

Briefing Paper

Addressing Approved Transplant Fellowship Training Programs Bylaws

OPTN/UNOS Membership and Professional Standards Committee

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Addressing Approved Transplant Fellowship Training Programs Bylaws

Affected Bylaws:

OPTN Bylaws Appendices E.2.A (Formal 2-year Transplant Fellowship Pathway), E.3.A (Transplant Nephrology Fellowship Pathway), E.3.C (Three-year Pediatric Nephrology Fellowship Pathway), E.3.D (Twelve-month Pediatric Transplant Nephrology Fellowship Pathway), E.3.E (Combined Pediatric Nephrology Training and Experience Pathway), E.4.A (Transplant Surgeon Fellowship Training Programs), E.4.B (Transplant Physician Fellowship Training Programs), E.5.C (Conditional Approval for a Pediatric Component), E.6.D (Primary Open Living Donor Kidney Surgeon), F.3.A (Formal 2-year Transplant Fellowship Pathway), F.6 (Approved Liver Surgeon Transplant Fellowship Programs), F.11.A (Full Intestine Surgeon Approval Pathway), F.14 (Approved Intestine Surgeon Transplant Fellowship Programs), G.2.A (Formal 2-year Transplant Fellowship Pathway), G.3.A (Twelve-month Transplant Medicine Fellowship Pathway), G.7 (Approved Pancreas Transplant Surgeon Fellowship Training Programs), J.3.A (Additional Primary Surgeon Requirements for Upper Limb Transplant Programs), and J.3.B (Additional Primary Surgeon Requirements for Head and Neck Transplant Programs)

Sponsoring Committee:

Membership and Professional Standards

Public Comment Period:

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Executive Summary

Key personnel training pathways in the Bylaws for kidney and liver transplant programs require that the training occurred at a fellowship program approved by the Membership and Professional Standards Committee (MPSC), and that the MPSC will review training programs "every five years or any time the program director changes." The MPSC does not regularly review or formally approve transplant training programs, nor has it done so historically. This proposal recommends deleting Bylaws that reference the MPSC's approval and routine review of transplant fellowship programs to address this discrepancy, while retaining language that validates the rigor of the training program cited by a key personnel applicant applying through one of the Bylaws' training pathways. The proposal also recommends some clerical changes to simplify these Bylaws sections. Making these proposed changes to the Bylaws supports the OPTN strategic plan goal of promoting the efficient management of the OPTN.

What problem will this proposal address?

There is disparity between what is stated in the Bylaws and what the MPSC actually does when considering the transplant training program of key personnel applicants who apply through one of the Bylaws' training pathways. Key personnel training pathways in the Bylaws for kidney and liver transplant programs require that the training occurred at a fellowship program approved by the MPSC, and that the MPSC will review training programs "every five years or any time the program director changes." Although the MPSC does review where a key personnel applicant gained their fellowship experience when applying through one of the training pathways, the MPSC does not formally approve or regularly review transplant training programs, nor has it done so historically.

Why should you support this proposal?

This proposal addresses longstanding requirements (the OPTN/UNOS Board of Directors adopted the earliest version of these requirements in November 1987) that establish actions that have never been formally undertaken by the MPSC. This proposal eliminates this discrepancy between the Bylaws and how the MPSC functionally operates, while retaining language to define what types of transplant fellowship training programs are acceptable for the purposes of evaluating prospective primary transplant surgeons or primary transplant physicians who apply through one of the Bylaws key personnel training pathways. Adopting this proposal will effectively align the Bylaws with how the MPSC currently operates during the evaluation of key personnel applicants who apply through one of the training pathways in the Bylaws.

How was this proposal developed?

The Bylaws addressed in this proposal evolved directly from language that the OPTN/UNOS Board of Directors originally adopted in November 1987. The Board adopted these Bylaws to define what constituted an accepted training program for evaluating individuals' qualifications to serve as transplant program key personnel. Prior to the Board's decision in November 1987, key personnel requirements were rather basic; for example, primary transplant surgeons needed to be board certified and have one year of "formal training" and one year of experience at a designated transplant program, or three years of experience at a designated transplant program. In processing these early membership applications, the MPSC recognized a need to develop operational guidelines for defining what constituted "formal training." Subsequent to the development and usage of these operational guidelines, the MPSC recommended their incorporation in the Bylaws. The Board heeded this recommendation, and adopted the MPSC's "formal training" operational guidelines as Bylaws in November 1987.

The Board originally adopted these basic membership requirements to establish a standard that every transplant program is led by experienced individuals. As the field of transplantation began to develop, little distinction was made between training and experience because transplantation was a new field in which new experiences facilitated new knowledge and training. As transplantation became more commonplace and mature as a medical specialty, it was necessary to distinguish appropriate experience gained through training as compared to experience gained during clinical practice for the purpose of recognizing well-qualified key personnel. During the initial development of these Bylaws in the late eighties, extensive, closely-supervised training was provided through programs approved by the American Society of Transplant Surgeons (ASTS). This is reflected in the "formal training" criteria adopted by the OPTN/UNOS Board of Directors in 1987, which includes automatic approval of programs approved for training by ASTS.

Although most primary transplant surgeon applicants obtain their fellowship training at an ASTS approved program, the OPTN is prohibited from endorsing a single entity or business due to anti-competitive legal considerations. To avoid these concerns, the Bylaws also include explicit requirements that detail necessary components of a non-ASTS approved surgical training program. These Bylaws provide a means other than through an ASTS-approved fellowship program to qualify as a transplant program's primary surgeon through an OPTN Bylaws training pathway.

As transplantation has grown and evolved, so have the requirements in the key personnel Bylaws. Key personnel Bylaws now include organ specific considerations and a number of more detailed requirements. Although the key personnel requirements have increased in number and rigor, the Bylaws originally adopted in November 1987 that detail what “formal training” entails are quite similar to current Bylaws, including an expectation that transplant training programs are reviewed every five years, or when the program director changes.

The MPSC has raised questions about the requirement to review transplant training programs, recognizing that the MPSC does not perform such reviews, nor has it done so historically. Furthermore, the MPSC believes that the logistics and resources necessary to regularly monitor fellowship training program requirements would be significant, and likely duplicative of fellowship evaluations and accreditations performed by other organizations. The disparity between what is required in the Bylaws and how the MPSC actually operates prompted the Committee to review the Bylaws pertaining to transplant fellowship program approval by the MPSC.

As the majority of the problematic Bylaws regarding transplant fellowship approval pertain to abdominal primary transplant surgeons, and considering ASTS’ role in developing surgical transplant fellowship curriculum, the MPSC engaged ASTS representatives to provide its feedback and recommendations for modifying these Bylaws. Discussion yielded agreement that the scope of the proposed changes should be focused on the elimination of problematic Bylaws language regarding the MPSC review and approval process, and other changes that would streamline these sections of the Bylaws. The proposed Bylaws changes to those sections that pertain to primary kidney transplant surgeons, primary open living donor kidney surgeons, primary liver transplant surgeons, primary pancreas transplant surgeons, and primary intestine transplant surgeons provided at the end of this proposal are the product of the recommendations provided by ASTS.

Of these proposed edits, the most significant is the elimination of the problematic language regarding MPSC review and approval of fellowship programs. The remaining proposed deletions reflect the elimination of duplicative requirements found elsewhere in the Bylaws or requirements that are arbitrary and thus unenforceable. The few instances of proposed new language reflects an attempt to communicate more clearly the remaining requirements in these Bylaws pertaining to surgical transplant fellowships.

Following the review of those Bylaws focused on surgical transplant fellowships, the MPSC proceeded to engage representatives from the American Society of Transplantation (AST) to address similar problematic language found in OPTN Bylaws Appendix E.4.B (Transplant Physician Fellowship Training Programs), which addresses fellowship experience cited by primary kidney transplant physician applicants. Conversations with AST yielded similar changes: elimination of the problematic language regarding MPSC review and approval of transplant nephrology fellowships; elimination of requirements that are arbitrary to evaluate or duplicative of requirements established elsewhere in the Bylaws; and addition of language intended to make the remaining requirements clearer (included in these additions are formatting changes to align the structure of Appendix E.4.B with what is proposed for the those sections that focus on abdominal surgical transplant fellowships).

