

**ATTACHMENT I
TO APPENDIX B OF UNOS BYLAWS**

Designated Transplant Program Criteria

XIII. Transplant Programs.

- A. In order to qualify for membership, a transplant program must utilize, for its histocompatibility testing, a laboratory that meets the UNOS Standards for Histocompatibility testing, as described in UNOS Bylaws Appendix B, Attachment II, and is approved by the UNOS Membership and Professional Standards Committee.
- B. In order to qualify for membership, a transplant program must have letters of agreement or contracts with either an IOPO or hospital-based organ procurement organization which complies with the criteria as outlined in Attachment III to the extent applicable to hospital-based organ procurement organizations. These membership criteria are based substantially upon the Center for Medicare/Medicaid Services (CMS). Conditions for coverage for Organ Procurement Organizations, September 29, 1996.
- C. 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 transplant physician, must submit to UNOS in writing a Program Coverage Plan, which documents how 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. The Program coverage Plan must address the following requirements:

- (1) All transplant programs 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 unless a written explanation is provided that justifies the current level of coverage to the satisfaction of the MPSC. All transplant programs shall provide patients with a written summary of the Program Coverage Plan, at the time of listing and when there are any substantial changes in program or personnel.
- (2) When “on call” a 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 must be readily available in a timely manner to facilitate organ acceptance, procurement, and implantation.
- (4) 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.

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, and training and affirm that they are "currently" a member in good standing.

- D. In addition to the foregoing requirements, to qualify for membership in UNOS, a transplant program must have a clinical service which meets the following criteria.

(1) Kidney Transplantation

- (a) 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) Programs found acceptable for training by the Education Committee of the American Society of Transplant Surgeons are acceptable to UNOS; or
- (bb) Programs that meet all of the following criteria:
 - (i) The program must be located at a medical center which transplants one or more organs.
 - (ii) The program must be reviewed every five (5) years.

- (iii) The program must be at an institution with a proven commitment to graduate medical education.
- (iv) The program director must be a board certified surgeon who meets the UNOS criteria as a transplant surgeon.
- (v) The program must be at an institution affiliated with a UNOS qualified histocompatibility laboratory.
- (vi) The program must be at an institution affiliated with a UNOS qualified organ procurement organization.
- (vii) The program must perform at least 60 kidney transplants each year (deceased and living-related donors) to qualify for training in kidney transplantation.
- (viii) The training program must have adequate clinical and laboratory research facilities and should have adequate faculty with appropriate training to provide proper experience in research.
- (ix) Any program having no trainees during the period of five (5) years between reviews must reapply as a new program. If the program director changes, the program will be reviewed.

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) Surgeons qualifying by virtue of having completed two years of fellowship must have performed at least 30 kidney transplants as primary surgeon or first assistant over the two year period. These cases must be documented. Documentation should include the date of transplant, medical record and/or UNOS identification number, and the role of the surgeon in the operative procedure. Beginning January 1, 2007, this log must be signed by the director of the training program.
 - (ii) The surgeon must have performed at least 15 kidney procurements as primary surgeon or first assistant over the two-year period. At least 3 of these donors must be multiple organ and at least 10 must be deceased. These cases must be documented. Documentation should include the date of procurement, medical record and/or UNOS identification number, and location of the donor.

- (iii) A qualified transplant surgeon shall have a current working knowledge (direct involvement in kidney transplant patient care within the last two years) of kidney transplantation including the management of patients with end stage renal disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate post-operative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient, histologic interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long term outpatient care.
- (iv) That the above training was at a medical center with a kidney transplant training program which is approved by the Education Committee of the American Society of Transplant Surgeons or UNOS as described in sections (aa) or (bb) in the case of foreign training, accepted as equivalent training by the MPSC.
- (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) That the individual has written a detailed letter to UNOS outlining his/her training and experience in UNOS approved kidney transplant program(s) or its foreign equivalent.
- (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) The surgeon performs as primary surgeon or first assistant, over a minimum of 2 years and a maximum of 5 years, 45 or more kidney transplant procedures at a UNOS member kidney transplant program or its foreign equivalent. These cases must be documented. Documentation should include the date of transplant, medical record and/or UNOS identification number, and the role of the surgeon in the operative procedure. This log should be signed by the program director, division chief, or department chair from program where the experience was gained.

To qualify as a kidney transplant surgeon, each year of “experience” must be substantive and relevant. Each year of experience should include pre-operative assessment, operation as primary surgeon.

- (ii) The surgeon must have performed at least 15 kidney procurements as primary surgeon or first assistant. At least 3 of these procurement procedures must be multiple organ and at least 10 must be deceased. These cases must be documented. Documentation should include the date of procurement, medical record and/or UNOS identification number and location of the donor.

- (iii) A qualified transplant surgeon shall have a current working knowledge (direct involvement in kidney transplant patient care within the last two years) of kidney transplantation including the management of patients with end stage renal disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient, histologic interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long term outpatient care.

- (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) That the individual has written a detailed letter to UNOS outlining his/her experience in a UNOS approved kidney transplant program or its foreign equivalent.
- (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 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) If as of July 1, 2006, the surgeon serves as the designated kidney transplant surgeon for a qualified UNOS kidney transplant program and meets the kidney transplant surgeon criteria in effect prior to that date, the surgeon's kidney transplant program will continue to be UNOS-qualified in this respect so long as this same surgeon continues in his/her position with the program. If the surgeon ceases to serve the kidney transplant program in question, that program must have on-site a kidney transplant surgeon who meets the requirements of C(1)(a) and (cc), (dd), or (ee) above in order to remain UNOS-qualified. If the surgeon ceases to serve the kidney transplant program that he/she served as of July 1, 2006, and desires to become the designated kidney transplant surgeon at another program, he/she must meet the requirements of C(1)(a) and (cc), (dd), or (ee) above.

- (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) Programs found acceptable by the AST/ASN Adult Renal Transplant Training Accreditation Program; or
- (bb) Programs that meet all of the following criteria:
 - (i) The program must be UNOS approved as a Renal Transplant Program and be affiliated with an ACGME approved nephrology program. Transplant programs that are not UNOS approved and/or affiliated with an ACGME approved nephrology program will be evaluated on a case-by-case basis.
 - (ii) The program must perform at least 10 renal transplants per year for each first year, general

nephrology fellow in training and an additional 30 transplants per year for each renal transplant fellow to be trained.

- (iii) The program must have a full-time faculty member or members capable of teaching a curriculum with a broad base of knowledge in transplant medicine. The curriculum must include training and experience in end-stage renal disease, training in the selection of appropriate transplant recipients and donors, experience in the immediate and long term care of the transplant recipient, and training in the performance of renal transplant biopsies. Additionally there must be an emphasis on the management of immunosuppressive agents and the evaluation of renal transplant dysfunction. Combined surgical and medical rounds should be conducted on a regular basis.
- (iv) The program must provide patient co-management responsibility with transplant surgeons from the peri-operative through the outpatient period. The renal trainee must primarily manage the transplant recipient's medical care including hypertension, diabetes, and dialytic problems. Trainees must also serve as a primary member of the transplant team and participate in making decisions about immunosuppression. The transplant renal fellow must be primarily responsible for 30 in-patient renal transplant recipients and 30 outpatient recipients over a period of 12 months. Outpatient follow-up must be continuous for a minimum of at least three months. Training must be completed within 12 continuous months; a minimum of six months of training must be performed in inpatient clinical service.
- (v) The transplant fellow must perform a minimum of 10 transplant biopsies during the training period.
- (vi) The renal transplant fellow must observe at least three renal transplants (cadaveric and living related or living unrelated) and also must observe at least three procurement procedures.

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) That the individual will have had one year of specialized training in transplantation under the direct supervision of a qualified kidney transplant physician and in conjunction with a kidney transplant surgeon at a UNOS approved renal transplant center that conducts 30 or more transplants each year. That the 12 months of specialized training be contiguous and consists of a minimum of six months on the clinical transplant service with the remaining months consisting of transplant related experience such as time in a tissue typing laboratory, on another solid organ transplant service or conducting basic or clinical transplant research.
- (ii) That the above training be in addition to other clinical requirements for general nephrology training.
- (iii) That the individual will have been involved in the primary care of 30 or more kidney transplant recipients and will have followed these 30 patients for a minimum of three months from the time of their transplant. The application must be supported by a recipient log. Such a log should include at least the medical record and/or UNOS identification number of the recipient and date of transplant. Beginning January 1, 2007, this log must be signed by the director of the training program and/or the primary transplant physician at that transplant program.
- (iv) That the individual has a current working knowledge (direct involvement in kidney transplant patient care within the last two years) of kidney transplantation including the management of patients with end stage renal disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient, histologic interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long term outpatient care. The didactic curriculum for obtaining this knowledge should be approved by the Residency Review Committee for Internal Medicine (RRC-IM) of the Accreditation Council for Graduate Medical Education (ACGME).
- (v) The individual should participate as an observer in three multiple organ procurements and three transplants that include the kidney. In addition the physician should observe the evaluation of the donor and donor process and management of at least 3 multiple organ donors which include the kidney. These cases must be documented. Documentation

should include date of procurement, medical record and/or UNOS identification number and location of the donor.

- (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) That the above training be performed at a hospital with a fellowship training program, in adult nephrology, which is accredited by the RRC-IM.
 - (viii) That the individual has written a detailed letter to UNOS outlining his/her experience in a UNOS approved kidney transplant program or its foreign equivalent.
 - (ix) This option for qualification as the primary kidney transplant physician shall cease to exist for applications received after January 1, 2010.
- (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) That the individual will have had one year of specialized training in transplantation under the direct supervision of a qualified kidney transplant physician and in conjunction with a kidney transplant surgeon at a UNOS approved renal transplant center that conducts 30 or more transplants each year. That the 12 months of specialized training be contiguous and consists of a minimum of six months on the clinical transplant service with the remaining months consisting of transplant related experience such as time in a tissue typing laboratory, on another solid

organ transplant service or conducting basic or clinical transplant research.

- (ii) That the above training be in addition to other clinical requirements for general nephrology training.
- (iii) That the individual will have been involved in the primary care of 30 or more renal transplant recipients and will have followed these 30 patients for a minimum of three months from the time of their transplant. The application must be supported by a recipient log. Such a log should include at least the medical record and/or UNOS identification number of the recipient and date of transplant. Beginning January 1, 2007, this log must be signed by the director of the training program and/or the primary transplant physician at that transplant program.
- (iv) That the individual has a current working knowledge (direct involvement in kidney transplant patient care within the last two years) of kidney transplantation including the management of patients with end stage renal disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient, histologic interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long term outpatient care. The didactic curriculum for obtaining this knowledge should be approved by the Residency Review Committee for Internal Medicine (RRC-IM) of the Accreditation Council for Graduate Medical Education (ACGME).
- (v) The individual should participate as an observer in three organ procurements and three kidney transplants. In addition, the physician should observe the evaluation of the donor and donor process and management of at least 3 multiple organ donors which include the kidney. These cases must be documented. Documentation should include date of procurement, medical record and/or UNOS identification number and location of the donor.
- (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) That the individual has written a detailed letter to UNOS outlining his/her experience in a UNOS approved kidney transplant program or its foreign equivalent.
- (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) That the acquired clinical experience is gained over a minimum of 2 years and a maximum of 5 years on an active kidney transplant service as the kidney transplant physician or under the direct supervision of a qualified kidney transplant physician and in conjunction with a kidney transplant surgeon at a UNOS approved kidney transplant center or its foreign equivalent.
 - (ii) That the individual has been involved in the primary care of 45 or more kidney transplant recipients, and has followed these patients for a minimum of 3 months from the time of their transplant. The application must be supported by a recipient log. Such a log should include at least the medical record and/or UNOS identification number of the recipient and date of transplant. This log should be signed by the program director, division chief, or department chair from program where the experience was gained.
 - (iii) That the individual has a current working knowledge (direct involvement in kidney transplant patient care within the last two years) of kidney transplantation including the management of patients with end stage renal disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and

complications of immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient, histologic interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long term outpatient care.

- (iv) The individual should participate as an observer in three organ procurements and three renal transplants. In addition, the physician should observe the evaluation of the donor and donor process and management of at least 3 multiple organ donors which include the kidney. These cases must be documented. Documentation should include the date of procurement, medical records and/or UNOS identification number, and location of donor.
- (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) During the 3 years, the trainee will have been involved in the primary care of 10 or more kidney transplants recipients and will have followed 30 patients for a minimum of six months from the time of their transplant under the direct supervision of a qualified kidney transplant physician in conjunction

with a qualified kidney transplant surgeon. It will be permitted, if the pediatric nephrology program director elects, to have a portion of the transplant experience carried out at another transplant service, or center, to meet the patient number requirements. The application must be supported by a recipient log. Such a log should include at least the medical record and/or UNOS identification number of the recipient and date of transplant. Beginning January 1, 2007, this log must be signed by the director of the training program and/or the primary transplant physician at that transplant program.

