

APPENDIX A TO BYLAWS

UNITED NETWORK FOR ORGAN SHARING

Application and Hearing Procedures For Members and Designated Transplant Programs

1.01A Nature of Membership/Designated Transplant Program Status

Any transplant hospital, organ procurement organization or independent histocompatibility laboratory, or organization, institution, or individual with an interest in the fields of organ donation or transplantation that demonstrates compliance with all applicable UNOS membership criteria shall be entitled to become a Member upon completion of the prescribed application process and satisfaction of applicable requirements. Additionally, in the case of Transplant Hospital Members that request status as a designated transplant program for one or more organs, the Member shall be entitled to attain such status upon completion of the prescribed application process and satisfaction of applicable requirements. Membership shall be extended only to institutions, agencies, laboratories, entities, and individuals who consistently meet the membership qualifications, and requirements established from time to time by the Board of Directors. The rights, privileges, and responsibilities of Members as set forth in the UNOS Articles of Incorporation, Bylaws and Policies may be amended by the Board of Directors from time to time. See Figure A-1 for a general overview of the application process for membership in the OPTN. UNOS designated transplant program status will not be granted for types of clinical, vascularized organ transplantation for which UNOS has not yet established criteria. In order to initiate or conduct clinical, vascularized organ transplantation for which there are no established criteria, including but not limited to multi-visceral organ transplants, an institution must be a UNOS member transplant center approved for transplantation of at least one other organ; in the case of abdominal multi-visceral transplants, the approved organ must be liver.

1.02A Duration of Membership

The term of an OPO, Transplant Hospital, or Histocompatibility Laboratory Member shall be for an indefinite period, provided that a failure to conform to membership requirements (as established from time to time by the Board of Directors) shall be cause for corrective action as described in Section 2 of this Appendix A, which may impact UNOS membership status, and a failure to qualify as a UNOS Member shall be cause for removal pursuant to Articles 1.10 and 1.11 of the Bylaws. The term of Medical/Scientific Members; Public Organization Members; Business Members; or Individual Members shall be two years, provided that a failure to qualify as a Member shall be cause for removal pursuant to Articles 1.10 and 1.11 of the Bylaws. Any of these Members may serve for successive terms upon application and approval for such term. A Medical/Scientific Member; Public Organization Member; Business Member; or Individual Member may resign at any time by written notice to the Executive Director.

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:** For OPO, Transplant Hospital, and Histocompatibility Laboratory Members, information as to whether the applicant has currently in force liability insurance with at least \$1,000,000 limits of coverage per occurrence. Coverage must be provided by an insurer that is either licensed or approved by the insurance regulatory agency of the state in which the applicant's principal office is located. In lieu of insurance coverage, evidence of equivalent coverage through a funded self-insurance arrangement shall suffice. At UNOS' request the applicant or member shall furnish a current certificate of insurance;
- (d) **Administrative Remedies:** A statement whereby the Member agrees that, when an adverse ruling is made with respect to membership or designated transplant program status, the Member will exhaust the administrative remedies afforded by these Bylaws and applicable Federal regulations before resorting to formal legal action; and
- (e) **Release of Information to HHS:** A statement whereby the Member authorizes the release of any and all information to HHS regarding applications for membership or designation as a transplant program in UNOS, and activities for monitoring and enforcing UNOS membership criteria, policies, and Federal regulations as described in these Bylaws.

