

Notice of OPTN Policy and Guidelines Changes

National Heart Review Board for Pediatrics

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| Sponsoring Committee: | Thoracic Organ Transplantation |
| Policies Affected: | <i>6.4: Adult and Pediatric Status Exceptions</i> <i>6.4.A: Review Board and Committee Review of Status Exceptions</i> <i>6.4.A.i: Review Board Appeals</i> <i>6.4.A.ii: Committee Appeals</i> |
| Guidelines Affected: | <i>National Heart Review Board for Pediatrics Operational Guidelines</i> <i>OPTN Heart Review Board (HRB) Guidelines</i> |
| Public Comment: | January 22, 2020 – March 24, 2020 |
| Board Approved: | June 8, 2020 |
| Effective Date: | Pending implementation and notice to OPTN members |

Purpose of Policy and Guidelines Changes

Changes to pediatric heart allocation policy implemented in October 2016 were intended to better align candidates in statuses based on similar medical urgencies. However, subsequent analyses indicated that there had been little change in waiting list mortality for the sickest candidates. Additionally, a higher proportion of Status 1A transplants went to recipients with exceptions as opposed to recipients who met the criteria established in policy, following implementation. At the same time, candidates waiting in Status 1A by exception had lower waiting list mortality than other candidates with the same medical priority. The use of Status 1A exceptions varied across regions following the policy changes.

The Organ Procurement and Transplantation Network (OPTN) Thoracic Organ Transplantation Committee (Thoracic Committee) and OPTN Pediatric Transplantation Committee (Pediatric Committee) agreed that fragmented operation of the different regional review boards (RRBs) and the lack of pediatric transplantation specialists serving as RRB reviewers contributed to the increase in Status 1A exceptions and the regional differences among approved Status 1A exceptions.

Creating a National Heart Review Board (NHRB) for Pediatrics is intended to improve the quality and consistency of the process used to evaluate pediatric heart candidate exception requests. The NHRB will be comprised of representatives from pediatric heart programs all over the country. Each new exception request will be assigned to nine randomly selected representatives for review. The use of reviewers who are specialists in pediatric heart transplantation is aimed at increasing the quality of the evaluation of the exception requests. The national board will be used to minimize local differences and improve consistency. On July 1, 2020, the Thoracic Organ Transplantation Committee will be eliminated, and a new Heart Transplantation Committee and a new Lung Transplantation Committee will begin operations.

Proposal History

Following implementation in 2016, the Thoracic and Pediatric Committees monitored the impact of the pediatric heart allocation changes. Findings from the monitoring reports suggested an increase in the use of Status 1A and 1B exceptions on behalf of pediatric heart candidates. The two committees established a workgroup with a focus on improving the decision-making regarding exception requests. This proposal incorporates the workgroup's effort by creating a National Heart Review Board for Pediatrics, and implementing operational guidelines to establish the Board's representation, as well as voting and appeals processes. The proposal received significant support during the public comment period held from January 2020 through March 2020.

Summary of Changes

The changes included in this proposal are listed below:

- **Policy:** The changes to policy will create a National Heart Review Board for Pediatrics charged with retrospectively reviewing pediatric Status 1A and Status 1B exception applications.
- **Operational Guidelines:** The proposal creates operational guidelines for the National Heart Review Board for Pediatrics, including how representation on the Board is apportioned, defining representatives' responsibilities as part of the NHRB, and establishing voting procedures and an appeals process. In addition, creation of the National Heart Review Board for Pediatrics operational guidelines require revisions to the OPTN Heart Review Board (HRB) Guidelines.

Implementation

Pediatric heart transplant programs will need to undergo training for staff in new voting processes, use of UNetSM, and changes to the exception request forms. These programs may appoint a representative and an alternate to both the RRB and the NHRB for Pediatrics. There is no anticipated change to current monitoring.

This proposal will require programming by UNOS IT. The NHRB for Pediatrics will largely mirror the existing National Liver Review Board and help to streamline the review board system in UNetSM.

Affected Policy Language

New language is underlined (example) and language that is deleted is struck through (~~example~~).

6.4 Adult and Pediatric Status Exceptions

A heart candidate can receive a status by qualifying for an exception according to *Table 6-3* below.