- (ii) The transplant experience in pediatric patients shall be gained at a center which is UNOS-approved, with a qualified kidney transplant physician and a qualified kidney transplant surgeon, which performs an average of at least 10 pediatric kidney transplants a year.
- (iii) The individual must have a current working knowledge (direct involvement in kidney transplant patient care within the last two years) of kidney transplantation including the management of pediatric patients with end-stage renal disease, the selection of appropriate pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative care including those issues of management unique to the pediatric recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the pediatric recipient including side-effects of drugs and complications of immunosuppression, the effects of transplantation and immunosuppressive agents on growth and development, differential diagnosis of renal dysfunction in the allograft recipient, manifestation of rejection in the pediatric patient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long-term outpatient care of pediatric allograft recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient. The didactic curriculum for obtaining this knowledge shall be approved by the RRC-Ped of the ACGME.
- (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) In addition, the individual should participate as an observer in three organ procurements and three pediatric kidney transplants. In addition the physician should observe the evaluation of the donor and donor process and management of at least 3 multiple organ donors which include the kidney. These cases must be documented. Documentation should include the date of procurement, medical records and/or UNOS identification number, and location of donor.
- (vi) That the individual has written a detailed letter to UNOS outlining his/her training and experience in a UNOS approved kidney transplant program(s) or its foreign equivalent.
- (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) During the fellowship the trainee will have been involved in the primary care of 10 or more kidney transplant recipients and will have followed 30 patients for a minimum of six months from the time of their transplant under the direct supervision of a qualified kidney transplant physician in conjunction with a qualified kidney transplant surgeon. It will be permitted, if the pediatric nephrology program director elects, to have a portion of the transplant experience carried out at another transplant service, or center, to meet the patient number requirements. The application must be supported by a recipient log. Such a log should include at least the medical record and/or UNOS identification number of the recipient and date of transplant. Beginning January 1, 2007, this log must be signed by the director of the training program and/or the primary transplant physician at that transplant program.

- (ii) The transplant experience in pediatric patients shall be gained at a center which is UNOS-approved, with a qualified kidney transplant physician and a qualified kidney transplant surgeon, which performs an average of at least 10 pediatric kidney transplants a year.
- (iii) The individual must have a current working knowledge (direct involvement in kidney transplant patient care within the last two years) of kidney transplantation including the management of pediatric patients with end-stage renal disease, the selection of appropriate pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative care including those issues of management unique to the pediatric recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the pediatric recipient including side-effects of drugs and complications of immunosuppression, the effects of transplantation and immunosuppressive agents on growth and development, differential diagnosis of renal dysfunction in the allograft recipient, manifestation of rejection in the pediatric patient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long-term outpatient care of pediatric allograft recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient. The didactic curriculum for obtaining this knowledge shall be approved by the RRC-Ped of the ACGME.
- (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) The individual should participate as an observer in three organ procurements and three pediatric kidney transplants. In addition, the physician should observe the evaluation of the donor and donor process and management of at least 3 multiple organ donors which include the kidney. These cases must be documented. Documentation should include the date of procurement, medical records and/or UNOS identification number, and location of donor.
- (vi) That the individual has written a detailed letter to UNOS outlining his/her training and experience in a UNOS approved kidney transplant program(s) or its foreign equivalent.
- (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) That the physician has a minimum of 2 years of experience accumulated during fellowship, after fellowship, or as an accumulation during both periods at a UNOS-approved kidney transplant center. During the 2 or more years of experience, the physician will have been involved in the primary care of 10 or more kidney transplant recipients and will have followed 30 patients for a minimum of six months from the time of their transplant under the direct supervision of a qualified kidney transplant physician and in conjunction with a qualified kidney transplant surgeon. The application must be supported by a recipient log. Such a log should include at least the medical record and/or UNOS identification number of the recipient and date of transplant. Beginning January 1, 2007, these patient logs must be signed by the director of the training program and/or the primary transplant physician at that transplant program training program; and the director of the program where post-fellowship experience was gained.
 - (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) This curriculum should be a part of a Residency Review Committee approved or pediatric nephrology didactic curriculum.
- (iv) The individual must have a current working knowledge (direct involvement in kidney transplant patient care within the last two years) of kidney transplantation including the management of pediatric patients with end-stage renal disease, the selection of appropriate pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative care including those issues of management unique to the pediatric recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the pediatric recipient including side-effects of drugs and complications of immunosuppression, the effects of transplantation and immunosuppressive agents on growth and development, differential diagnosis of renal dysfunction in the allograft recipient, manifestation of rejection in the pediatric patient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long-term outpatient care of pediatric allograft recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient. The didactic curriculum for obtaining this knowledge shall be approved by the RRC-Ped of the ACGME.
- (v) The individual should participate as an observer in three organ procurements and three pediatric kidney transplants. In addition, the physician should observe the evaluation of the donor and donor process and management of at least 3 multiple organ donors which include the kidney. These cases must be documented. Documentation should include the date of procurement, medical records and/or UNOS identification number, and location of donor
- (vi) That the individual has written a detailed letter to UNOS outlining his/her training and experience in a UNOS approved kidney transplant program(s) or its foreign equivalent.

- (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 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.

- (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) That the remaining parts of (cc) or (ee), as applicable, are met.
- (ii) That the individual has been involved in the primary care of 23 or more kidney transplant recipients, and has followed these patients for a minimum of 3 months from the time of their transplant. The application must be supported by a recipient log. Such a log should include at least the medical record and/or UNOS identification number of the recipient and date of transplant. Beginning January 1, 2007, this log should be signed by the program director, division chief, or department chair from program where the experience was gained.
- (iii) That if the individual is qualifying as primary transplant physician by virtue of acquired clinical experience, this experience is equal to 12 months on an active kidney transplant service as the kidney transplant physician or under the direct supervision of a qualified kidney transplant physician and in conjunction with a kidney transplant surgeon at a UNOS approved kidney transplant center. This 12 month period of experience on the transplant service must be acquired over a maximum of 2 years.
- (iv) That a consulting relationship with counterparts at another member transplant center approved for kidney transplantation has been established and documented.
- (v) That activity reports are submitted to UNOS at two month intervals describing the transplant activity and results, physician recruitment efforts, and such other operating conditions as may be required by the Membership and Professional Standards Committee to demonstrate to the satisfaction of the Committee ongoing quality and efficient patient care. The reports must show that the individual is making sufficient progress to meet the objective of involvement in the primary care of at least 45 kidney transplant recipients or that the program is making sufficient progress in recruiting and bringing to the program a transplant physician who meets this criterion as well as all other UNOS criteria for a qualified renal transplant physician by the date that is 12 months from the date of approval of the program under this section.
- (vi) If the program is unable to demonstrate that it has an individual on site who can meet the requirements as described in sections (cc), (dd), (ee), (ff), (gg), (hh), or (ii) above at the end of 12 months, it shall

inactivate. The requirements for program inactivation are described in Section II. The Membership and Professional Standards Committee may consider on a case by case basis, and grant a six month extension to a program that provides substantive evidence of progress towards completing the requirements but is unable to complete the requirements within one year.

- (kk) If as of July 1, 2006, the physician serves as the designated kidney transplant physician for a qualified UNOS kidney transplant program and meets the kidney transplant physician criteria in effect prior to that date, the physician's kidney transplant program will continue to be UNOS-qualified in this respect so long as this same physician continues in his/her position with the program. If the physician ceases to serve the kidney transplant program in question, that program must have on-site a kidney transplant physician who meets the requirements of (cc), (dd), (ee), (ff), (gg), or (hh), or (ii) above in order to remain UNOS-qualified. If the physician ceases to serve the kidney transplant program that he/she served as of July 1, 2006, and desires to become the designated kidney transplant physician at another program, he/she must meet the requirements of (cc), (dd), (ee), (ff), (gg), or (hh), or (ii) above.

(2) **Kidney Transplant Programs that Perform Living Donor Kidney Recovery:** Kidney transplant programs that perform living donor kidney recovery ("kidney recovery hospital") must demonstrate the following:

- a. Personnel and Resources: Kidney recovery hospitals must demonstrate the following regarding personnel and resources:
- (i) That the kidney recovery hospital meets the qualifications of a kidney transplant program as set forth above; and
 - (ii) In order to perform open donor nephrectomies, a qualifying kidney donor surgeon must be on site and must meet one of the criteria set forth below:
 - (1) Completed an accredited ASTS fellowship with a certificate in kidney; or
 - (2) Performed no fewer than 10 open nephrectomies (to include deceased donor nephrectomy, removal of polycystic or diseased kidneys, etc.) as primary surgeon or first assistant.
 - (iii) If the center wishes to perform laparoscopic donor nephrectomies, a qualifying kidney donor surgeon must be on site and must have:
 - (1) Acted as primary surgeon or first assistant in performing no fewer than 15 laparoscopic nephrectomies within the prior 5-year period, seven (7) of which were performed as a primary surgeon. Role of the surgeon could be documented by a letter from fellowship program director.

It is recognized that in the case of pediatric living donor or kidney paired donation transplantation, the living organ donation may occur at a hospital that is distinct from the approved transplant hospital.

All surgical procedures identified for the purpose of surgeon qualification must be documented. Documentation should include the date of the surgery, medical records identification and/or UNOS identification number, the role of the surgeon in the operative procedure, and the type of procedure (open or laparoscopic).

- (iv) The kidney recovery hospital must have the resources available to assess the medical condition of and specific risks to the potential living donor;
- (v) The psychosocial assessment should include an assessment of the potential donor's capacity to make an informed decision and confirmation of the voluntary nature of proceeding with the evaluation and donation; and
- (vi) That the kidney recovery hospital has an independent donor advocate (IDA) who is not involved with the potential recipient evaluation, is independent of the decision to transplant the potential recipient and, consistent with the IDA protocol referred to below, is a knowledgeable advocate for the potential living donor. The goals of the IDA are:
 - (1) to promote the best interests of the potential living donor;
 - (2) to advocate the rights of the potential living donor; and
 - (3) to assist the potential living donor in obtaining and understanding information regarding the:
 - (a) consent process;
 - (b) evaluation process;
 - (c) surgical procedure; and
 - (d) benefit and need for follow-up.

b. Protocols: Kidney recovery hospitals must demonstrate that they have the following protocols:

- (i) Living Donation Process: Kidney recovery hospitals must develop, and once developed must comply with written protocols to address all phases of the living donation process. Specific protocols shall include the evaluation, pre-operative, operative, post-operative care, and submission of required follow-up forms at 6 months, one-year, and two-years post donation.

Kidney recovery hospitals must document that all phases of the living donation process were performed in adherence to the hospital's protocol. This documentation must be maintained and made available upon request.

- (ii) Independent Donor Advocate: Kidney transplant programs that perform living donor kidney transplants must develop, and once developed, must comply with written protocols for the duties and

responsibilities of Independent Donor Advocate (IDA) that include, but are not limited to, the following elements:

- (1) a description of the duties and primary responsibilities of the IDA to include procedures that ensure the IDA:
 - (a) promotes the best interests of the potential living donor;
 - (b) advocates the rights of the potential living donor; and
 - (c) assists the potential donor in obtaining and understanding information regarding the:
 - (i) consent process;
 - (ii) evaluation process;
 - (iii) surgical procedure; and
 - (iv) benefit and need for follow-up.
- (iii) Medical Evaluation: Kidney recovery hospitals must develop, and once developed, must comply with written protocols for the medical evaluation of the potential living donors that must include, but are not limited to, the following elements:
 - (1) a thorough medical evaluation by a physician and/or surgeon experienced in living donation to assess and minimize risks to the potential donor post-donation, which shall include a screen for any evidence of occult renal and infectious disease and medical co-morbidities, which may cause renal disease;
 - (2) a psychosocial evaluation of the potential living donor by a psychiatrist, psychologist, or social worker with experience in transplantation (criteria defined in Appendix B, Attachment I) to determine decision making capacity, screen for any pre-existing psychiatric illness, and evaluate any potential coercion;
 - (3) screening for evidence of transmissible diseases such as cancers and infections; and
 - (4) anatomic assessment of the suitability of the organ for transplant purposes.
- (iv) Informed Consent: Kidney recovery hospitals must develop, and once developed, must comply with written protocols for the Informed Consent for the Donor Evaluation Process and for the Donor Nephrectomy, which include, at a minimum, the following elements:
 - (1) discussion of the potential risks of the procedure including the medical, psychological, and financial risks associated with being a living donor;
 - (2) assurance that all communication between the potential donor and the transplant center will remain confidential;
 - (3) discussion of the potential donor's right to opt out at any time during the donation process;

- (4) discussion that the medical evaluation or donation may impact the potential donor's ability to obtain health, life, and disability insurance;
 - (5) disclosure by the kidney recovery hospital that it is required, at a minimum, to submit Living Donor Follow-up forms addressing the health information of each living donor at 6 months, one-year, and two-years post donation. The protocol must include a plan to collect the information about each donor; and
 - (6) the telephone number that is available for living donors to report concerns or grievances through the OPTN.
 - (7) documentation of disclosure by the kidney recovery hospital to potential donors that the sale or purchase of human organs is a federal crime and that it is unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation. This documentation must be maintained in the potential donor's official medical record.
- c. Kidney Paired Donation: Members that choose to participate in any OPTN kidney paired donation must agree to abide by the kidney paired donation program rules. Potential violations may be forwarded by the Kidney Transplantation Committee to the Membership and Professional Standards Committee for review.

(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) Programs found acceptable for training by the Education Committee of the American Society of Transplant Surgeons are acceptable to UNOS; or
- (bb) Programs that meet all of the following criteria:
 - (i) The program must be located at a medical center which transplants one or more organs.
 - (ii) The program must be reviewed every five (5) years.
 - (iii) The program must be at an institution with a proven commitment to graduate medical education.
 - (iv) The program director must be a board certified surgeon who meets the UNOS criteria as a transplant surgeon.
 - (v) The program must be at an institution affiliated with a UNOS qualified histocompatibility laboratory.
 - (vi) The program must be at an institution affiliated with a UNOS qualified organ procurement organization.
 - (vii) The program must perform at least 50 liver transplants each year to qualify for hepatic transplantation training.
 - (viii) The training program must have adequate clinical and laboratory research facilities and should have adequate faculty with appropriate training to provide proper experience in research.
 - (ix) Any program having no trainees during the period of five (5) years between reviews must reapply as a new program. If the program director changes, the program will be reviewed.