A few of the proposed changes to OPTN Bylaws Appendix E.4.B cannot be appropriately labeled with any of these general themes, and are detailed further here. First, the volume of kidney transplants that the training program must perform has been modified to align with what is currently required by the AST Adult Transplant Nephrology Fellowship Training Accreditation Program (a similar change is also proposed in OPTN Bylaws Appendix E.3.A.).¹ Additionally, it is proposed that the biopsy requirement in Appendix E.4.B.5 be eliminated. This section focuses on fellowship program requirements, not individual fellow requirements, and the MPSC believes fellow-specific requirements should be removed from this section. This proposal does not include this requirement elsewhere in the Bylaws, as the inclusion of a biopsy requirement was specifically considered, and ultimately not proposed, with the MPSC’s proposal to

¹ <http://www.txnephaccreditation.org/list-eligibility-criteria>

update the primary kidney transplant physician Bylaws that it distributed for public comment during fall 2016, and that the OPTN/UNOS Board of Directors adopted in December 2016.²

Review of these Bylaws by AST also prompted questions about language that requires transplant medicine fellowship curriculum to be approved by the respective Residency Review Committee (RRC) of the Accreditation Council for Graduate Medical Education (ACGME). Nephrologists representing AST indicated that the RRC/ACGME do not have a role in setting transplant fellowship curriculum, to the extent outlined in these Bylaws, for either nephrology or pancreas physicians. Feedback requested from pediatric transplant nephrologists echoed this sentiment as it pertains to pediatric transplant nephrology fellowships. Considering this guidance, the proposal recommends deleting these references to RRC/ACGME curriculum approval in OPTN Bylaws Appendices E.3.A, E.3.D, E.3.E, E.5.C, and G.3.A. It is important to note that this proposal does not include changes to RRC/ACGME program accreditation requirements found in OPTN Bylaws Appendix E.3.C and F.3.C (one reference is deleted in E.3.C, but only because it is duplicative of similar language found earlier in that section that will remain). These sections of the Bylaws establish a training pathway for individuals who completed a three-year pediatric nephrology fellowship and a three-year pediatric gastroenterology fellowship, respectively. As the RRC/ACGME does establish fellowship program requirements for these specialties, the MPSC believes that it is appropriate to retain these references in these sections of the Bylaws.^{3,4}

Finally, although Appendix J (Membership Requirements for Vascularized Composite Allograft (VCA) Transplant Programs) does not include language regarding periodic MPSC review of approved fellowship programs, it does reference fellowship programs that are “approved by the MPSC.” For consistency throughout the Bylaws, edits are proposed to OPTN Bylaws Appendices J.3.A.2.A and J.3.B.2.A to remove references to “MPSC approved” fellowship programs. With these edits, these sections now just focus on what is required of VCA key personnel applicants without additional qualifiers reiterating that fellowship programs meeting these requirements will be accepted/approved by the MPSC.

How well does this proposal address the problem statement?

This proposal completely addresses the disparity between how the MPSC functionally operates and the process currently established in the Bylaws regarding the MPSC’s ongoing review and approval of transplant fellowship programs. Further, the proposed changes preserve the Bylaws’ recognition of ASTS and AST transplant fellowships while still providing a list of transplant fellowship program minimal requirements to accommodate the possibility of other non-ASTS/non-AST transplant fellowships, and with respect to federal anti-competitive statutes.

This proposal could be criticized for proposing the deletion of Bylaws that differ from normal MPSC operations rather than changing the MPSC’s operations such that it adheres to the process established in the Bylaws. The MPSC opted to modify the Bylaws as it did not believe it would be worthwhile for the OPTN to expend the significant resources that would be needed to review transplant fellowship programs regularly. To do so would unnecessarily duplicate the considerable effort and resources that other organizations already invest in this process.

Was this proposal changed in response to public comment?

No. The MPSC voted to send the Bylaws language changes proposed during public comment for the OPTN/UNOS Board of Directors’ final consideration at its December 2017 meeting (34 support, 0 oppose, 0 abstentions).

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:

² https://optn.transplant.hrsa.gov/media/1998/mpsc_brief_kimd_201612.pdf#page=4

³ http://www.acgme.org/Portals/0/PFAssets/ProgramRequirements/328_nephrology_peds_2016.pdf

⁴ http://www.acgme.org/Portals/0/PFAssets/ProgramRequirements/332_gastroenterology_peds_2016.pdf

- *Support for the proposal.*
 - This was the predominant response, including support from all eleven regions, AST, ASTS, and NATCO. The MPSC indicated its appreciation for these commenters' review and support of the proposal.
- *An individual commenter stated that requiring that the fellowship program is at an institution that has an ACGME approved training program in general surgery or nephrology is unnecessary as long as the program has been approved for training by the American Society of Transplant Surgeons (AST), American Society of Transplantation (AST) Adult Transplant Nephrology Fellowship Training Program, or the Royal College of Physicians and Surgeons of Canada (RCPSC).*
 - The MPSC appreciates the commenter's review of this proposal. It is important to note that the requirement that a fellowship training program be at an institution that has ACGME approval in general surgery or nephrology specifically applies to those fellowship programs that *are not* approved by ASTS, AST Adult Transplant Nephrology Fellowship Training Program, or RCPSC. Because the OPTN is prohibited from endorsing specific entities or businesses, these additional fellowship training program requirements are necessary so that a transplant program key personnel applicant has the option of qualifying through one of the fellowship pathways in the Bylaws without necessarily having completed their training at an program approved by ASTS, AST Adult Transplant Nephrology Fellowship Training Program, or RCPSC. Key personnel applicants applying through one of the Bylaws' fellowship training pathways who did not perform their fellowship training at an ASTS, AST Adult Transplant Nephrology Fellowship Training Program, or RCPSC approved fellowship program must have obtained their fellowship training at an institution with ACGME approval, in addition to the other requirements specified in the proposed Bylaws.

Which populations are impacted by this proposal?

There will be no direct impact to any populations of the transplant community. This proposal addresses Bylaws that establish an MPSC operational action that has historically not been performed. Adopting this proposal will effectively align the Bylaws with how the MPSC currently operates with respects to evaluating key personnel applicants applying through one of the Bylaws' training pathways.

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:* There is no impact to this goal.
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* There is no impact to this goal.
4. *Promote living donor and transplant recipient safety:* There is no impact to this goal.
5. *Promote the efficient management of the OPTN:* The efficient management of the OPTN is supported through these proposed changes by aligning the Bylaws with how the MPSC functionally operates with regards to the focus of this proposal and by increasing the consistency of key personnel requirements across all transplant program types.

How will the OPTN implement this proposal?

The MPSC will present these changes for the OPTN/UNOS Board of Directors' consideration at its December 2017 meeting. Assuming the Board adopts these changes, they would become effective on March 1, 2018.

Implementing the changes detailed in this proposal will align the Bylaws with how the MPSC currently operates when evaluating key personnel applicants who have applied through a “fellowship pathway.” As such, the OPTN’s implementation effort will primarily consist of updating the Bylaws found on the OPTN website on the effective date of these changes.

How will members implement this proposal?

No action will be required of members upon the implementation of these proposed Bylaws changes.

Will this proposal require members to submit additional data?

No, this proposal does not require additional data collection.

How will members be evaluated for compliance with this proposal?

This proposal primarily eliminates Bylaws that pertain to MPSC approval of fellowship training programs. Compliance with remaining Bylaws will be expected, but there are no member compliance considerations that directly result from these changes.

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

Considering the primary problem driving these proposed changes is operational in nature, deleting Bylaws as recommended in this proposal will successfully address this problem. Nevertheless, the MPSC will monitor if these changes yield consequences that it did not anticipate. Should any unanticipated negative consequences be realized, the MPSC would work towards another solution that corrects those.

1 Policy or Bylaws Language

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

2 **RESOLVED**, that changes to Bylaws E.2.A (Formal 2-year Transplant Fellowship Pathway), E.3.A
3 (Transplant Nephrology Fellowship Pathway), E.3.C (Three-year Pediatric Nephrology Fellowship
4 Pathway), E.3.D (Twelve-month Pediatric Transplant Nephrology Fellowship Pathway), E.3.E
5 (Combined Pediatric Nephrology Training and Experience Pathway), E.4.A (Transplant Surgeon
6 Fellowship Training Programs), E.4.B (Transplant Physician Fellowship Training Programs), E.5.C
7 (Conditional Approval for a Pediatric Component), E.6.D(Primary Open Living Donor Kidney
8 Surgeon), F.3.A (Formal 2-year Transplant Fellowship Pathway), F.6 (Approved Liver Surgeon
9 Transplant Fellowship Programs), F.11.A (Full Intestine Surgeon Approval Pathway), F.14
10 (Approved Intestine Surgeon Transplant Fellowship Programs), G.2.A (Formal 2-year Transplant
11 Fellowship Pathway), G.3.A (Twelve-month Transplant Medicine Fellowship Pathway), G.7
12 (Approved Pancreas Transplant Surgeon Fellowship Training Programs), J.3.A (Additional
13 Primary Surgeon Requirements for Upper Limb Transplant Programs), and J.3.B (Additional
14 Primary Surgeon Requirements for Head and Neck Transplant Programs), as set forth below, are
15 hereby approved, effective pending implementation and notice to OPTN members.
16

17 E.2 Primary Kidney Transplant Surgeon Requirements

18 A. Formal 2-year Transplant Fellowship Pathway

19 Surgeons can meet the training requirements for primary kidney transplant surgeon by
20 completing a formal 2-year surgical transplant fellowship if the following conditions are met:
21

- 22 1. The surgeon performed at least 30 kidney transplants as the primary surgeon or first
23 assistant during the 2-year fellowship period. These transplants must be documented in the
24 surgeon's fellowship operative log. The date of transplant, the role of the surgeon in the
25 procedure, the medical record number or other unique identifier that can be verified by the
26 OPTN Contractor, and the fellowship director's signature must be provided with this log.
- 27 2. The surgeon performed at least 15 kidney procurements as primary surgeon or first assistant.
28 At least 10 of these procurements must be from deceased donors. These procurements must
29 have been performed anytime during the surgeon's fellowship and the two years immediately
30 following fellowship completion. These procedures must be documented in the surgeon's
31 fellowship operative log. The date of procurement and Donor ID must be provided with this
32 log.
- 33 3. The surgeon has maintained a current working knowledge of kidney transplantation, defined
34 as direct involvement in kidney transplant patient care in the last 2 years. This includes the
35 management of patients with end stage renal disease, the selection of appropriate recipients
36 for transplantation, donor selection, histocompatibility and tissue typing, performing the
37 transplant operation, immediate postoperative and continuing inpatient care, the use of
38 immunosuppressive therapy including side effects of the drugs and complications of
39 immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient,
40 histological interpretation of allograft biopsies, interpretation of ancillary tests for renal
41 dysfunction, and long term outpatient care.
- 42 4. This training was completed at a hospital with a kidney transplant training program approved
43 by ~~the Fellowship Training Committee~~ of the American Society of Transplant Surgeons, the
44 Royal College of Physicians and Surgeons of Canada, or another recognized surgical
45 fellowship training program accepted by the OPTN Contractor as described in the *Section E.4*

46 *Approved Kidney Transplant Surgeon and Physician Fellowship Training Programs* that
47 follows.

