

Children's

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

OPERATING PROCEDURES/POLICIES

Committee: Institutional Review Board
Policy Number: IRB 28
Effective Date: May 8, 2006

POLICY TITLE: FACILITATED IRB REVIEW FOR STUDIES APPROVED BY THE NATIONAL CANCER INSTITUTE (NCI) PEDIATRIC CENTRAL INSTITUTIONAL REVIEW BOARD (PedCIRB)

POLICY:

In accordance with the NCI Pediatric Central IRB Authorization Agreement duly executed by Children's Institutional Official, Children's IRB shall conduct a facilitated review of studies which have been reviewed and approved by the PedCIRB. The facilitated review by Children's IRB is to determine if Children's shall accept the review of the PedCIRB for the study or request a Children's IRB review of the study at a convened meeting. The overall division of responsibilities between the PedCIRB and Children's (the local) IRB are detailed in the signed IRB Authorization Agreement.

PROCEDURE:

- 28.1 The local investigators at Children's shall determine if they wish to enroll participants in a PedCIRB approved study. If they determine they wish to participate, a local investigator shall be assigned to be the local Principal Investigator.
- 28.2 The local Principal Investigator shall download from the PedCIRB web site all of the PedCIRB approved documents for that study. Two copies of these documents shall be submitted to Children's IRB for facilitated review. The documents for each study shall include:
- A. The PedCIRB application;
 - B. The approved protocol;
 - C. The approved consent forms and assent forms;
 - D. The approved case report forms;
 - E. Minutes and other documentation from the PedCIRB review;

- F. The Investigator's brochure for investigational new drug studies;
 - G. Data and safety monitoring plan (if a separate document); DSMB charter, when applicable;
 - H. Other documents approved by the PedCIRB and available on their web site that would provide relevant information for the facilitated IRB review of the study.
- 28.3 In addition to the PedCIRB documentation described in 28.2 above, the local principal investigator shall complete and submit two copies the Facilitated IRB Review form. This form provides information specific to local institutional concerns for the conduct of the research at Children's.
- 28.4 Facilitated review shall be carried out by the IRB Chair. The Chair may designate one or more qualified voting members of the Children's IRB to serve on a Subcommittee conducting the facilitated review. Any member designated to conduct a facilitated review shall have the qualifications and knowledge required to review the study to ensure local institutional policies and requirements are met.
- 28.5 The designated member(s) conducting the facilitated review shall review the PedCIRB documents and the Facilitated IRB review form and recommend one of the following actions:
- A. Accept the study as approved by the PedCIRB;
 - B. Accept the study with "de minimus" modifications;
 - C. Refer the study for full IRB review by Children's IRB. This action will be requested when facilitated review identifies changes or additions that are recommended for the protocol or consent form that do not meet the PedCIRB criteria of "de minimus" modifications.
- 28.6 The NCI Pediatric Central IRB Authorization Agreement (see Appendix 10.D.) allows Children's IRB to make minor modifications to protocols to increase participants' safety or clarify procedures. Children's IRB may also make minor wording changes or additions to the consent forms to improve comprehension as long as the changes do not alter the meaning of the PedCIRB approved consent form. Local boilerplate additions to the informed consent specific to state and local law, institutional requirements or IRB policies shall be added to the local consent form used at Children's. These shall include, but are not limited to:
- A. The names and contact information of the local PI and other research team members;
 - B. A 24-Hour Emergency Telephone Number annotated with instructions on who to call, e.g., oncologist on call;
 - C. Contact information for Children's IRB for local participants who have questions about their or their child's rights as research participants.

Contact information of the local researchers for participants to call in the event of a research related injury or for questions about the research;

- D. Indication on who will be given copies of the signed consent form, including the participants or their parents, the researchers' file, and patient's medical record if the research involves care or treatment;
 - E. Separate HIPAA authorization on Children's authorization form, specific to the research.
- 28.7 The local PI shall indicate on the Facilitated IRB form the readability scores of the consent and assent form.
- 28.8 If the designated reviewer(s) accept PedCIRB review, the IRB Manager shall notify the local PI and the PedCIRB by completing the Facilitated Review Acceptance Form on its website. The PedCIRB review date becomes the official review date for the study and the PedCIRB becomes the IRB of record for the study. The PedCIRB will then conduct all amendment reviews, non-local SAE reviews, and continuing reviews. These reviews will be posted on the PedCIRB website and e-mail notification will be sent about these reviews to Children's IRB and the local PI.
- 28.9 If the designated reviewer(s) decide to accept the PedCIRB review and minor changes are made, the minor changes required shall be communicated in writing to the local PI. Once the local PI has made the minimal modifications as requested and the designated reviewer(s) agree to accept the PedCIRB review, the IRB Manager shall notify the local PI and the PedCIRB by completing the Facilitated Review Acceptance Form on its website.
- 28.10 If the designated reviewer(s) request changes or modifications to the consent form or the protocol that do not meet the criteria of minimal modifications as determined by the PedCIRB, the Agreement requires that the study be sent to Children's full IRB for review. If the designated reviewer(s) make this determination, the IRB Manager shall notify the local Principal Investigator. The local PI will decide if he or she wants to pursue full IRB approval by Children's IRB and if so submit the appropriate application for full Children's IRB review.
- 28.11 Once Children's accepts PedCIRB approved studies under the Facilitated Review process, the PedCIRB shall be the IRB responsible for ongoing and continuing review. PedCIRB is responsible to ensure:
- A. Approved studies meet all federal regulatory requirements for initial and continuing review of studies;
 - B. Approved consent forms meet all federal regulatory requirements for informed consent;
 - C. Documents used in the PedCIRB initial and ongoing approval of studies are made available to Children's IRB as needed;

