

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

OPERATING PROCEDURES/POLICIES

Committee: Institutional Review Board
Policy Number: IRB-22
Effective Date: June 20, 2005

POLICY TITLE:

EXPEDITED REVIEW

POLICY:

Certain types of research activities, involving no more than minimal risk, will be eligible for expedited review. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life during the performance of routine physical or psychological examination or tests. The IRB Chair shall determine if a research activity meets the criteria for expedited review.

PROCEDURE:

General Expedited Review Procedures

22.1 The IRB shall use the expedited procedure to review the following research activities:

- A. **New and continuing research studies** which meet one of the list of categories of research that may be approved through an expedited review procedure [45 CFR 46.110(b)(1) and 21 CFR 56.110(b)(1)]. This list is published by HHS and FDA in the Federal Register. See Appendix 7 for a current list of the "Research Activities That May Be Reviewed Through Expedited Procedures."
- B. **Minor changes in previously approved research** during the period for which approval is authorized [45 CFR 46.110(b)(2) and 21 CFR 56.110(b)(2)]. Minor changes are defined as those that do not materially affect an assessment of the risks and benefits of the study and do not substantially change the specific aims/design of the research.
- C. **Contingencies for approval as requested by the convened IRB during**

its initial or continuing review process as long as the contingencies for final approval do not materially affect an assessment of the risks and benefits of the study and do not substantially change the specific aims/design of the research.

- 22.2 Under an expedited review procedure, the review shall be carried out by the IRB Chair. The Chair may designate one or more voting members to serve on a Subcommittee conducting an expedited review of the research activity. Any member designated to conduct an expedited review of a research activity shall be an experienced member of the IRB with the training and knowledge necessary to conduct an expedited review. No member of the IRB may conduct an expedited review of a specific research activity for which they have a conflict of interest. The IRB member(s) conducting expedited review of the specific research activity are referred to as the Subcommittee.
- 22.3 In reviewing the research, the designated reviewers (Subcommittee) shall exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review at a convened meeting of the IRB in which a quorum is established and the majority of the members present vote to disapprove the research. [45 CFR 46.110(b) and 21 CFR 110(b)].
- 22.4 Expedited review of a new project may be requested by the investigator at the time of application. Alternatively, the IRB Chair may determine an application submitted qualifies for expedited review. The final determination that a new project qualifies for expedited review is made by the Subcommittee.
- 22.5 New applications considered for expedited review that the Subcommittee determine do not meet the criteria for expedited review will be referred to the full IRB for review.
- 22.6 The Subcommittee shall apply the criteria for IRB approval of new research as outlined in the federal regulations 45 CFR 46.111 and 21 CFR 56.111 and IRB policy 11.

Expedited review of new and continuing research activities

- 22.7 Each expedited reviewer (member of the Subcommittee) shall receive the following materials in order to conduct an in-depth review of a proposed **new** research activity:
- A. Complete copy of the IRB application. If the research activity solely involves the use of confidential, existing records, data or specimens the researcher will use the IRB application developed specifically for these

types of research activities. (Appendix 12.B.) For all other new research activities the researcher will use the IRB-SAC application. (Appendix 12.A.)

- B. Research protocol, if available. A protocol may not be necessary if sufficient detail is provided in the IRB application form.
- C. Copies of any funding proposals supporting the research activity. These funding proposals would be listed in the IRB application form under the section entitled Funding.
- D. The proposed consent and assent forms, if applicable. If the researcher is requesting waiver of consent and HIPAA authorization, detailed information on how the research meets the federal criteria for waiver of consent and waiver of authorization. [45 CFR 46.116(d) and 45 CFR 164.512 (i) (2)]
- E. Copies of any recruitment materials to be used, if applicable.
- F. Copies of surveys, questionnaires to be used, if applicable.
- G. Copies of signed confidentiality oaths, agreements, if researcher is requesting approval to review private and protected health information without consent and authorization.
- H. Copies of the research data collection forms to be used.

22.8 Each expedited reviewer (member of the Subcommittee) shall receive the following materials in order to conduct an in-depth review of a **continuing** research activity.

- A. A complete copy of the IRB application, including the original IRB application, all previously approved modifications and previously approved status reports (renewals of continuing studies).
- B. A complete status report that describes the progress of the research in the last period of approval of the project. There are two status report forms available to researchers. For research involving only the use of existing and confidential records, data or specimens, there is a Status Report designed specifically for this type of research activity. (Appendix 12.E.) For all other continuing research activities, the researcher shall use the Status Report designed for all other types of studies. (Appendix 12.D.)
- C. Copies of any new materials to be used or revised materials to be used based on proposed changes requested in the status report. These may include but are not limited to: new or revised consent and assent forms, recruitment materials, data collection forms, confidentiality oaths or agreements.

22.9 The Subcommittee of the IRB shall promptly notify the principal investigator in writing of the Subcommittee's determinations after review of the new or continuing research activity. The Subcommittee may:

- A. Approve as submitted;
- B. Approve when specific contingencies are satisfactorily met;