- 48 5. The following letters are submitted directly to the OPTN Contractor:
- 49 a. A letter from the director of the training program and chairman of the department or
50 hospital credentialing committee verifying that the surgeon has met the above
51 requirements and is qualified to direct a kidney transplant program.
- 52 b. A letter of recommendation from the fellowship training program's primary surgeon and
53 transplant program director outlining the surgeon's overall qualifications to act as a
54 primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and
55 familiarity with and experience in adhering to OPTN obligations, and any other matters
56 judged appropriate. The MPSC may request additional recommendation letters from the
57 primary physician, primary surgeon, director, or others affiliated with any transplant
58 program previously served by the surgeon, at its discretion.
- 59 c. A letter from the surgeon that details the training and experience the surgeon has gained
60 in kidney transplantation.
- 61

62 **E.3 Primary Kidney Transplant Physician Requirements**

63 **A. Transplant Nephrology Fellowship Pathway**

64 Physicians can meet the training requirements for a primary kidney transplant physician during a
65 separate transplant nephrology fellowship if the following conditions are met:

66

- 67 1. The physician completed at least 12 consecutive months of specialized training in
68 transplantation under the direct supervision of a qualified kidney transplant physician and
69 along with a kidney transplant surgeon at a kidney transplant program that performs ~~30~~ 50 or
70 more transplants each year. The training must have included at least 6 months of clinical
71 inpatient transplant service. The remaining time must have consisted of transplant-related
72 experience, such as experience in a tissue typing laboratory, on another solid organ
73 transplant service, or conducting basic or clinical transplant research.
- 74 2. During the fellowship period, the physician was directly involved in the primary care of 30 or
75 more newly transplanted kidney recipients and continued the outpatient follow-up of these
76 recipients for a minimum of 3 months from the time of transplant. If the physician's fellowship
77 was longer than 12 months, the physician also must have been directly involved in the
78 outpatient follow-up of at least 30 kidney recipients for an additional period of 3 consecutive
79 months. The care must be documented in a log that includes the date of transplant and the
80 recipient medical record number or other unique identifier that can be verified by the OPTN
81 Contractor. This recipient log must be signed by the director of the training program or the
82 transplant program's primary transplant physician.
- 83 3. During the fellowship period, the physician was directly involved in the evaluation of 25
84 potential kidney recipients, including participation in selection committee meetings. These
85 potential kidney recipient evaluations must be documented in a log that includes each
86 evaluation date and is signed by the director of the training program or the transplant
87 program's primary transplant physician.
- 88 4. During the fellowship period, the physician was directly involved in the evaluation of 10
89 potential living kidney donors, including participation in selection committee meetings. These
90 potential living kidney donor evaluations must be documented in a log that includes each
91 evaluation date and the potential living kidney donor's medical record number or other unique
92 identifier than can be verified by the OPTN Contractor. This potential living kidney donor

- 93 evaluation log must be signed by the director of the training program or the transplant
94 program's primary transplant physician.
- 95 5. The physician has maintained a current working knowledge of kidney transplantation, defined
96 as direct involvement in kidney transplant care in the last 2 years. This includes the
97 management of patients with end stage renal disease, the selection of appropriate recipients
98 for transplantation, donor selection, histocompatibility and tissue typing, immediate
99 postoperative patient care, the use of immunosuppressive therapy including side effects of
100 the drugs and complications of immunosuppression, differential diagnosis of renal
101 dysfunction in the allograft recipient, histological interpretation of allograft biopsies,
102 interpretation of ancillary tests for renal dysfunction, and long term outpatient care. ~~The~~
103 ~~curriculum for obtaining this knowledge should be approved by the Residency Review~~
104 ~~Committee for Internal Medicine (RRC-IM) of the Accreditation Council for Graduate Medical~~
105 ~~Education (ACGME).~~
- 106 6. The physician must have observed at least 3 kidney procurements, including at least 1
107 deceased donor and 1 living donor. The physician must have observed the evaluation,
108 donation process, and management of these donors. These observations must be
109 documented in a log that includes the date of procurement and Donor ID.
- 110 7. The physician must have observed at least 3 kidney transplants. The observation of these
111 transplants must be documented in a log that includes the transplant date, donor type, and
112 medical record number or other unique identifier that can be verified by the OPTN Contractor.
- 113 8. The following letters are submitted directly to the OPTN Contractor:
- 114 a. A letter from the director of the training program and the supervising qualified kidney
115 transplant physician verifying that the physician has met the above requirements and is
116 qualified to direct a kidney transplant program.
- 117 b. A letter of recommendation from the fellowship training program's primary physician and
118 transplant program director outlining the physician's overall qualifications to act as a
119 primary transplant physician, as well as the physician's personal integrity, honesty, and
120 familiarity with and experience in adhering to OPTN obligations and compliance
121 protocols, and any other matters judged appropriate. The MPSC may request additional
122 recommendation letters from the primary physician, primary surgeon, director, or others
123 affiliated with any transplant program previously served by the physician, at its discretion.
- 124 c. A letter from the physician that details the training and experience the physician has
125 gained in kidney transplantation.

126
127 The training requirements outlined above are in addition to other clinical requirements for general
128 nephrology training.
129

130 **C. Three-year Pediatric Nephrology Fellowship Pathway**

131 A physician can meet the requirements for primary kidney transplant physician by completion of 3
132 years of pediatric nephrology fellowship training as required by the American Board of Pediatrics
133 in a program accredited by the Residency Review Committee for Pediatrics (RRC-Ped) of the
134 ACGME. The training must contain at least 6 months of clinical care for transplant patients, and
135 the following conditions must be met:

- 136
137 1. During the 3-year training period the physician was directly involved in the primary care of 10
138 or more newly transplanted kidney recipients for at least 6 months from the time of transplant
139 and followed 30 transplanted kidney recipients for at least 6 months, under the direct
140 supervision of a qualified kidney transplant physician and in conjunction with a qualified
141 kidney transplant surgeon. The pediatric nephrology program director may elect to have a

- 142 portion of the transplant experience completed at another kidney transplant program in order
143 to meet these requirements. This care must be documented in a log that includes the date of
144 transplant, and the recipient medical record number or other unique identifier that can be
145 verified by the OPTN Contractor. This recipient log must be signed by the training program's
146 director or the primary physician of the transplant program.
- 147 2. The experience caring for pediatric patients occurred with a qualified kidney transplant
148 physician and surgeon at a kidney transplant program that performs an average of at least 10
149 pediatric kidney transplants a year.
 - 150 3. During the fellowship period, the physician was directly involved in the evaluation of 25
151 potential kidney recipients, including participation in selection committee meetings. These
152 potential kidney recipient evaluations must be documented in a log that includes each
153 evaluation date and is signed by the director of the training program or the transplant
154 program's primary transplant physician.
 - 155 4. The physician has maintained a current working knowledge of kidney transplantation, defined
156 as direct involvement in kidney transplant patient care over the last 2 years. This includes the
157 management of pediatric patients with end-stage renal disease, the selection of appropriate
158 pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing,
159 immediate post-operative care including those issues of management unique to the pediatric
160 recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the
161 pediatric recipient including side-effects of drugs and complications of immunosuppression,
162 the effects of transplantation and immunosuppressive agents on growth and development,
163 differential diagnosis of renal dysfunction in the allograft recipient, manifestation of rejection
164 in the pediatric patient, histological interpretation of allograft biopsies, interpretation of
165 ancillary tests for renal dysfunction, and long-term outpatient care of pediatric allograft
166 recipients including management of hypertension, nutritional support, and drug dosage,
167 including antibiotics, in the pediatric patient. ~~The curriculum for obtaining this knowledge must
168 be approved by the Residency Review Committee (RRC) - Ped of the ACGME.~~
 - 169 5. The physician must have observed at least 3 kidney procurements, including at least 1
170 deceased donor and 1 living donor. The physician must have observed the evaluation,
171 donation process and management of these donors. These observations must be
172 documented in a log that includes the date of procurement and Donor ID.
 - 173 6. The physician must have observed at least 3 kidney transplants involving a pediatric
174 recipient. The observation of these transplants must be documented in a log that includes the
175 transplant date, donor type, and medical record number or other unique identifier that can be
176 verified by the OPTN Contractor.
 - 177 7. The following letters are submitted directly to the OPTN Contractor:
 - 178 a. A letter from the director and the supervising qualified transplant physician and surgeon
179 of the fellowship training program verifying that the physician has met the above
180 requirements and is qualified to direct a kidney transplant program.
 - 181 b. A letter of recommendation from the fellowship training program's primary physician and
182 transplant program director outlining the physician's overall qualifications to act as a
183 primary transplant physician, as well as the physician's personal integrity, honesty, and
184 familiarity with and experience in adhering to OPTN obligations, and any other matters
185 judged appropriate. The MPSC may request additional recommendation letters from the
186 primary physician, primary surgeon, director, or others affiliated with any transplant
187 program previously served by the physician, at its discretion.
 - 188 c. A letter from the physician that details the training and experience the physician has
189 gained in kidney transplantation.
- 190

