

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

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

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

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

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.