporary only and shall cease to exist for applications for primary liver transplant physician received after more specific criteria for primary transplant physician serving predominantly pediatric patients are incorporated into these By-Laws and implemented. Additionally, the physician must demonstrate satisfactorily that he/she has maintained a current working knowledge (direct involvement in liver transplant patient care within the last two years) of all aspects of liver transplantation and patient care.

The MPSC or an Ad Hoc Subcommittee of at least four committee members appointed by the Chairperson of the MPSC at his/her discretion is authorized to conduct the preliminary interview and make an interim determination. Such determinations shall be advisory to the MPSC and/or Board of Directors, which is the body responsible for final decisions with respect to membership and transplant designation applications, and shall be effective on an interim basis pending final decisions by the MPSC and/or Board, or action as may be directed through due process.

- (hh) In the case of a change in the primary liver transplant physician at a UNOS approved transplant program, if items (aa) iii or (cc) i-ii are not met, the replacement physician, must be a gastroenterologist/hepatologist, and can function as a liver transplant physician for a maximum period of twelve months if the following conditions are met:

(i) - (vi) [No Changes]

(ii) [No Changes]

**(4). Live Donor Liver Transplant Programs.** [No Changes]

**(5) Pancreas Transplantation**

- (a) Transplant Surgeon - Each transplant center must have on site a qualified transplant pancreas surgeon. A pancreas transplant surgeon shall be a physician with an M.D. or D.O. degree or equivalent degree from another country who is

licensed to practice medicine in his/her state or political jurisdiction and has been accepted onto the medical staff of the applicant hospital. Such a surgeon must complete a minimum of one year formal transplant fellowship training and one year of experience or complete a two year formal transplant fellowship at a transplant program meeting UNOS membership criteria in pancreas transplantation. In lieu of a two year formal transplant fellowship, two years of experience with a transplant program meeting the criteria for acceptance into UNOS will suffice.

The surgeon shall have and current certification by either the American Board of Surgery, the American Board of Urology, the American Board of Osteopathic Surgery, or their foreign equivalent. If board certification in Urology is pending (as in the case of one just finished training) conditional approval may be granted for a 12-month period, with the possibility of its being renewed for an additional 12-month period to allow time for the completion of certification. The individual shall provide a letter from the applicant hospital's credentialing committee stating that the surgeon continues to meet all requirements to be in good standing.

A formal training program for transplant pancreas surgeons requires that formal training must occur in a training program approved by the Membership and Professional Standards Committee of UNOS. The criteria for approval of such a program are as follows:

(aa) - (bb) [No Changes]

To qualify as a pancreas transplant surgeon, the training/experience requirements will be met if the following conditions of either (cc), (dd), or (ee) are met.

(cc) Training during the applicant's transplant fellowship. For pancreas requirements for the transplant surgeon can be met during a two-year transplant fellowship if the following conditions are met:

(i) – (iv) [No Changes]

(v) The individual has a letter, sent directly to UNOS from the director of that training program and chairman of the department or credentialing committee, verifying that the fellow has met the above requirements, and that the fellow is qualified to direct a pancreas transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary surgeon, and the transplant program director at the fellowship training program attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(vi) [No Changes]

(dd) For pancreas transplantation, if the transplant surgeon requirements have not been met, as outlined above in options-(cc), the requirements can be met by acquired clinical experience if the following conditions are met.

(i) – (iii) [No Changes]

(iv) The surgeon has a letter, sent directly to UNOS, from the director of this transplant program and chairman of the department or credentialing committee, verifying that the surgeon has met the above requirements, and is qualified to direct a pancreas transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary surgeon, and the transplant program director at the transplant program last served by the individual attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) [No Changes]

(ee) In the event that a surgeon cannot qualify under the requirements of any of the other criteria for primary pancreas transplant surgeon, transplant programs serving predominantly pediatric patients may petition the OPTN/UNOS Membership and Professional Standards Committee for and receive approval of the surgeon to function as the primary pancreas transplant surgeon provided that the surgeon can demonstrate to the satisfaction of the Membership and Professional Standards Committee and OPTN/UNOS Board of Directors that his/her training and/or experience in performing pancreas transplantation is equivalent to that described in the above requirements. Additionally, the surgeon must demonstrate satisfactorily that he/she has maintained a current working knowledge (direct involvement in pancreas transplant patient care within the last two years) of all aspects of pancreas transplantation and patient care.