191 **D. Twelve-month Pediatric Transplant Nephrology Fellowship**
 192 **Pathway**

193 The requirements for the primary kidney transplant physician can be met during a separate
 194 pediatric transplant nephrology fellowship if the following conditions are met:

- 195
- 196 1. The physician has current board certification in pediatric nephrology by the American Board
 197 of Pediatrics, the Royal College of Physicians and Surgeons of Canada, or is approved by
 198 the American Board of Pediatrics to take the certifying exam.
 - 199 2. During the fellowship, the physician was directly involved in the primary care of 10 or more
 200 newly transplanted kidney recipients for at least 6 months from the time of transplant and
 201 followed 30 transplanted kidney recipients for at least 6 months, under the direct supervision
 202 of a qualified kidney transplant physician and in conjunction with a qualified kidney transplant
 203 surgeon. The pediatric nephrology program director may elect to have a portion of the
 204 transplant experience completed at another kidney transplant program in order to meet these
 205 requirements. This care must be documented in a recipient log that includes the date of
 206 transplant, and the recipient medical record number or other unique identifier that can be
 207 verified by the OPTN Contractor. This log must be signed by the training program director or
 208 the primary physician of the transplant program.
 - 209 3. The experience in caring for pediatric patients occurred at a kidney transplant program with a
 210 qualified kidney transplant physician and surgeon that performs an average of at least 10
 211 pediatric kidney transplants a year.
 - 212 4. During the four years that include the physician's three-year pediatric nephrology fellowship
 213 and twelve-month pediatric transplant nephrology fellowship, the physician was directly
 214 involved in the evaluation of 25 potential kidney recipients, including participation in selection
 215 committee meetings. These potential kidney recipient evaluations must be documented in a
 216 log that includes each evaluation date and is signed by the director of the training program or
 217 the transplant program's primary transplant physician.
 - 218 5. The physician has maintained a current working knowledge of kidney transplantation, defined
 219 as direct involvement in kidney transplant patient care in the past 2 years. This includes the
 220 management of pediatric patients with end-stage renal disease, the selection of appropriate
 221 pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing,
 222 immediate post-operative care including those issues of management unique to the pediatric
 223 recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the
 224 pediatric recipient including side-effects of drugs and complications of immunosuppression,
 225 the effects of transplantation and immunosuppressive agents on growth and development,
 226 differential diagnosis of renal dysfunction in the allograft recipient, manifestation of rejection
 227 in the pediatric patient, histological interpretation of allograft biopsies, interpretation of
 228 ancillary tests for renal dysfunction, and long-term outpatient care of pediatric allograft
 229 recipients including management of hypertension, nutritional support, and drug dosage,
 230 including antibiotics, in the pediatric patient. ~~The curriculum for obtaining this knowledge must
 231 be approved by the Residency Review Committee (RRC) - Ped of the ACGME.~~
 - 232 6. The physician must have observed at least 3 kidney procurements, including at least 1
 233 deceased donor and 1 living donor. The physician must have observed the evaluation,
 234 donation process, and management of these donors. These observations must be
 235 documented in a log that includes the date of procurement and Donor ID.
 - 236 7. The physician must have observed at least 3 kidney transplants involving a pediatric
 237 recipient. The observation of these transplants must be documented in a log that includes the

238 transplant date, donor type, and medical record number or other unique identifier that can be
239 verified by the OPTN Contractor.

- 240 8. The following letters are submitted directly to the OPTN Contractor:
- 241 a. A letter from the director and the supervising qualified transplant physician and surgeon
 - 242 of the fellowship training program verifying that the physician has met the above
 - 243 requirements and is qualified to become the primary transplant physician of a designated
 - 244 kidney transplant program.
 - 245 b. A letter of recommendation from the fellowship training program's primary physician and
 - 246 transplant program director outlining the physician's overall qualifications to act as a
 - 247 primary transplant physician, as well as the physician's personal integrity, honesty, and
 - 248 familiarity with and experience in adhering to OPTN obligations, and any other matters
 - 249 judged appropriate. The MPSC may request additional recommendation letters from the
 - 250 primary physician, primary surgeon, director, or others affiliated with any transplant
 - 251 program previously served by the physician, at its discretion.
 - 252 c. A letter from the physician that details the training and experience the physician has
 - 253 gained in kidney transplantation.

254 **E. Combined Pediatric Nephrology Training and Experience Pathway**

256 A physician can meet the requirements for primary kidney transplant physician if the following
257 conditions are met:

- 258 1. The physician has current board certification in pediatric nephrology by the American Board
- 259 of Pediatrics, the Royal College of Physicians and Surgeons of Canada, or is approved by
- 260 the American Board of Pediatrics to take the certifying exam.
- 261 2. The physician gained a minimum of 2 years of experience during or after fellowship, or
- 262 accumulated during both periods, at a kidney transplant program.
- 263 3. During the 2 or more years of accumulated experience, the physician was directly involved in
- 264 the primary care of 10 or more newly transplanted kidney recipients for at least 6 months
- 265 from the time of transplant and followed 30 transplanted kidney recipients for at least 6
- 266 months, under the direct supervision of a qualified kidney transplant physician, along with a
- 267 qualified kidney transplant surgeon. This care must be documented in a recipient log that
- 268 includes the date of transplant, and the recipient medical record number or other unique
- 269 identifier that can be verified by the OPTN Contractor. This log must be signed by the training
- 270 program director or the primary physician of the transplant program.
- 271 4. The physician was directly involved in the evaluation of 25 potential kidney recipients,
- 272 including participation in selection committee meetings. These potential kidney recipient
- 273 evaluations must be documented in a log that includes each evaluation date and be signed by
- 274 the program director, division Chief, or department Chair from the program where the
- 275 physician gained this experience.
- 276 5. The physician has maintained a current working knowledge of kidney transplantation, defined
- 277 as direct involvement in kidney transplant patient care during the past 2 years. This includes
- 278 the management of pediatric patients with end-stage renal disease, the selection of
- 279 appropriate pediatric recipients for transplantation, donor selection, histocompatibility and
- 280 tissue typing, immediate post-operative care including those issues of management unique to
- 281 the pediatric recipient, fluid and electrolyte management, the use of immunosuppressive
- 282 therapy in the pediatric recipient including side-effects of drugs and complications of
- 283 immunosuppression, the effects of transplantation and immunosuppressive agents on growth
- 284 and development, differential diagnosis of renal dysfunction in the allograft recipient,
- 285

- 286 manifestation of rejection in the pediatric patient, histological interpretation of allograft
287 biopsies, interpretation of ancillary tests for renal dysfunction, and long-term outpatient care
288 of pediatric allograft recipients including management of hypertension, nutritional support,
289 and drug dosage, including antibiotics, in the pediatric patient. ~~The curriculum for obtaining
290 this knowledge must be approved by the Residency Review Committee (RRC) – Ped of the
291 ACGME or a Residency Review Committee.~~
- 292 6. The physician must have observed at least 3 kidney procurements, including at least 1
293 deceased donor and 1 living donor. The physician must have observed the evaluation,
294 donation process, and management of these donors. These observations must be
295 documented in a log that includes the date of procurement and Donor ID.
 - 296 7. The physician must have observed at least 3 kidney transplants involving a pediatric
297 recipient. The observation of these transplants must be documented in a log that includes the
298 transplant date, donor type, and medical record number or other unique identifier that can be
299 verified by the OPTN Contractor.
 - 300 8. The following letters are submitted directly to the OPTN Contractor:
 - 301 a. A letter from the supervising qualified transplant physician and surgeon who were directly
302 involved with the physician documenting the physician's experience and competence.
 - 303 b. A letter of recommendation from the fellowship training program's primary physician and
304 transplant program director outlining the physician's overall qualifications to act as a
305 primary transplant physician, as well as the physician's personal integrity, honesty, and
306 familiarity with and experience in adhering to OPTN obligations, and any other matters
307 judged appropriate. The MPSC may request additional recommendation letters from the
308 primary physician, primary surgeon, Director, or others affiliated with any transplant
309 program previously served by the physician, at its discretion.
 - 310 c. A letter from the physician that details the training and experience the physician has
311 gained in kidney transplantation.

