

Consider Primary Transplant Surgeon Requirement- Primary or First Assistant on Transplant Cases

OPTN/UNOS Membership and Professional Standards Committee

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Consider Primary Transplant Surgeon Requirement- Primary or First Assistant on Transplant Cases

Affected Bylaws: OPTN Bylaws Appendices E.2.A (Formal 2-year Transplant Fellowship Pathway), E.2.B (Clinical Experience Pathway), E.6.D (Primary Open Living Donor Kidney Surgeon), E.6.E (Primary Laparoscopic Living Donor Kidney Surgeon), F.3.A (Formal 2-year Transplant Fellowship Pathway), F.3.B (Clinical Experience Pathway), F.8.A (Living Donor Surgeon Requirements), G.2.A (Formal 2-year Transplant Fellowship Pathway), G.2.B (Clinical Experience Pathway), H.2.A (Cardiothoracic Surgery Residency Pathway), H.2.B (Twelve-month Heart Transplant Fellowship Pathway), I.2.A (Cardiothoracic Surgery Residency Pathway), I.2.B (Twelve-month Lung Transplant Fellowship Pathway)

Sponsoring Committee: Membership and Professional Standards
Public Comment Period: August 15, 2016 – October 15, 2016

Executive Summary

Primary transplant surgeons are required to perform a set number of transplants and procurements as the “primary surgeon or first assistant.” Primary thoracic transplant surgeons must perform a certain number of these procedures as the primary surgeon, but the Bylaws do not specify this for abdominal surgeons. Considering this, and that the responsibilities of a surgical first assistant are not consistent across institutions, the MPSC has raised concerns that surgeons could qualify as a transplant program’s primary surgeon though they may have never performed critical surgical transplant functions that would be expected of a primary transplant surgeon leading a designated program. This proposal recommends that an abdominal surgeon applying through the clinical experience pathway must have performed at least half of the required transplants and procurements as the primary or co-surgeon. Additionally, this proposal recommends that all cases accepted towards transplant training program requirements should also count towards OPTN/UNOS Bylaws requirements for all surgeons applying through training pathways. Requiring all primary transplant surgeons applying through clinical experience pathways to have performed a certain number of transplants and procurements as the primary surgeon is intended to promote patient safety and improve outcomes by assuring that each transplant program is led by individuals who have sufficient training and experience in organ transplantation.

What problem will this proposal solve?

The Bylaws require that designated transplant programs have certain key personnel on site, including a qualified primary surgeon who meets requirements outlined in the Bylaws. Among other things, the Bylaws currently require individuals wishing to serve as a designated transplant program's primary transplant surgeon to have performed a set number of transplants and procurements as the "primary surgeon or first assistant." Primary thoracic transplant surgeons must perform a certain number of these procedures as the primary surgeon, but the Bylaws do not specify this for abdominal surgeons. As such, abdominal surgeons could qualify as a transplant program's primary surgeon though they may have never performed critical surgical transplant functions that would be expected of a primary transplant surgeon leading a designated program.

Why should you support this proposal?

The changes presented in this proposal stem directly from recommendations developed by a Joint Societies Working Group (JSWG), and are representative of a collaborative effort between the American Society of Transplantation (AST), the American Society of Transplant Surgeons (ASTS), the North American Transplant Coordinators Organization (NATCO), and the MPSC.

There are two primary components to the changes recommended in this proposal regarding the required case experience for primary transplant surgeons: what is required when applying through a training pathway, and what is required of abdominal surgeons applying through the clinical experience pathway. The JSWG stated it was necessary to look at this problem from those two perspectives considering billing implications of the primary surgeon/first assistant designation for residents and fellows. The JSWG recommended that the MPSC focus on training operative logs when evaluating the experience of surgeons applying through fellowship or residency pathways. This decision was guided by the rationale that if a fellowship program accepts a surgeon's involvement in a transplant or procurement towards completion of their training, then the OPTN should also accept these cases towards key personnel Bylaws requirements. For abdominal surgeons applying through a clinical experience pathway, the JSWG indicated it was unreasonable that someone could qualify without some transplant and procurement experience as the primary surgeon. To rectify this, the JSWG recommended that individuals applying to become a primary transplant surgeon for an abdominal transplant program must perform at least 50% of their reported transplants and procurements as the primary surgeon.

The proposed fellowship pathway changes should simplify the MPSC's evaluation of experience reported by surgeons applying through this pathway, which will yield more efficient reviews of these applications. Similarly, these changes should clarify this process for members when trying to assess if certain staff (or potential staff) meet Bylaws requirements, and when completing the membership applications for surgeons applying through residency or training pathways. Also, the proposed changes to the abdominal primary transplant surgeon clinical experience pathways establish more consistent standards for abdominal primary transplant surgeons.

How was this proposal developed?

In 2013 the MPSC created a working group to address a number of issues in the Bylaws' key personnel requirements that it had repeatedly noted as ambiguous, unenforceable, or prompted repeated questions from members or the MPSC. Included in the topics assigned to this working group was a review of primary transplant surgeon requirements in the Bylaws that state transplants and procurements cited on a key personnel application must have been performed as "primary surgeon or first assistant." While the MPSC Working Group began addressing the list of topics it had been assigned, the Joint Societies Policy Steering Committee met in May 2014 and opted for the formation of a Joint Societies Working Group (JSWG) to address the key personnel Bylaws projects being worked on by the MPSC.

When presented with this topic, the JSWG believed that the primary surgeon/first assistant requirements in primary transplant surgeon Bylaws needed to be reconsidered from two perspectives: what is required when applying through a training pathway, and what is required when applying through the clinical experience pathway.

The JSWG first focused on these requirements as they pertain to primary transplant surgeon training pathways (e.g., OPTN Bylaws Appendix E.2.A (Formal 2-year Transplant Fellowship Pathway); OPTN Bylaws Appendix H.2A (Cardiothoracic Surgery Residency Pathway)). The JSWG stated that fellows are always noted as an assisting surgeon on hospital billing records, so differentiating between primary surgeon or first assistant experience during a surgeon's fellowship is not the best way to assess that they have requisite training and experience that would be expected of a primary transplant surgeon. The JSWG also acknowledged that training pathways for primary transplant surgeons rely on quality training and experience gained during fellowship or residency, and the Bylaws requirements in these pathways generally reflect standards that must be met to complete one's fellowship or residency training. As such, the JSWG suggested that if the transplant or procurement experience has been accepted to count towards the completion of training program requirements, then the OPTN should also allow those cases to count towards the primary surgeon requirements found in the Bylaws in each respective training pathway. To evaluate this, primary transplant surgeon applicants applying through the fellowship pathway will be required to provide a copy of their residency or fellowship operative log. The JSWG confirmed that this should apply to all of the residency and fellowship pathways currently in the Bylaws for primary transplant surgeons.