Table 6-3: Exception Qualification and Periods

| Requested Status: | Qualification: | Initial Review | Duration: | Extensions: |
|-------------------|--|--|-----------|---|
| Adult status 1 | <ol style="list-style-type: none"> Candidate is admitted to the transplant hospital that registered the candidate on the waiting list Transplant physician believes, using acceptable medical criteria, that a heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status | RRBs retrospectively review requests for status 1 exceptions | 14 days | <ul style="list-style-type: none"> Require RRB approval for each successive 14 day period RRB will review and decide extension requests retrospectively |
| Adult status 2 | <ol style="list-style-type: none"> Candidate is admitted to the transplant hospital that registered the candidate on the waiting list Transplant physician believes, using acceptable medical criteria, that a heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status | RRBs retrospectively review requests for status 2 exceptions | 14 days | <ul style="list-style-type: none"> Require RRB approval for each successive 14 day period RRB will review and decide extension requests retrospectively |
| Adult status 3 | <ol style="list-style-type: none"> Candidate is admitted to the transplant hospital that registered the candidate on the waiting list Transplant physician believes, using acceptable medical criteria, that a heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status | RRBs retrospectively review requests for status 3 exceptions | 14 days | <ul style="list-style-type: none"> Require RRB approval for each successive 14 day period RRB will review and decide extension requests retrospectively |
| Adult status 4 | Transplant physician believes, using acceptable medical | RRBs retrospectively | 90 days | <ul style="list-style-type: none"> Require RRB approval for each |

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|---------------------|--|--|------------|---|
| | criteria, that a heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status | review requests for status 4 exceptions | | successive 90 day period <ul style="list-style-type: none"> • RRB will review and decide extension requests retrospectively |
| Pediatric status 1A | <ul style="list-style-type: none"> • Candidate is admitted to the transplant hospital that registered the candidate on the waiting list • Transplant physician believes, using acceptable medical criteria, that a heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status | <u>The national heart review board (NHRB) RRBs</u> retrospectively reviews requests for Status 1A-exceptions | 14 days | <ul style="list-style-type: none"> • Require <u>The NHRB</u> approval for each successive 14 day period • <u>The NHRB RRB</u> will review and decide extension requests retrospectively • If no extension request is submitted, the candidate will be assigned pediatric status 1B |
| Pediatric status 1B | Transplant physician believes, using acceptable medical criteria, that a heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status | <u>The NHRB RRBs</u> retrospectively reviews requests for Status 1B exceptions | Indefinite | <ul style="list-style-type: none"> • Not required as long as candidate's medical condition remains the same |

The candidate's transplant physician must submit a justification form to the OPTN Contractor with the requested status and the rationale for granting the status exception.

6.4.A Review Board RRB and Committee Review of Status Exceptions

The heart RRB reviews applications for adult and pediatric status exceptions and extensions retrospectively. The national heart review board (NHRB) reviews applications for pediatric status exceptions and extensions retrospectively.

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

6.4.A.i. Review Board RRB Appeals

If the review board RRB denies an exception or extension request, the candidate's transplant program must either appeal to the relevant review board RRB within 1 day of receiving notification of the review board RRB denial, or assign the candidate to the status for which the candidate qualifies within 1 day of receiving notification of the review board RRB denial.

6.4.A.ii Committee Appeals

If the review board RRB denies the appeal, the candidate's transplant program must within 1 day of receiving notification of the denied appeal either appeal to the Thoracic Organ Heart Transplantation Committee or assign the candidate to the status for which the candidate qualifies. If the Thoracic Heart Transplantation Committee agrees with the review board's RRB's decision, the candidate's transplant program must assign the candidate to the status for which the candidate qualifies within 1 day of receiving notification of the denied Committee appeal. If the transplant program does not assign the candidate to the status for which the candidate qualifies within 1 day of receiving notification of the denied Committee appeal, then the Committee will refer the case to the MPSC.

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Operational Guidelines Language

National Heart Review Board for Pediatrics

Operational Guidelines

Overview

The purpose of the National Heart Review Board (NHRB) for pediatrics is to provide fair, equitable, and prompt peer review of pediatric candidate status 1A- and status 1B- justification form applications submitted by transplant programs for candidates whose medical urgency is not accurately reflected by the standard pediatric listing criteria for heart allocation. Justification form applications will be referred to throughout these guidelines as “applications” and include initial exception application, extension exception applications, and appeals.

