

## *Notice of OPTN Policy, Bylaw, and Guidelines Changes*

# Creation of OPTN Heart and Lung Committees

<b>Sponsoring Committee:</b>	<b>Thoracic Organ Transplantation</b>
<b>Policies Affected:</b>	<b>3.7.A: Applications for Modifications of Waiting Time</b> <b>6.4.A: RRB and Committee Review of Status Exceptions</b> <b>6.4.A.ii: Committee Appeals</b> <b>10.2.B: Lung Candidates with Exceptional Cases</b> <b>10.2.B.i: LRB Review Process</b> <b>10.2.B.ii: LRB Decision Overrides</b> <b>10.2.B.iii: Estimated Values Approved by the LRB</b> <b>10.2.B.iv: LAS Diagnoses Approved by the LRB</b> <b>10.2.B.v: LAS Approved by the LRB</b>
<b>Bylaw Affected:</b>	<b>Article VII: Permanent Standing Committees</b>
<b>Board Approved:</b>	<b>March 10, 2020</b>
<b>Effective Date:</b>	<b>July 1, 2020</b>

### Summary of Changes

This proposal dissolves the Thoracic Organ Transplantation Committee (Thoracic Committee) and creates two new OPTN committees in its place: the Lung Transplantation Committee (Lung Committee) and the Heart Transplantation Committee (Heart Committee). Policy, Bylaw, and Guideline changes clarify or assign responsibilities that are currently specified as “Thoracic Committee” to “Lung Committee” or “Heart Committee” as appropriate.

### Purpose of Changes

This will allow for more complete and balanced representation of the thoracic community when developing changes to heart and lung transplant policies. This proposal will also authorize additional staffing and financial resources to support presumed increases in heart and lung policy-related work.

### Implementation

The OPTN published a call for nominations for volunteers for the new committees through March 25, 2020. Members were invited to participate in the nomination process for regional and at large representatives for both the Heart and Lung Committees. New committee members and leadership positions will be approved by the current OPTN Vice President consistent with the standard committee appointment process.

The new committees will officially begin work on July 1, 2020.

## Affected Policy Language

New language is underlined (example) and language that is deleted is struck through (~~example~~). Only sections of Policies with approved changes are included here; sections of Policies not represented here are not affected.

### 3.7 Waiting Time Modifications

#### 3.7.A Applications for Modifications of Waiting Time

To apply for a waiting time modification, the candidate’s transplant program must submit an application to the OPTN Contractor with *all* of the following information:

1. The requested listing date and documentation showing an intent to register the candidate at the requested listing date.
2. Documentation or a statement showing that the candidate qualified for the waiting time according to the organ-specific *OPTN Policies 6 through 12*.
3. A corrective action plan, if the application is due to an error.
4. The name and signature of the candidate’s physician or surgeon.
5. Signatures indicating agreement from all applicable transplant programs in the OPO. If a signature cannot be obtained from a transplant program, the submitting program must explain the efforts it made to obtain a signature and include any stated reasons for disagreement with the request.

Upon receipt of a complete application and required documentation, the OPTN Contractor will forward the application, without person-identified data, according to *Table 3-4* that follows:

**Table 3-4: Waiting Time Modification Application Review**

If the candidate requests a waiting time modification for the following organ:	Then the application will be reviewed by the:
Kidney	Kidney Waiting Time Modifications Subcommittee
Liver	A subcommittee of the Liver and Intestinal Organ Transplantation Committee, appointed by the Chair of the Liver and Intestinal Organ Transplantation Committee
<del>Thoracic</del>	<del>A subcommittee of the Thoracic Transplantation Committee, appointed by the Chair of the Thoracic Transplantation Committee</del>
<u>Heart</u>	<u>A subcommittee of the Heart Transplantation Committee, appointed by the Chair of the Heart Transplantation Committee</u>
<u>Lung</u>	<u>A subcommittee of the Lung Transplantation Committee, appointed by the Chair of the Lung Transplantation Committee</u>
Pancreas	Kidney or Pancreas Waiting Time Modifications Subcommittee
Intestine	A subcommittee of the Liver and Intestinal Organ Transplantation Committee, appointed by the Chair of the Liver and Intestinal Organ Transplantation Committee

21 Waiting list modification applications will be reviewed as follows:  
22

- 23 1. The reviewer will determine if it is appropriate to modify the candidate's waiting time as  
24 requested in the application and will notify the OPTN Contractor of the decision.
- 25 2. Upon notice, the OPTN Contractor will implement the waiting time modification.
- 26 3. The reviewer will report the modification, without person-identified data, to the relevant  
27 organ specific Committee.
- 28 4. The Committee will report the modification, without person-identified data, to the Board of  
29 Directors.  
30

#### 31 **6.4.A RRB and Committee Review of Status Exceptions**

32 The heart RRB reviews applications for adult and pediatric status exceptions and extensions  
33 retrospectively.  
34