To qualify as a liver 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 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) Surgeons qualifying by virtue of having completed two years of fellowship must have performed at least 45 liver transplants as primary surgeon or first assistant over the two year period. These cases must be documented. Documentation should include the date of transplant, medical record identification and/or UNOS number, and the role of the surgeon in the operative procedure. Beginning January 1, 2007,

this log must be signed by the director of the training program.

- (ii) The surgeon must have performed at least 20 liver procurements as primary surgeon or first assistant over the two-year period. These cases must be documented. Documentation should include the date of procurement, medical records and/or UNOS identification number and location of the donor. At least three of the procurement procedures must include selection and management of the donor. Beginning January 1, 2007, this log must be signed by the director of the training program.
- (iii) A qualified transplant surgeon shall have a current working knowledge (direct involvement in liver transplant patient care within the last two years) of liver transplantation including the management of patients with end stage liver disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate post-operative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of liver allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long term outpatient care.
- (iv) That the above training was at a medical center with a transplant training program which is approved by the Education Committee of the American Society of Transplant Surgeons or UNOS as described in section (aa) or (bb), or in the case of foreign training, accepted as equivalent training by the MPSC.
- (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) That the individual has written a detailed letter to UNOS outlining his/her training and experience in a UNOS approved liver transplant program(s) or its foreign equivalent.
- (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) The surgeon performs as primary surgeon or first assistant, over a minimum of 2 years and a maximum of 5 years, 60 or more liver transplant procedures at a UNOS member liver transplant program or its foreign equivalent. These cases must be documented. Documentation should include the date of transplant, medical record and/or UNOS identification number, and the role of the surgeon in the operative procedure. This log should be signed by the program director, division chief, or department chair from the program where the experience was gained.

To qualify as a liver transplant surgeon, each year of “experience” must be substantive and relevant. Each year of experience should include pre-operative assessment, operation as primary surgeon or first assistant and post-operative management:

- (ii) The surgeon must have performed at least 30 liver procurements as primary surgeon or first assistant. These cases must be documented. Documentation should include the date of procurement, medical record identification number and location of the donor. At least three of the procurement procedures must include selection and management of the donor.
- (iii) A qualified transplant surgeon shall have a current working knowledge (direct involvement in liver transplant patient care within the last two years) of liver transplantation including the management of patients with end stage liver disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate post-operative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of liver dysfunction in the allograft recipient, histologic interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long term outpatient care.
- (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) That the individual has written a detailed letter to UNOS outlining his/her experience in a UNOS approved liver transplant program or its foreign equivalent.

(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) If as of July 1, 2006, the surgeon serves as the designated liver transplant surgeon for a qualified UNOS liver transplant program and meets the liver transplant surgeon criteria in effect prior to that date, the surgeon's liver transplant program will continue to be UNOS-qualified in this respect so long as this same surgeon continues in his/her position with the program. If the surgeon ceases to serve the liver transplant program in question, that program must have on-site a liver transplant surgeon who meets the requirements of C(3) (cc), (dd) or (ee), above in order to remain UNOS-qualified. If the surgeon ceases to serve the liver transplant program that he/she served as of July 1, 2006, and desires to become the designated liver transplant surgeon at another program, he/she must meet the requirements of C(3) (cc), (dd) or (ee) above.

- (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) That the individual will have had one year of specialized training in transplantation under the direct supervision of a qualified liver transplant physician and in conjunction with a liver transplant surgeon at a UNOS approved liver transplant center. That the 12 months of specialized training be contiguous and consist of a minimum of three months on the clinical transplant service with the remaining months consisting of transplant related experience such as time in a tissue typing laboratory, on another solid organ transplant service or conducting basic or clinical transplant research.
 - (ii) That the individual will have been involved in the primary care of 30 or more liver transplant recipients and will have followed 30 patients for a minimum of three months from the time of their transplant. This application must be supported by a recipient log. Such a log should include at least the medical record and/or UNOS identification number and the date of transplant. Beginning January 1, 2007, this log must be signed by the director of the training program and/or the primary transplant physician at that transplant program.
 - (iii) That the individual has a current working knowledge (direct involvement in liver transplant patient care within the last two years) of liver transplantation including the management of patients with end stage liver disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of liver allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long term outpatient care.
 - (iv) The individual should participate as an observer in three liver procurements and three liver transplants. In addition, the physician should observe the evaluation of the donor and donor process, and management of at least 3 multiple organ donors that include the liver. These cases must be documented. Documentation should include date of procurement,

medical record and/or UNOS identification number and location of the donor.

- (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) That the above training be performed at a hospital with a fellowship training program, in adult gastroenterology, which is accredited by the ACGME RRC-IM.
- (vii) That the individual has written a detailed letter to UNOS outlining his/her experience in a UNOS approved liver transplant program or its foreign equivalent.
- (viii) This option for qualification as the primary liver transplant physician shall cease to exist for applications received after January 1, 2010.

- (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) That the individual will have had one year of specialized training in transplantation under the direct supervision of a qualified liver transplant physician and in conjunction with a liver transplant surgeon at a UNOS approved liver transplant center. That the 12 months of specialized training be contiguous and consist of a minimum of three months on the clinical transplant service with the remaining months consisting of transplant related experience such as time in a tissue typing laboratory, on another solid organ transplant service or conducting basic or clinical transplant research.

- (ii) That the above training be in addition to other clinical requirements for general gastroenterology training.
- (iii) That the individual will have been involved in the primary care of 30 or more liver transplant recipients, and will have followed 30 patients for a minimum of three months from the time of their transplant. This application must be supported by a recipient log. Such a log should include at least the medical record and/or UNOS identification number and the date of transplant. Beginning January 1, 2007, this log must be signed by the director of the training program and/or the primary transplant physician at that transplant program.
- (iv) That the individual has a current working knowledge of liver transplantation (direct involvement in liver transplant patient care within the last two years) including the management of patients with end stage liver disease, acute liver failure, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of liver allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long term outpatient care.
- (v) The individual should participate as an observer in three organ procurements and three liver transplants. In addition, the physician should observe the evaluation of the donor and donor process and management of at least 3 multiple organ donors that include the liver. These cases must be documented. Documentation should include date of procurement, medical record and/or UNOS identification number and location of the donor.
- (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) That the individual has written a detailed letter to UNOS outlining his/her experience in a UNOS approved liver transplant program or its foreign equivalent.
- (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) That the acquired clinical experience is gained over a minimum of 2 years and a maximum of 5 years on an active liver transplant service as the qualified liver transplant physician or under the direct supervision of a qualified liver transplant physician and in conjunction with a liver transplant surgeon at a UNOS approved liver transplant center or an active foreign liver transplant program accepted as equivalent by the MPSC.
 - (ii) That the individual has been involved in the primary care of 50 or more liver transplant recipients over a minimum of 2 years and a maximum of 5 years and has followed these patients for a minimum of three months from the time of their transplant. This application must be supported by a recipient log. Such a log should include at least the medical record and/or UNOS identification number and the date of transplant. This log should be signed by the program director, division chief, or department chair from program where the experience was gained.
 - (iii) That the individual has a current working knowledge of liver transplantation (direct involvement in liver transplant patient care within the last two years) including the management of patients with end stage liver disease, acute liver failure, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of liver allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long term outpatient care.

- (iv) The individual should participate as an observer in three organ procurements and three liver transplants. In addition, the physician should observe the evaluation of donor and donor process and management of at least 3 multiple organ donors that include the liver. These cases must be documented. Documentation should include date of procurement, medical record and/or UNOS identification number and location of the donor.
- (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) The transplant experience in pediatric patients shall be gained at a center which is UNOS-approved, with a qualified liver transplant physician and a qualified liver transplant surgeon, which performs an average of at least 10 liver transplants on pediatric patients per year.
 - (ii) During the fellowship, the trainee will have been involved in the primary care of 10 or more liver transplants on pediatric patients, and will have followed 20 patients for a minimum of three months from the time of their transplant under the direct supervision of a qualified liver transplant physician in

conjunction with a qualified liver transplant surgeon. The trainee must be directly involved in the pre-operative, peri-operative and post-operative care of 10 or more liver transplants in pediatric patients. It will be permitted, if the pediatric gastroenterology program director elects, to have a portion of the transplant experience carried out at another transplant service, or center, to meet the patient number requirements. This application must be supported by a recipient log. Such a log should include at least the medical record and/or UNOS identification number and the date of transplant. Beginning January 1, 2007, this log must be signed by the director of the training program and/or the primary transplant physician at that transplant program.

- (iii) The individual must have acquired a current working knowledge of liver transplantation (direct involvement in liver transplant patient care within the last two years) including the management of pediatric patients with end-stage liver disease acute liver failure, the selection of appropriate pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative care including those issues of management unique to the pediatric recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the pediatric recipient including side-effects of drugs and complications of immunosuppression, the effects of transplantation and immunosuppressive agents on growth and development, differential diagnosis of liver dysfunction in the allograft recipient, manifestation of rejection in the pediatric patient, histological interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long-term outpatient care of pediatric allograft recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient.
- (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) The individual should participate as an observer in three organ procurements and three liver transplants. In addition, the physician should observe the evaluation of donor and donor process and management of at least 3 multiple organ donors that include the liver. These cases must be documented. Documentation should include date of procurement, medical record and/or UNOS identification number and location of the donor.
 - (vi) That the individual has written a detailed letter to UNOS outlining his/her experience in a UNOS approved liver transplant program.
- (ee) The training/experience 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) The transplant experience in pediatric liver patients shall be gained at a center which is UNOS-approved, with a qualified liver transplant physician and a qualified liver transplant surgeon, which performs an average of at least 10 liver transplants on pediatric patients per year.
 - (ii) During the fellowship the trainee will have been involved in the primary care of 10 or more liver transplants on pediatric patients, and will have followed 20 patients for a minimum of three months from the time of their transplant under the direct supervision of a qualified liver transplant physician in conjunction with a qualified liver transplant surgeon. The trainee must be directly involved in the pre-operative, peri-operative and post-operative care of 10 or more liver transplants in pediatric patients. It will be permitted, if the pediatric gastroenterology program director elects, to have a portion of the transplant experience carried out at another transplant service, or center, to meet the patient number requirements. This application must be supported by a recipient log. Such a log should include at least the medical record and/or UNOS identification number and the date of transplant. Beginning January 1, 2007, this log must be signed by the director of the

training program and/or the primary transplant physician at that transplant program.

- (iii) The individual must have acquired a current working knowledge of liver transplantation (direct involvement in liver transplant patient care within the last two years) including the management of pediatric patients with end-stage liver disease, acute liver failure, the selection of appropriate pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative care including those issues of management unique to the pediatric recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the pediatric recipient including side-effects of drugs and complications of immunosuppression, the effects of transplantation and immunosuppressive agents on growth and development, differential diagnosis of liver dysfunction in the allograft recipient, manifestation of rejection in the pediatric patient, histological interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long-term outpatient care of pediatric allograft recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient.
- (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) The individual should participate as an observer in three organ procurements and three liver transplants. In addition, the physician should observe the evaluation of donor and donor process and management of at least 3 multiple organ donors that

include the liver. These cases must be documented. Documentation should include date of procurement, medical record and/or UNOS identification number and location of the donor.

- (vi) That the individual has written a detailed letter to UNOS outlining his/her experience in a UNOS approved liver transplant program.
- (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) That the physician has a minimum of 2 years of experience, accumulated during fellowship, after fellowship, or as an accumulation during both periods at a UNOS-approved liver transplant center. During the 2 or more years of experience, the physician will have been involved in the primary care of 10 or more liver transplants on pediatric patients and will have followed 20 patients for a minimum of six months from the time of their transplant under the direct supervision of a qualified liver transplant physician in conjunction with a qualified liver transplant surgeon. The trainee must be directly involved in the pre-operative, peri-operative and post-operative care of 10 or more liver transplants in pediatric patients. This application must be supported by a recipient log. Such a log should include at least the medical record and/or UNOS identification number and the date of transplant. Beginning January 1, 2007, this log must be signed by the director of the training program and/or the primary transplant physician at that transplant program.
 - (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) The individual must have acquired a current working knowledge (direct involvement in liver transplant patient care within the last two years) of liver transplantation including the management of pediatric patients with end-stage liver disease, the selection of appropriate pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative care including those issues of management unique to the pediatric recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the pediatric recipient including side-effects of drugs and complications of immunosuppression, the effects of transplantation and immunosuppressive agents on growth and development, differential diagnosis of liver dysfunction in the allograft recipient, manifestation of rejection in the pediatric patient, histological interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long-term outpatient care of pediatric allograft recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient.
- (iv) The individual should participate as an observer in three organ procurements and three liver transplants. In addition, the physician should observe the evaluation of donor and donor process and management of at least 3 multiple organ donors that include the liver. These cases must be documented. Documentation should include date of procurement, medical record and/or UNOS identification number and location of the donor.
- (v) That the individual has written a detailed letter to UNOS outlining his/her experience in a UNOS approved liver transplant program or its foreign equivalent.
- (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 Bylaws 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) That the remaining parts of (aa) or (cc), as applicable, are met.
 - (ii) That the individual has been involved in the primary care of 25 or more liver transplant recipients, and has followed these patients for a minimum of 3 months from the time of their transplant. The application must be supported by a recipient log. Such a log should include at least the medical record and/or

UNOS identification number of the recipient and date of transplant. Beginning January 1, 2007, this log must be signed by the director and/or the primary transplant physician at the transplant program where the individual trained or gained this experience.

