

Children's
Hospital & Regional Medical Center
Office of the Vice President for Research

OPERATING PROCEDURES/POLICIES

Committee: Institutional Review Board
Policy Number: IRB-32
Effective Date: June 20, 2005

POLICY TITLE:

**PRINCIPAL INVESTIGATOR'S APPEAL PROCESS OR
PROCESS TO REQUEST A RECONSIDERATION**

POLICY:

Principal investigators shall have the right to appeal a decision of the IRB. The Principal investigator shall request an appeal by notifying the IRB Chair. The appeal process is restricted to major determinations or actions of the IRB. The principal investigator may also request the IRB to reconsider an IRB finding, determination or requirement for approval by writing a request to the IRB Chair to reconsider a requirement for approval. Requests for an appeal or for reconsideration must be considered by the convened IRB.

PROCEDURE:

- 32.1 The Principal Investigator shall have the right to appeal a decision by the IRB by notifying the IRB Chair. This appeal process applies to the following decisions ONLY:
- A. The IRB's assessment of the risks and benefits of the proposed research;
 - B. The decision by the IRB to disapprove a study
- 32.2 The appeal should be initiated by preparing a letter to the IRB Chair addressing relevant issues. An appeal should provide new or additional information that was not available to the IRB at the time of its initial decision.
- 32.3 The IRB Chair shall decide if the issues addressed in the appeal letter warrant inviting the Principal Investigator to the next regularly scheduled IRB Board

- Meeting to present his/her justifications. In the majority of cases, the principal investigator will attend the IRB meeting to present his/her justifications for an appeal.
- 32.4 Any decision to reverse a disapproved study requires a vote of the convened IRB, unless the study was disapproved on administrative grounds. A reversal of a disapproved study must be carried by a majority of the voting members attending the IRB meeting. Appeals of a study disapproved on administrative grounds, are submitted to the Vice President for Research.
- 32.5 The principal investigator shall have the right to request the IRB to reconsider a decision it made regarding a required finding or determination or a condition of approval. The request for reconsideration should be initiated by preparing a letter to the IRB Chair addressing relevant issues. To reconsider an IRB decision, the principal investigator, should provide new or additional information that was not provided to the IRB at the time of its initial decision.
- 32.6 The IRB Chair shall decide if the issues addressed in the letter requesting a reconsideration warrant inviting the Principal Investigator to the next regularly scheduled IRB Board Meeting to present his/her justifications. In the majority of cases, the principal investigator will attend the IRB meeting to present his/her justifications for reconsideration.
- 32.7 Any decision to reverse an earlier determination, finding or condition for approval requires a vote of the convened IRB, and must be carried by a majority of the IRB members attending the meeting.
- 32.8 Immediately following the meeting, a member of the IRB staff shall notify the principal investigator by telephone of the IRB's decision to approve or disapprove the request for appeal or reconsideration. The IRB shall document in writing in the minutes for the meeting and in a letter to the principal investigator the IRB's decision and the rationale for its decision regarding the request to appeal or reconsider.

Submitting Committee: Institutional Review Board

Approved by: Douglas S. Diehema 6/20/05
Chair Date

Elizabeth Trias 6/20/05
Manager Date