Furthermore, the individual has a letter of recommendation from the person(s) named as primary surgeon, and the transplant program director at the fellowship training program or transplant program last served by the individual attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

A preliminary interview before the Committee shall be required as a part of the petition. This option for qualification as the primary pancreas transplant surgeon is temporary only and shall cease to exist for applications for primary pancreas transplant surgeon received after more specific criteria for primary transplant surgeons serving predominantly pediatric patients are incorporated into these By-Laws and implemented. The MPSC or an Ad Hoc Subcommittee of at least four committee members appointed by the Chairperson of the MPSC at his/her discretion is authorized to conduct the preliminary interview and make an interim determination. Such determinations shall be advisory to the MPSC and/or Board of Directors, which is the body responsible for final decisions with respect to membership and transplant designation applications, and shall be effective on an interim basis pending final decisions by the MPSC and/or Board, or action as may be directed through due process.

(ff) [No Changes]

- (b) Transplant Physician - Each pancreas transplant program must have on site a qualified transplant physician. A pancreas transplant physician shall be a physician with an M.D. or D.O. degree or equivalent degree from another country who is licensed to practice medicine in his/her state or political jurisdiction and has been accepted onto the medical staff of the applicant hospital.

The transplant physician shall have current certification by either the American Board of Internal Medicine, the American Board of Pediatrics, or their foreign equivalent. The individual shall provide a letter from the applicant hospital's credentialing committee stating that the physician continues to meet all requirements to be in good standing.

The transplant physician shall have at least one year of specialized formal training in transplantation medicine or, with some exceptions as set forth in item (ee), a minimum of two years documented experience in transplantation medicine with a transplant program that meets the qualifications for membership in UNOS.

To qualify as a pancreas transplant physician, the training/experience requirements will be met if the following conditions of either (aa), (bb), (cc) (dd), or (ee) are met.

- (aa) The training/experience requirements for the pancreas transplant physician can be met during the applicant's nephrology (endocrinology, diabetology) fellowship if the following conditions are met:

(i) – (v) [No Changes]

- (vi) That the individual has a letter sent directly to UNOS from the director of the individual fellowship training program as well as the supervising qualified pancreas transplant physician verifying that the fellow has satisfactorily met the above requirements and that he/she is qualified to become a medical director of a pancreas transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary physician, and the transplant program director at the fellowship training program attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(vii) – (ix) [No Changes]

(bb) The training requirements for the pancreas transplant physician can be met during a separate 12-month transplant medicine fellowship if the following conditions are met.

(i) – (v) [No Changes]

(vi) That the individual has a letter sent directly to UNOS from the director of the individual fellowship training program as well as the supervising qualified pancreas transplant physician verifying that the fellow has satisfactorily met the above requirements and that he/she is qualified to become a medical director of a pancreas transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary physician, and the transplant program director at the fellowship training program attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(vii)- (viii) [No Changes]

(cc) If a board certified or eligible nephrologist, (endocrinologist, or diabetologist) has not met the above requirements in a nephrology fellowship or transplantation medicine fellowship the training/experience requirements for the pancreas transplant physician can be met by acquired clinical experience if the following conditions are met:

(i) – (iv) [No Changes]

(v) That the individual has written a detailed letter to UNOS outlining his/her experience in a pancreas transplant program and in addition that supporting letters documenting the experience and competence of the individual from the qualified transplant physician and/or the pancreas transplant

surgeon who has been directly involved with the individual, have been sent to UNOS.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary physician, and the transplant program director at the transplant program last served by the individual attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

- (dd) In the event that a physician cannot qualify under the requirements of any of the other criteria for primary pancreas transplant physician, transplant programs serving predominantly pediatric patients may petition the OPTN/UNOS Membership and Professional Standards Committee for and receive approval of the physician to function as the primary pancreas transplant physician provided that the physician can demonstrate to the satisfaction of the Membership and Professional Standards Committee and OPTN/UNOS Board of Directors that his/her training and/or experience in the care of pancreas transplant patients is equivalent to that described in the above requirements. Additionally, the physician must demonstrate satisfactorily that he/she has maintained a current working knowledge (direct involvement in pancreas transplant patient care within the last two years) of all aspects of pancreas transplantation and patient care.