313 **E.4 Approved Kidney Transplant Surgeon and Physician Fellowship Training** 314 **Programs**

315 **A. Transplant Surgeon Fellowship Training Programs**

316 Surgeons qualifying as primary transplant surgeon based on completion of a formal 2-year formal
317 surgical transplant fellowship must complete their training at a fellowship program approved by
318 the American Society of Transplant Surgeons, the Royal College of Physicians and Surgeons of
319 Canada, or another recognized fellowship training program accepted by the OPTN Contractor
320 MPSC. Any program approved for training by the Fellowship Training Committee of the American
321 Society of Transplant Surgeons is automatically accepted by the MPSC, as well as any program
322 that meets the following criteria:

- 323
- 324 1. The program is at a transplant hospital that transplants one or more organs, including
325 kidneys.
- 326 2. The program is at an institution that has ACGME approved training in general surgery-a
327 proven commitment to graduate medical education.
- 328 ~~3. The program director is a board-certified surgeon who meets the OPTN Contractor~~
329 ~~requirements for primary kidney transplant surgeon.~~
- 330 ~~4. The program is at a hospital that is affiliated with a histocompatibility laboratory that meets~~
331 ~~the OPTN Contractor requirements for histocompatibility laboratories.~~

332 ~~5. The program is at a hospital that is affiliated with an organ procurement organization (OPO)~~
333 ~~that meets the OPTN Contractor requirements for OPOs.~~

334 ~~63. The program performs at least 60 kidney transplants during each year of the fellowship~~
335 ~~training from deceased or living donors.~~

336 ~~7. The program has the resources, including adequate clinical facilities, laboratory research~~
337 ~~facilities, and appropriately trained faculty and staff, to provide research experience.~~

338

339 ~~Training programs are reviewed by the MPSC every 5 years or any time the program director~~
340 ~~changes. If a program has no fellows during the 5 years between reviews, it must re-apply as a~~
341 ~~new program.~~

342

343 **B. Transplant Physician Fellowship Training Programs**

344 ~~A formal training program for primary kidney transplant physicians requires that training must be~~
345 ~~completed at a program approved by the MPSC. Any training program approved by the AST~~
346 ~~Adult Renal Transplant Training Accreditation Program is automatically accepted by the MPSC,~~
347 ~~as well as any program that meets the following criteria:~~

348 ~~Physicians qualifying as primary transplant physician based on completion of a formal transplant~~
349 ~~fellowship must complete their training at a fellowship program approved by the American Society~~
350 ~~of Transplantation Adult Transplant Nephrology Fellowship Training Program, the Royal College~~
351 ~~of Physicians and Surgeons of Canada, or another recognized fellowship training program~~
352 ~~accepted by the OPTN Contractor that meets the following criteria:~~

353

354 ~~1. The program is at a transplant hospital that transplants one or more organs, including~~
355 ~~kidneys. must be OPTN approved as a kidney transplant program and be affiliated with an~~
356 ~~ACGME approved nephrology program. Transplant programs that are not OPTN approved or~~
357 ~~affiliated with an ACGME approved nephrology program will be evaluated on a case-by-case~~
358 ~~basis.~~

359 ~~2. The program is at a hospital that has an ACGME approved nephrology program.~~

360 ~~23. The program performs at least 50 kidney transplants per year if the program is training one~~
361 ~~transplant nephrology fellow, and performs at least 30 additional kidney transplants per year~~
362 ~~for each additional fellow it trains. The program must perform at least 10 kidney transplants~~
363 ~~per year for each first year, general nephrology fellow in training and an additional 30~~
364 ~~transplants per year for each kidney transplant fellow to be trained.~~

365 ~~34. The program's must have a full-time faculty member or members capable of teaching a~~
366 ~~curriculum with a broad base of knowledge in transplant medicine. The curriculum must~~
367 ~~include training and experience in end-stage renal disease, training in the selection of~~
368 ~~appropriate transplant recipients and donors, experience in the immediate and long term care~~
369 ~~of the transplant recipient, and training in the performance of kidney transplant biopsies.~~
370 ~~Additionally there must be an emphasis on the management of immunosuppressive agents~~
371 ~~and the evaluation of kidney transplant dysfunction. Combined surgical and medical rounds~~
372 ~~should be conducted on a regular basis.~~

373 ~~45. The program must provide patient co-management responsibility with transplant surgeons~~
374 ~~from the peri-operative through the outpatient period. The kidney trainee must primarily~~
375 ~~manage the transplant recipient's medical care including hypertension, diabetes, and dialytic~~
376 ~~problems. Trainees must also serve as a primary member of the transplant team and~~
377 ~~participate in making decisions about immunosuppression. The transplant renal fellow must~~
378 ~~be primarily responsible for 30 in-patient renal transplant recipients and 30 outpatient~~
379 ~~recipients over a period of 12 months. Outpatient follow-up must be continuous for a~~

380 ~~minimum of at least 3 months. Training must be completed within 12 continuous months; a~~
381 ~~minimum of 6 months of training must be performed in inpatient clinical service.~~

382 ~~5. The transplant nephrology fellow must perform a minimum of 10 transplant biopsies during~~
383 ~~the training period.~~

384 ~~6. The transplant nephrology fellow must observe at least 3 kidney transplants and at least 3~~
385 ~~procurement procedures.~~

386

387 **E.5 Kidney Transplant Programs that Register Candidates Less than 18 Years** 388 **Old**

389 **C. Conditional Approval for a Pediatric Component**

390 A designated kidney transplant program can obtain conditional approval for a pediatric
391 component if *either* of the following conditions is met:

392

393 1. The program has a qualified primary pediatric kidney physician who meets *all* of the
394 requirements described in *Section E.5.B: Primary Pediatric Kidney Transplant Physician*
395 *Requirements* and a surgeon who meets *all* of the following requirements:

396

397 a. The surgeon meets all of the requirements described in *Section E.2: Primary Kidney*
398 *Transplant Surgeon Requirements*, including completion of at least one of the following
399 training or experience pathways:

400

- The formal 2-year transplant fellowship pathway as described in *Section E.2.A:*
401 *Formal 2-year Transplant Fellowship Pathway*

402

- The kidney transplant program clinical experience pathway, as described in *Section*
403 *E.2.B: Clinical Experience Pathway*

404

405 b. The surgeon has performed at least 5 kidney transplants, as the primary surgeon or first
406 assistant, in recipients less than 18 years old at the time of transplant. At least 1 of these
407 kidney transplants must have been in recipients less than 6 years old or weighing less
408 than 25 kilograms at the time of transplant. These transplants must have been performed
409 during or after fellowship, or across both periods. These transplants must be documented
410 in a log that includes the date of transplant, the recipient's date of birth, the recipient's
411 weight at transplant if less than 25 kilograms, the role of the surgeon in the procedure,
412 and the medical record number or other unique identifier that can be verified by the
413 OPTN Contractor.

414 c. The surgeon has maintained a current working knowledge of pediatric kidney
415 transplantation, defined as direct involvement in pediatric kidney transplant patient care in
416 the last 2 years. This includes the management of pediatric patients with end stage renal
417 disease, the selection of appropriate pediatric recipients for transplantation, donor
418 selection, histocompatibility and HLA typing, performing the pediatric transplant
419 operation, immediate postoperative and continuing inpatient care, the use of
420 immunosuppressive therapy including side effects of the drugs and complications of
421 immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient,
422 histological interpretation of allograft biopsies, interpretation of ancillary tests for renal
423 dysfunction, and long term outpatient care.

424

425 2. The program has a qualified primary pediatric kidney surgeon who meets *all* of the
426 requirements described in *Section E.5.A: Primary Pediatric Kidney Transplant Surgeon*
427 *Requirements* and a physician who meets *all* of the following requirements:

428

429 a. The physician has current board certification in pediatric nephrology by the American
430 Board of Pediatrics or the foreign equivalent, or is approved by the American Board of
431 Pediatrics to take the certifying exam.

- 432 b. The physician gained a minimum of 2 years of experience during or after fellowship, or
433 accumulated during both periods, at a kidney transplant program.
- 434 c. During the 2 or more years of accumulated experience, the physician was directly
435 involved in the primary care of 5 or more newly transplanted kidney recipients and
436 followed 15 newly transplanted kidney recipients for at least 6 months from the time of
437 transplant, under the direct supervision of a qualified kidney transplant physician, along
438 with a qualified kidney transplant surgeon. This care must be documented in a recipient
439 log that includes the date of transplant and the recipient medical record number or other
440 unique identifier that can be verified by the OPTN Contractor. This log must be signed by
441 the training program director or the primary physician of the transplant program.
- 442 d. The physician has maintained a current working knowledge of pediatric kidney
443 transplantation, defined as direct involvement in kidney transplant patient care during the
444 past 2 years. This includes the management of pediatric patients with end-stage renal
445 disease, the selection of appropriate pediatric recipients for transplantation, donor
446 selection, histocompatibility and HLA typing, immediate post-operative care including
447 those issues of management unique to the pediatric recipient, fluid and electrolyte
448 management, the use of immunosuppressive therapy in the pediatric recipients including
449 side-effects of drugs and complications of immunosuppression, the effects of
450 transplantation and immunosuppressive agents on growth and development, differential
451 diagnosis of renal dysfunction in the allograft recipient, manifestation of rejection in the
452 pediatric patient, histological interpretation of allograft biopsies, interpretation of ancillary
453 tests for renal dysfunction, and long-term outpatient care of pediatric allograft recipients
454 including management of hypertension, nutritional support, and drug dosage, including
455 antibiotics, in the pediatric patient. ~~The curriculum for obtaining this knowledge must be
456 approved by the Residency Review Committee (RRC) — Ped of the ACGME or a
457 Residency Review Committee.~~
- 458 e. The physician should have observed at least 3 organ procurements and 3 pediatric
459 kidney transplants. The physician should also have observed the evaluation, the donation
460 process, and management of at least 3 multiple organ donors who donated a kidney. If
461 the physician has completed these observations, they must be documented in a log that
462 includes the date of procurement and Donor ID.
- 463 f. The following letters are submitted directly to the OPTN Contractor:
 - 464 i. A letter from the supervising qualified transplant physician and surgeon who were
465 directly involved with the physician documenting the physician's experience and
466 competence.
 - 467 ii. A letter of recommendation from the fellowship training program's primary physician
468 and transplant program director outlining the physician's overall qualifications to act
469 as a primary transplant physician, as well as the physician's personal integrity,
470 honesty, and familiarity with and experience in adhering to OPTN obligations, and
471 any other matters judged appropriate. The MPSC may request additional
472 recommendation letters from the primary pediatric surgeon, Director, or others
473 affiliated with any transplant program previously served by the physician, at its
474 discretion.
 - 475 iii. A letter from the physician that details the training and experience the physician has
476 gained in kidney transplantation.

