

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

OPERATING PROCEDURES/POLICIES

Committee: Institutional Review Board
Policy Number: IRB-38
Effective Date: June 12, 2006

POLICY TITLE:

**PRELIMINARY REVIEW (PRE-REVIEW) PROCESS AND IRB SUBMISSION STANDARDS
FOR NEW AND CONTINUING REVIEW APPLICATIONS**

POLICY:

The Human Subjects Protection Program (HSPP) staff shall conduct a pre-review of all new and continuing review IRB applications. The pre-review ensures the IRB application and supporting documents provide the information necessary for the IRB to make its determinations. There may be information requested by the IRB during review that was not requested during pre-review due in part to different analysis emphases (HSPP pre-review: regulatory emphasis; IRB review: ethical emphasis).

PROCEDURE:

- 38.1 The principal investigator (PI) shall submit (from his/her own e-mail account) to the IRB one complete copy of an IRB application with all relevant attachments to the IRB at its e-mail address at irb@seattlechildrens.org. Incomplete applications shall be returned to the PI for resubmission to the IRB when complete.
- 38.2 Confirmation of the application received and assignment of the Regulatory Analyst for pre-review will be sent to the PI.
- 38.3 The Regulatory Analyst shall conduct the pre-review and provide pre-review comments to the PI in a timely manner.

NEW RESEARCH STUDIES:

- 38.4 For each **new** study the Regulatory Analyst shall review the IRB application to ensure the following submission standards:
 - A. The IRB application is complete so that the IRB has the information required to conduct the review of the study;
 - B. The consent and assent forms for the study meet Children's standards for consent and assent forms (Consent Form and Assent Form Checklist). The consent and assent

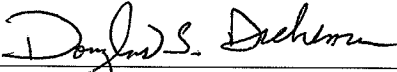
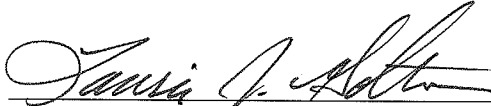
- forms shall follow Children's template format;
- C. All recruitment materials are included and meet Children's standards for recruitment (IRB Policy 24);
 - D. All questionnaires, surveys, and documents that research participants will be asked to complete are included. Note: The IRB does not require copies of certain standard instruments that may be used in research (such as IQ tests, the Diagnostic Interview Schedule (DIS), or standard tests involving tasks that measure motor function, memory, perception, or vocabulary). For tests that involve tasks, researchers shall provide a summary of the tasks involved;
 - E. A detailed research protocol is included if available. The IRB expects protocols to be available for industry sponsored studies, multicenter clinical trials, and investigator initiated studies that involve greater than minimal risk;
 - F. The Investigators' Brochure (or equivalent information) for investigational new drug studies is included;
 - G. The Manufacturer's Brochure (or equivalent information) for investigational new medical device studies is included;
 - H. Complete copies of each submitted funding proposal to support the research activities covered in the IRB application are included. Exceptions include:
 - 1. For cooperative review group funding that provides support to conduct multiple clinical trials but the funding proposal does not describe any individual research studies (e.g., Children's Oncology Group, the AIDS Clinical Trials Group);
 - 2. For center or program project grants, the IRB reviews only the project that pertains to the human subjects activities covered in the IRB application (not the entire center grant);
 - J. Complete set of the research case report or data collection forms is included;
 - K. For multicenter studies, copies of sample consent forms prepared by the sponsor if available.
- 38.5 The Regulatory Analyst conducting the pre-review shall notify the PI by e-mail of what information is needed to proceed with the IRB review of the study. This correspondence will include suggested next steps for toward IRB review.
- 38.6 The PI shall respond to the pre-review queries by submitting a revised application via e-mail (from his/her own e-mail account) to irb@seattlechildrens.org.
- 38.7 Upon receipt, the Regulatory Analyst shall review the revised application to ensure that the information necessary for the IRB to make its determinations has been provided. If required information is still missing, the Regulatory Analyst shall notify the PI. If the submission is complete, the study will be scheduled for review by the IRB. *Note: No hard copy or PI signature is required at this point. A hard copy of the revised application with an original PI signature *will be required* when the submission is in final form and ready for approval (IRB Policy 11).
- 38.8 Once a new study has been forwarded to the IRB committee members for review, any primary reviewer from that committee shall have the authority to request additional supporting information or documents from the PI prior to the scheduled IRB meeting. This request shall be made either directly by the primary reviewer or through the Regulatory Analyst.

CONTINUING RESEARCH STUDIES:

- 38.9 For each **continuing review (renewal)** study undergoing pre-review, the Regulatory Analyst shall review the status report (renewal application) to ensure the following submission standards are met:
- A. The IRB status report is complete and the IRB will have the information required to do the continuing review of the ongoing research study (see IRB policy 14 and 22).
 - B. Copies of all currently approved consent and assent forms are provided. When the PI is requesting changes to the research that affect the consent and assent forms, copies of the currently approved consent and assent form with the proposed changes shall be provided.
 - C. Copies of the modification report and funding report attachments.
 - D. Copies of supplemental materials requested in the status report if they apply to the ongoing research activity (e.g., data and safety monitoring board (DSMB) reports, copies of publications resulting from the research, etc.).
 - E. Any submission of information or materials that suggests that material changes have been implemented without IRB approval or that IRB approved procedures are not being followed shall be forwarded immediately to the Office of Institutional Assurances (OIA) Manager. The OIA Manager shall advise the HSPP staff on next steps required to investigate possible non-compliance.
- 38.10 Upon receipt of a complete status report and supporting materials, the Regulatory Analyst shall forward the same for IRB review. The PI and HSPP staff are responsible for collaborating to ensure that IRB review can be conducted prior to the expiration date of the current research approval period.

Submitting Committee: _____ Institutional Review Board

Approved by: _____

 _____ Chair, IRB	6/12/06 _____ Date
 _____ Manager, OIA	6/12/06 _____ Date