- (iii) That if the individual is qualifying as primary transplant physician by virtue of acquired clinical experience, this experience must be a minimum of 12 months on an active liver transplant service as the qualified liver transplant physician or under the direct supervision of a qualified liver transplant physician and in conjunction with a liver transplant surgeon at a UNOS approved liver transplant center or an active foreign liver transplant program accepted as equivalent by the MPSC. This 12 month period of experience on the transplant service must be acquired over a maximum of 2 years.
 - (iv) That a consulting relationship with counterparts at another member transplant center approved for liver transplantation has been established and documented.
 - (v) That activity reports are submitted to UNOS at two month intervals describing the transplant activity and results, physician recruitment efforts, and such other operating conditions as may be required by the Membership and Professional Standards Committee to demonstrate to the satisfaction of the Committee ongoing quality and efficient patient care. The reports must show that the individual is making sufficient progress to meet the objective of involvement in the primary care of at least 50 transplant recipients or that the program is making sufficient progress in recruiting and bringing to the program a transplant physician who meets this criterion as well as all other UNOS criteria for a qualified liver transplant physician by the date that is 12 months from the date of approval of the program under this section.
 - (vi) If the program is unable to demonstrate that it has an individual on site who can meet the requirements as described in sections (aa), (bb), (cc), (dd), (ee), (ff), or (gg) above at the end of 12 months, it shall inactivate. The requirements for program inactivation are described in Section II. The Membership and Professional Standards Committee may consider, on a case by case basis, and grant a six month extension to a program that provides substantive evidence of progress towards completing the requirements but is unable to complete the requirements within one year.
- (ii) If as of July 1, 2006, the physician serves as the designated liver transplant physician for a qualified UNOS liver

transplant program and meets the liver transplant physician criteria in effect prior to that date, the physician's liver transplant program will continue to be UNOS-qualified in this respect so long as this same physician continues in his/her position with the program. If the physician ceases to serve the liver transplant program in question, that program must have on site a liver transplant physician who meets the requirements of (aa), (bb) (cc), (dd), (ee), (ff), (gg), or (hh) above in order to remain UNOS-qualified. If the physician ceases to serve the liver transplant program that he/she served as of July 1, 2006, and desires to become the designated liver transplant physician at another program, he/she must meet the requirements of (aa), (bb), (cc), (dd), (ee), (ff), (gg), or (hh), above.

(c) Qualifications for Director of Liver Transplant Anesthesia

Liver transplant programs shall designate a Director of Liver Transplant Anesthesia who has expertise in the area of peri-operative care of the patient-undergoing liver transplantation and can serve as an advisor to other members of the team.

The Director of Liver Transplant Anesthesia shall be a Diplomate of the American Board of Anesthesiology (or hold an equivalent foreign certification).

Administrative Responsibilities:

The Director of Liver Transplant Anesthesia should be a designated member of the transplant team and will be responsible for establishing internal policies for anesthesiology participation in the peri-operative care of liver transplant patients. These policies will be developed in the context of the institutional needs, transplant volume, and quality initiatives.

The policy must establish a clear communication channel between the transplant anesthesiology service and services from other disciplines that participate in the care of liver transplant patients. The types of activities to consider include peri-operative consults; participation in candidate selection, and in morbidity and mortality conferences (M&M Conferences); and development of intra-operative guidelines based on existing and published knowledge.

Clinical Responsibilities should include but are not limited to the following:

- Pre-operative assessment of transplant candidates;
- Participation in candidate selection;
- Intra-operative management;
- Post-operative visits;
- Participation on the Selection Committee;
- Consultation preoperatively with subspecialists as needed; and
- Participate in M&M Conferences

Qualifications:

1. The Director of Liver Transplant Anesthesia should have one of the following:
 - a. Fellowship training in Critical Care Medicine, Cardiac Anesthesiology, Liver Transplant Fellowship, that includes the peri-operative care of at least 10 liver transplant recipients, or
 - b. Within the last five years, experience in the peri-operative care of at least 20 liver transplant recipients in the operating room. Experience acquired during postgraduate (residency) training shall not count for this purpose.
 2. The Director of Liver Transplant Anesthesia should earn a minimum of 8 hours of credit in transplant related educational activities from the Council for Continuing Medical Education (ACCME®) Category I Continuing Medical Education (CME) within the most recent 3 year period.
- (4) **Liver Transplant Programs that Perform Living Donor Liver Recovery.** Liver transplant programs that perform living donor liver recovery (“liver recovery hospital”) must demonstrate the following:
- a. Personnel and Resources: Liver recovery hospitals must demonstrate the following:
 - (i) That the liver recovery hospital meets the qualifications of a liver transplant program as set forth above; and.
 - (ii) That the liver recovery hospital has on site no fewer than two surgeons who qualify as liver transplant surgeons under UNOS Bylaws Appendix B, Attachment I, and who have demonstrated experience as the primary surgeon or first assistant in 20 major hepatic resectional surgeries (to include living donor operations, splits, reductions, resections, etc.), 7 of which must have been live donor procedures, within the prior 5-year period. These cases must be documented. Documentation should include the date of the surgery, medical records identification and/or UNOS identification number, and the role of the surgeon in the operative procedure. It is recognized that in the case of pediatric living donor transplantation, the live organ donation may occur at a center that is distinct from the approved transplant center;
 - (iii) The liver recovery hospital must have the resources available to assess the medical condition of and specific risks to the potential living donor;
 - (iv) The psychosocial assessment should include an assessment of the potential living donor’s capacity to make an informed decision and confirmation of the voluntary nature of proceeding with the evaluation and donation; and
 - (v) That the liver recovery hospital has an independent donor advocate (IDA) who is not involved with the potential recipient evaluation, is independent of the decision to

transplant the potential recipient and, consistent with the protocol referred to below, is a knowledgeable advocate for the potential living donor. The goals of the IDA are:

- (1) to promote the best interests of the potential living donor;
- (2) to advocate the rights of the potential living donor; and
- (3) to assist the potential living donor in obtaining and understanding information regarding the:
 - (a) consent process;
 - (b) evaluation process;
 - (c) surgical procedure; and
 - (d) benefit and need for follow-up.

b. Protocols: Liver recovery hospitals must demonstrate that they have the following protocols:

- (i) Living Donation Process: Liver recovery hospitals must develop, and once developed must comply with written protocols to address all phases of the living donation process. Specific protocols shall include the evaluation, pre-operative, operative, post-operative care, and submission of required follow-up forms at 6 months, one-year, and two-year post donation.

Liver recovery hospitals must document that all phases of the living donation process were performed in adherence to the center's protocol. This documentation must be maintained and made available upon request.

- (ii) Independent Donor Advocate: Liver recovery hospitals must develop, and once developed, must comply with written protocols for the duties and responsibilities of the Independent Donor Advocate that include, but are not limited, to the following elements:

- (1) a description of the duties and primary responsibilities of the IDA to include procedures that ensure that the IDA:
 - (a) promotes the best interests of the potential living donor;
 - (b) advocates the rights of the living donor; and
 - (c) assists the potential donor in obtaining and understanding information regarding the:
 - (i) consent process;
 - (ii) evaluation process;
 - (iii) surgical procedure; and
 - (iv) benefit and need for follow-up.

- (iii) Medical Evaluation: Liver recovery hospitals must develop, and once developed, must comply with written protocols for the medical evaluation of the potential living donors must include, but are not limited to the following elements:
 - (1) a thorough medical evaluation by a physician and/or surgeon experienced in living donation to assess and minimize risks to the potential donor post-donation, which shall include a screen for any evidence of occult liver disease;
 - (2) a psychosocial evaluation of the potential living donor by a psychiatrist, psychologist or social worker with experience in transplantation (criteria defined in Appendix B, Attachment I) must also be provided to assess decision making capacity, screen for any pre-existing psychiatric illness, and evaluate potential coercion;
 - (3) screening for evidence of transmissible diseases such as cancers and infections; and
 - (4) a radiographic assessment to ensure adequate anatomy and volume of the donor and of the remnant liver.

- (iv) Informed Consent: Liver recovery hospitals must develop, and once developed, must comply with written protocols for the Informed Consent for the Donor Evaluation Process and for the Donor Hepatectomy, which include, at a minimum, the following elements:
 - (1) discussion of the potential risks of the procedure including the medical, psychological, and financial risks associated with being a living donor;
 - (2) assurance that all communication between the potential donor and the transplant center will remain confidential;
 - (3) discussion of the potential donor's right to opt out at any time during the donation process;
 - (4) discussion that the medical evaluation or donation may impact the potential donor's ability to obtain health, life, and disability insurance;
 - (5) disclosure by the liver recovery hospital that it is required, at a minimum, to submit Living Donor Follow-up forms addressing the health information of each living donor at 6 months, one-year, and two-years post donation. The protocol must include a plan to collect the information about each donor; and

- (6) the telephone number that is available for living donors to report concerns or grievances through the OPTN.
 - (7) documentation of disclosure by the liver recovery hospital to potential donors that the sale or purchase of human organs is a federal crime and that it is unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation. This documentation must be maintained in the potential donor's official medical record.
- c. Conditional Approval Status: If the liver recovery hospital does not have on site a second surgeon who can meet the requirement for having performed 7 live donor liver procedures within the prior 5-year period, but who has completed the requirement for obtaining experience in 20 major hepatic resection surgeries (as described above), as well as all of the other requirements to be designated as a primary liver transplant surgeon, the liver recovery hospital may be eligible for Conditional Approval Status. The liver recovery hospital can be granted one year to fully comply with applicable membership criteria with a possible one year extension. This option shall be available to new programs as well as previously approved programs that experience a change in key personnel. During this period of conditional approval, both of the designated surgeons must be present at the donor's operative procedure.

The liver recovery hospital shall comply with such interim operating policies and procedures as shall be required by the Membership and Professional Standards Committee (MPSC).

This may include the submission of reports describing the surgeon's progress towards meeting the requirements and such other operating conditions as may be required by the MPSC to demonstrate ongoing quality and efficient patient care. The liver recovery hospital must provide a report prior to the conclusion of the first year of conditional approval, which must document that that the surgeon has met or is making sufficient progress to meet the objective of performing 7 live donor liver procedures or that the program is making sufficient progress in recruiting and bringing to the program a transplant surgeon who meets this criterion as well as all other criteria for a qualified live donor liver surgeon. Should the surgeon meet the requirements prior to the end of the period of conditional approval, the program may submit a progress report and request review by the MPSC.

The liver recovery hospital must comply with all applicable policies and procedures and must demonstrate continuing progress toward full compliance with Criteria for Institutional Membership.

The liver recovery program's approval status shall be made available to the public.

If the liver recovery hospital is unable to demonstrate that it has two designated surgeons on site who can fully meet the primary living donor liver surgeon requirements [as described above] at the end of the 2-year conditional approval period, it must stop performing living donor liver recoveries by either

- (i) inactivating the living donor part of the program for a period up to 12 months; or
- (ii) relinquishing the designated transplant program status for the living donor part of the liver transplant program until it can meet the requirements for full approval.

(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 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) Programs found acceptable for training by the Education Committee of the American Society of Transplant Surgeons are acceptable to UNOS; or
- (bb) Programs that meet all of the following criteria:
 - (i) The program must be located at a medical center which transplants one or more organs.
 - (ii) The program must be reviewed every five (5) years.
 - (iii) The program must be at an institution with a proven commitment to graduate medical education.

- (iv) The program director must be a board certified surgeon who meets the UNOS criteria as a transplant surgeon.
- (v) The program must be at an institution affiliated with a UNOS qualified histocompatibility laboratory.
- (vi) The program must be at an institution affiliated with a UNOS qualified organ procurement organization.
- (vii) The program must perform at least 20 pancreas transplants each year to qualify for pancreatic transplantation training.
- (viii) The training program must have adequate clinical and laboratory research facilities and should have adequate faculty with appropriate training to provide proper experience in research.
- (ix) Any program having no trainees during the period of five (5) years between reviews must reapply as a new program. If the program director changes, the program will be reviewed.

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) Surgeons qualifying by virtue of having completed two years of fellowship must have performed at least 15 pancreas transplants as primary surgeon or first assistant over the two year period. These cases must be documented. Documentation should include the date of transplant, medical record and/or UNOS identification number, and the role of the surgeon in the operative procedure. Beginning January 1, 2007, this log must be signed by the director of the training program.
 - (ii) The surgeon must have performed at least 10 pancreas procurements as primary surgeon or first assistant over the two year period. These cases must be documented. Documentation should include the date of procurement, medical record and/or UNOS identification number and location of the donor. Beginning January 1, 2007, this log must be signed by the director of the training program.
 - (iii) A qualified transplant surgeon shall have a current working knowledge (direct involvement in pancreas

transplant patient care within the last two years) of pancreas transplantation including the management of patients with Diabetes Mellitus, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate post-operative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient, histologic interpretation of allograft biopsies, interpretation of ancillary tests for pancreatic dysfunction, and long term outpatient care.