477
478 A designated kidney transplant program's conditional approval for a pediatric component is
479 valid for a maximum of 24 months.
480

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

482 **D. Primary Open Living Donor Kidney Surgeon**

483 A kidney donor surgeon who performs open living donor nephrectomies must be on site and must
484 meet *one* of the following criteria:
485

- 486 ■ ~~Completion of an accredited American Society of Transplant Surgeons (ASTS) a formal 2-~~
 487 ~~year surgical transplant fellowship with in kidney certification at a fellowship program~~
 488 ~~approved by the American Society of Transplant Surgeons, the Royal College of Physicians~~
 489 ~~and Surgeons of Canada, or other recognized fellowship training program accepted by the~~
 490 ~~OPTN Contractor as described in Section E.4.A: Transplant Surgeon Fellowship Training~~
 491 ~~Programs.~~
- 492 ■ Completion of at least 10 open nephrectomies, including deceased donor nephrectomies or
 493 the removal of diseased kidneys, as primary surgeon, co-surgeon, or first assistant. At least 5
 494 of these open nephrectomies must have been performed as the primary surgeon or co-
 495 surgeon. The open nephrectomies must be documented in a log that includes the date of
 496 recovery, the role of the surgeon in the procedure, the type of procedure (open or
 497 laparoscopic), and the medical record number or Donor ID.

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

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

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

- 503
- 504 1. The surgeon performed at least 45 liver transplants as primary surgeon or first assistant
 505 during the 2-year fellowship period. These transplants must be documented in the surgeon's
 506 fellowship operative log. The date of transplant, the role of the surgeon in the procedure, the
 507 medical record number or other unique identifier that can be verified by the OPTN Contractor,
 508 and the fellowship director's signature must be provided with this log.
 - 509 2. The surgeon performed at least 20 liver procurements as primary surgeon or first assistant.
 510 These procurements must have been performed anytime during the surgeon's fellowship and
 511 the two years immediately following fellowship completion. These procedures must be
 512 documented in the surgeon's fellowship operative log. The date of procurement and Donor ID
 513 must be provided with this log.
 - 514 3. The surgeon has maintained a current working knowledge of liver transplantation, defined as
 515 direct involvement in liver transplant patient care within the last 2 years. This includes the
 516 management of patients with end stage liver disease, the selection of appropriate recipients
 517 for transplantation, donor selection, histocompatibility and tissue typing, performing the
 518 transplant operation, immediate postoperative and continuing inpatient care, the use of
 519 immunosuppressive therapy including side effects of the drugs and complications of
 520 immunosuppression, differential diagnosis of liver allograft dysfunction, histologic
 521 interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and
 522 long term outpatient care.
 - 523 4. The training was completed at a hospital with a liver transplant training program approved by
 524 the ~~Fellowship Training Committee~~ of the American Society of Transplant Surgeons, the
 525 Royal College of Physicians and Surgeons of Canada, or another recognized fellowship
 526 training program accepted by the OPTN Contractor as described in *Section F.6: Approved*
 527 *Liver Surgeon Transplant Fellowship Programs* that follows.
 - 528 5. The following letters are submitted directly to the OPTN Contractor:
 - 529 a. A letter from the director of the training program verifying that the surgeon has met the
 530 above requirements, and is qualified to direct a liver transplant program.
 - 531 b. A letter of recommendation from the fellowship training program's primary surgeon and
 532 transplant program director outlining the surgeon's overall qualifications to act as primary

- 533 transplant surgeon, as well as the surgeon's personal integrity, honesty, familiarity with
534 and experience in adhering to OPTN obligations, and other matters judged appropriate.
535 The MPSC may request additional recommendation letters from the primary physician,
536 primary surgeon, director, or others affiliated with any transplant program previously
537 served by the surgeon, at its discretion.
- 538 c. A letter from the surgeon that details his or her training and experience in liver
539 transplantation.

541 **F.6 Approved Liver Surgeon Transplant Fellowship Programs**

542 Surgeons qualifying as primary transplant surgeon based on completion of a formal 2-year formal surgical
543 transplant fellowship must complete their training at a fellowship program approved by the American
544 Society of Transplant Surgeons, the Royal College of Physicians and Surgeons of Canada, or another
545 recognized fellowship training program accepted by the OPTN Contractor MPSC. Any program approved
546 for training by the Fellowship Training Committee of the American Society of Transplant Surgeons is
547 automatically accepted by the MPSC, as well as any program that meets the following criteria:

- 549 1. The program is at a transplant hospital that transplants one or more organs, including livers.
- 550 2. The program is at an institution that has ACGME approved training in general surgery ~~a proven~~
551 ~~commitment to graduate medical education.~~
- 552 3. ~~The program director is a board-certified surgeon who meets the OPTN Contractor requirements for~~
553 ~~primary liver transplant surgeon.~~
- 554 4. ~~The program is at a hospital that is affiliated with a histocompatibility laboratory that meets the OPTN~~
555 ~~Contractor requirements for histocompatibility laboratories.~~
- 556 5. ~~The program is at a hospital that is affiliated with an organ procurement organization (OPO) that~~
557 ~~meets the OPTN Contractor requirements for OPOs.~~
- 558 6. ~~The program performs at least 50 liver transplants during each year of the fellowship training from~~
559 ~~deceased or living donors.~~
- 560 7. ~~The program has the resources, including adequate clinical facilities, laboratory research facilities,~~
561 ~~and appropriately trained faculty and staff, to provide research experience.~~

562
563 ~~Training programs are reviewed by the MPSC every 5 years or any time the program director changes. If~~
564 ~~a program has no fellows during the 5 years between reviews, it must re-apply as a new program.~~
565

566 **F.11 Primary Intestine Transplant Surgeon Requirements**

567 **A. Full Intestine Surgeon Approval Pathway**

568 Surgeons can be fully approved as a primary intestine transplant surgeon by completing a formal
569 surgical transplant fellowship or by completing clinical experience at an intestine transplant
570 program if *all* of the following conditions are met:
571

- 572 1. The surgeon performed 7 or more intestine transplants at a designated intestine transplant
573 program, to include the isolated bowel and composite grafts, as primary surgeon or first
574 assistant within the last 10 years. These transplants must be documented in a log that
575 includes the date of transplant, the role of the surgeon in the procedure, and the medical
576 record number or other unique identifier that can be verified by the OPTN Contractor. This log
577 must be signed by the program director, division chief, or department chair from the program
578 where the experience or training was gained.
- 579 2. The surgeon performed 3 or more intestine procurements as primary surgeon or first
580 assistant. These procurements must include 1 or more organ recovery that includes a liver.

581 These procedures must be documented in a log that includes the date of procurement and
 582 Donor ID. This log must be signed by the program director, division chief, or department chair
 583 from the program where the experience or training was gained.

584 3. The surgeon has maintained a current working knowledge of intestine transplantation,
 585 defined as direct involvement in intestine transplant patient care within the last 5 years. This
 586 includes the management of patients with short bowel syndrome or intestinal failure, the
 587 selection of appropriate recipients for transplantation, donor selection, histocompatibility and
 588 tissue typing, performing the transplant operation, immediate postoperative and continuing
 589 inpatient care, the use of immunosuppressive therapy including side effects of the drugs and
 590 complications of immunosuppression, differential diagnosis of intestine allograft dysfunction,
 591 histologic interpretation of allograft biopsies, interpretation of ancillary tests for intestine
 592 dysfunction, and long term outpatient care.

593 4. The training was completed at a hospital with an intestinal transplant training program
 594 approved by the American Society of Transplant Surgeons, ~~(ASTS)~~ or the Royal College of
 595 Physicians and Surgeons of Canada, or another recognized fellowship training program
 596 accepted by the OPTN Contractor as described in Section F.14: Approved Intestine
 597 Transplant Surgeon Fellowship Training Programs that follows.