The JSWG proceeded to consider these requirements for primary transplant surgeons applying through the clinical experience pathways (e.g., OPTN Bylaws Appendix F.2.B (Clinical Experience Pathway); OPTN Bylaws Appendix I.2.C (Clinical Experience Pathway)). To initiate the discussions, it was noted that primary heart transplant surgeons applying through the clinical experience pathway must have performed at least 15 (of a required 20) heart transplants as the primary surgeon, and that primary lung transplant surgeons must have performed at least 10 (of a required 15) transplants as the primary surgeon. The JSWG suggested that key personnel Bylaws for abdominal primary transplant surgeons should similarly include a set number of procedures that must have been performed as the primary surgeon. Further discussion yielded the recommendation that at least 50% of the procurements and transplants required of primary transplant surgeons who apply through a clinical experience pathway must have been performed as the primary surgeon. The JSWG discussed other possible thresholds, and expressed some concern about the arbitrary nature of the percentage to be included in this proposal. The JSWG was unable to determine a less arbitrary means to determine an appropriate threshold, and agreed to proceed with 50% of cases as the primary surgeon. Although the JSWG accepted that the arbitrariness of this decision as a weakness of this proposal, it believed that this solution was reasonable and the simplest way to address this problem.

The JSWG also considered if this recommendation should apply to the thoracic primary transplant surgeon clinical experience pathways. Unaware of any explicit problems that have resulted from the current requirements in the primary heart and primary lung transplant surgeon Bylaws, the JSWG indicated it was hesitant to recommend modifications to these sections. Although this would result in some inconsistency in the primary transplant surgeon requirements across all organs, the JSWG opted not to recommend applying these proposed changes to the clinical experience pathways for thoracic organ transplant programs unless feedback from the thoracic transplant community clearly indicates that this change is necessary.

The JSWG presented these recommendations to the MPSC and the Joint Societies Policy Steering Committee, and both groups endorsed proposed changes with no concerns raised. Upon the MPSC's endorsement, it drafted proposed Bylaws modifications to accommodate these recommendations (as presented in this proposal). An additional consideration raised by the MPSC while drafting this proposal was the inclusion of cases performed as co-surgeon. The MPSC noted that this designation is common in abdominal surgery transplants, and that the experience is meaningful relative to the intent of these

primary transplant surgeon requirements. Thoracic surgeons on the MPSC indicated this designation is not commonly used in heart or lung transplantation. Accordingly, the MPSC agreed that the term “co-surgeon” should be included for abdominal transplant surgeons applying through clinical experience pathways, and that cases reported as “co-surgeon” should be viewed, for the purposes of these Bylaws, as equivalent to primary surgeon cases. The JSWG obtained an update on this approach during a subsequent teleconference, and did not express any objections.

How well does this proposal address the problem statement?

Requiring abdominal organ primary transplant surgeons to have performed at least 50% of their reported transplants and procurements as the primary surgeon further standardizes expectations of all primary transplant surgeons at abdominal organ transplant programs across the country. These proposed changes should eliminate any concerns about the potential approval of a primary transplant surgeon who has not performed critical surgical transplant functions that would be expected of a primary transplant surgeon leading a designated program.

In addition to addressing these concerns, the proposed changes for acceptable case experience when applying through a residency or fellowship pathway should simplify the MPSC’s evaluation of these applicants, and similarly, member determination of which staff could meet the primary transplant surgeon requirements through the training pathways.

The JSWG and MPSC realize that the recommended 50% primary surgeon threshold was reached arbitrarily. Nevertheless, both groups believe this is a reasonable and necessary requirement to include in the Bylaws.

Was this proposal changed in response to public comment?

No. The MPSC voted in support (36 support, 0 oppose, 0 abstentions) of sending the Bylaws language proposed during public comment for the OPTN/UNOS Board of Directors final consideration at its December 2016 meeting.

Prior to reaching this decision, the MPSC reviewed all of the public comments provided in response to this proposal. MPSC discussion yielded the following responses to the feedback provided:

- *Support for the proposal.*
 - This was the predominant response from the regions, organizations, and individuals that commented on the proposal and the MPSC appreciates the commenters’ review and support of this proposal.
- *An individual commenter stated that the proposal’s inclusion of the term “co-surgeon,” and counting these cases as equivalent to primary surgeon cases, creates a new potential loophole due to the different uses of the term “co-surgeon” across institutions.*
 - The MPSC appreciates the review and support of this proposal. Regarding inclusion of the term “co-surgeon” the MPSC believes it is necessary to retain this term in the proposal to avoid potential questions about “co-surgeon” cases that may be cited on membership applications. Noting that the terms “primary, co-surgeon, and first assistant” are associated with billing codes for a surgeon’s role in a procedure, the Committee is comfortable with the responsibility reflected with “co-surgeon” cases and counting those cases as equivalent to primary surgeon cases for the purpose of this Bylaws requirement.
- *The OPTN/UNOS Pediatric Transplantation Committee (Pediatric Committee) indicated that it does not recommend changes to the primary transplant surgeon requirement for transplant programs with an approved pediatric component. Subsequent staff correspondences clarified that the Pediatric Committee’s comments pertain to the proposed Bylaws included in this proposal, not the recently approved but not-yet-implemented pediatric component Bylaws.*