- (iv) That the above training was at a medical center with a pancreas transplant training program which is approved by the Education Committee of the American Society of Transplant Surgeons or UNOS as described in section (a) or in the case of foreign training, accepted as equivalent training by the MPSC.
- (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) That the individual has written a detailed letter to UNOS outlining his/her training and experience in UNOS approved pancreas transplant program(s) or its foreign equivalent.
- (dd) For pancreas transplantation, if the transplant surgeon requirements have not been met, as outlined above in option (cc), the requirements can be met by acquired clinical experience if the following conditions are met:
- (i) The surgeon performs as primary surgeon or first assistant, over a minimum of 2 years and a maximum

of 5 years, 20 or more pancreas transplant procedures at a UNOS member pancreas transplant program or its foreign equivalent. These cases must be documented. Documentation should include the date of transplant, medical record and/or UNOS identification number, and the role of the surgeon in the operative procedure. To qualify as a pancreas transplant surgeon, each year of “experience” must be substantive and relevant. Each year of experience should include pre-operative assessment, operation as primary surgeon or first assistant and post-operative management. This log should be signed by the program director, division chief, or department chair from program where the experience was gained.

- (ii) The surgeon must have performed at least 10 pancreas procurements as primary surgeon or first assistant. These cases must be documented. Documentation should include the date of procurement, medical record and/or UNOS identification number and location of the donor.
- (iii) A qualified transplant surgeon shall have a current working knowledge (direct involvement in pancreas transplant patient care within the last two years) of pancreas transplantation including the management of patients with Diabetes Mellitus, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate post-operative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of pancreatic dysfunction in the allograft recipient, histologic interpretation of allograft biopsies, interpretation of ancillary tests for pancreatic dysfunction, and long term outpatient care.
- (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) That the individual has written a detailed letter to UNOS outlining his/her experience in a UNOS approved pancreas transplant program or its foreign equivalent.
- (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 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) If as of July 1, 2006, the surgeon serves as the designated pancreas transplant surgeon for a qualified UNOS pancreas transplant program and meets the pancreas transplant surgeon criteria in effect prior to that date, the surgeon's pancreas transplant program will continue to be UNOS-qualified in this respect so long as this same surgeon continues in his/her position with the program. If the surgeon ceases to serve the pancreas transplant program in question, that program must have on-site a pancreas transplant surgeon who meets the requirements of C(5)(a) and (cc), (dd), or (ee), above in order to remain UNOS-qualified. If the surgeon ceases to serve the pancreas transplant program that he/she served as of July 1, 2006, and desires to become the designated pancreas transplant surgeon at another program, he/she must meet the requirements of C(5) and (cc), (dd), or (ee) above.

(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) That the individual will have had one year of specialized training in transplantation under the direct supervision of a qualified pancreas transplant physician and in conjunction with a pancreas transplant surgeon at a UNOS approved pancreas transplant center. That the 12 months of specialized training be contiguous and consists of a minimum of six months on the clinical transplant service with the remaining months consisting of transplant related experience such as time in a tissue typing laboratory, on another solid organ transplant service or conducting basic or clinical transplant research.

- (ii) That the above training be in addition to other clinical requirements for general nephrology, endocrinology or diabetology training.
- (iii) That the individual will have been involved in the primary care of 8 or more pancreas transplant recipients and will have followed these 8 patients for a minimum of three months from the time of their transplant. The application must be supported by a recipient log. Such a log should include at least the medical record and/or UNOS identification number of the recipient and date of transplant. Beginning January 1, 2007, this log must be signed by the director of the training program and/or the primary transplant physician at that transplant program.
- (iv) That the individual has a current working knowledge (direct involvement in pancreas transplant patient care within the last two years) of pancreas transplantation including the management of patients with end stage pancreas disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of pancreas dysfunction in the allograft recipient, histologic interpretation of allograft biopsies, interpretation of ancillary tests for pancreas dysfunction, and long term outpatient care.
- (v) The individual should participate as an observer in three organ procurements and three pancreas transplants. In addition the physician should observe the evaluation of the donor and donor process, and management of at least 3 multiple donors which include the pancreas. These cases must be documented. Documentation should include the date of procurement, medical record and/or UNOS identification number and location of the donor.
- (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) That the above training be performed at a hospital with a fellowship training program, in adult nephrology (endocrinology, diabetology), which is accredited by the RRC-IM.
 - (viii) That the individual has written a detailed letter to UNOS outlining his/her experience in a UNOS approved pancreas transplant program.
 - (ix) This option for qualification as the primary pancreas transplant physician shall cease to exist for applications received after January 1, 2010.
- (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) That the individual will have had one year of specialized training in pancreas transplantation under the direct supervision of a qualified pancreas transplant physician and in conjunction with a pancreas transplant surgeon at a UNOS approved pancreas transplant center. That the 12 months of specialized training be contiguous and consists of a minimum of six months on the clinical transplant service with the remaining months consisting of transplant related experience such as time in a tissue typing laboratory, or another solid organ transplant service or conducting basic or clinical transplant research.
 - (ii) That the above training be in addition to other clinical requirements for general nephrology, (endocrinology, or diabetology) training.
 - (iii) That the individual will have been involved in the primary care of 8 or more recent pancreas transplant recipients and will have followed these 8 patients for a minimum of three months from the time of their transplant. The application must be supported by a recipient log. Such a log should include at least the medical record and/or UNOS identification number of the recipient and date of transplant. Beginning January 1, 2007, this log must be signed by the director of the training program and/or the primary transplant physician at that transplant program.

- (iv) That the individual has a current working knowledge (direct involvement in pancreas transplant patient care within the last two years) of pancreas transplantation including the management of patients with end stage pancreas disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of pancreas dysfunction in the allograft recipient, histologic interpretation of allograft biopsies, interpretation of ancillary tests for pancreas dysfunction, and long term outpatient care. The didactic curriculum for obtaining this knowledge should be approved by the Residency Review Committee for Internal Medicine (RRC-IM) of the Accreditation Council for Graduate Medical Education (ACGME).
- (v) The individual should participate as an observer in three organ procurements and three pancreas transplants. In addition the physician should observe the evaluation of the donor and donor process, and management of at least 3 multiple donors which include the pancreas. These cases must be documented. Documentation should include the date of procurement, medical record and/or UNOS identification number and location of the donor.
- (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) The didactic curriculum of this transplant medicine fellowship should be approved by the RRC-IM.

- (viii) That the individual has written a detailed letter to UNOS outlining his/her experience in a UNOS approved pancreas transplant program.
- (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) That the acquired clinical experience is gained over a minimum of 2 years and a maximum of 5 years on an active pancreas transplant service as the pancreas transplant physician or under the direct supervision of a qualified pancreas transplant physician and in conjunction with a pancreas transplant surgeon at a UNOS approved pancreas transplant program or its foreign equivalent.
 - (ii) That the individual has been involved in the primary care of 15 or more pancreas transplant recipients and has followed these patients for a minimum of 3 months from the time of their transplant. The application must be supported by a recipient log. Such a log should include at least the medical record and/or UNOS identification number of the recipient and date of transplant. This log should be signed by the program director, division chief, or department chair from program where the experience was gained.
 - (iii) That the individual has a current working knowledge (direct involvement in pancreas transplant patient care within the last two years) of pancreas transplantation including the management of patients with end stage pancreas disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of pancreas dysfunction in the allograft recipient, histologic interpretation of allograft biopsies, interpretation of ancillary tests for pancreas dysfunction, and long term outpatient care.
 - (iv) The individual should participate as an observer in three organ procurements and three pancreas transplants. In addition, the physician should observe the evaluation of the donor and donor process, and management of at least 3 multiple donors that include the pancreas. These cases must be documented. Documentation should include the date of procurement, medical record and/or UNOS identification number and location of the donor.

- (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 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.

- (ee) In the case of a change in the primary transplant physician at a UNOS approved pancreas transplant program, if items (aa) iii or (cc) i-ii are not met, the replacement physician, a nephrologist/endocrinologist/diabetologist can function as a pancreas transplant physician for a maximum period of twelve months if the following conditions are met:
 - (i) That the remaining parts of (aa) or (cc), as applicable, are met.
 - (ii) That if the individual is qualifying as primary transplant physician by virtue of training, the individual has been involved in the primary care of 4 or more pancreas transplant recipients, and has followed these patients for a minimum of three months from the time of their transplant. The application must be supported by a recipient log. Such a log should include at least the medical record and/or UNOS identification number of the recipient and date of transplant. Beginning January 1, 2007 this log must be signed by the program director, division chief, or department chair from program where the experience was gained.
 - (iii) That if the individual is qualifying as the primary pancreas transplant physician by virtue of acquired clinical experience, this experience is equal to 12 months on an active pancreas transplant service as the pancreas transplant physician or under the direct supervision of a qualified pancreas transplant physician and in conjunction with a pancreas transplant surgeon at a UNOS approved pancreas transplant center. Additionally, the individual will have been involved in the primary care of eight or more pancreas transplant recipients, and have followed these patients for a minimum of three months from the time of their transplant. This 12

month period of experience on the transplant service must be acquired over a maximum of 2 years.

The application must be supported by a recipient log. Such a log should include at least the medical record and/or UNOS identification number of the recipient and date of transplant

- (iv) That a consulting relationship with counterparts at another member transplant center approved for pancreas transplantation has been established and documented.
- (v) That activity reports are submitted to UNOS at two month intervals describing the transplant activity and results, physician recruitment efforts, and such other operating conditions as may be required by the Membership and Professional Standards Committee to demonstrate to the satisfaction of the Committee ongoing quality and efficient patient care. The reports must show that the individual is making sufficient progress to meet the objective of involvement in the primary care of at least 8 (training) or 15 (experience), as applicable, transplant recipients or that the program is making sufficient progress in recruiting and bringing to the program a transplant physician who meets this criterion as well as all other UNOS criteria for a qualified pancreas transplant physician by the date that is 12 months from the date of approval of the program under this section.
- (vi) If the program is unable to demonstrate that it has an individual on site who can meet the requirements as described in sections (aa), (bb), (cc), or (dd), above at the end of 12 months, it shall inactivate. The requirements for program inactivation are described in section II. The Membership and Professional Standards Committee may consider, on a case by case basis, and grant a six month extension to a program that provides substantive evidence of progress towards completing the requirements but is unable to complete the requirements within one year.
- (ff) If as of July 1, 2006, the physician serves as the designated pancreas transplant physician for a qualified UNOS pancreas transplant program and meets the pancreas transplant physician criteria in effect prior to that date, the physician's pancreas transplant program will continue to be UNOS-qualified in this respect so long as this same physician continues in his/her position with the program. If the physician ceases to serve the pancreas transplant program in question, that program must have on site a pancreas transplant physician who meets the requirements of (aa), (bb) (cc), (dd), or (ee) above in order to remain UNOS-qualified. If the physician ceases to serve the pancreas transplant program that

he/she served as of July 1, 2006, and desires to become the designated pancreas transplant physician at another program, he/she must meet the requirements of (aa), (bb) (cc), (dd), or (ee) above.

(6) Pancreatic Islet Transplantation

The following provisions apply to all pancreatic islet transplantation programs, including those programs that are already approved as OPTN/UNOS Members. Pancreatic islet transplantation programs approved under the previous criteria must submit an application documenting their compliance with the new criteria. For pancreatic islet transplantation, programs must meet all of the following criteria:

- (a) Approved Pancreas Transplant Program – The program must be located at a medical center approved under the OPTN/UNOS Bylaws to perform whole pancreas transplantation, or meet the requirements for an exception to this criterion as set forth in this Section XII (C)(6)(h) below.
- (b) Reporting – The program must submit data to UNOS through use of standardized forms. Data requirements include submission of information on all deceased and living donors, potential transplant recipients, and actual transplant recipients. Pending development of standardized data forms for pancreatic islet transplantation, the program must provide patient logs to UNOS every six months and on an annual basis, reporting transplants performed, by patient name, social security number, date of birth, and donor identification number, as well as whether patient is alive or dead, and whether the pancreas was allocated for islet or whole organ transplantation. The logs shall be cumulative. Additionally, for each donor pancreas allocated to the program for islet transplantation, the program must report to UNOS whether the islets were used for clinical islet transplantation and, if not, why and their ultimate disposition, together with such other information as requested on the Pancreatic Islet Donor Form.
- (c) Transplant Surgeon - The program must have on site a qualified surgeon who is designated as the primary surgeon for the pancreatic islet transplant program and meets the requirements for pancreas transplant surgeon set forth in these Bylaws, Appendix B, Section XII (C)(5)(a).
- (d) Transplant Physician - The program must have on site a qualified physician who is designated as the primary physician for the pancreatic islet transplant program and meets the requirements for pancreas transplant physician set forth in these Bylaws, Appendix B, Section XII (C)(5)(b).
- (e) Transplant Facilities – The program must document adequate clinical and laboratory facilities for pancreatic islet transplantation as defined by current regulations provided by the Food and Drug Administration (FDA). The program also must document the required Investigational New Drug (IND) application as reviewed by the FDA is in effect.
- (f) Radiology Expertise/Ancillary Personnel – The program must have a collaborative relationship with a physician qualified to cannulate the

portal system under direction of the transplant surgeon. It is further recommended that the program have on site or adequate access to:

- (i) A board-certified endocrinologist.
- (ii) A physician, administrator, or technician with experience in compliance with FDA regulations, and
- (iii) A laboratory-based researcher with experience in pancreatic islet isolation and transplantation.

Adequate access is defined by an agreement of affiliation with counterparts at another institution who employ individuals with the expertise described above.