1.04A Processing the Application

- (1) **Applicant's Burden:** The applicant shall have the burden of producing adequate information for a proper evaluation of the applicant's qualifications.
- (2) **Statement of Release and Immunity From Liability:** The following are express conditions applicable to any applicant during the period membership is sought and to any Member during the term of membership. By applying for membership, an applicant expressly accepts these conditions during the processing and consideration of the application, regardless of whether or not the applicant is granted membership or designation as a transplant program.
 - (a) To the fullest extent permitted by law, the applicant or Member extends absolute immunity to, and releases from liability, UNOS and its representatives and any third party with respect to any and all civil liability which might arise from any acts, communications reports, recommendations, or disclosures involving an applicant or Member, performed, made, requested or received by UNOS and its representatives, to, from, or by any third party, including other Members concerning activities relating but not limited to:
 - (1) applications for membership or designation as a transplant program;

- (2) proceedings regarding monitoring and enforcement of membership requirements, change in membership or designated transplant program status or termination of membership, or other policies of or regulations applicable to UNOS;
 - (3) hearings and appellate reviews; and
 - (4) other committee activities relating to the membership status or status as a designated transplant program of either an applicant or a Member and concerning statements, investigations, materials provided, or inquiries, oral or written, relating to an applicant's or Member's qualifications, as well as the inspection of all records and documents that may be material to such questions.
- (b) Any act, communication, report, recommendation or disclosure, with respect to any such applicant or Member made in good faith and at the request of an authorized representative of UNOS, anywhere at anytime, for the purposes set forth in (a) above shall be privileged as components of medical peer review to the fullest extent permitted bylaw. Such peer review privilege shall extend to employees of UNOS and its authorized representatives, and to any third parties who either supply or are supplied information and to any of the foregoing authorized to receive, release or act upon the same;
 - (c) As used in this section, the term "UNOS and its representatives" means the Corporation, its officers, its Board of Directors, and their appointed representatives or employees, consultants to UNOS, the Corporation's attorney and his or her partners, assistants or designees, and all Members, organizations or other persons who have any responsibility for obtaining or evaluating the applicant's or Member's qualifications and/or acting upon his or her application or membership or designated transplant program status and any authorized representative of any of the foregoing;
 - (d) As used in this section, the term "third parties" means all individuals or government agencies, organizations, associations, partnerships and corporations, from whom information has been requested by UNOS or its authorized representatives or who have requested such information from UNOS and its authorized representatives; and
 - (e) The immunity and release from liability provided in this section shall not apply to acts of willful misconduct by UNOS and its representatives.
- (3) **Verification of Information:** The applicant shall deliver a completed application (including the supporting documentation and such other information that may be relevant to consideration of the applicant's qualifications) to the Chairman of the Membership and Professional Standards Committee or Executive Director or the designated representative of either of them, who shall in timely fashion seek to collect or verify the qualification evidence submitted. The Chairman or the Executive Director or the designated representative of either of them shall promptly notify the applicant of any problems in obtaining the information required and it shall then be the applicant's obligation to obtain the required information.

Designated staff representatives will conduct a preliminary review of all applications (including the required support documentation and such other information that may be relevant to consideration of the applicant's qualifications) for the purpose of assessing completeness before presenting it to the Membership and Professional Standards Committee (MPSC) for review. This review will be conducted for all application types. Applications that are not appropriately completed and that are missing the key supporting information and/or documents will not be forwarded to the MPSC for review. Key information and/or documents for applying for changes in key personnel include, without limitation, physician or surgeon Curriculum Vitae, letter of commitment, letter(s) of reference, transplant log, and Board certification, as well as surgeon transplant operative notes, where applicable, and procurement notes and/or log. Key information and/or documents for applications for Membership or designated transplant program status include, without limitation, OPO or Histocompatibility Laboratory contract/letter, where applicable, in addition to the information/documentation associated with key personnel listed above. Applications not completed

in the appropriate manner will be deemed “incomplete.” The Chair or the Executive Director or the designated representative of the MPSC will notify the applicant of the incomplete status as well as their available options.

- (4) **Membership and Professional Standards Committee (MPSC):** The Membership and Professional Standards Committee shall review complete the application, the supporting documentation, and such other information available to it that may be relevant to consideration of the applicant’s qualifications. The Chairman or the Executive Director shall prepare for the Board of Directors on the prescribed form a written report and recommendations as to whether membership and/or designated transplant program status is recommended. The reason for each recommendation shall be stated and supported by references to the completed application and all other documentation considered by the Committee, all of which shall be included with the report. Any minority views shall also be reduced to writing, supported by reasons and references, and included with the majority report.