Furthermore, the individual has a letter of recommendation from the person(s) named as primary physician, and the transplant program director at the fellowship training program or transplant program last served by the individual attesting to the individual's overall qualifications to act as primary physician, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

A preliminary interview shall be required as part of the petition. This option for qualification as the primary pancreas transplant physician is temporary only and shall cease to exist for applications for primary pancreas transplant physician received after more specific criteria for primary transplant physician serving predominantly pediatric patients are incorporated into these By-Laws and implemented. The MPSC or an Ad Hoc Subcommittee of at least four committee members appointed by the Chairperson of the MPSC at his/her discretion is authorized to conduct the preliminary interview and make an interim determination. Such determinations shall be advisory to the MPSC and/or Board of Directors, which is the body responsible for final decisions with respect to membership and transplant designation applications, and shall be effective on an interim basis pending final

decisions by the MPSC and/or Board, or action as may be directed through due process.

(ee) [No Changes]

(ff) [No Changes]

**(6) Pancreatic Islet Transplantation** [No Changes]

**(7) Heart Transplantation**

- (a) Transplant Surgeon - Each heart transplant program must have on site a qualified transplant surgeon. A heart transplant surgeon shall be a physician with an M.D. or D.O. degree or equivalent degree from another country who is licensed to practice medicine in his/her state or political jurisdiction and has been accepted onto the medical staff of the applicant hospital.

Such surgeon shall have current certification by the American Board of Thoracic Surgery or its foreign equivalent. If board certification in thoracic surgery is pending (as in the case of one just finished training) conditional approval may be granted for a 24-month period, with the possibility of its being renewed for an additional 24-month period to allow time for the completion of certification.

The individual shall provide a letter from the applicant hospital's credentialing committee stating that the surgeon continues to meet all requirements to be in good standing.

If an individual is certified by the American Board of Thoracic Surgery or its foreign equivalent, then the individual must maintain their certification in the American Board or its foreign equivalent..

To qualify as a heart transplant surgeon, the training/experience requirements will be met if the following conditions of either (aa), (bb), (cc), or (dd) are met.

- (aa) The training requirements for the heart transplant surgeon can be met during the applicant's cardiothoracic surgery residency if the following conditions are met:**

(i)- (iii) [No Changes]

- (iv) The individual has a letter, sent directly to UNOS from the director of that training program verifying that the resident has met the above requirements, and that the resident is qualified to direct a heart transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary surgeon, and the transplant program director at the fellowship training program attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary

surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) – (vi) [No Changes]

- (bb) For heart transplantation, when the training requirements for transplant surgeon have not been met during one's cardiothoracic surgery residency, they can be met during a subsequent 12-month heart transplant fellowship if all the following conditions are met:

(i) – (iii) [No Changes]

- (iv) The fellow has a letter, sent directly to UNOS from the director of that training program verifying that the fellow has met the above requirements, and that the fellow is qualified to direct a heart transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary surgeon, and the transplant program director at the fellowship training program attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) – (vi) [No Changes]

- (cc) For heart transplantation, if the transplant surgeon requirements have not been met, as outlined above, in a cardiothoracic residency or heart transplant fellowship, the requirement can be met by experience if the following conditions are met.

(i) – (iii) [No Changes]

- (iv) That the surgeon has a detailed letter sent directly to UNOS from the director of the program at which this experience is acquired, which verifies that the surgeon has met the above requirements, and is qualified to direct a heart transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary surgeon, and the transplant program director at the transplant program last served by the individual attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician,

primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) [No Changes]

- (dd) In the event that a surgeon cannot qualify under the requirements of any of the other criteria for primary heart transplant surgeon, transplant programs serving predominantly pediatric patients may petition the OPTN/UNOS Membership and Professional Standards Committee for and receive approval of the surgeon to function as the primary heart transplant surgeon provided that the surgeon can demonstrate to the satisfaction of the Membership and Professional Standards Committee and OPTN/UNOS Board of Directors that his/her training and/or experience in performing heart transplantation is equivalent to that described in the above requirements. Additionally, the surgeon must demonstrate satisfactorily that he/she has maintained a current working knowledge (direct involvement in heart transplant patient care within the last two years) of all aspects of heart transplantation and patient care.