- (g) Islet Isolation – Pancreatic islets must be isolated in a facility with an FDA IND application in effect, with documented collaboration between the program and such facility.
- (h) Programs Not Located at an Approved Pancreas Transplant Program – A program that meets all requirements for a pancreatic islet transplant program set forth in these Bylaws, including, without limitation, requirements applicable generally for membership and without regard to organ specificity, with the sole exception that the program is not located at a medical center approved under the OPTN/UNOS Bylaws to perform whole pancreas transplantation, may nevertheless qualify as a pancreatic islet transplant program if the following additional criteria are met to the satisfaction of the OPTN/UNOS Membership and Professional Standards Committee and Board of Directors:
 - (i) The program demonstrates a documented affiliation relationship with a UNOS approved pancreas transplant program, including on-site admitting privileges for the primary whole pancreas transplant surgeon and physician,
 - (ii) The program provides written protocols demonstrating its commitment and ability to counsel patients regarding all their options for appropriate medical treatment for diabetes, and
 - (iii) The program demonstrates availability of qualified personnel to address pre-, peri-, and post-operative care issues regardless of the treatment option ultimately selected.

A preliminary interview with the Membership and Professional Standards Committee shall be required.

(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) The individual performed as primary surgeon or first assistant 20 or more heart or heart/lung transplant procedures during his/her cardiothoracic surgery residency. These cases must be documented. Documentation should include the date of transplant, medical record and/or UNOS identification number, and the role of the surgeon (primary surgeon or first assistant) in the operative procedure. Beginning January 1, 2007, this log must be signed by the director of the training program.
 - (ii) That the resident performed as primary surgeon or first assistant 10 or more heart or heart/lung procurement procedures under the supervision of a qualified heart transplant surgeon. These cases must be documented. Documentation should include the date of procurement, medical records and/or UNOS identification number, and location of the donor. Beginning January 1, 2007, this log must be signed by the director of the training program.
 - (iii) The individual has been involved in and has 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 including performing the transplant operation, donor selection, use of mechanical assist devices, recipient selection, post-operative hemodynamic care, post-operative immunosuppressive therapy, and outpatient follow-up.
 - (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) That the individual has written a detailed letter to UNOS outlining his/her training in a UNOS approved heart transplant program or its foreign equivalent.
 - (vi) The above training was at a medical center with a cardiothoracic training program that is approved by the American Board of Thoracic Surgery, or in the case of foreign training, accepted as the equivalent training by the UNOS Membership and Professional Standards Committee with a recommendation from the Thoracic Organ Transplantation Committee.
- (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) The fellow performed as primary surgeon or first assistant 20 or more heart or heart/lung transplant procedures during his/her heart transplant fellowship. These cases must be documented. Documentation should include the date of transplant, medical record and/or UNOS identification number, and the role of the surgeon (primary surgeon or first assistant) in the operative procedure. Beginning January 1, 2007, this log must be signed by the director of the training program.
 - (ii) That the fellow performed as primary surgeon or first assistant 10 or more heart or heart/lung procurement procedures under the supervision of a qualified heart transplant surgeon. These cases must be documented. Documentation should include the date of procurement, medical records and/or UNOS identification number, and location of the donor. Beginning January 1, 2007, this log must be signed by the director of the training program.

- (iii) The fellow has been involved in and has 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 including performing the transplant operation, donor selection, use of mechanical assist devices, recipient selection, post-operative hemodynamic care, post-operative immunosuppressive therapy, and outpatient follow-up.
- (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) That the individual has written a detailed letter to UNOS outlining his/her training in a UNOS approved heart transplant program or its foreign equivalent.
 - (vi) The above training was at a medical center with a cardiothoracic training program that is approved by the American Board of Thoracic Surgery. Alternatively, the above training could be obtained at a center accepted as the foreign equivalent by the UNOS Membership and Professional Standards Committee with a recommendation from the Thoracic Organ Transplantation Committee.
- (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) The surgeon performs as primary surgeon or first assistant, over a minimum of 2 or a maximum of 5 years, 20 or more heart or heart/lung transplant procedures at a UNOS member heart transplant program or its foreign equivalent. The surgeon must

have performed at least 15 of these cases as the primary surgeon. Transplants performed during board qualifying surgical residency or fellowship does not count). These cases must be documented. Documentation should include the date of transplant, medical record and/or UNOS identification number, and the role of the surgeon (primary surgeon or first assistant) in the operative procedure. This log should be signed by the program director, division chief, or department chair from program where the experience was gained.

- (ii) That the surgeon performed as primary surgeon or first assistant 10 or more heart or heart/lung procurement procedures under the supervision of a qualified heart transplant surgeon. These cases must be documented. Documentation should include the date of procurement, medical records and/or UNOS identification number, and location of the donor.
- (iii) The surgeon has been involved in and has 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 including performing the transplant operation, donor selection, use of mechanical assist devices, recipient selection, post-operative hemodynamic care, post-operative immuno-suppressive therapy, and out-patient follow-up.
- (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) That the individual has written a detailed letter to UNOS outlining his/her experience in a UNOS approved heart transplant program or its foreign equivalent.

- (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 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.

- (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) That the individual will have been involved in the primary care of 20 or more heart or heart/lung transplant recipients from the time of their transplant. This training will have been under the direct supervision of a qualified cardiac transplant physician and in conjunction with a cardiac transplant surgeon at a UNOS approved cardiac transplant center that conducts 20 or more heart or heart/lung transplants each year. This application must be supported by a recipient log. Such a log should include at least the medical record and/or UNOS identification number, and the date of transplant. Beginning January 1, 2007, this log must be signed by the director of the training program and/or the primary transplant physician at that transplant program.
 - (ii) That the individual has been involved with and has a current working knowledge (direct involvement in heart transplant patient care within the last two years) of heart transplantation, including the care of acute and chronic heart failure, donor selection, use of mechanical assist devices, recipient selection, pre and post-operative hemodynamic care, post-operative immunosuppressive therapy, histologic interpretation and grading of myocardial biopsies for rejection, and long-term outpatient follow-up.
 - (iii) The individual should participate as an observer in 3 organ procurements and 3 heart transplants. In addition the individual should observe the evaluation of the donor and donor process, and management of at least 3 multiple organ donors which include the heart and/or heart/lung. These cases must be documented. Documentation should include the date of procurement, medical record and/or UNOS identification number, and location of the donor.

- (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) That the individual has written a detailed letter to UNOS outlining his/her training in a UNOS approved heart transplant program(s) or its foreign equivalent.
 - (vi) That the above training be performed at a hospital with an American Board of Internal Medicine certified fellowship training program in adult cardiology and/or American Board of Pediatrics certified fellowship training program in pediatric cardiology, or in the case of foreign training, accepted as the equivalent the Membership and Professional Standards Committee.
 - (vii) This option for qualification as the primary heart transplant physician shall cease to exist for applications received after January 1, 2010.
- (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) That the individual will have been involved in the primary care of 20 or more heart or heart/lung transplant recipients from the time of transplant. This training will have been under the direct supervision of a qualified heart transplant physician and in conjunction with a heart transplant surgeon. This application must be supported by a recipient log. Such a log should include at least the medical record and/or UNOS identification number and the date of

transplant. Beginning January 1, 2007, this log must be signed by the director of the training program and/or the primary transplant physician at that transplant program.

- (ii) That the individual has been involved with and has a current working knowledge (direct involvement in heart transplant patient care within the last two years) of heart transplantation, including the area of acute and chronic heart failure, donor selection, use of mechanical assist devices, recipient selection, pre- and post-operative hemodynamic care, post-operative immunosuppressive therapy, histologic interpretation in grading of myocardial biopsies for rejection, and long-term outpatient follow-up.
- (iii) The individual should participate as an observer in 3 organ procurements and 3 heart transplants. In addition the individual should observe the evaluation of the donor and donor process, and management of 3 multiple organ donors which include the heart and/or heart/lung. These cases must be documented. Documentation should include the date of procurement, medical record and/or UNOS identification number, and location of the donor.
- (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) That the above training be performed at a hospital with an American Board of Internal Medicine certified fellowship training program in adult cardiology and/or American Board of Pediatrics certified fellowship training program in pediatric cardiology or, in the case of foreign training,

accepted as the equivalent the Membership and Professional Standards Committee.

- (vi) That the individual has written a detailed letter to UNOS outlining his/her training and experience in a UNOS approved heart transplant program(s) or its foreign equivalent.
- (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) That the acquired clinical experience occurs over a minimum of 2 years and a maximum of 5 years on an active heart transplant service as the heart transplant physician or under the direct supervision of a qualified heart transplant physician and in conjunction with a heart transplant surgeon at a UNOS approved heart transplant program or its foreign equivalent.
 - (ii) The individual will have been involved in the primary care of 20 or more heart or heart/lung transplant recipients from the time of their transplant. This experience will have been as the cardiac transplant physician or under the direct supervision of a qualified cardiac transplant physician or in conjunction with a cardiac transplant surgeon. The individual must have followed these patients for a minimum of 3 months post transplant. This application must be supported by a recipient log. Such a log should include at least the medical record and/or UNOS identification number and the date of transplant. This log should be signed by the director and/or the primary transplant physician at the transplant program where the individual gained this experience.
 - (iii) That the individual has been involved with and has a current working knowledge (direct involvement in heart transplant patient care within the last two years) of heart transplantation, including the care of acute and chronic heart failure, donor selection, use of mechanical assist devices, recipient selection, pre- and post-operative hemodynamic care, post-operative immunosuppressive therapy, histologic interpretation and grading of myocardial biopsies for rejection, and long-term outpatient follow-up.
 - (iv) The individual should participate as an observer in 3 organ procurements and 3 heart transplants. In addition the individual should observe the evaluation of the donor and donor process, and management of 3 multiple organ donors which include the heart and/or

heart/lung. These cases must be documented. Documentation should include the date of procurement, medical record and/or UNOS identification number, and location of the donor.

- (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) That the individual has written a detailed letter to UNOS outlining his/her training and experience in UNOS approved heart transplant program(s) or its foreign equivalent.

- (dd) If as July 1, 2006, the physician serves as the designated heart transplant physician for a qualified UNOS heart transplant program and meets the heart transplant physician criteria in effect prior to that date, the physician's heart transplant program will continue to be UNOS-qualified in this respect so long as this same physician continues in his/her position with the program. If the physician ceases to serve the heart transplant program in question, that program must have on site a heart transplant physician who meets the requirements of (aa), (bb), (cc), (ee), (ff), or (gg) above and below in order to remain UNOS-qualified. If the physician ceases to serve the heart transplant program that he/she served as of July 1, 2006, and desires to become the designated heart transplant physician at another program, he/she must meet the requirements of (aa), (bb), (cc), (ee), (ff), or (gg) above and below.

- (ee) If the physician is not a cardiologist, he/she can function as a heart transplant physician if the following conditions are met:
 - (i) That items (aa)i-iii and (aa) iv are met.
 - (ii) That the individual is board certified or eligible in Internal Medicine and in the subspecialty of his/her

major area of interest and qualified through specific training or experience to be a transplant physician for other solid organ transplantation.

- (iii) Adequate association with cardiology service must be documented by letters of support.
- (iv) This option for qualification as the primary heart transplant physician shall cease to exist for applications received after January 1, 2007.
- (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 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.

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

(i) That the remaining parts of (aa) or (cc), as applicable, are met.

(ii) That if the individual is qualifying as primary transplant physician by virtue of training, the individual will have been involved in the primary care of 10 or more heart or heart/lung transplant recipients from the time of their transplant. This training will have been under the direct supervision of a qualified cardiac transplant physician and in conjunction with a cardiac transplant surgeon at a UNOS approved cardiac transplant center that conducts 20 or more heart or heart/lung transplants each year.

The application must be supported by a recipient log. Such a log should include at least the medical record and/or UNOS identification number of the recipient and date of transplant. Beginning January 1, 2007, this log must be signed by the director and/or the primary transplant physician at the transplant program where the individual trained or gained this experience.

(iii) That if the individual is qualifying as primary heart transplant physician by virtue of acquired clinical experience, this experience must be a minimum of 12 months on an active heart transplant service as the heart transplant physician or under the direct supervision of a qualified heart transplant physician and in conjunction with a heart transplant surgeon at a UNOS approved heart transplant center. This 12 month period of experience on the transplant service must be acquired over a maximum of 2 years.

Additionally, the individual will have been involved in the primary care of 10 or more heart or heart/lung

transplant recipients from the time of their transplant. This experience will have been as the heart transplant physician or under the direct supervision of a qualified heart transplant physician or in conjunction with a heart transplant surgeon. The individual must have followed these patients for a minimum of three months post transplant. The application must be supported by a recipient log. Such a log should include at least the medical record and/or UNOS identification number of the recipient and date of transplant. This log should be signed by the director of the program and/or the primary transplant physician at that transplant program where the individual had training or gained experience.

- (iv) That a consulting relationship with counterparts at another UNOS member transplant center approved for heart transplantation has been established and documented.
- (v) That activity reports are submitted to UNOS at two month intervals describing the transplant activity and results, physician recruitment efforts, and such other operating conditions as may be required by the Membership and Professional Standards Committee to demonstrate to the satisfaction of the Committee ongoing quality and efficient patient care. The reports must show that the individual is making sufficient progress to meet the objective of involvement in the primary care of at least 20 heart transplant recipients or that the program is making sufficient progress in recruiting and bringing to the program a transplant physician who meets this criterion as well as all other UNOS criteria for a qualified heart transplant physician by the date that is 12 months from the date of approval of the program under this section.
- (vi) If the program is unable to demonstrate that it has an individual on site who can meet the requirements as described in sections (aa), (bb), (cc), (ee), or (ff) above at the end of 12 months, it shall inactivate. The requirements for program inactivation are described in Section II. The Membership and Professional Standards Committee may consider, on a case by case basis, and grant a six month extension to a program that provides substantive evidence of progress towards completing the requirements but is unable to complete the requirements within one year.

