1. Overview

The purpose of the Heart Review Board (HRB) is to provide fair, equitable, and prompt peer review of adult candidate status 1-4 and pediatric candidate status 1A- and status 1B- justification form applications submitted by transplant programs. Justification form applications will be referred to throughout these guidelines as “applications” and include initial submissions, extension requests, and appeals.

2. Representation

A. Every designated heart transplant program may participate on the HRB. Each HRB will consist of a minimum of representation from three programs.

B. The Regional Councillor or the Councillor’s designee selects a heart transplant physician or surgeon affiliated with a designated heart transplant program within his or her OPTN region to serve as the HRB Chair. The HRB Chair will be called upon to decide tie votes and may not simultaneously represent his or her transplant program as an HRB member.

C. The HRBs vary in size and rotate as determined by each OPTN region. Since larger HRBs may pose operational or administrative challenges, some HRBs rotate membership to ensure each transplant program is represented on the HRB for one term each year.

D. Each program represented on the HRB must identify one primary and at least one alternate representative to the OPTN Contractor. It is the responsibility of each transplant program to provide the OPTN Contractor with the contact information for both the HRB primary and alternate representatives. Should an HRB primary representative leave his or her transplant program, then the transplant program’s alternate representative will become the new HRB primary representative, and the program must provide the OPTN Contractor with the contact information for another alternate representative. The program can also choose to keep the existing alternate representative and provide the OPTN Contractor with the contact information for a new RB primary representative.

E. If a transplant hospital inactivates or withdraws its heart program, it may not participate in the HRB. The term of the transplant program’s representative on the HRB ends upon program’s inactivation or withdrawal from the OPTN. However, the transplant hospital’s participation may resume once it has reactivated its heart program.

Responsibilities of HRB representatives

HRB primary and alternate representatives must:

A. Complete the OPTN/UNOS Confidentiality Agreement and Certification Regarding Conflicts of Interest form prior to serving on the HRB.

B. Evaluate the eligibility criteria of other approved applications to achieve consistency in decision-making and determine whether this candidate meets similar levels of medical urgency and potential for benefit.

C. Vote to approve or not approve applications according to the timelines specified in the guidelines below. When voting to “not approve” an application, the voter should provide comments or questions to the program submitting the application to support the vote.
4. Voting Procedures

A. Retrospective Review of Status Exceptions

The HRB will review all applications that require HRB review retrospectively. During the entirety of the retrospective review, extension, and/or appeal process, the candidate’s status will be equal to the requested status and the transplant program must follow all OPTN policies applicable to the requested status.

At the termination of the application or appeal process, if the requested status is not approved, then the transplant program must change the candidate’s status to the status for which the candidate qualifies under policy within 1 day of receiving notification of denial or initiate an appeal as described below.

B. Regional Rotation

The HRB will review applications from another OPTN region on a rotating basis. The same HRB that reviewed an initial application will review extension requests and appeals associated with the candidate, with the exception of applications that are extended or appealed after the regional rotation to different regions occurs.

C. Eligibility to Vote

An HRB primary or alternate representative’s vote will not be valid and will not count towards a quorum in any case in which the member has a conflict of interest.

D. HRB Case Review and Vote

The OPTN Contractor will first send all applications to the HRB primary representative. If the primary representative has not voted within 3 business days of when the OPTN Contractor sends the application to the HRB, then the OPTN Contractor will send the case to the alternate representative. Thereafter, both the HRB member and alternate representative may vote on the application within 7 days of when the OPTN Contractor originally sent the application to the HRB. If the HRB member and the alternate representative both submit votes for the same application, then the OPTN Contractor will count the vote from whomever voted first.

In order for a decision to be rendered, a majority vote is required. A majority vote requires more than half of the HRB representatives (or their alternates) voting on the application. If all HRB representative have voted and the vote is tied, the HRB chair will be contacted to break the tie.

Voting will close at the earliest of when:
- all eligible voters have voted;
- a majority of all eligible voters have voted to approve or deny a request; or
- 7 days after the OPTN Contractor sends the request to the HRB

HRB review of applications (initial submissions, extensions, and appeals) are decided as described in Table 1, below:

<table>
<thead>
<tr>
<th>If the vote is…</th>
<th>Then the application is…</th>
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<tbody>
<tr>
<td>Majority vote to approve</td>
<td>Approved</td>
</tr>
<tr>
<td>All voters tied and HRB chair votes to approve</td>
<td>Approved</td>
</tr>
<tr>
<td>Majority vote to not approve</td>
<td>Not approved</td>
</tr>
</tbody>
</table>

|
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All voters tied and HRB chair votes to not approve  |  Not approved
All voters tied and HRB chair does not break tie  |  Approved
No majority vote reached  |  Approved

Once voting is closed, a HRB member or alternate can no longer vote on that case.

The OPTN Contractor will maintain the results of the HRB’s vote. If an application is not approved, the OPTN Contractor will notify the program that submitted the application and will provide the transplant program with comments or questions made by the HRB members, but will not provide the votes of specific HRB members.

5. Appeal Process

A. Appeal to the Review Board

If the HRB does not approve an initial or extension request application, the candidate’s transplant program must either submit an appeal application to the HRB within 1 day of receiving notification of the HRB decision, or assign the candidate to the status for which the candidate qualifies within 1 day of notification of the HRB’s decision.

The transplant program may submit additional written information justifying the requested exception status, and may include responses to the comments of dissenting HRB members. This additional information will be provided to HRB members for further consideration.

If the application is not appealed to the HRB within 1 day of receiving the notification of the HRB’s decision, the appeal process is not available.

Appealed applications are adjudicated as described in Table 1, above.

B. Appeals of HRB Denials to the Thoracic Committee and MPSC Review

If the HRB denies the appeal of an initial application or extension request application, the candidate’s transplant program must either appeal to the Thoracic Organ Transplantation Committee within 1 day of receiving notification of the denied appeal or assign the candidate to the status for which the candidate qualifies within 1 day of notification of the denied appeal.

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

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

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

6. Extensions

The HRB will retrospectively review extension request applications. If an application will expire before the deadline for the HRB or Committee to decide on the application, and the transplant program submits a request for an extension of that application, then the HRB or Committee will vote on the extension application request, and the original application will be automatically closed out.
7. Administration

The central office for each HRB is maintained by the OPTN Contractor. The HRB efforts are coordinated by the OPTN Contractor.

Data sent to the HRBs for action or review will not contain hospital, program, or candidate identifying information.

HRB member responses may be shared with the transplant program if a HRB member specifically asks that comments be shared with the program, regardless of the voting outcome.