- 598 5. The following letters are submitted to the OPTN Contractor:
- 599 a. A letter from the qualified intestine transplant physician and surgeon who have been
 600 directly involved with the surgeon documenting the surgeon's experience and
 601 competence.
 - 602 b. A letter of recommendation from the primary surgeon and transplant program director at
 603 the fellowship training program or transplant program last served by the surgeon outlining
 604 the surgeon's overall qualifications to act as a primary transplant surgeon, as well as the
 605 surgeon's personal integrity, honesty, and familiarity with and experience in adhering to
 606 OPTN obligations, and any other matters judged appropriate. The MPSC may request
 607 additional recommendation letters from the primary surgeon, primary physician surgeon,
 608 director, or others affiliated with any transplant program previously served by the
 609 physician, at its discretion.
 - 610 c. A letter from the surgeon that details the training and experience the surgeon gained in
 611 intestine transplantation.

612
 613 **F.14 Approved Intestine Surgeon Transplant Fellowship Programs**

614 Surgeons qualifying as primary transplant surgeon ~~through~~ based on completion of a formal transplant
 615 fellowship must complete their training at a fellowship program approved by the American Society of
 616 Transplant Surgeons, the Royal College of Physicians and Surgeons of Canada, or another recognized
 617 fellowship training program accepted by the OPTN Contractor MPSC. ~~Any program approved by the~~
 618 ~~Fellowship Training Committee of the American Society of Transplant Surgeons is automatically accepted~~
 619 ~~by the MPSC, as well as any program that meets all of the following criteria:~~

- 620
- 621 1. The program is at a transplant hospital that transplants ~~one~~ two or more organs, including liver and
 622 intestines.
- 623 2. The program is at an institution that has ACGME approved training in general surgery ~~a proven~~
 624 ~~commitment to graduate medical education.~~
- 625 ~~3. The program director is a board-certified surgeon who meets the OPTN Contractor requirements for~~
 626 ~~primary intestine transplant surgeon.~~
- 627 ~~4. The program is at a hospital that is affiliated with a histocompatibility laboratory that meets the OPTN~~
 628 ~~Contractor requirements for histocompatibility laboratories.~~
- 629 ~~5. The program is at a hospital that is affiliated with an organ procurement organization (OPO) that~~

630 ~~meets the OPTN Contractor requirements for OPOs.~~

631 ~~63. The program performs at least 10 intestine transplants during each year of the fellowship training.~~

632 ~~7. The program has the resources, including adequate clinical facilities, laboratory research facilities,~~
633 ~~and appropriately trained faculty and staff, to provide research experience.~~

634

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

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

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

639

640 1. The surgeon performed at least 15 pancreas transplants as primary surgeon or first assistant.
641 These transplants must be documented in the surgeon's fellowship operative log. The date of
642 transplant, the role of the surgeon in the procedure, the medical record number or other
643 unique identifier that can be verified by the OPTN Contractor, and the fellowship director's
644 signature must be provided with this log.

645 2. The surgeon performed at least 10 pancreas procurements as primary surgeon or first
646 assistant. These procurements must have been performed anytime during the surgeon's
647 fellowship and the two years immediately following fellowship completion. These cases must
648 be documented in the surgeon's fellowship operative log. The date of procurement, Donor ID,
649 and the fellowship director's signature must be provided with this log.

650 3. The surgeon has maintained a current working knowledge of pancreas transplantation,
651 defined as direct involvement in patient care within the last 2 years. This includes the
652 management of patients with diabetes mellitus, the selection of appropriate recipients for
653 transplantation, donor selection, histocompatibility and tissue typing, performing the
654 transplant operation, immediate postoperative and continuing inpatient care, the use of
655 immunosuppressive therapy including side effects of the drugs and complications of
656 immunosuppression, differential diagnosis of pancreas dysfunction in the allograft recipient,
657 histological interpretation of allograft biopsies, interpretation of ancillary tests for pancreatic
658 dysfunction, and long term outpatient care.

659 4. The training was completed at a hospital with a pancreas transplant training program
660 approved by the ~~Fellowship Training Committee of the American Society of Transplant~~
661 ~~Surgeons, the Royal College of Physicians and Surgeons of Canada, or another recognized~~
662 fellowship training program accepted by the OPTN Contractor as described in *Section G.7:*
663 *Approved Pancreas Transplant Surgeon Fellowship Training Programs* that follows.

664 5. The following letters are submitted directly to the OPTN Contractor:

665 a. A letter from the director of the training program and chairman of the department or
666 hospital credentialing committee verifying that the fellow has met the above requirements
667 and is qualified to direct a pancreas transplant program.

668 b. A letter of recommendation from the fellowship training program's primary surgeon and
669 transplant program director outlining the surgeon's overall qualifications to act as primary
670 transplant surgeon as well as the surgeon's personal integrity, honesty, familiarity with
671 and experience in adhering to OPTN obligations, and any other matters judged
672 appropriate. The MPSC may request similar letters of recommendation from the primary
673 physician, primary surgeon, director, or others affiliated with any transplant program
674 previously served by the surgeon, at its discretion.

675 c. A letter from the surgeon that details the training and experience the surgeon has gained
676 in pancreas transplantation.

677

678 **G.3 Primary Pancreas Transplant Physician Requirements**

679 **A. Twelve-month Transplant Medicine Fellowship Pathway**

680 Physicians can meet the training requirements for a primary pancreas transplant physician during
 681 a separate 12-month transplant medicine fellowship if the following conditions are met:

- 682 1. The physician completed 12 consecutive months of specialized training in pancreas
 683 transplantation at a pancreas transplant program under the direct supervision of a qualified
 684 pancreas transplant physician along with a pancreas transplant surgeon. The training must
 685 have included at least 6 months on the clinical transplant service. The remaining time must
 686 have consisted of transplant-related experience, such as experience in a tissue typing
 687 laboratory, on another solid organ transplant service, or conducting basic or clinical transplant
 688 research.
- 689 2. During the fellowship period, the physician was directly involved in the primary care of 8 or
 690 more newly transplanted pancreas recipients and followed these recipients for a minimum of
 691 3 months from the time of transplant. The care must be documented in a log that includes the
 692 date of transplant and medical record number or other unique identifier that can be identified
 693 by the OPTN Contractor. This recipient log must be signed by the director of the training
 694 program or the transplant program's primary transplant physician.
- 695 3. The physician has maintained a current working knowledge of pancreas transplantation,
 696 defined as direct involvement in pancreas transplant patient care within the last 2 years. This
 697 includes the management of patients with end stage pancreas disease, the selection of
 698 appropriate recipients for transplantation, donor selection, histocompatibility and tissue
 699 typing, immediate post-operative patient care, the use of immunosuppressive therapy
 700 including side effects of the drugs and complications of immunosuppression, differential
 701 diagnosis of pancreas dysfunction in the allograft recipient, histological interpretation of
 702 allograft biopsies, interpretation of ancillary tests for pancreas dysfunction, and long term
 703 outpatient care.
- 704 4. The physician must have observed at least 3 pancreas procurements. The physician must
 705 have also observed the evaluation, donation process, and management of these donors.
 706 These observations must be documented in a log that includes the date of procurement and
 707 Donor ID.
- 708 5. The physician must have observed at least 3 pancreas transplants. The observation of these
 709 transplants must be documented in a log that includes the transplant date and medical record
 710 number or other unique identifier that can be verified by the OPTN Contractor.
- 711 ~~6. The curriculum of this transplant medicine fellowship should be approved by the Residency
 712 Review Committee for Internal Medicine (RRC-IM) of the Accreditation Council for Graduate
 713 Medical Education (ACGME).~~
- 714 ~~7. The following letters are submitted directly to the OPTN Contractor:~~
- 715 ~~a. A letter from director of the training program and supervising qualified pancreas
 716 transplant physician send a letter directly to the OPTN Contractor verifying that the fellow
 717 has met the above requirements and is qualified to direct a pancreas transplant program.~~
- 718 ~~b. A letter of recommendation from the fellowship training program's primary physician and
 719 transplant program director outlining the physician's overall qualifications to act as
 720 primary transplant physician as well as the physician's personal integrity, honesty,
 721 familiarity with and experience in adhering to OPTN obligations, and any other matters
 722 judged appropriate. The MPSC may request similar letters of recommendation from the
 723 primary physician, primary surgeon, director, or others affiliated with any transplant
 724 program that the physician previously served, at its discretion.~~
- 725

726 c. A letter from the physician that details the training and experience the physician has
727 gained in pancreas transplantation.