(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) That the resident performed as primary surgeon or first assistant 15 or more lung and/or heart/lung transplant procedures of which at least one-half must be single and/or double-lung procedures under the direct supervision of a qualified lung transplant surgeon and in conjunction with a qualified lung transplant physician at a UNOS-approved lung transplant center.

These cases must be documented. Documentation should include the date of transplant, medical record and/or UNOS identification number, and the role of the surgeon (primary surgeon or first assistant) in the operative procedure. Beginning January 1, 2007, this log must be signed by the director of the training program.

(ii) That the resident performed as primary surgeon or first assistant 10 or more lung procurement procedures under the supervision of a qualified lung transplant surgeon. These cases must be documented. Documentation should include the date of procurement, medical records and/or UNOS identification number and location of the donor.

(iii) That the resident has been involved in, and has 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, including the care of acute and chronic lung failure,

cardiopulmonary bypass, donor selection, recipient selection, pre- and postoperative ventilator care, postoperative immunosuppressive therapy, histologic interpretation and grading of lung biopsies for rejection, and long-term outpatient follow-up. This training must include the other clinical requirements for Thoracic Surgery.

- (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) That the individual has written a detailed letter to UNOS outlining his/her training and experience in a UNOS approved lung transplant program(s) or its foreign equivalent.+

- (vi) That the above training was at a hospital with a cardiothoracic surgery training program that is approved by the American Board of Thoracic Surgery, or in the case of foreign training, accepted as equivalent training by the UNOS Membership and Professional Standards Committee with a recommendation from the Thoracic Organ Transplantation Committee.

- (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) That the fellow performed as primary surgeon or first assistant 15 or more lung and/or heart/lung transplant procedures of which at least one-half must be single and/or double-lung procedures under the direct supervision of a qualified lung transplant surgeon and in conjunction with a qualified lung transplant

physician at a UNOS-approved lung transplant center.

These cases must be documented. Documentation should include the date of transplant, medical record and/or UNOS identification number, and the role of the surgeon (primary surgeon or first assistant) in the operative procedure. Beginning January 1, 2007, this log must be signed by the program director, division chief, or department chair from program where the experience was gained.

- (ii) That the fellow performed as primary surgeon or first assistant 10 or more lung procurement procedures under the supervision of a qualified lung transplant surgeon. These cases must be documented. Documentation should include the date of procurement, medical records and/or UNOS identification number and location of the donor.
- (iii) That the fellow has been involved with, and has 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, including performing the transplant operation, acute and chronic lung failure, cardiopulmonary bypass, donor selection, recipient selection, pre- and postoperative ventilator care, postoperative immunosuppressive therapy, histologic interpretation in grading of lung biopsies for rejection, and long-term outpatient follow-up.
- (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) That the individual has written a detailed letter to UNOS outlining his/her training and experience in a UNOS approved lung transplant program(s) or its foreign equivalent.

- (vi) That the above training was at a cardiothoracic surgery training program that is approved by the American Board of Thoracic Surgery. Alternatively, the above training could be obtained at a center accepted as the equivalent by the Membership and Professional Standards Committee with a recommendation from the Thoracic Organ Transplantation Committee.

- (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) That the surgeon performed as primary surgeon or first assistant 15 or more lung and/or heart/lung transplant procedures over a minimum of two years and a maximum of 5 years. At least one-half of the procedures must be single and/or double-lung). The surgeon must have performed at least 10 of these cases as the primary surgeon. In addition to lung transplantation, the surgeon also must be actively involved with cardiothoracic surgery. These cases must be documented. Documentation should include the date of transplant, medical record and/or UNOS identification number, and the role of the surgeon (primary surgeon or first assistant) in the operative procedure. This log should be signed by the program director, division chief, or department chair from the program where the experience was gained.
 - (ii) That the surgeon performed 10 or more lung procurement procedures. These cases must be documented. Documentation should include the date of procurement, medical records and/or UNOS identification number and location of the donor.
 - (iii) That the surgeon has been involved with, and has 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, including performing the transplant operation, the care of acute and chronic lung failure, cardiopulmonary bypass, donor selection, recipient selection, pre- and postoperative pulmonary care, postoperative immunosuppressive therapy, histologic interpretation and grading of lung biopsies for rejection, and long-term outpatient follow-up.
 - (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) That the individual has written a detailed letter to UNOS outlining his/her training and/or experience in a UNOS approved lung transplant program(s) or its foreign equivalent.

- (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 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.

- (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) That the fellow has participated in the primary care of 15 or more lung and/or heart/lung transplant patients from the time of their transplant and under the direct supervision of a qualified lung transplant physician and in conjunction with a qualified lung transplant surgeon at a UNOS-approved lung transplant center or its foreign equivalent. At least one-half of these patients must be single and/or double-lung transplant recipients. This application must be supported by a recipient log. Such a log should include at least the medical record and/or UNOS identification number and the date of transplant. Beginning January 1, 2007, this log must be signed by the director of the training program and/or the primary transplant physician at that transplant program.
 - (ii) That the fellow has been involved with, and has a current working knowledge (direct involvement in lung transplant patient care within the last two years) of all aspects of lung transplant patient care,

including the care of acute and chronic lung failure, cardiopulmonary bypass, donor selection, recipient selection, pre- and postoperative ventilator care, postoperative immunosuppressive therapy, histologic interpretation and grading of lung biopsies for rejection, and long-term outpatient follow-up. This training must be in addition to other clinical requirements for pulmonary medicine training.

- (iii) The individual should participate as an observer in 3 or more lung or heart/lung procurement procedures and 3 lung transplants. In addition, the individual should observe the evaluation of the donor and donor process, and management of at least 3 multiple organ donors which include the lung or heart/lung donors. These cases must be documented. Documentation should include the date of procurement, medical record and/or UNOS identification number, and location of the donor.
- (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) That the individual has written a detailed letter to UNOS outlining his/her training and experience in a UNOS approved lung transplant program(s) or its foreign equivalent.
- (vi) That the above training be performed at a hospital with an American Board of Internal Medicine-certified fellowship training program in adult pulmonary medicine and/or American Board of Pediatrics certified fellowship training program in pediatric pulmonary medicine or in the case of foreign training, accepted as equivalent training by the Membership and Professional Standards

Committee with a recommendation from the Thoracic Organ Transplantation Committee.

- (vii) This option for qualification as the primary lung transplant physician shall cease to exist for physicians board eligible or certified in adult pulmonary medicine and named as the primary physician in applications received after January 1, 2010.
- (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) That the fellow has participated in the primary care of 15 or more lung and/or heart/lung transplant patients from the time of their transplant and under the direct supervision of a qualified lung transplant physician and in conjunction with a qualified lung transplant surgeon at a UNOS-approved lung transplant center or its foreign equivalent. At least one-half of these patients must be single and/or double-lung transplant recipients. This application must be supported by a recipient log. Such a log should include at least the medical record and/or UNOS identification number and the date of transplant. Beginning January 1, 2007, this log must be signed by the director of the training program and/or the primary transplant physician at that transplant program.
 - (ii) That the fellow has been involved with, and has a current working knowledge (direct involvement in lung transplant patient care within the last two years) of all aspects of lung transplant patient care, including acute and chronic lung failure, cardiopulmonary bypass, donor selection, recipient selection, pre and postoperative ventilator care, postoperative immunosuppressive therapy, histologic interpretation in grading of lung biopsies for rejection, and long-term outpatient follow-up.
 - (iii) The individual should participate as an observer in 3 or more lung or heart/lung procurement procedures and 3 lung transplants. In addition the individual should participate in the evaluation of the donor and donor process and management of at least 3 multiple organ donors which include the lung or heart/lung donors. These cases must be documented. Documentation should include the date of procurement, medical record and/or UNOS identification number, and location of the donor.
 - (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) That the individual has written a detailed letter to UNOS outlining his/her training in a UNOS approved lung transplant program(s) or its foreign equivalent.
 - (vi) That the above training be performed at a hospital with an American Board of Internal Medicine certified fellowship training program in adult pulmonary medicine and/or American Board of Pediatrics certified fellowship training program in pediatric pulmonary medicine or in the case of foreign training, accepted as equivalent training by the Membership and Professional Standards Committee with a recommendation from the Thoracic Organ Transplantation Committee.
- (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) That the acquired clinical experience is gained over a minimum of 2 years and a maximum of 5 years on an active lung transplant service as the lung transplant physician, or under the direct supervision of a qualified lung transplant physician and in conjunction with a lung transplant surgeon at a UNOS approved lung transplant center or its foreign equivalent.
 - (ii) That the physician has participated in the primary care of 15 or more lung and/or heart/lung transplant patients at a UNOS-approved lung transplant center or its foreign equivalent. At least one-half of these patients must be single and/or double-lung transplant recipients. The individual must have followed these patients for a minimum of 3 months from the date of

their transplant. This application must be supported by a recipient log. Such a log should include at least the medical record and/or UNOS identification number and the date of transplant. This log should be signed by the director and/or the primary transplant physician at the transplant program where the individual gained this experience.

- (iii) That the physician has been involved with, and has a current working knowledge (direct involvement in lung transplant patient care within the last two years) of all aspects of lung transplant patient care, including the care of acute and chronic lung failure, cardiopulmonary bypass, donor selection, recipient selection, pre- and post-operative pulmonary care, post-operative immuno-suppressive therapy, histologic interpretation and grading of lung biopsies for rejection, and long-term outpatient follow-up.
- (iv) The individual should participate as an observer in 3 or more lung or heart/lung procurement procedures and 3 lung transplants. In addition the individual should participate in the evaluation of the donor and donor process, and management of at least 3 multiple organ donors which include the lung or heart/lung donors. These cases must be documented. Documentation should include the date of procurement, medical record and/or UNOS identification number, and location of the donor.
- (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) That the individual has written a detailed letter to UNOS outlining his/her training and experience in a UNOS approved lung transplant program(s) or its foreign equivalent.

- (dd) If the physician is not a pulmonologist, he/she can function as a lung transplant physician if the following conditions are met:
- (i) That items (aa)i-iii and (aa)vi are met.
 - (ii) That the individual is board certified or eligible in Internal Medicine and in the subspecialty of his/her major area of interest and qualified through specific training or experience to be a transplant physician for other solid organ transplantation.
 - (iii) Adequate association with pulmonology service must be documented by letters of support.
 - (iv) This option for qualification as the primary lung transplant physician shall cease to exist for applications received after January 1, 2007.
- (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 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

(ff) In the case of a change in the primary lung transplant physician at a UNOS approved transplant program, if items

(aa) i or (cc) i-ii are not met, the replacement physician, a pulmonologist, can function as a lung transplant physician for a maximum period of twelve months if the following conditions are met:

(i) That the remaining parts of (aa) or (cc), as applicable, are met.

(ii) That if the individual is qualifying as primary transplant physician by virtue of training, the individual will have participated in the primary care of eight or more lung and/or heart/lung transplant recipients from the time of their transplant. This training will have been under the direct supervision of a qualified lung transplant physician and in conjunction with a qualified lung transplant surgeon at a UNOS approved lung transplant center or its foreign equivalent. At least one-half of these patients must be single and/or double lung transplant recipients.

The application must be supported by a recipient log. Such a log should include at least the medical record and/or UNOS identification number of the recipient and date of transplant. Beginning January 1, 2007, this log must be signed by the director of the program and/or the primary transplant physician at that transplant program where the individual trained.

(iii) That if the individual is qualifying as primary transplant physician by virtue of acquired clinical experience, this experience is equal to 12 months on an active lung transplant service as the lung transplant physician or under the direct supervision of a qualified lung transplant physician and in conjunction with a lung transplant surgeon at a UNOS approved lung transplant center. This 12 month period of experience on the transplant service must be acquired over a maximum of 2 years.

Additionally, the individual will have participated in the primary care of eight or more lung and/or

heart/lung transplant recipients at a UNOS approved lung transplant center or its foreign equivalent. At least one-half of these patients must be single and/or double lung transplant recipients. The individual must have followed these patients for a minimum of three months from the date of their transplant.

The application must be supported by a recipient log. Such a log should include at least the medical record and/or UNOS identification number of the recipient and date of transplant. This log should be signed by the director of the program and/or the primary transplant physician at that transplant program where the individual gained this experience/training.

- (iv) That a consulting relationship with counterparts at another UNOS member transplant center approved for lung transplantation has been established and documented.
- (v) That activity reports are submitted to UNOS at two month intervals describing the transplant activity and results, physician recruitment efforts, and such other operating conditions as may be required by the Membership and Professional Standards Committee to demonstrate to the satisfaction of the Committee ongoing quality and efficient patient care. The reports must show that the individual is making sufficient progress to meet the objective of involvement in the primary care of at least 15 lung transplant recipients or that the program is making sufficient progress in recruiting and bringing to the program a transplant physician who meets this criterion as well as all other UNOS criteria for a qualified lung transplant physician by the date that is 12 months from the date of approval of the program under this section.
- (vi) If the program is unable to demonstrate that it has an individual on site who can meet the requirements as described in sections (aa), (bb), (cc), (dd), or (ee) above at the end of 12 months, it shall inactivate. The requirements for program inactivation are described in Section II. The Membership and Professional Standards Committee may consider, on a case by case basis, and grant a six month extension to a program that provides substantive evidence of progress towards completing the requirements but is unable to complete the requirements within one year.