- The MPSC does not support inserting special considerations in each respective key personnel pathway to make a separate standard for programs that predominantly transplant pediatric patients. The Committee's decision was primarily driven by its consideration of the OPTN/UNOS Board of Directors' approval of the pediatric component Bylaws in December 2015 which eliminated the "alternative pathway for predominantly pediatric programs" throughout the Bylaws. With the recent elimination of these pathways, the Committee did not think it was appropriate to reestablish the precedent that pediatric programs necessitate special, less-rigorous membership considerations at this time - prior to the implementation of the pediatric component Bylaws proposal - and especially not through a post-public comment change to this proposal. Nevertheless, even though the "alternative pathway for predominantly pediatric programs" are still active Bylaws due to the pediatric component Bylaws not being implemented yet, this primary/first assistant proposal did not specifically address the "alternative pathway for predominantly pediatric programs" as they have technically been deleted. As such, the "alternative pathway for predominantly pediatric programs" will remain as is- and aligned with the Pediatric Committee's feedback on this proposal – until those alternative pathways are ultimately deleted upon the implementation of the pediatric component Bylaws.
- *The Children's Hospital of Pittsburgh and AST suggested that the recommendations included in this proposal also be applied to the recently approved but not-yet-implemented Bylaws regarding the establishment of key personnel requirements for intestinal organ transplant programs and pediatric components.*
 - The MPSC appreciates the review and comments provided in response to its specific requests for feedback on this proposal. As indicated above in the original proposal, the Committee was hesitant to apply the recommendations presented in this proposal to those sections of the Bylaws without more feedback from the community in consideration of the numerous case volume concerns raised during the public comment discussion of each of these proposals. Unfortunately, the feedback provided on this topic was limited and did not include formal responses from the respective sponsoring committees of those recently approved Bylaws proposals. Although the Pediatric Committee did not address this proposal as it applies to the recently approved pediatric component Bylaws, it did provide concerns about the general proposal (see above). The Committee inferred that if the Pediatric Committee was not generally supportive of this proposal as it may apply to pediatric programs, then it likely would not be in support of extending these recommendations to the pediatric component Bylaws. Considering all this, and discussing how to proceed with this particular aspect of this proposal, the Committee ultimately indicated it was not comfortable modifying these newly approved but not-yet-implemented Bylaws with this proposal.

Which populations are impacted by this proposal?

As primary transplant surgeons are required at every transplant program, and as these proposed changes address primary transplant surgeon requirements, these proposed changes have the potential to impact all patient populations; however, the effect realized by any individual patient or patient population is likely to be negligible as these changes are primarily operational in nature.

How does this proposal impact the OPTN Strategic Plan?

1. *Increase the number of transplants:* There is no impact to this goal.
2. *Improve equity in access to transplants:* Additional Bylaws requirements always have the potential to impact transplant access. Additional requirements may not be attainable for certain programs, which could eventually result in the approval of fewer transplant programs. Ultimately, the MPSC believes it would be unlikely that these changes pose a significant burden on

transplant programs, and thus expects that these changes will have negligible impact on patient access.

3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* The primary purpose of key personnel Bylaws is to establish a standard that each transplant program is led by individuals who have sufficient training and experience in organ transplantation. Expanding the requirements for abdominal organ primary transplant surgeons applying through the clinical experience pathways further standardizes what is expected of all primary transplant surgeons at abdominal organ transplant programs across the country. A higher level of required experience should promote improved outcomes for patients on the waiting list, living donors, and transplant recipients.
4. *Promote living donor and transplant recipient safety:* The primary purpose of key personnel Bylaws is to establish a standard that each transplant program is led by individuals who have sufficient training and experience in organ transplantation. Expanding the requirements for abdominal organ primary transplant surgeons applying through the clinical experience pathways further standardizes what is expected of all primary transplant surgeons at abdominal organ transplant programs across the country. A higher level of required experience should promote living donor and transplant recipient safety.
5. *Promote the efficient management of the OPTN:* The proposed fellowship pathway changes should simplify the MPSC's evaluation of experience reported by surgeons applying through this pathway, which will yield more efficient reviews of these applications. Similarly, these changes should simplify this process for members when trying to assess if certain staff (or potential staff) meet Bylaws requirements, and when completing the membership applications for surgeons applying through residency or training pathways.

How will the OPTN implement this proposal?

Assuming the Board adopts these changes, members will be alerted through a policy notice. All applications received on or after the March 1, 2017, implementation date, would be evaluated by the MPSC considering these new Bylaws.

How will members implement this proposal?

No immediate action will be required of members upon the implementation of these proposed changes. Membership and key personnel change applications submitted on or after the implementation of these proposed changes will be evaluated relative to these requirements.

Transplant Hospitals

With the adoption of the changes provided in this proposal, transplant hospitals that are proposing primary transplant surgeons through one of the OPTN Bylaws fellowship or residency pathways will be required to submit with their application the proposed primary transplant surgeon's operative log from their training.

Will this proposal require members to submit additional data?

This proposal does not necessitate the collection of any new data; however, there are additional considerations that members should be mindful of when submitting primary transplant surgeon key personnel applications. If the primary transplant surgeon applicant is qualifying through a training pathway, then the applicant will need to supply a copy of their training operative log. Cases included on

these operative logs that have been accepted towards meeting the training program's requirements will also be accepted by the OPTN towards primary transplant surgeon training pathway requirements. Primary kidney, liver, and pancreas transplant surgeon applicants applying through the respective clinical experience pathways must make sure that at least half of the cases cited on their application were performed as the primary surgeon or co-surgeon.

How will members be evaluated for compliance with this proposal?

All membership and key personnel applications proposing a primary transplant surgeon that are received by UNOS on or after the implementation date of these changes would be evaluated against these new requirements. All primary transplant surgeon applicants applying through a residency or fellowship pathway will be required to provide a copy of their training operative log to document their involvement in the requisite number of transplants and procurements. All cases included on the training operative log that are accepted towards fellowship completion will also be accepted by the OPTN. Abdominal organ primary transplant surgeon applicants applying through the clinical experience pathway will be required to have performed at least half of their reported transplants and procurements as primary surgeon or co-surgeon.

How will the sponsoring Committee evaluate whether this proposal was successful post implementation?

These proposed changes will necessarily prevent surgeons at abdominal organ programs from qualifying as the primary transplant surgeon without having performed critical surgical transplant functions that would be expected of a primary transplant surgeon leading a designated program. The impact of these changes will be evaluated as the MPSC receives primary kidney, liver, and pancreas transplant surgeon key personnel applications. The MPSC will assess primary transplant surgeon application deficiencies, as well as the type and frequency of questions raised about these new requirements. The MPSC will monitor if these changes yield a trend of negative consequences that it did not anticipate.