Representation

Each pediatric heart transplant program with an active pediatric component may appoint a primary representative and an alternate representative to the NHRB. Transplant programs are encouraged to appoint representatives from both cardiology and cardiac surgery who have active pediatric heart transplant experience. Pediatric heart transplant programs are not required to appoint a representative to the NHRB.

Primary and alternate representatives serve one-year terms. A pediatric heart transplant program may appoint the same primary and/or alternate representative to serve consecutive terms.

If a transplant hospital withdraws or inactivates its heart transplant program or the pediatric component, it may not participate in the NHRB. However, the transplant hospitals’ participation may resume once it has reactivated the transplant program and the pediatric heart component.

If at any time, a representative is no longer eligible to review an application, that application may be randomly reassigned to another reviewer.

Responsibilities of Primary and Alternate Representatives

Prior to each term of service, primary and alternate representatives are required to sign the *Confidentiality and Conflict of Interest Statement* and complete orientation training.

Representatives must vote within 3 days on all initial exception applications, exception extension applications, and appeals. On day 4, if the vote has not been completed, then the application will be randomly reassigned to another representative. The original reviewer will receive a notification that the application has been reassigned.

Primary representatives must notify UNOS in advance of absences, during which the alternate will fulfill the responsibilities of the representative.

If a primary or alternate representative does not vote on an open application within 3 days on 3 separate instances within a 12 month period, the Chair of the Heart Transplantation Committee (Chair) may remove the individual from the NHRB. If a representative or alternate does not vote because a case is approved and closed before the 3 day timeframe expires, it is not considered a failure to vote. A representative or alternate who has been removed for failure to perform the duties required is not eligible to serve again for 3 years.

If a pediatric heart transplant program exhibits a pattern of non-responsiveness, as evidenced by the removal of 2 members from the NHRB, the Chair may suspend the program’s participation for a period of 3 months after notifying the program director. Further non-compliance with the review board process may result in cessation of the program’s representation on the NHRB until such a time as the transplant program can satisfactorily assure the Chair that it has addressed the causes of non-compliance.

Voting Procedure

Each initial exception application is assigned retrospectively to a randomly generated group of nine representatives of the NHRB. The random selection process will include a metric for program size as an additional selection criterion. Program size will be re-calculated at least annually. A representative may vote to approve or deny the application, or ask that the application be reassigned. The NHRB will retrospectively review extension exception applications. Each extension exception application is assigned to the same group of nine representatives who reviewed the initial exception application.

Voting will close at the earliest of when:

- 5 reviewers have voted to approve an application;
- 5 reviewers have voted to deny an application; or
- 6 days after the first reviewer received the application

When voting is closed, NHRB review of applications is decided as described in Table 1, below:

Table 1: Effect of NHRB Votes

| <u>Of the votes submitted, if...</u> | <u>Then the application is...</u> |
|--|-----------------------------------|
| <u>Majority vote to approve</u> | <u>Approved</u> |
| <u>An equal number of voters have voted to approve as deny</u> | <u>Approved</u> |
| <u>Majority vote to not approve</u> | <u>Not approved</u> |

Representatives no longer have the ability to vote after voting is closed.

Appeal Process

A pediatric heart transplant program may appeal the NHRB decision to deny an exception application. Patients are not eligible to appeal exception applications. All reviewer comments are available in UNetSM. The NHRB advises programs to respond to the comments of dissenting reviewers in the appeal.

Each appeal is assigned to the same group of nine representatives who reviewed the initial exception application. A representative may vote to approve or deny the application, or ask that the application be reassigned.

Voting will close at the earliest of when:

- 5 reviewers have voted to approve an application;
- 5 reviewers have voted to deny an application; or
- 6 days after the first reviewer received the application

When voting is closed, NHRB review of appeals is decided as described in Table 2, below:

Table 2: Effect of NHRB Appeal Votes

| <u>Of the votes submitted, if...</u> | <u>Then the appeal is...</u> |
|--|------------------------------|
| <u>Majority vote to approve</u> | <u>Approved</u> |
| <u>An equal number of voters have voted to approve as deny</u> | <u>Approved</u> |
| <u>Majority vote to not approve</u> | <u>Not approved</u> |

If the appeal is denied, the pediatric heart transplant program may initiate a final appeal to the Heart Transplantation Committee (Heart Committee).