35 If the candidate is transplanted and the RRB does not approve the initial exception or extension  
36 request or any appeal, then the case will be referred to the ~~Thoracic~~ Heart Transplantation  
37 Committee. If the ~~Thoracic~~ Heart Transplantation Committee agrees with the RRB's decision,  
38 then the ~~Thoracic~~ Heart Transplantation Committee may refer the case to Membership &  
39 Professional Standards Committee (MPSC) for review according to *Appendix L* of the OPTN  
40 Bylaws.  
41

#### 42 **6.4.A.ii Committee Appeals**

43 If the RRB denies the appeal, the candidate's transplant program must within 1 day of  
44 receiving notification of the denied appeal either appeal to the ~~Thoracic~~ Heart  
45 Transplantation Committee or assign the candidate to the status for which the candidate  
46 qualifies. If the ~~Thoracic~~ Heart Transplantation Committee agrees with the RRB's decision,  
47 the candidate's transplant program must assign the candidate to the status for which the  
48 candidate qualifies within 1 day of receiving notification of the denied Committee appeal. If  
49 the transplant program does not assign the candidate to the status for which the candidate  
50 qualifies within 1 day of receiving notification of the denied Committee appeal, then the  
51 Committee will refer the case to the MPSC.  
52

#### 53 **10.2.B Lung Candidates with Exceptional Cases**

54 The ~~Thoracic Organ~~ Lung Transplantation Committee establishes guidelines for special case  
55 review by the LRB.  
56

57 If a candidate's transplant program believes that a candidate's current priority or LAS does not  
58 appropriately reflect the candidate's medical urgency for transplant, the transplant program  
59 may request approval of a specific priority or LAS by the LRB. The transplant program can also  
60 ask the LRB to approve specific estimated values or diagnoses.  
61

62 For lung candidates less than 12 years old, transplant programs may request classification as an  
63 adolescent candidate for the purposes of *Policy 10.4.C: Allocation of Lungs from Deceased*  
64 *Donors at Least 18 Years Old* and *Policy 10.4.D: Allocation of Lungs from Deceased Donors Less*  
65 *than 18 Years Old*. Candidates receiving this exception will also maintain their pediatric

66 classification for the purposes of *Policy 10.4.D: Allocation of Lungs from Deceased Donors Less*  
67 *than 18 Years Old.*

68  
69 **10.2.B.i LRB Review Process**

70 Requests for approval of estimated values, diagnoses, specific LAS, or adolescent classification  
71 exceptions require prospective review by the LRB. The transplant hospital must submit requests  
72 for LRB review to the OPTN Contractor, and accompany each request for special review with a  
73 supporting narrative. The LRB will have seven days to reach a decision regarding the request,  
74 starting from the date that the OPTN Contractor sends the request to the LRB.

75  
76 If the LRB denies a request upon initial review, then the transplant program may choose to  
77 appeal the decision and request reconsideration by the LRB. The transplant program has seven  
78 days from the date of the initial denial of the initial request to appeal. The LRB has seven days to  
79 reach a decision on the appeal, starting from the date that the OPTN Contractor sends the  
80 appealed request to the LRB. If the LRB does not complete its review of an initial request or  
81 appeal within seven days of receiving it, then the candidate will not receive the requested LAS,  
82 diagnosis, estimated value, or adolescent classification, and the OPTN Contractor will send the  
83 request or appeal to the ~~Thoracic Organ~~ Lung Transplantation Committee for further review.

84  
85 Requests to register a candidate less than 12 years old as priority 1 require retrospective LRB  
86 review by the LRB.

87  
88 **10.2.B.ii LRB Decision Overrides**

89 If the LRB denies a transplant hospital's initial request or appeal for an estimated value,  
90 adolescent classification, or specific LAS on appeal, the transplant hospital has the option to  
91 override the decision of the LRB. If the transplant hospital elects to override the decision of the  
92 LRB, then the OPTN Contractor will send the request or appeal to the ~~Thoracic Organ~~ Lung  
93 Transplantation Committee for review. This review by the ~~Thoracic Organ~~ Lung Transplantation  
94 Committee may result in further referral of the matter to the Membership and Professional  
95 Standards Committee (MPSC). If the MPSC agrees with the ~~Thoracic Organ~~ Lung Transplantation  
96 Committee's decision, a member who has registered a candidate with an unapproved estimated  
97 value, adolescent classification, or LAS will be subject to action according to *Appendix L:*  
98 *Reviews, Actions, and Due Process of the OPTN Bylaws.*

99  
100 **10.2.B.iii Estimated Values Approved by the LRB**

101 Approved estimated values approved by the LRB or ~~Thoracic~~ Lung Transplantation Committee  
102 are valid until an actual value is reported to the OPTN Contractor or a new estimated value is  
103 reported to the OPTN Contractor.