Policy or Bylaws Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

1 **Appendix E:**

2 **Membership and Personnel Requirements for Kidney** 3 **Transplant Programs**

4 **E.2 Primary Kidney Transplant Surgeon Requirements**

5 **A. Formal 2-year Transplant Fellowship Pathway**

6 Surgeons can meet the training requirements for primary kidney transplant surgeon by
7 completing a 2-year transplant fellowship if the following conditions are met:
8

- 9 1. The surgeon performed at least 30 kidney transplants as the primary surgeon or first
10 assistant during the 2-year fellowship period. These transplants must be documented in the
11 surgeon's fellowship operative log, a log that includes ~~the~~ the date of transplant, the role of the
12 surgeon in the procedure, and the medical record number or other unique identifier that can
13 be verified by the OPTN Contractor, and the fellowship director's signature must be provided
14 with this log. This log must be signed by the director of the training program.
- 15 2. The surgeon performed at least 15 kidney procurements as primary surgeon or first assistant.
16 At least 10 of these procurements must be from deceased donors. These procurements must
17 have been performed anytime during the surgeon's fellowship and the two years immediately
18 following fellowship completion. These procedures must be documented in the surgeon's
19 fellowship operative log, a log that includes ~~the~~ The date of procurement, location of the donor,
20 and Donor ID must be provided with this log.
- 21 3. The surgeon has maintained a current working knowledge of kidney transplantation, defined
22 as direct involvement in kidney transplant patient care in the last 2 years. This includes the
23 management of patients with end stage renal disease, the selection of appropriate recipients
24 for transplantation, donor selection, histocompatibility and tissue typing, performing the
25 transplant operation, immediate postoperative and continuing inpatient care, the use of
26 immunosuppressive therapy including side effects of the drugs and complications of
27 immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient,
28 histological interpretation of allograft biopsies, interpretation of ancillary tests for renal
29 dysfunction, and long term outpatient care.
- 30 4. This training was completed at a hospital with a kidney transplant training program approved
31 by the Fellowship Training Committee of the American Society of Transplant Surgeons, the
32 Royal College of Physicians and Surgeons of Canada, or accepted by the OPTN Contractor
33 as described in the *Section E.4 Approved Kidney Transplant Surgeon and Physician*
34 *Fellowship Training Programs* that follows.
- 35 5. The following letters are submitted directly to the OPTN Contractor:
 - 36 a. A letter from the director of the training program and chairman of the department or
37 hospital credentialing committee verifying that the surgeon has met the above
38 requirements and is qualified to direct a kidney transplant program.
 - 39 b. A letter of recommendation from the fellowship training program's primary surgeon and
40 transplant program director outlining the surgeon's overall qualifications to act as a

41 primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and
42 familiarity with and experience in adhering to OPTN obligations, and any other matters
43 judged appropriate. The MPSC may request additional recommendation letters from the
44 primary physician, primary surgeon, director, or others affiliated with any transplant
45 program previously served by the surgeon, at its discretion.

46 c. A letter from the surgeon that details the training and experience the surgeon has gained
47 in kidney transplantation.
48

49 **B. Clinical Experience Pathway**

50 Surgeons can meet the requirements for primary kidney transplant surgeon through clinical
51 experience gained post-fellowship if the following conditions are met:
52

53 1. The surgeon has performed 45 or more kidney transplants over a 2 to 5-year period as
54 primary surgeon, co-surgeon, or first assistant at a designated kidney transplant program. Of
55 these 45 kidney transplants, 23 or more must have been performed as primary surgeon or
56 co-surgeon. The transplants must be documented in a log that includes the date of
57 transplant, the role of the surgeon in the procedure, and medical record number or other
58 unique identifier that can be verified by the OPTN Contractor. The log should be signed by
59 the program director, division chief, or department chair from the program where the
60 experience was gained. Each year of the surgeon's experience must be substantive and
61 relevant and include pre-operative assessment of kidney transplant candidates, performance
62 of transplants as primary surgeon or first assistant, and post-operative care of kidney
63 recipients.

64 2. The surgeon has performed at least 15 kidney procurements as primary surgeon, co-
65 surgeon, or first assistant. Of these 15 kidney procurements, at least 8 must have been
66 performed as primary surgeon or co-surgeon. At least 10 of these procurements must be
67 from deceased donors. These cases must be documented in a log that includes the date of
68 procurement, location of the donor, and Donor ID.

69 3. The surgeon has maintained a current working knowledge of kidney transplantation, defined
70 as direct involvement in kidney transplant patient care in the last 2 years. This includes the
71 management of patients with end stage renal disease, the selection of appropriate recipients
72 for transplantation, donor selection, histocompatibility and tissue typing, performing the
73 transplant operation, immediate postoperative and continuing inpatient care, the use of
74 immunosuppressive therapy including side effects of the drugs and complications of
75 immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient,
76 histological interpretation of allograft biopsies, interpretation of ancillary tests for renal
77 dysfunction, and long term outpatient care.

78 4. The following letters are submitted directly to the OPTN Contractor:

79 a. A letter from the director of the transplant program and Chairman of the department or
80 hospital credentialing committee verifying that the surgeon has met the above
81 qualifications and is qualified to direct a kidney transplant program.