Furthermore, the individual has a letter of recommendation from the person(s) named as primary surgeon, and the transplant program director at the fellowship training program or transplant program last served by the individual attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

A preliminary interview before the Committee shall be required as a part of the petition. This option for qualification as the primary heart transplant surgeon is temporary only and shall cease to exist for applications for primary heart transplant surgeon received after more specific criteria for primary transplant surgeons serving predominantly pediatric patients are incorporated into these By-Laws and implemented. The MPSC or an Ad Hoc Subcommittee of at least four committee members appointed by the Chairperson of the MPSC at his/her discretion is authorized to conduct the preliminary interview and make an interim determination. Such determinations shall be advisory to the MPSC and/or Board of Directors, which is the body responsible for final decisions with respect to membership and transplant designation applications, and shall be effective on an interim basis pending final decisions by the MPSC and/or Board, or action as may be directed through due process.

- (b) Transplant Physician - Each heart transplant program must have on site a qualified transplant physician. A transplant physician for heart transplantation shall be a physician with an M.D. or D.O. degree or equivalent degree from another country who is licensed to practice medicine in his/her state or political jurisdiction and has been accepted onto the medical staff of the applicant hospital. If an individual is certified by the American Board and its foreign equivalent, the individual must maintain currency in the American Board.

The heart transplant physician shall maintain current board certification or have achieved eligibility in adult or pediatric cardiology by the American Board of Internal Medicine or American Board of Pediatrics or their foreign equivalent.

The individual shall provide a letter from the applicant hospital's credentialing committee stating that the physician continues to meet all requirements to be in good standing.

To qualify as a heart transplant physician, the training/experience requirement will be met if the following conditions of either (aa), (bb), (cc), (ee), (ff), or (gg) are met:

(aa) The training requirements for the heart transplant physician can be met with the applicant's cardiology fellowship if the following conditions are met:

(i) – (vi) [No Changes]

(iv) That the individual has a letter sent directly to UNOS from the director of the individual fellowship training program as well as the supervising qualified heart transplant physician verifying the fellow has met the above requirements and that he or she has qualified to become a medical director of a heart transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary physician, and the transplant program director at the fellowship training program attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) - (vii) [No Changes]

(bb) When the training requirements for the heart transplant physician have not been met during a cardiology fellowship, they can be met by completing a separate 12-month transplant cardiology fellowship if all of the following conditions are met, and the individual is a board certified or eligible cardiologist.

(i) – (iii) [No Changes]

(iv) That the individual has a letter sent directly to UNOS from the director of the individual fellowship training program as well as the supervising qualified heart transplant physician verifying that the fellow has met the above requirements and that he or she has qualified to become a medical director of a cardiac transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary physician, and the transplant program director at the fellowship training program attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) –(vi) [No Changes]

(cc) If the cardiologist has not met the above requirements in a cardiology fellowship or specific cardiac transplant fellowship, the requirements can be met by acquired clinical experience if the following conditions are met, and the individual is a board certified cardiologist.

(i) - (iv) [No Changes]

(v) There should be a supporting letter from either the cardiac transplant physician or the cardiac transplant surgeon at the cardiologist's institution who has been directly involved with the individual and can certify his or her competence.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary physician, and the transplant program director at the transplant program last served by the individual attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(vi) [No Changes]

(dd) [No Changes]

(ee) [No Changes]

(ff) In the event that a physician cannot qualify under the requirements of any of the other criteria for primary heart transplant physician, transplant programs serving predominantly pediatric patients may petition the OPTN/UNOS Membership and Professional Standards Committee for and receive approval of the physician to function as the primary heart transplant physician provided that the physician can demonstrate to the satisfaction of the Membership and Professional Standards Committee and OPTN/UNOS Board of Directors that his/her training and/or experience in the care of heart transplant patients is

equivalent to that described in the above requirements. Additionally, the physician must demonstrate satisfactorily that he/she has maintained a current working knowledge (direct involvement in patient care within the last two years) of all aspects of heart transplantation and patient care.

Furthermore, the individual has a letter of recommendation from the person(s) named as primary physician or primary physician, and the transplant program director at the fellowship training program or transplant program last served by the individual attesting to the individual's overall qualifications to act as primary physician, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

A preliminary interview shall be required as part of the petition. This option for qualification as the primary heart transplant physician is temporary only and shall cease to exist for applications for primary heart transplant physician received after more specific criteria for primary transplant physician serving predominantly pediatric patients are incorporated into these By-Laws and implemented. The MPSC or an Ad Hoc Subcommittee of at least four committee members appointed by the Chairperson of the MPSC at his/her discretion is authorized to conduct the preliminary interview and make an interim determination. Such determinations shall be advisory to the MPSC and/or Board of Directors, which is the body responsible for final decisions with respect to membership and transplant designation applications, and shall be effective on an interim basis pending final decisions by the MPSC and/or Board, or action as may be directed through due process.