For processing of applications for approval of new transplant centers or new transplant programs, the applicant center may request accelerated review, providing documentation of the reason for the request. 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 make determinations regarding applications for membership or designation as a transplant program. Such determinations shall be advisory to the 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 Board or action as may be directed through due process.

- (a) **Recommendations for Approval.** Upon issuing a recommendation for approval, the applicant is approved on an interim basis. This approval is effective until review by the full MPSC (if not already accomplished) and final determination by the Board of Directors. Such interim approval shall (subject to final action by the full Board) grant the applicant status as a Member or designated transplant program, as applicable; shall not extend beyond the date of the Board meeting following the meeting of the full MPSC, subsequent to the subcommittee’s grant of interim approval or at which the interim approval is granted by the full Committee (as applicable) except as otherwise specified in Section 1.05A below; and shall expire if the Board does not approve the interim action.
- (b) **Recommendations for Rejection.** Upon issuing a recommendation for rejection, the application is rejected on an interim basis. This rejection is effective until review by the full MPSC (if not already accomplished) and final determination by the Board of Directors. Such interim rejection shall (subject to final action by the full Board) result in denial of membership or designated transplant program status pending due process, including any rights of appeal to the Secretary, and a different decision.

1.05A Effect of Membership and Professional Standards Committee Action

- (a) **Favorable Recommendation:** When the recommendation of the MPSC is favorable to the applicant, the MPSC Chairman shall promptly forward its report and recommendation, together with all supporting documentation, to the Board of Directors. The Board of Directors shall then review the application and act on it at its next regular meeting at which a quorum is present after receipt of the application unless it is not able to do so due to, for example, receipt of the application from the MPSC ten (10) working days or less before a regular meeting, in which case it shall defer review and action until the following regular meeting at which a quorum is present. A majority vote of the Board members present at any meeting at which a quorum is present is required to elect a Member.
- (b) **Adverse Recommendation:** When the recommendation of the MPSC (or Ad Hoc Subcommittee of the MPSC) is adverse to the applicant, the MPSC Chairman shall immediately notify the applicant and the applicant shall be entitled to the procedural rights as provided in section 3.01 A and following entitled “Interviews and Hearings.” The applicant shall exercise its procedural rights prior to submission of the adverse recommendation to the Board of Directors.

1.06A Time Periods for Processing

Applications for membership and designated transplant program status shall be considered in a timely and good faith manner by all individuals and groups required by these Bylaws to act thereon and, except for good cause, shall be processed within the time periods specified in this section. The MPSC (or Ad Hoc Subcommittee of the MPSC) shall act on an application with a recommendation for acceptance and grant of interim approval or a recommendation for rejection resulting in disallowance of membership or designated transplant program status on an interim basis pending due process within 90 days after receiving it. The Board of Directors shall then review and act on the application at its next regular meeting at which a quorum is present after receipt of the application unless it is unable to do so, in which case it may, in its discretion, defer review and action until the following regular meeting at which a quorum is present. Recommendations for rejection resulting in interim rejection of membership or designated transplant program status pending due process shall entitle the applicant to procedural rights as specified in Article 3.01(4) of this Appendix A to the Bylaws.

1.07A Reapplication After Adverse Membership Decision

An applicant who has been denied UNOS membership or designated transplant program status shall be reconsidered for membership or designation for transplantation for the particular organ upon reapplication. The reapplication will be evaluated based on membership criteria in effect at the time of reapplication. Any such reapplication shall be processed as an initial application and the applicant shall submit such additional information as the MPSC or the Board of Directors may require to demonstrate that the basis for the earlier adverse action no longer exists.