82 b. A letter of recommendation from the primary surgeon and transplant program director at
83 the transplant program last served by the surgeon outlining the surgeon's overall
84 qualifications to act as a primary transplant surgeon, as well as the surgeon's personal
85 integrity, honesty, and familiarity with and experience in adhering to OPTN obligations
86 and compliance protocols, and any other matters judged appropriate. The MPSC may
87 request additional recommendation letters from the primary physician, primary surgeon,

- 88 director, or others affiliated with any transplant program previously served by the
89 surgeon, at its discretion.
90 c. A letter from the surgeon that details the training and experience the surgeon has gained
91 in kidney transplantation.
92

93 **E.6 Kidney Transplant Programs that Perform Living Donor Recovery**

94 **D. Primary Open living Donor Kidney Surgeon**

95 A kidney donor surgeon who performs open living donor nephrectomies must be on site and
96 must meet *one* of the following criteria:
97

- 98 ■ Completion of an accredited American Society of Transplant Surgeons (ASTS) fellowship
99 with kidney certification.
- 100 ■ Completion of at least 10 open nephrectomies, including deceased donor nephrectomies or
101 the removal of diseased kidneys, as primary surgeon, co-surgeon, or First Assistant. At
102 least 5 of these open nephrectomies must have been performed as the primary surgeon or
103 co-surgeon. The open nephrectomies must be documented in a log that includes the date of
104 recovery, the role of the surgeon in the procedure, the type of procedure (open or
105 laparoscopic), and the medical record number or Donor ID.
106

107 **E. Primary Laparoscopic Living Donor Kidney Surgeon**

108 A surgeon who performs laparoscopic living donor kidney recoveries must be on site and must
109 have completed at least 15 laparoscopic nephrectomies in the last 5 years as primary surgeon,
110 co-surgeon, or first assistant. Seven of these nephrectomies must have been performed as ~~the~~
111 primary surgeon or co-surgeon, and this role should be documented by a letter from the
112 fellowship program director, program director, division chief, or department chair from the
113 program where the surgeon gained this experience. The laparoscopic nephrectomies must be
114 documented in a log that includes the date of the surgery, the role of the surgeon in the
115 procedure, the type of procedure (open or laparoscopic), and the medical record number or
116 Donor ID.
117

118 **Appendix F:** 119 **Membership and Personnel Requirements for Liver** 120 **Transplant Programs and Intestine Transplant Programs**

121 **F.3 Primary Liver Transplant Surgeon Requirements**

122 **A. Formal 2-year Transplant Fellowship Pathway**

123 Surgeons can meet the training requirements for primary liver transplant surgeon by completing a
124 2-year transplant fellowship if the following conditions are met:

- 125 1. The surgeon performed at least 45 liver transplants as primary surgeon or first assistant
126 during the 2-year fellowship period. These transplants must be documented in the surgeon's
127 fellowship operative log, a log that includes ~~the~~ the date of transplant, the role of the surgeon in
128 the procedure, and the medical record number or other unique identifier that can be verified
129 by the OPTN Contractor, and the fellowship director's signature must be provided with this
130 log. ~~This log must be signed by the director of the training program.~~

- 131 2. The surgeon performed at least 20 liver procurements as primary surgeon or first assistant.
132 These procurements must have been performed anytime during the surgeon's fellowship and
133 the two years immediately following fellowship completion. These procedures must be
134 documented in the surgeon's fellowship operative log, a log that includes ~~†~~The date of
135 procurement, location of the donor, and Donor ID must be provided with this log. ~~This log~~
136 ~~must be signed by the director of the training program.~~
- 137 3. The surgeon has maintained a current working knowledge of liver transplantation, defined as
138 direct involvement in liver transplant patient care within the last 2 years. This includes the
139 management of patients end stage liver disease, the selection of appropriate recipients for
140 transplantation, donor selection, histocompatibility and tissue typing, performing the
141 transplant operation, immediate postoperative and continuing inpatient care, the use of
142 immunosuppressive therapy including side effects of the drugs and complications of
143 immunosuppression, differential diagnosis of liver allograft dysfunction, histologic
144 interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and
145 long term outpatient care.
- 146 4. The training was completed at a hospital with a transplant training program approved by the
147 Fellowship Training Committee of the American Society of Transplant Surgeons, the Royal
148 College of Physicians and Surgeons of Canada, or accepted by the OPTN Contractor as
149 described in *Section F.6. Approved Liver Surgeon Transplant Fellowship Programs* that
150 follows.
- 151 5. The following letters are submitted directly to the OPTN Contractor:
- 152 a. A letter from the director of the training program verifying that the surgeon has met the
153 above requirements, and is qualified to direct a liver transplant program.
- 154 b. A letter of recommendation from the fellowship training program's primary surgeon and
155 transplant program director outlining the surgeon's overall qualifications to act as primary
156 transplant surgeon, as well as the surgeon's personal integrity, honesty, familiarity with
157 and experience in adhering to OPTN obligations, and other matters judged appropriate.
158 The MPSC may request additional recommendation letters from the primary physician,
159 primary surgeon, director, or others affiliated with any transplant program previously
160 served by the surgeon, at its discretion.
- 161 c. A letter from the surgeon that details his or her training and experience in liver
162 transplantation.

163 **B. Clinical Experience Pathway**

164 Surgeons can meet the requirements for primary liver transplant surgeon through clinical
165 experience gained post-fellowship, if the following conditions are met:
166

- 167
- 168 1. The surgeon has performed 60 or more liver transplants over a 2 to 5-year period as primary
169 surgeon, co-surgeon, or first assistant at a designated liver transplant program. Of these 60
170 liver transplants, 30 or more must have been performed as primary surgeon or co-surgeon.
171 These transplants must be documented in a log that includes the date of transplant, the role
172 of the surgeon in the procedure, and medical record number or other unique identifier that
173 can be verified by the OPTN Contractor. This log should be signed by the program director,
174 division chief, or department chair from the program where the experience was gained. Each
175 year of the surgeon's experience must be substantive and relevant and include pre-operative
176 assessment of liver transplant candidates, transplants performed as primary surgeon or first
177 assistant, and post-operative management of liver recipients.

- 178 2. The surgeon has performed at least 30 liver procurements as primary surgeon, co-surgeon,
179 or first assistant. Of these 30 liver procurements, at least 15 must have been performed as
180 primary surgeon or co-surgeon. These procedures must be documented in a log that includes
181 the date of procurement, location of the donor, and Donor ID.
- 182 3. The surgeon has maintained a current working knowledge of liver transplantation, defined as
183 direct involvement in liver transplant patient care within the last 2 years. This includes the
184 management of patients with end stage liver disease, the selection of appropriate recipients
185 for transplantation, donor selection, histocompatibility and tissue typing, performing the
186 transplant operation, immediate postoperative and continuing inpatient care, the use of
187 immunosuppressive therapy including side effects of the drugs and complications of
188 immunosuppression, differential diagnosis of liver dysfunction in the allograft recipient,
189 histologic interpretation of allograft biopsies, interpretation of ancillary tests for liver
190 dysfunction, and long term outpatient care.
- 191 4. The following letters are sent directly to the OPTN Contractor:
- 192 a. A letter from the director of the transplant program and chairman of the department or
193 hospital credentialing committee verifying that the surgeon has met the above
194 requirements, and is qualified to direct a liver transplant program.
- 195 b. A letter of recommendation from the primary surgeon and transplant program director at
196 the transplant program last served by the surgeon outlining the surgeon's overall
197 qualifications to act as primary transplant surgeon, as well as the surgeon's personal
198 integrity, honesty, familiarity with and experience in adhering to OPTN obligations, and
199 other matters judged appropriate. The MPSC may request additional recommendation
200 letters from the primary physician, primary surgeon, director, or others affiliated with any
201 transplant program previously served by the surgeon, at its discretion.
- 202 c. A letter from the surgeon that details the training and experience the surgeon gained in
203 liver transplantation.
- 204

