

**Children's Hospital and Health System, Inc.
Administrative Policy and Procedure
Children's Research Institute**

**SUBJECT: Institutional Review Board (IRB)
Research Revisions and Amendments**

POLICY

I. Purpose:

- A. To define the Children's Hospital of Wisconsin (CHW) Institutional Review Board (IRB) requirements for investigators reporting revisions or changes to the protocol, informed consent form, recruitment materials, and/or other changes.
- B. Investigator deviations from or non-adherence to the protocol in order to eliminate apparent immediate hazards to a subject are not subject to this policy. [See "IRB Protocol Deviations Unanticipated Problems in Human subjects Research" for applicable reporting requirements]

II. Policy:

- A. The IRB is responsible for oversight of all research conducted at CHW. It is imperative that all changes to an approved research project, during the year for which approval has been granted, be submitted to the IRB for review and approval before initiation of said changes. The only exceptions to this requirement are when the change must be made to eliminate apparent immediate hazards to the subject.
- B. Revisions or changes to the protocol, informed consent, recruitment materials and other study procedures:
 - 1. Investigators shall submit any revisions or changes to the current protocol, recruitment materials, informed consent form and/or other study procedures for IRB review and approval prior to initiation of the changes. Revisions / changes of a procedural nature that must be reviewed by the full IRB should be submitted with the normal committee deadlines in mind in order to ensure review at the next IRB meeting. Revisions / changes minor nature, and/or corrections can be reviewed through the expedited review process and can be submitted at any time, but should be submitted prior to initiation. Generally the same criteria used to determine expedited initial review of revisions and amendments.

2. With the exception of minor changes, new recruitment materials or changes to previously approved recruiting materials must be reviewed by the full IRB. Examples of minor changes include, but are not limited to, changes in the medium only (e.g., print versus radio advertisements) and changes in contact information.
 3. In order to simplify this procedure, the IRB "Amendment Form" must be completed. The proposed change(s) must be clearly described. The current procedure should be described together with the proposed change and the rationale(s) for each change. Revisions to the current protocol and/or informed consent form must be highlighted and clearly summarized. Revisions to the sponsor's protocol must also be made in the investigator's summary. Revisions without adequate explanation and/or highlighting will be returned to the investigator for proper completion prior to forwarding the materials to the IRB for review.
- C. Effect on period for continuing review: Revisions / changes to a currently approved protocol may alter the initial or previous risk-benefit determination. Consistent with an increased risk determination, the IRB may elect to set a shorter interval for continuing review than was originally assigned to the project at the time of initial review or last continuing review. However, the interval may not be extended by setting a date greater than one year from the date of the initial review or last continuing review.
- D. Effect on subjects already enrolled: The IRB shall make the final determination as to whether subjects already enrolled need be apprised of revisions/ changes to the study and the manner in which subjects shall be apprised including, but not limited to, requiring all subjects be re-consented.
- E. The investigator will be notified in writing of receipt of the referenced submission(s) and any action taken by the IRB, including the time period for continuing review whether or not changed from the date set at the initial review or last continuing review.

PROCEDURE

- A. Investigators shall complete and submit the IRB "Amendment Form" for all changes / revisions not implemented to eliminate apparent immediate hazards to subjects in accordance with the instructions provided on the cover page of the form.

- B. The IRB Coordinator, in conjunction with the IRB Chair, will review all submissions and determine whether an expedited review process is appropriate in accordance with policy, "IRB Expedited Review." If appropriate, the IRB Coordinator and Chair will then designate one or more IRB members to review the submission. Changes approved through the expedited review process will be reported in the IRB Administrative Report at the next scheduled IRB meeting.
- C. The primary reviewer system may be utilized for changes requiring review by the full IRB, with the exception of changes to recruitment materials.
- D. It is the IRB Coordinator's responsibility to notify the investigator in accordance with the requirements of section II.E., above.

Previously Approved by the Medical Executive Committee 08/2006
Reviewed 08/2010

(signed copy on file)

Peggy Troy, President of CHHS

References:

Documentation (Documents & Forms):

- A. IRB Amendment Form