(gg) [No Changes]

## **(8) Lung Transplantation**

- (a) Transplant Surgeon - Each lung transplant center must have on site a qualified lung transplant surgeon. A lung transplant surgeon shall be a physician with an M.D. or D.O. degree or equivalent degree from another country who is licensed to practice medicine in his/her state or political jurisdiction and has been accepted onto the medical staff of the applicant hospital.

Such a surgeon shall have current certification by the American Board of Thoracic Surgery or its foreign equivalent. If board certification in thoracic surgery is pending (as in the case of where the surgeon has just completed training) conditional approval may be granted for a 24-month period, with the possibility of its being renewed for an additional 24-month period to allow time for completion of certification.

The individual shall provide a letter from the applicant hospital's credentialing committee stating that the surgeon continues to meet all requirements to be in good standing.

If an individual is certified by the American Board of Thoracic Surgery or its foreign equivalent, then the individual must maintain their certification in the American Board or its foreign equivalent.

To qualify as a lung transplant surgeon, the training/experience requirements will be met if the following conditions of either (aa), (bb), (cc), or (dd) are met:

(aa) The training requirements for lung transplant surgeon can be met during the applicant's cardiothoracic surgery residency if the following conditions are met:

(i) – (iii) [No Changes]

(iv) That the resident has a letter sent directly to UNOS from the director of that training program verifying that the resident has met the above requirements and that he/she is qualified to direct a lung transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary surgeon, and the transplant program director at the fellowship training program attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) - (vi) [No Changes]

(bb) For lung transplantation, when the training requirements for transplant surgeon have not been met during the applicant's cardiothoracic surgery residency, the requirements may be fulfilled during a subsequent 12-month transplant fellowship if all the following conditions are met:

(i) – (iii)

(iv) That the fellow has a letter sent directly to UNOS from the director of that training program verifying that the fellow is qualified to direct a lung transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary surgeon, and the transplant program director at the fellowship training program attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary

surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) - (vi) [No Changes]

(cc) For lung transplantation, if the transplant surgeon requirements have not been met as specified above, in a thoracic surgery residency or lung transplant fellowship, the requirements may be met by acquired clinical experience if the following conditions are met:

(i) – (iii) [No Changes]

(iv) That the surgeon has a detailed letter sent directly to UNOS from the director of the program at which this experience is acquired which verifies that the surgeon has met the above requirements, and is qualified to direct a lung transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary surgeon, and the transplant program director at the transplant program last served by the individual attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) [No Changes]

(dd) In the event that a surgeon cannot qualify under the requirements of any of the other criteria for primary lung transplant surgeon, transplant programs serving predominantly pediatric patients may petition the OPTN/UNOS Membership and Professional Standards Committee for and receive approval of the surgeon to function as the primary lung transplant surgeon provided that the surgeon can demonstrate to the satisfaction of the Membership and Professional Standards Committee and OPTN/UNOS Board of Directors that his/her training and/or experience in performing lung transplantation is equivalent to that described in the above requirements.

Additionally, the surgeon must demonstrate satisfactorily that he/she has maintained a current working knowledge (direct involvement in patient care within the last two years) of all aspects of lung transplantation and patient care.

Furthermore, the individual has a letter of recommendation from the person(s) named as primary surgeon, and the transplant program director at the fellowship training program or transplant program last served by the individual attesting to the individual's overall qualifications to act as primary surgeon, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as

deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

A preliminary interview before the Committee shall be required as a part of the petition. This option for qualification as the primary lung transplant surgeon is temporary only and shall cease to exist for applications for primary lung transplant surgeon received after more specific criteria for primary transplant surgeons serving predominantly pediatric patients are incorporated into these By-Laws and implemented. The MPSC or an Ad Hoc Subcommittee of at least four committee members appointed by the Chairperson of the MPSC at his/her discretion is authorized to conduct the preliminary interview and make an interim determination. Such determinations shall be advisory to the MPSC and/or Board of Directors, which is the body responsible for final decisions with respect to membership and transplant designation applications, and shall be effective on an interim basis pending final decisions by the MPSC and/or Board, or action as may be directed through due process.