205 **F.8 Liver Transplant Programs that Perform Living Donor Recovery**

206 **A. Living Donor Surgeon Requirements**

207 A liver recovery hospital must have on site *at least* 2 surgeons who:

208

- 209 1. Meet the primary liver transplant surgeon requirements as outlined in *Section F.3* above.
- 210 2. Have demonstrated experience as the primary surgeon, co-surgeon, or first assistant by
211 completion of at least 20 major liver resection surgeries, including living donor procedures,
212 splits, reductions, and resections, within the past 5 years. Of these 20 major liver resection
213 surgeries, Seven of these procedures 7 must have been live donor procedures, and at least
214 10 must have been performed as the primary surgeon or co-surgeon. These procedures must
215 be documented in a log that includes the date of the surgery, the role of the surgeon in the
216 procedure, and the medical record number or other unique identifier that can be verified by
217 the OPTN Contractor.
- 218

219 In the case of pediatric living donor transplantation, it may be necessary that the live organ
220 recovery occurs at a hospital that is distinct from the approved liver transplant program.

221

222 **Appendix G:**

223 **Membership and Personnel Requirements for Pancreas and** 224 **Pancreatic Islet Transplant Programs**

225 **G.2 Primary Pancreas Transplant Surgeon Requirements**

226 **A. Formal 2-year Transplant Fellowship Pathway**

227 Surgeons can meet the training requirements for primary pancreas transplant surgeon by
 228 completing a 2-year transplant fellowship if the following conditions are met:

- 229 1. The surgeon performed at least 15 pancreas transplants as primary surgeon or first assistant.
 230 These transplants must be documented in the surgeon's fellowship operative log, a log that
 231 includes the date of transplant, the role of the surgeon in the procedure, and the medical
 232 record number or other unique identifier that can be verified by the OPTN Contractor, and the
 233 fellowship director's signature must be provided with this log. This log must be signed by the
 234 director of the training program.
 235
- 236 2. The surgeon performed at least 10 pancreas procurements as primary surgeon or first
 237 assistant. These procurements must have been performed anytime during the surgeon's
 238 fellowship and the two years immediately following fellowship completion. These cases must
 239 be documented in the surgeon's fellowship operative log, a log that includes the
 240 date of procurement, location of the donor, and Donor ID, and the fellowship director's signature
 241 must be provided with this log. This log must be signed by the director of the training
 242 program.
 243
- 244 3. The surgeon has maintained a current working knowledge of pancreas transplantation,
 245 defined as direct involvement in patient care within the last 2 years. This includes the
 246 management of patients with diabetes mellitus, the selection of appropriate recipients for
 247 transplantation, donor selection, histocompatibility and tissue typing, performing the
 248 transplant operation, immediate postoperative and continuing inpatient care, the use of
 249 immunosuppressive therapy including side effects of the drugs and complications of
 250 immunosuppression, differential diagnosis of pancreas dysfunction in the allograft recipient,
 251 histological interpretation of allograft biopsies, interpretation of ancillary tests for pancreatic
 252 dysfunction, and long term outpatient care.
- 253 4. The training was completed at a hospital with a pancreas transplant training program
 254 approved by the Fellowship Training Committee of the American Society of Transplant
 255 Surgeons, the Royal College of Physicians and Surgeons of Canada, or accepted by the
 256 OPTN Contractor as described in *Section G.7. Approved Pancreas Transplant Surgeon*
Fellowship Training Programs that follows.
- 257 5. The following letters are submitted directly to the OPTN Contractor:
 - 258 a. A letter from the director of the training program and chairman of the department or
 259 hospital credentialing committee verifying that the fellow has met the above requirements
 260 and is qualified to direct a pancreas transplant program.
 - 261 b. A letter of recommendation from the fellowship training program's primary surgeon and
 262 transplant program director outlining the surgeon's overall qualifications to act as primary
 263 transplant surgeon as well as the surgeon's personal integrity, honesty, familiarity with
 264 and experience in adhering to OPTN obligations, and any other matters judged
 265 appropriate. The MPSC may request similar letters of recommendation from the primary
 266 physician, primary surgeon, director, or others affiliated with any transplant program
 267 previously served by the surgeon, at its discretion.
 - 268 c. A letter from the surgeon that details the training and experience the surgeon has gained
 269 in pancreas transplantation.

270 **B. Clinical Experience Pathway**

271

272 Surgeons can meet the requirements for primary pancreas transplant surgeon through clinical
273 experience gained post-fellowship if the following conditions are met:

- 274
- 275 1. The surgeon has performed 20 or more pancreas transplants over a 2 to 5-year period as
276 primary surgeon, co-surgeon, or first assistant, at a designated pancreas transplant program.
277 Of these 20 pancreas transplants, 10 or more must have been performed as primary surgeon
278 or co-surgeon. These transplants must be documented in a log that includes the date of
279 transplant, the role of the surgeon in the procedure, and medical record number or other
280 unique identifier that can be verified by the OPTN Contractor. This log should be signed by
281 the program director, division chief, or department chair from the program where the
282 experience was gained. Each year of the surgeon's experience must be substantive and
283 relevant and include pre-operative assessment of pancreas transplant candidates,
284 transplants performed as primary surgeon or first assistant, and post-operative care of
285 pancreas recipients.
 - 286 2. The surgeon has performed at least 10 pancreas procurements as primary surgeon, co-
287 surgeon, or first assistant. Of these 10 pancreas procurements, at least 5 must have been
288 performed as primary surgeon or co-surgeon. These procurements must be documented in a
289 log that includes the date of procurement, location of the donor, and Donor ID.
 - 290 3. The surgeon has maintained a current working knowledge of pancreas transplantation,
291 defined as direct involvement in pancreas transplant patient care within the last 2 years. This
292 includes the management of patients with diabetes mellitus, the selection of appropriate
293 recipients for transplantation, donor selection, histocompatibility and tissue typing, performing
294 the transplant operation, immediate postoperative and continuing inpatient care, the use of
295 immunosuppressive therapy including side effects of the drugs and complications of
296 immunosuppression, differential diagnosis of pancreatic dysfunction in the allograft recipient,
297 histological interpretation of allograft biopsies, interpretation of ancillary tests for pancreatic
298 dysfunction, and long term outpatient care.
 - 299 4. The following letters are submitted directly to the OPTN Contractor:
 - 300 a. A letter from the director of the transplant program and chairman of the department or
301 hospital credentialing committee verifying that the surgeon has met the above
302 requirements and is qualified to direct a pancreas transplant program.
 - 303 b. A letter of recommendation from the primary surgeon and director at the transplant
304 program last served by the surgeon outlining the surgeon's overall qualifications to act as
305 primary transplant surgeon as well as the surgeon's personal integrity, honesty, familiarity
306 with and experience in adhering to OPTN obligations, and any other matters judged
307 appropriate. The MPSC may request similar letters of recommendation from the primary
308 physician, primary surgeon, director, or others affiliated with any transplant program
309 previously served by the individual, at its discretion.
 - 310 c. A letter from the surgeon that details the training and experience the surgeon has gained
311 in pancreas transplantation.
- 312

313 **Appendix H:**
314 **Membership and Personnel Requirements for Heart**
315 **Transplant Programs**

316 **H.2 Primary Heart Transplant Surgeon Requirements**

317 **A. Cardiothoracic Surgery Residency Pathway**

318 Surgeons can meet the training requirements for primary heart transplant surgeon by completing
319 a cardiothoracic surgery residency if *all* the following conditions are met:

- 320
- 321 1. The surgeon performed at least 20 heart or heart/lung transplants as primary surgeon or first
322 assistant during the cardiothoracic surgery residency. These transplants must be
323 documented in the surgeon's cardiothoracic surgery residency operative log. ~~in a log that~~
324 ~~includes~~ The date of transplant, role of the surgeon in the procedure, and medical record
325 number or other unique identifier that can be verified by the OPTN Contractor, and the
326 training program director's signature must be provided with this log. This log must be signed
327 ~~by the director of the training program.~~
- 328 2. The surgeon performed at least 10 heart or heart/lung procurements as primary surgeon or
329 first assistant under the supervision of a qualified heart transplant surgeon. These
330 procurements must have been performed anytime during the surgeon's cardiothoracic
331 surgery residency and the two years immediately following cardiothoracic surgery residency
332 completion. These procedures must be documented in the surgeon's cardiothoracic surgery
333 residency operative log. ~~a log that includes~~ The date of procurement, location of the donor,
334 and Donor ID, and the training program director's signature must be provided with this log.
335 ~~This log must be signed by the director of the training program.~~
- 336 3. The surgeon has maintained a current working knowledge of all aspects of heart
337 transplantation, defined as a direct involvement in heart transplant patient care within the last
338 2 years. This includes performing the transplant operation, donor selection, use of
339 mechanical assist devices, recipient selection, post-operative hemodynamic care,
340 postoperative immunosuppressive therapy, and outpatient follow-up.
- 341 4. This training was completed at a hospital with a cardiothoracic surgery training program
342 approved by the American Board of Thoracic Surgery or the Royal College of Physicians and
343 Surgeons of Canada.
- 344 5. The following letters are submitted directly to the OPTN Contractor:
- 345 a. A letter from the director of the training program verifying that the surgeon has met the
346 above requirements and is qualified to direct a heart transplant program.
- 347 b. A letter of recommendation from the training program's primary surgeon and transplant
348 program director outlining the individual's overall qualifications to act as primary
349 transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity
350 with and experience in adhering to OPTN obligations, and any other matters judged
351 appropriate. The MPSC may request additional recommendation letters from the primary
352 physician, primary surgeon, director, or others affiliated with any transplant program
353 previously served by the surgeon, at its discretion.
- 354 c. A letter from the surgeon that details the training and experience the surgeon has gained
355 in heart transplantation.

356 **B. Twelve-month Heart Transplant Fellowship Pathway**

358 Surgeons can meet the training requirements for primary heart transplant surgeon by completing
359 a 12-month heart transplant fellowship if the following conditions are met:

- 360
- 361 1. The surgeon performed at least 20 heart or heart/lung transplants as primary surgeon or first
362 assistant during the 12-month heart transplant fellowship. These transplants must be
363 documented in the surgeon's fellowship operative log. ~~a log that includes~~ The date of

- 364 transplant, the role of the surgeon in the procedure, ~~and~~ the medical record number or other
365 unique identifier that can be verified by the OPTN Contractor, and the fellowship director's
366 signature must be provided with this log. This log must be signed by the director of the
367 training program.
- 368 2. The surgeon performed at least 10 heart or heart/lung procurements as primary surgeon or
369 first assistant under the supervision of a qualified heart transplant surgeon. These
370 procurements must have been performed anytime during the surgeon's fellowship and the
371 two years immediately following fellowship completion. These procedures must be
372 documented in the surgeon's fellowship operative log. a log that includes ~~†~~The date of
373 procurement, location of the donor, ~~and~~ Donor ID, and the training program director's
374 signature must be provided with this log. This log must be signed by the director of the
375 training program.
- 376 3. The surgeon has maintained a current working knowledge of all aspects of heart
377 transplantation, defined as a direct involvement in heart transplant patient care within the last
378 2 years. This includes performing the transplant operation, donor selection, the use of
379 mechanical circulatory assist devices, recipient selection, post-operative hemodynamic care,
380 postoperative immunosuppressive therapy, and outpatient follow-up.
- 381 4. This training was completed at a hospital with a cardiothoracic surgery training program
382 approved by the American Board of Thoracic Surgery or the Royal College of Physicians and
383 Surgeons of Canada.
- 384 5. The following letters are submitted directly to the OPTN Contractor:
- 385 a. A letter from the director of the training program verifying that the surgeon has met the
386 above requirements and is qualified to direct a heart transplant program.
- 387 b. A letter of recommendation from the training program's primary surgeon and transplant
388 program director outlining the individual's overall qualifications to act as primary
389 transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity
390 with and experience in adhering to OPTN obligations, and any other matters judged
391 appropriate. The MPSC may request additional recommendation letters from the primary
392 physician, primary surgeon, director, or others affiliated with any transplant program
393 previously served by the surgeon, at its discretion.
- 394 c. A letter from the surgeon that details the training and experience the surgeon has gained
395 in heart transplantation.