728
729 The above training is in addition to other clinical requirements for general nephrology,
730 endocrinology, or diabetology training.
731

732 **G.7 Approved Pancreas Transplant Surgeon Fellowship Training Programs**

733 Surgeons qualifying as primary transplant surgeons based on completion of a formal 2-year surgical
734 transplant fellowship must complete their training at a fellowship program approved by Fellowship training
735 programs accredited by the Fellowship Training Committee of the American Society of Transplant
736 Surgeons, the Royal College of Physicians and Surgeons of Canada, or another recognized fellowship
737 training program accepted by ~~are acceptable to the OPTN Contractor or all programs that meets~~ the
738 following criteria:

- 739
- 740 1. The program ~~must be~~ is located at a transplant hospital that transplants one or more organs,
741 including pancreas.
 - 742 ~~2. The program must be reviewed every 5 years by the OPTN Contractor.~~
 - 743 ~~3. The program must be~~ is at an institution that has ACGME approved training in general surgery with a
744 proven commitment to graduate medical education.
 - 745 ~~4. The program director must be a board certified surgeon who meets the requirements of a primary~~
746 ~~transplant surgeon.~~
 - 747 ~~5. The program must be at an institution affiliated with a histocompatibility laboratory member.~~
 - 748 ~~6. The program must be at an institution affiliated with an organ procurement organization member.~~
 - 749 ~~7. The program must~~ performs at least 20 pancreas transplants during each year of fellowship training
750 to qualify for pancreas transplantation training.
 - 751 ~~8. The training program must have adequate clinical and laboratory research facilities.~~
 - 752 ~~9. The training program should have adequate faculty with appropriate training to provide proper~~
753 ~~research experience.~~

754
755 ~~Training programs are reviewed by the MPSC every 5 years or any time the program director changes. If~~
756 ~~a program has no fellows during the 5 years between reviews, it must re-apply as a new training program.~~
757

758 **J.3 Primary VCA Transplant Surgeon Requirements**

759 **A. Additional Primary Surgeon Requirements for Upper Limb** 760 **Transplant Programs**

761 In addition to the requirements as described in section J.3 above, the surgeon for an upper limb
762 transplant program must meet *both* of the following:

- 763 1. Must meet at least *one* of the following:
 - 764 a. Have current certification by the American Board of Plastic Surgery, the American Board
765 of Orthopedic Surgery, the American Board of Surgery, or the foreign equivalent. In the
766 case of a surgeon who has just completed training and whose board certification is
767 pending, the Membership and Professional Standards Committee (MPSC) may grant
768 conditional approval for 24 months to allow time for the surgeon to complete board
769 certification, with the possibility of renewal for an additional 12-month period.
 - 770 b. If the surgeon does not have board certification, the surgeon may qualify by gaining all of
771 the following relevant clinical experience:
 - 772 i. Observation of at least 2 multi-organ procurements and acted as the first-assistant or

- 773 primary surgeon on at least 1 VCA procurement.
- 774 ii. Pre-operative evaluation of at least 3 potential upper limb transplant candidates.
- 775 iii. Acted as primary surgeon of a least 1 upper limb transplant.
- 776 iv. Post-operative follow-up of at least 1 upper limb recipient for 1 year post-transplant.
- 777

778 The multi-organ procurement experience must be documented in a log that includes the
779 Donor ID or other unique identifier that can be verified by the OPTN Contractor. The
780 experience for upper limb transplant procedures must be documented in a log that includes
781 the dates of procedures and evaluations, the role of the surgeon, and the medical record
782 number or other unique identifier that can be verified by the OPTN Contractor. This log must
783 be signed by the program director, division chief, or department chair where the experience
784 was gained.

785
786 If a primary surgeon qualified under 1.b leaves the transplant program, the replacement for
787 this surgeon must meet the requirements of 1.a. As of September 1, 2018, pathway 1.b will
788 no longer be available and all primary surgeons must meet the requirements of 1.a.

- 789
- 790 2. Completion of at least *one* of the following:
 - 791 a. ~~A fellowship program in hand surgery that is approved by the MPSC.~~ Any Accreditation
 - 792 Council of Graduate Medical Education (ACGME) approved fellowship program in hand
 - 793 surgery is automatically accepted by the MPSC.
 - 794 b. A fellowship program in hand surgery that meets *all* of the following criteria ~~will also be~~
 - 795 ~~accepted:~~
 - 796 i. The program is at a hospital that has inpatient facilities, operative suites and
 - 797 diagnostic treatment facilities, outpatient facilities, and educational resources.
 - 798 ii. The program is at an institution that has a proven commitment to graduate medical
 - 799 education.
 - 800 iii. The program director must have current certification in the sub-specialty by the
 - 801 American Board of Orthopedic Surgery, the American Board of Plastic Surgery, or
 - 802 American Board of Surgery.
 - 803 iv. The program should have at least 2 physician faculty members with hand surgery
 - 804 experience and current medical licensure who are actively involved in the instruction
 - 805 and supervision of fellows during the time of accredited education.
 - 806 v. The program is at a hospital that has affiliated rehabilitation medicine services.
 - 807 vi. The program has the resources, including adequate clinical facilities, laboratory
 - 808 research facilities, and appropriately trained faculty and staff, to provide research
 - 809 experience.
 - 810 c. At least 2 years of consecutive and independent practice of hand surgery and must have
 - 811 completed a minimum number of upper limb procedures as the primary surgeon shown in
 - 812 *Table J-1* below. This includes completion of pre-operative assessments and post-
 - 813 operative care for a minimum of 90 days after surgery. These procedures must be
 - 814 documented in a log that includes the date of the procedure and the medical record
 - 815 number or other unique identifier that can be verified by the OPTN Contractor. This log
 - 816 must be signed by the program director, division chief, or department chair where the
 - 817 experience was gained. Surgery of the hand includes only those procedures performed
 - 818 on the upper limb below the elbow.
 - 819

820
821**Table J-1: Minimum Procedures for Upper Limb Primary Transplant Surgeons**

Type of Procedure	Minimum Number of Procedures
Bone	20
Nerve	20
Tendon	20
Skin or Wound Problems	14
Contracture or Joint Stiffness	10
Tumor	10
Microsurgical Procedures	10
Free flaps	10
Non-surgical management	6
Replantation or Transplant	5

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B. Additional Primary Surgeon Requirements for Head and Neck Transplant Programs

In addition to the requirements as described in section J.3 above, the transplant surgeon for a head and neck transplant program must meet *both* of the following:

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1. Must meet at least *one* of the following:
 - a. Have current certification by the American Board of Plastic Surgery, the American Board of Otolaryngology, American Board of Oral and Maxillofacial Surgery, the American Board of Surgery, or the foreign equivalent. In the case of a surgeon who has just completed training and whose board certification is pending, the Membership and Professional Standards Committee (MPSC) may grant conditional approval for 24 months to allow time for the surgeon to complete board certification, with the possibility of renewal for an additional 12-month period.
 - b. If the surgeon does not have board certification, the surgeon may qualify by gaining all of the following relevant clinical experience:
 - i. Observation of at least 2 multi-organ procurements and acted as the first-assistant or primary surgeon on at least 1 VCA procurement.
 - ii. Pre-operative evaluation of at least 3 potential head and neck transplant candidates.
 - iii. Acted as primary surgeon of a least 1 head and neck transplant.
 - iv. Post-operative follow up of at least 1 head and neck recipient for 1 year post-transplant.

The multi-organ procurement experience must be documented in a log that includes the Donor ID or other unique identifier that can be verified by the OPTN Contractor. The experience for head and neck procedures must be documented in a log that includes the dates of procedures and evaluations, the role of the surgeon, and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair where the experience was gained.

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If a primary surgeon qualified under 1.b leaves the transplant program, the replacement for this surgeon must meet the requirements of 1.a. As of September 1, 2018, pathway 1.b will no longer be available and all primary surgeons must meet the requirements of 1.a.

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861

2. Completion of at least *one* of the following:
 - a. ~~A fellowship program in otolaryngology, plastic, oral and maxillofacial, or craniofacial surgery that is approved by the MPSC. Any ACGME-approved fellowship program in~~

- 862 ~~otolaryngology, plastic, oral and maxillofacial, or craniofacial surgery is automatically~~
 863 ~~accepted by the MPSC.~~
- 864 b. A fellowship program in otolaryngology, plastic, oral and maxillofacial, or craniofacial
 865 surgery that meets all of the following criteria:
- 866 i. The program is at a hospital that has inpatient facilities, operative suites and
 867 diagnostic treatment facilities, outpatient facilities, and educational resources.
 - 868 ii. The program is at an institution that has a proven commitment to graduate medical
 869 education.
 - 870 iii. The program director must have current certification in the sub-specialty by the
 871 American Board of Plastic Surgery, the American Board of Otolaryngology, American
 872 Board of Oral and Maxillofacial Surgery.
 - 873 iv. The program should have at least two physician faculty members with head and neck
 874 surgery experience and current medical licensure who are actively involved in the
 875 instruction and supervision of fellows during the time of accredited education.
 - 876 v. The program is at a hospital that has affiliated rehabilitation medicine services.
 - 877 vi. The program has the resources, including adequate clinical facilities, laboratory
 878 research facilities, and appropriately trained faculty and staff, to provide research
 879 experience.
- 880 c. At least 2 years of consecutive and independent practice of head and neck surgery. The
 881 surgeon must have completed at least 1 face transplant as primary surgeon or first-
 882 assistant, or a minimum number of head and neck procedures as the primary surgeon as
 883 shown in *Table J-2* below. This includes completion of pre-operative assessments and
 884 post-operative care for a minimum of 90 days after surgery. These procedures must be
 885 documented in a log that includes the dates of procedures and evaluations, the role of
 886 the surgeon and the medical record number, Donor ID, or other unique identifier that can
 887 be verified by the OPTN Contractor. This log must be signed by the program director,
 888 division chief, or department chair where the experience was gained.

Table J-2: Minimum Procedures for Head and Neck Primary Transplant Surgeons

Type of Procedure	Minimum Number of Procedures
Facial trauma with bone fixation	10
Head or neck free tissue reconstruction	10