If an initial exception application will expire before the deadline for the NHRB for Pediatrics or the NHRB for Pediatrics Appeals Workgroup to decide on the application, and the transplant program submits an application for an extension of that application, then the extension exception application will be put on hold until the appeal of the initial exception application has been resolved. If the appeal of the original exception application is resolved in favor of the pediatric heart transplant program's request, then the extension exception application will be released and assigned to the same group of nine representatives who reviewed the initial exception application. If the appeal of the original exception application is resolved against the pediatric heart transplant program, then the extension exception application will not be eligible for review and thus, not approved.

Appeals to the Heart Transplantation Committee

The Heart Committee may delegate review of appeals to a NHRB for Pediatrics Appeals Workgroup of at least five members which may consist of members of the Heart Committee, Pediatric Committee, or other pediatric heart physicians or surgeons.

If the appeal achieves a majority of affirmative votes, it will be approved. In the event of a tie, the appeal will be approved. If either the program or a representative requests that the appeal be considered on a conference call, then a call will be scheduled with the NHRB for Pediatrics Appeals Workgroup.

OPTN Adult Heart Regional Review Board (HRB RRB)

Operational Guidelines

Overview

The purpose of the Adult Heart Regional Review Board (HRBRRB) 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.

1. Representation

- A. Every designated heart transplant program may participate on the HRB RRB. Each HRB 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 HRB RRB Chair. The HRB RRB Chair will be called upon to decide tie votes and may not simultaneously represent his or her transplant program as an HRB RRB member.
 - C. The HRBs RRBs vary in size and rotate as determined by each OPTN region. Since larger HRBs RRBs may pose operational or administrative challenges, some HRBs RRBs rotate membership to ensure each transplant program is represented on the HRB RRB for one term each year.
 - D. Each program represented on the HRB RRB 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 RRB primary and alternate representatives. Should an HRB RRB primary representative leave his or her transplant program, then the transplant program’s alternate representative will become the new HRB RRB 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 RRB primary representative.
 - E. If a transplant hospital inactivates or withdraws its heart program, it may not participate in the HRB RRB. The term of the transplant program’s representative on the HRB 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.
- 1. Responsibilities of HRB RRB representatives**
- HRB RRB 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 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.

2. Voting Procedures

A. Retrospective Review of Status Exceptions

The HRB RRB will review all applications that require HRB 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 HRB 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 HRB RRB will review applications from another OPTN region on a rotating basis. The same HRB 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. HRB RRB Case Review and Vote

~~The OPTN Contractor will first send all applications~~ All applications will first be sent to the HRB RRB primary representative. If the primary representative has not voted within 3 business days of when the OPTN Contractor sends the application to the HRB RRB receiving the application, then the OPTN Contractor will send the case will be sent to the alternate representative. Thereafter, both the HRB RRB member and alternate representative may vote on the application within 7 days of when the OPTN Contractor originally sent the application application was originally provided to the HRB RRB. If the HRB 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 HRB RRB representatives (or their alternates) voting on the application. If all HRB RRB representative have voted and the vote is tied, the HRB 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 ~~or deny~~ a request
- a majority of all eligible voters have voted to deny a request; or
- 7 days after the ~~OPTN Contractor sends the request is sent~~ to the HRB RRB

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

Table 1: Effect of HRB RRB Votes

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

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

The OPTN ~~Contractor~~ will maintain the results of the HRB's RRB'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 RRB members, but will not provide the votes of specific HRB RRB members.

5. Appeal Process

A. Appeal to the Review Board

If the HRB RRB does not approve an initial or extension request application, the candidate's transplant program must either submit an appeal application to the HRB RRB within 1 day of receiving notification of the HRB RRB decision, or assign the candidate to the status for which the candidate qualifies within 1 day of notification of the HRB's 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 HRB RRB members. This additional information will be provided to HRB RRB members for further consideration.

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

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

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

If the HRB RRB denies the appeal of an initial application or extension request application, the candidate's transplant program must either appeal to the Thoracic Organ 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 ~~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~~ Heart Transplantation Committee within one day of receiving the notification of the ~~HRB~~ RRB decision, the appeal process is not available.

6. Extensions

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

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

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

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