104  
105 **10.2.B.iv LAS Diagnoses Approved by the LRB**

106 A diagnosis that has been approved by the LRB or the ~~Thoracic Organ~~ Lung Transplantation  
107 Committee is valid indefinitely, or until an adjustment is requested and, if necessary, approved  
108 by the LRB.

109

110 **10.2.B.v LAS Approved by the LRB**

111 An LAS approved by the LRB or the ~~Thoracic~~ Lung Transplantation Committee will remain valid  
112 for six months from the date the candidate's LAS is updated, (or from the candidate's twelfth  
113 birthday, whichever occurs later). If the candidate is still on the waiting list six months after the  
114 date the LAS is updated, then the candidate's LAS will be computed as described in Policy *10.1:*  
115 *Priorities and Score Assignments for Lung Candidates* unless a new LAS or priority request is  
116 submitted to the OPTN Contractor.

## Affected Bylaw Language

New language is underlined (example) and language that is deleted is struck through (~~example~~). Only sections of Bylaws with approved changes are included here; sections of Bylaws not represented here are not affected.

### 117 **Article VII: Permanent Standing Committees**

118 The OPTN will have the following permanent standing Committees:

119

120 ■ Ethics

121 ■ Heart Transplantation

122 ■ Histocompatibility

123 ■ Kidney Transplantation

124 ■ Liver and Intestinal Organ Transplantation

125 ■ Living Donor

126 ■ Lung Transplantation

127 ■ Membership and Professional Standards

128 ■ Minority Affairs

129 ■ Operations and Safety

130 ■ Organ Procurement Organization

131 ■ Pancreas Transplantation

132 ■ Patient Affairs

133 ■ Pediatric Transplantation

134 ■ Policy Oversight Committee

135 ■ ~~Thoracic Organ Transplantation~~

136 ■ Transplant Administrators

137 ■ Transplant Coordinators

138

139 The Committees are advisory to the Board of Directors, which makes the final decisions of the OPTN.

140 The standing Committees will provide initial review and analysis of proposed policies and initiatives  
141 based on their collective expertise and unique perspectives, and present their recommendations to the  
142 Board of Directors.

143

144 Committees may also be advisory to each other when Committee interest and expertise overlap. When  
145 Committees evaluate proposals jointly, they should present to the Board of Directors either a common  
146 recommendation or a report that summarizes the continued disagreement.

147

148 Committees may have additional responsibilities as defined by the OPTN Bylaws and Policies.

149 Committees' role in developing policies and standards is further defined in *Article XI: Adoption of*  
150 *Policies* of these Bylaws.

## Affected Guidelines

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### 151 **OPTN Heart Review Board (HRB) Guidelines**

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#### 153 **5. Appeal Process**

##### 154 **B. Appeals of HRB Denials to the ~~Thoracic~~ Heart Transplantation Committee** 155 **and MPSC Review**

156

157 If the HRB denies the appeal of an initial application or extension request application, the candidate's  
158 transplant program must either appeal to the ~~Thoracic Organ~~ Heart Transplantation Committee  
159 (Committee) within ~~±~~ one day of receiving notification of the denied appeal or assign the candidate to  
160 the status for which the candidate qualifies within 1 day of notification of the denied appeal.

161

162 The transplant program may provide the OPTN Contractor with additional information about the case,  
163 which the OPTN Contractor will send to the Committee. The Committee will approve or not approve  
164 each appeal within 7 days of submission of the case to the Committee.

165

166 Referral of cases to the Committee will include information about the number of previous case referrals  
167 from that transplant program and the outcome of those referrals.

168

169 If the application is not appealed to the ~~Thoracic~~ Heart Transplantation Committee within one day of  
170 receiving the notification of the HRB decision, the appeal process is not available.

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### 172 **OPTN Lung Review Board (LRB) Guidelines**

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#### 174 **2. Representation on the LRB**

175 A. The LRB is composed of 9 individual lung transplant surgeons or lung transplant physicians, including  
176 3 pediatric members selected in rotation from a national pool of active lung transplant programs  
177 that have agreed to participate on the LRB. Six LRB members represent active adult lung transplant  
178 programs and 3 members represent active pediatric lung transplant programs. The Chair of the  
179 ~~OPTN/UNOS Thoracic Organ~~ Lung Transplantation Committee (the Committee) shall appoint a  
180 primary LRB member from among those selected to serve as the LRB Chair for a 2-year term. Each  
181 active lung transplant program shall have the opportunity to rotate onto the LRB.

182

183 B. LRB members serve a term of 2 years. Service terms will be staggered among the LRB members to  
184 ensure that at no time more than 5 terms will end. This requirement is to preserve the continuity of  
185 the LRB and the efficiency of its operation. If additional LRB representatives are to be appointed to  
186 the LRB due to a change in the operational guidelines, the Chair of the ~~Thoracic~~ Lung  
187 Transplantation Committee will select the additional members and establish the terms of their initial  
188 appointment.