

OPTN Adult Heart Regional Review Board (RRB) Operational Guidelines

1. Overview

The purpose of the Adult Heart Regional Review Board (RRB) is to provide fair, equitable, and prompt peer review of adult candidate status 1-4 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 RRB. Each RRB 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 RRB Chair. The RRB Chair will be called upon to decide tie votes and may not simultaneously represent his or her transplant program as an RRB member.
- C. The RRBs vary in size and rotate as determined by each OPTN region. Since larger RRBs may pose operational or administrative challenges, some RRBs rotate membership to ensure each transplant program is represented on the RRB for one term each year.
- D. Each program represented on the RRB must identify one primary and at least one alternate representative. It is the responsibility of each transplant program to provide the contact information for both the RRB primary and alternate representatives. Should an RRB primary representative leave his or her transplant program, then the transplant program’s alternate representative will become the new RRB primary representative, and the program must provide the contact information for another alternate representative. The program can also choose to keep the existing alternate representative and provide the contact information for a new RRB primary representative.
- E. If a transplant hospital inactivates or withdraws its heart program, it may not participate in the RRB. The term of the transplant program’s representative on the RRB 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.

3. Responsibilities of RRB representatives

RRB primary and alternate representatives must:

- A. Complete the OPTN Confidentiality Agreement and Certification Regarding Conflicts of

Interest form prior to serving on the RRB.

- 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 RRB will review all applications that require RRB 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. Eligibility to Vote

An RRB 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.

C. Regional Rotation

The RRB will review applications from another OPTN region on a rotating basis. The same RRB 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.

D. RRB Case Review and Vote

All applications will first be sent to the RRB primary representative. If the primary representative has not voted within 3 business days of the RRB receiving the application, then the case will be sent to the alternate representative. Thereafter, both the RRB member and alternate representative may vote on the application within 7 days of when the application was originally provided to the RRB. If the RRB member and the alternate representative both submit votes for the same application, then the OPTN Contractor will count the vote from whomever voted first will be counted.

In order for a decision to be rendered, a majority vote is required. A majority vote requires more than half of the RRB representatives (or their alternates) voting on the application. If all RRB representative have voted and the vote is tied, the RRB 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 a request
- a majority of all eligible voters have voted to deny a request; or
- 7 days after the request is sent to the RRB

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

Table 1: Effect of RRB Votes

If the vote is...	Then the application is...
Majority vote to approve	Approved
All voters tied and RRB chair votes to approve	Approved
Majority vote to not approve	Not approved
An equal number of voters have voted to approve as deny and RRB chair votes to not approve	Not approved
An equal number of voters have voted to approve as deny and RRB chair does not break tie	Approved
No majority vote reached	Approved

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

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

5. Appeal Process

A. Appeal to the Review Board

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

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

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

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

B. Appeals of RRB Denials to the Heart Transplantation Committee and MPSC Review

If the RRB denies the appeal of an initial application or extension request application, the candidate's transplant program must either appeal to the Heart Transplantation Committee (Committee) within one 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 with additional information about the case, which the OPTN 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 Heart Transplantation Committee within one day of receiving the notification of the RRB decision, the appeal process is not available.

6. Extensions

The RRB will retrospectively review extension request applications. If an application will expire before the deadline for the RRB or Committee to decide on the application, and the transplant program submits a request for an extension of that application, then the RRB 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 RRB is maintained by the OPTN. The RRB efforts are coordinated by the OPTN.

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

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