- (b) Transplant Physician - Each lung transplant center must have on site a qualified lung transplant physician. A lung transplant physician shall be a physician with an M.D. or D.O. degree or equivalent degree from another country who is licensed to practice medicine in his/her state or political jurisdiction and has been accepted onto the medical staff of the applicant hospital.

The lung transplant physician shall maintain current board certification or have achieved eligibility in adult or pediatric pulmonary medicine by the American Board of Internal Medicine, the American Board of Pediatrics or the foreign equivalent. The individual shall provide a letter from the applicant hospital's credentialing committee stating that the physician continues to meet all requirements to be in good standing.

To qualify as a lung transplant physician, the training/experience requirements will be fulfilled if the following conditions of either (aa), (bb), (cc), (dd), (ee), or (ff) are met:

- (aa) The training requirements for the primary lung transplant physician can be met during the applicant's pulmonary medicine fellowship if the following conditions are met:

(i) - (iii) [No Changes]

- (iv) That the fellow has a letter sent directly to UNOS from the director of the individual fellowship training program as well as the supervising qualified lung transplant physician verifying the fellow has met the above requirements and that/she is qualified to be the medical director of a lung transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary physician, and the transplant program director at the fellowship training program attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with

and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) - (vii) [No Changes]

(bb) For lung transplantation, when the training requirements for lung transplant physician have not been fulfilled during a pulmonary medicine fellowship, the requirements can be met during a separate 12-month transplant pulmonology fellowship if all of the following conditions are met:

(i) - (iii) [No Changes]

(iv) That the fellow has a letter sent directly to UNOS from the director of the individual fellowship training program as well as the supervising qualified lung transplant physician verifying that the fellow has met the above requirements and that he/she is qualified to be a medical director of a lung transplant program.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary physician, and the transplant program director at the fellowship training program attesting to the individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

(v) - (vi) [No Changes]

(cc) If the physician has not met the above requirements in a pulmonary fellowship or specific transplant pulmonology fellowship, the requirements can be met by acquired clinical experience if the following conditions are met and the individual is a board certified pulmonologist:

(i) - (iv) [No Changes]

(v) There should be a supporting letter from either the lung transplant physician or the lung transplant surgeon at the pulmonologist's institution who has been directly involved with the individual and certify his/her competence.

Additionally, that the individual has a letter of recommendation from the person(s) named as primary physician, and the transplant program director at the transplant program last served by the individual attesting to the

individual's overall qualifications to act as primary physician addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

- (vi) [No Changes]
- (dd) [No Changes]
- (ee) In the event that a physician cannot qualify under the requirements of any of the other criteria for primary lung transplant physician, transplant programs serving predominantly pediatric patients may petition the OPTN/UNOS Membership and Professional Standards Committee for and receive approval of the physician to function as the primary lung transplant physician provided that the physician can demonstrate to the satisfaction of the Membership and Professional Standards Committee and OPTN/UNOS Board of Directors that his/her training and/or experience in the care of lung transplant patients is equivalent to that described in the above requirements.

Additionally, the physician must demonstrate satisfactorily that he/she has maintained a current working knowledge (direct involvement in lung transplant patient care within the last two years) of all aspects of lung transplantation and patient care.

Furthermore, the individual has a letter of recommendation from the person(s) named as primary physician, and the transplant program director at the fellowship training program or transplant program last served by the individual attesting to the individual's overall qualifications to act as primary physician, addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate. The MPSC, at its discretion, may request similar letters of recommendation from the primary physician, primary surgeon, director, or other personnel affiliated with any transplant program previously served by the individual.

A preliminary interview shall be required as part of the petition. This option for qualification as the primary lung transplant physician is temporary only and shall cease to exist for applications for primary lung transplant physician received after more specific criteria for primary transplant physician serving predominantly pediatric patients are incorporated into these By-Laws and implemented. The MPSC or an Ad Hoc Subcommittee of at least four committee members appointed by the Chairperson of the MPSC at his/her discretion is authorized to conduct the preliminary interview and make an interim determination. Such determinations shall be advisory to the MPSC and/or Board of Directors, which is the body responsible for final decisions with respect to membership and transplant designation applications, and shall be effective on an interim basis pending final decisions by the MPSC and/or Board, or action as may be directed through due process.

(ff) [No Changes]

(9) Heart/lung Transplantation

[No Changes]

(10)–(22) [No Changes]

D. [No Changes]

E. [No Changes]