(9) Heart/lung Transplantation

- (a) Transplant Surgeon - Each heart/lung transplant center must have on site a qualified transplant surgeon who meets the requirements specified in UNOS Bylaws Appendix B, Attachment I, Section XII,

(7)(a) or Section XII, (8)(a), and have UNOS approved programs in both heart transplantation and lung transplantation.

- (b) Transplant Physician - Each heart/lung transplant center must have on site a qualified transplant physician who meets the requirements specified in UNOS Bylaws Appendix B, Attachment I, Section XII, (7)(b) or Section XII, (8)(b), and have UNOS approved programs in both heart transplantation and lung transplantation.
- (c) If as of July 1, 2006, the surgeon or physician serves as the designated transplant surgeon or physician for a qualified UNOS heart/lung transplant program and meets the heart/lung transplant surgeon or physician criteria in effect prior to that date, the surgeon's or physician's heart/lung transplant program will continue to be UNOS-qualified in this respect so long as this same surgeon and/or physician continues in his/her position with the program. If the surgeon or physician ceases to serve the heart/lung transplant program in question, that program must have on site a heart/lung transplant surgeon and/or physician who meets the requirements of (a) or (b) above in order to remain UNOS-qualified. If the surgeon or physician ceases to serve the heart/lung transplant program that he/she served as of July 1, 2006, and desires to become the designated heart/lung transplant physician at another program, he/she must meet the requirements of (a) or (b) above.

- (10) **Survival Rates.** In the distribution of survival rates of all UNOS members a transplant program with a low (as defined below) survival rate would be subject to evaluation by the Membership and Professional Standards Committee ("MPSC") to determine if the low survival rate may be accounted for by patient mix or some other unique clinical aspect of the transplant program in question. The MPSC may conduct a site visit to the program at Member expense and may require the Member to adopt a plan for quality improvement.

Those programs whose actual observed patient and/or graft survival rates fall below their expected rates by more than a threshold will be reviewed. The absolute values of relevant parameters in the formula may be different for different organs, and may be reviewed and modified by the MPSC, subject to Board approval.

While the precise numerical criteria may be selected by the MPSC, the initial criteria employed to identify programs with low patient and/or graft survival rates will include the finding that observed events minus expected events is >3 and the observed events divided by expected events is greater than 1.5; and there exists an one sided p value of <0.05 .

Observed events represent deaths or graft losses as reported in UNOS database. Expected events represent deaths or graft losses as calculated utilizing organ specific transplant models. Incomplete follow-up data will be treated as a graft loss or patient deaths in the context of this analysis.

If a program's performance cannot be explained by patient mix or some other unique clinical aspect of the transplant program in question, the Member, in cooperation with the MPSC, shall adopt and promptly implement an appropriate plan for quality improvement. The Member's failure to do so shall constitute a violation of UNOS requirements.

- (11) **Facilities.** A successful transplant program requires extensive facilities. Consequently institutions must allocate sufficient operating and recovery room resources, intensive care resources and surgical beds and personnel to the transplant program.
- (12) **Recipient Selection.** Selection of transplant recipients and the distribution of donor organs are two essential functions of a transplant program. Following the membership criteria established by the National Organ Procurement and Transplant Network (OPTN/UNOS) the transplant program must establish procedures for selecting transplant candidates and distributing organs in a fair and equitable manner.
- (13) **Patient Notification.** The transplant program must notify patients in writing: (i) within ten business days (a) of the patient's being placed on the Waiting List including the date the patient was listed, or (b) of completion of the patient's evaluation as a candidate for transplantation, that the evaluation has been completed and that the patient will not be placed on the List at this time, which ever is applicable; and (ii) within ten business days of removal from the Waiting List as a transplant candidate for reasons other than transplantation or death that the patient has been removed from the Waiting List. Each such written notification must reference and include the OPTN contractor's "Patient Information Letter," which provides the telephone number that is available to patients and others to report concerns or grievances through the OPTN. All candidates currently on the Waiting List should be notified by their listing center about the patient notification hotline, or other information as directed by the Executive Committee. The transplant program must maintain documentation of these notifications and make it available to UNOS upon request for purposes of monitoring policy compliance.

NOTE: UNOS Bylaw, Appendix B, Attachment I, XIII-Transplant Programs, (Section 13-Patient Notification) above is a duplicate of OPTN/UNOS Bylaws, Appendix B II, Transplant Hospitals, (Section F-Patient Notification) and will be consolidated during the ongoing bylaws rewrite efforts being undertaken by UNOS.

- (14) **Collaborative Support.** The proper care and management of transplant recipients often requires the assistance of both physicians other than surgeons and ancillary health professionals. The transplant program, therefore, must show evidence of collaborative involvement with experts in the field of hepatology, radiology, pediatrics, infectious disease, nephrology with dialysis capability, pulmonary medicine with respiratory therapy support, pathology, immunology, anesthesiology, physical therapy and rehabilitation medicine.
- (15) **Ancillary Services.** The matching of transplant recipients and donors, as well as routine evaluation and follow-up of transplant patients requires sophisticated laboratory facilities. Therefore, the transplant program must have immediate access to sophisticated microbiology, clinical chemistry, tissue typing, radiology services, as well as the facilities required for monitoring immunosuppressive drugs.
- (16) **Blood Bank Support.** Access to large quantities of blood is necessary, particularly for liver transplant patients. Therefore, it is essential that the transplant program have extensive blood bank support.
- (17) **Transplant Mental Health and Social Support Services.** Mental health and social support services are essential for the total care of transplant recipients, living donors and their families. Such services must be available. All transplant

programs should identify appropriately trained individuals who are designated members of the transplant team and have primary responsibility for coordinating the psychosocial needs of transplant candidates, recipients, living donors and families. They will work with patients and families in a compassionate, culturally competent, and tactful manner in order to facilitate access and provide continuity of care. Specific responsibilities should include, but are not limited to:

Direct patient care, including:

Psychosocial evaluation of potential living donors and recipients;
Substance abuse evaluation, treatment, referral, monitoring;
Individual counseling;
Crisis intervention;
Support groups/newsletters;
Patient care conferences;
Advocacy;
Patient and family education;
Referral to community services, e.g., vocational rehabilitation, housing;
Ongoing knowledge of social services available, regulations; and
Death, dying, and bereavement counseling.

Other:

Transplant team building;
Department meetings, e.g., staff, process improvement;
Participation in organ donation awareness initiatives; and
Participation with community advocacy groups, e.g., National Kidney Foundation and the Coalition for Donation.

- (18) **Review and Evaluation.** Because transplant outcome data for each transplant program(s) will be a means of determining continued UNOS approval, and UNOS activity and outcome must be determined to set UNOS membership standards, provide regular reports to the membership, and meet federal contract requirements, the accurate and timely submission of data stipulated and approved by UNOS is required of all members. Those transplant program(s) not in compliance will be considered for probation from UNOS by the Membership Committee and the Board of Directors of UNOS.

The evaluation of the means by which members collect and submit data, as well as the accuracy and timeliness of submitted data will be accomplished by UNOS.

- (19) **Clinical Transplant Coordinator.** All transplant programs should identify one or more staff members who will be responsible for coordinating clinical aspects of patient care. The clinical transplant coordinator shall be a designated member of the transplant team and will be assigned primary responsibility for coordinating clinical aspects of care. The coordinator will work with patients and their families beginning with the evaluation for transplantation and continuing through and after transplantation, in a compassionate and tactful manner in order to help facilitate access to and provide continuity of care. The coordinator will also work with other members of the transplant team, including physicians, surgeons, nurses, social workers, financial coordinators, and administrative personnel at the transplant program. The coordinator should be a registered nurse or other licensed clinician who performs or oversees a team of

other healthcare personnel and support staff in performing the functions (listed below).

Specific responsibilities should include, but are not limited, to:

Candidate Phase:

1. Assures the performance of necessary studies to determine a patient's candidacy;
2. Participates in both patient and family education;
3. Assists in the evaluation and selection of potential living donors;
4. Maintains appropriate monitoring of patients' status throughout work-up and while on the deceased donor organ transplant waiting list.

Transplant/Inpatient Phase:

1. Assumes lead in directing responsibility of all patient and family education;
2. Maintains communication with patients' referring physicians;
3. Contributes to the education and acts as the resource person regarding transplantation for all staff nurses;
4. Acts as liaison between patients' families and other health care team members;
5. Prepares patients for discharge and outpatient follow-up.

Recipient Phase:

1. Monitors and follows all diagnostic studies;
2. Evaluates patient health status on a regular basis;
3. Communicates all patient issues and concerns to appropriate transplant physicians;
4. Coordinates comprehensive care with other team members (i.e. financial coordinator, social worker, dietician, etc).

Additional responsibilities may include but are not limited to clinical research studies, public and professional education and completion of all required data as established by UNOS. Coordinators may also be involved with the organ procurement process by taking organ offer calls, dispatching the organ procurement team, and arranging for potential organ recipients to be admitted to the hospital.

- (20) **Financial Coordinator.** All transplant centers should identify one or more staff members who will be responsible for coordinating and clarifying patient-specific financial aspects of care. The Financial Coordinator shall be a designated member of the transplant team and will be assigned primary responsibility for coordinating financial aspects of care. The Coordinator will work with patients and their families beginning with the evaluation for transplantation and continuing through and after transplantation, in a compassionate and tactful manner in order to help facilitate access to and provide continuity of care. The Coordinator will also work with other members of the transplant team, insurers and administrative personnel at the Transplant Center.

Specific responsibilities should include, but are not limited, to:

1. Obtaining detailed patient insurance benefit information for all aspects of the transplant process, including, but not limited to, outpatient prescription drugs, organ acquisition, follow-up clinic visits, and travel and housing if necessary.

2. Discussing benefits and other transplant financial issues with patients and/or family members during initial evaluation.
3. Advising patients on insurance and billing issues and options. Serving as a resource for patients and their family members on financial matters.
4. Obtaining all necessary payor authorizations. Verifying transplant coverage and other medical benefits and acquiring necessary referrals and authorizations.
5. Monitoring and updating information regarding insurance data, physicians, authorizations, and preferred providers. Assisting patients with questions concerning insurance and other financial issues.
6. Identifying and effectively communicating financial information to transplant team members, patients and their families with emphasis on identifying any potential patient out-of-pocket liability.
7. Working with patients, their families and team members when possible to help address insurance coverage gaps via alternative funding options.
8. Facilitating resolution of patient billing issues.

(21) **Routine Referral Procedures.** Transplant centers, as a condition of UNOS membership, must implement and practice appropriate routine referral procedures for all potential donors. Transplant centers will be expected to demonstrate compliance based upon an annual medical record review, performed in collaboration with the OPO. Centers found to be out of compliance will be reviewed by the Membership and Professional Standards Committee.

(22) **Clinical Transplant Pharmacist.** All transplant programs should identify one or more pharmacists who will be responsible for providing pharmaceutical care to solid organ transplant recipients. The clinical transplant pharmacist should be a designated member of the transplant team and will be assigned primary responsibility for providing comprehensive pharmaceutical care to transplant recipients in a culturally competent manner. The transplant pharmacist will work with patients and their families, and members of the transplant team, including physicians, surgeons, nurses, clinical coordinators, social workers, financial coordinators and administrative personnel at the transplant program. The transplant pharmacist should be a licensed pharmacist with experience in transplant pharmacotherapy, who performs or oversees a team of other healthcare personnel and support staff in performing the functions listed below.

Specific responsibilities should include but are not limited to:

Perioperative Phase:

1. Evaluates, identifies and solves medication related problems for transplant recipients;
2. Educates transplant recipients and their family members on transplant medications and adherence to medication regimen;
3. Acts as liaison (advocate) between patient and patients' families and other health care team members regarding medication issues;
4. Prepares and assists with discharge planning for all transplant recipients; and
5. Provides drug information for all members of the transplant team.

Post Transplant Phase:

1. Evaluates transplant recipient medication regimens on a regular basis;
2. Communicates all transplant recipient medication issues and concerns to appropriate members of the transplant team; and
3. Assists with designing, implementing, and monitoring of comprehensive care plans with other team members (i.e. transplant coordinators, financial coordinator, social worker, dietician, etc.).

Additional responsibilities may include but are not limited to clinical research studies, quality assurance of medication regimens, public and professional education.

- E. Veterans Administration Hospitals that are Dean's Committee Hospitals and share a common university based transplant team, need not make independent application to UNOS, but may be considered members under the university program with which they are affiliated. Independent Veterans Administration Hospitals, or Veterans Administration Hospitals which are not Dean's Committee Hospitals sharing a common university based transplant team, must submit application and be approved for UNOS membership in order to list patients and have access to donor organs shared through the network.
- F. Relocation and Transfer of Established Transplant Programs. An established transplant program described in Section III, C, (2) may be transferred from one UNOS member clinical transplant center to another center within the same metropolitan area if the following requirements are met:
- (1) Both UNOS member transplant centers shall voluntarily consent in writing to such transfer of established program status and to the transfer of one or more transplant programs of the original facility to the new hospital;
 - (2) The transplant surgeon, transplant physician, immunology, tissue typing and organ procurement services associated with the original transplant center must be available to the new hospital by utilization of substantially the same personnel as have been performing these services in the original institution;
 - (3) The original facility voluntarily agrees in writing to inactive status for those transplant programs being relocated from the original facility for at least three months and to relinquish its established status for those programs being relocated until such later time as it shall have attained that status based solely upon transplants performed at the original facility after the transfer;
 - (4) Conditionally approved programs may be transferred to the new hospital along with the established program, provided that the conditionally approved program requirements in effect at the time of transfer are met;
 - (5) The new hospital must meet UNOS transplant center membership criteria.