396 **Appendix I:**

397 **Membership and Personnel Requirements for Lung** 398 **Transplant Programs**

399 **I.2 Primary Lung Transplant Surgeon Requirements**

400 **A. Cardiothoracic Surgery Residency Pathway**

401 Surgeons can meet the training requirements for primary lung transplant surgeon by completing a
402 cardiothoracic surgery residency if the following conditions are met:

- 403
- 404 1. During the cardiothoracic surgery residency, the surgeon has performed at least 15 lung or
405 heart/lung transplants as primary surgeon or first assistant under the direct supervision of a
406 qualified lung transplant surgeon and in conjunction with a lung transplant physician at a lung
407 transplant program. At least half of these transplants must be lung procedures. These
408 transplants must be documented in the surgeon's cardiothoracic surgery residency operative

- 409 ~~log, a log that includes~~ The date of transplant, role of the surgeon in the procedure, and
410 medical record number or other unique identifier that can be verified by the OPTN Contractor,
411 ~~and the training program director's signature must be provided with this log. This log must be~~
412 ~~signed by the director of the training program.~~
- 413 2. The surgeon performed at least 10 lung procurements as primary surgeon or first assistant
414 under the supervision of a qualified lung transplant surgeon. These procedures must be
415 documented in the surgeon's cardiothoracic surgery residency operative log. ~~a log that~~
416 ~~includes~~ The date of procurement, location of the donor, and Donor ID must be provided with
417 this log.
 - 418 3. The surgeon has maintained a current working knowledge of all aspects of lung
419 transplantation, defined as a direct involvement in lung transplant patient care within the last
420 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass,
421 donor selection, recipient selection, pre- and postoperative ventilator care, postoperative
422 immunosuppressive therapy, histological interpretation and grading of lung biopsies for
423 rejection, and long-term outpatient follow-up. This training must also include the other clinical
424 requirements for thoracic surgery.
 - 425 4. This training was completed at a hospital with a cardiothoracic training program approved by
426 the American Board of Thoracic Surgery, or the Royal College of Physicians and Surgeons of
427 Canada.
 - 428 5. The following letters are submitted directly to the OPTN Contractor:
 - 429 a. A letter from the director of the training program verifying that the surgeon has met the
430 above requirements and is qualified to direct a lung transplant program.
 - 431 b. A letter of recommendation from the program's primary surgeon and transplant program
432 director outlining the individual's overall qualifications to act as primary transplant
433 surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and
434 experience in adhering to OPTN obligations and compliance protocols, and any other
435 matters judged appropriate. The MPSC may request additional recommendation letters
436 from the primary physician, primary surgeon, director, or others affiliated with any
437 transplant program previously served by the surgeon, at its discretion.
 - 438 c. A letter from the surgeon that details the training and experience the surgeon has gained
439 in lung transplantation.
- 440
441

441 **B. Twelve-month Lung Transplant Fellowship Pathway**

442 Surgeons can meet the training requirements for primary lung transplant surgeon by completing a
443 12-month lung transplant fellowship if the following conditions are met:

- 444
- 445 1. The surgeon has performed at least 15 lung or heart/lung transplants under the direct
446 supervision of a qualified lung transplant surgeon and in conjunction with a qualified lung
447 transplant physician as primary surgeon or first assistant during the 12-month lung transplant
448 fellowship. At least half of these transplants must be lung procedures. These transplants
449 must be documented in the surgeon's fellowship operative log. ~~a log that includes~~ The date
450 of transplant, the role of the surgeon in the procedure, and the medical record number or
451 other unique identifier that can be verified by the OPTN Contractor, and the fellowship
452 director's signature must be provided with this log. ~~This log must be signed by the director of~~
453 ~~the program.~~
 - 454 2. The surgeon has performed at least 10 lung procurements as primary surgeon or first
455 assistant under the supervision of a qualified lung transplant surgeon. These procurements
456 must have been performed anytime during the surgeon's fellowship and the two years

- 457 immediately following fellowship completion. These procedures must be documented in the
458 surgeon's fellowship operative log. ~~a log that includes~~ The date of procurement, location of
459 the donor, and Donor ID must be provided with this log.
- 460 3. The surgeon has maintained a current working knowledge of all aspects of lung
461 transplantation, defined as a direct involvement in lung transplant patient care within the last
462 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass,
463 donor selection, recipient selection, pre- and postoperative ventilator care, postoperative
464 immunosuppressive therapy, histological interpretation and grading of lung biopsies for
465 rejection, and long-term outpatient follow-up.
- 466 4. This training was completed at a hospital with a cardiothoracic training program approved by
467 the American Board of Thoracic Surgery, or the Royal College of Physicians and Surgeons of
468 Canada.
- 469 5. The following letters are submitted directly to the OPTN Contractor:
- 470 a. A letter from the director of the training program verifying that the surgeon has met the
471 above requirements and is qualified to direct a lung transplant program.
- 472 b. A letter of recommendation from the training program's primary surgeon and transplant
473 program director outlining the individual's overall qualifications to act as primary
474 transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity
475 with and experience in adhering to OPTN obligations, and any other matters judged
476 appropriate. The MPSC may request additional recommendation letters from the primary
477 physician, primary surgeon, director, or others affiliated with any transplant program
478 previously served by the surgeon, at its discretion.
- 479 c. A letter from the surgeon that details the training and experience the surgeon has gained
480 in lung transplantation.

#