C. Refer to the full IRB for review.

- 22.10 If the Subcommittee's action is to approve (22.9 A. or B.) the Subcommittee shall document under what category of expedited review the study was approved. Other determinations that must be met to meet federal regulations, e.g., waiver of consent or waiver of authorization, shall also be documented. This documentation shall be in the letter sent to the PI indicating the study was approved as submitted (Appendix 17.J. or 17.K.) or the study will be approved when specific contingencies are satisfactorily met (Appendix 17.I) The Department Director, the Division Director, if applicable, and the institutional official for the IRB shall be copied on the IRB's letters to researchers for new expedited studies which are approved as submitted or approved with minor contingencies. This letter shall document the required findings for approval of the research and the category of expedited research that applies to the research activity.
- 22.11 For studies which are reviewed and given contingent approval, the response from the principal investigator addressing the IRB's contingencies for approval shall be reviewed by the IRB Chair. If the researcher complies with all contingencies for approval, the IRB Chair shall approve the research. If the researcher asks the Subcommittee to reconsider any of Subcommittee's contingencies for approval or provides new information not previously submitted with the expedited review application and materials, all members of the IRB serving on the Subcommittee shall review the response from the PI and determine the Subcommittee's action.
- 22.12 All new and continuing studies, which are reviewed and approved by the Subcommittee under the expedited review process, shall be reported to the full IRB at the next convened meeting of the IRB. The studies are described in the Expedited Report. The Expedited Report provides the full IRB a description of the research activity, the specific expedited category of research under which the research was approved, copies of the correspondence between the Subcommittee and the Principal Investigator, the names of the IRB members serving on the Subcommittee and the date of approval. (Appendix 17.A.)
- 22.13 Copies of new or continuing research applications approved under the expedited review process are available to members of the full IRB upon request. IRB members may request that an activity which has been approved under the expedited review procedure be reviewed by the full board.
- 22.14 Research approved under the expedited review process shall be reviewed for continuing IRB approval no less frequently than once a year from the date of approval. A study considered eligible for expedited review at the time of initial review shall be eligible for expedited review at the time of continuing

review, provided the risk has not changed during the course of the study and the study continues to meet the criteria for expedited review.

Expedited review of modifications to currently approved research activities

- 22.15 Minor changes to ongoing research activities as defined above in item 22.1.B. may be reviewed by a designated Subcommittee as described in item 22.2. Examples of modifications that may be considered minor under the definition provided in item 22.1.B. above include but are not limited to:
- A. Adding a new funding source;
 - B. Adding or removing qualified research team members;
 - C. Narrowing the inclusion criteria or broadening of the exclusion criteria;
 - D. Changes in the number of participants to be enrolled;
 - E. Editorial changes to the consent forms or recruitment materials that improve readability, eliminate confusion, correct typographical errors.
 - F. Changes in study procedures which enhance the protections and monitoring of research participants or reduce discomforts but do not substantially alter the risk vs. benefit assessment, the study design or aims, the category of research involving children.
- 22.16 The following information is required for a review of a modification request:
- A. A letter from the principal investigator or qualified research investigator on the project describing in sufficient detail the proposed changes and the rationale for such changes.
 - B. Any new materials or revised materials that are affected by the proposed modification. Examples include but are not limited to: consent or assent forms, recruitment materials, surveys or questionnaires, data collection forms, and funding proposals.
- 22.17 The determination that a modification request meets the definition in item 22.1. A. and qualifies for expedited review is made by the Subcommittee of the IRB based on a detailed review of the modification request and materials submitted. If the Subcommittee determines the modification request does not qualify for expedited review, the modification shall be referred to the full IRB for review at a convened meeting.
- 22.18 If the Subcommittee determines the modification qualifies for expedited review, the Subcommittee may either approve the modification request as submitted or notify the principal investigator of the contingencies that must be met for the Subcommittee to grant final approval of the proposed modification.
- 22.19 The Subcommittee shall promptly notify the principal investigator in writing of its determination regarding the proposed modification, i.e., refer to the full IRB, approve as submitted, or approve if contingencies are met. The

Subcommittee shall communicate with the principal investigator how the changes in the research shall be communicated to currently enrolled research participants, if such notification is needed.

- 22.20 The approval of minor modifications to ongoing research studies does not alter the current period of approval assigned to the research project. The research must undergo continuing review at the interval established at the last time the project was reviewed and approved by the convened IRB.
- 22.21 All modifications which are reviewed and approved by the Subcommittee under the expedited review process shall be reported to the full IRB at the next convened meeting of the IRB. The studies are described in the Modification Report. The Modification Report provides the full IRB members a description of the modification request approved, the names of the IRB members serving on the Subcommittee and the date of approval. (Appendix 17.B.)
- 22.22 Copies of modifications approved by the Subcommittee under the expedited review process are available to members of the full IRB upon request. IRB members may request that a modification approved under the expedited review procedure be reviewed by the full board.

Expedited Review of Responses

- 22.23 A Subcommittee may review the principal investigator's written response to the contingencies for approval as requested by the convened IRB during its initial or continuing review process. These contingencies are detailed in a written letter from the IRB (contingency letter). The contingencies for final approval may be reviewed only by a Subcommittee of the IRB under an expedited review process when the contingencies, i.e., changes or clarifications, are not substantive. Contingencies which materially affect the assessment of the risks and benefits of the study, affect the IRB's determinations and findings, (e.g., category of research with children that applies, waiver or alteration of requirements for consent), or substantially change the specific aims or design of the research must be reviewed by a convened IRB.
- 22.24 The Subcommittee reviewing responses shall consist of the IRB Chair and any other IRB members designated by the IRB Chair. Additional IRB members may be either one or both of the primary reviewers assigned to the new study or a member with a particular expertise to evaluate the written response (e.g., pharmacist or biostatistician).
- 22.25 The Subcommittee shall review the responses to ensure the investigator has adequately addressed the contingencies for final approval and that the response to the contingencies does not materially affect the assessment of

the risks and benefits of the study, the convened IRB's determinations and findings, or the aims or design of the research.

- 22.26 If the Subcommittee determines that the IRB's contingencies for final approval have been met and no substantive changes were made, the IRB Chair may grant final approval for the new or continuing research study on behalf of the IRB.

- 22.27 If the Subcommittee determines that the written response from the investigator involves substantive changes or clarifications to the research, the response shall be referred for review by the convened IRB at the next IRB meeting.

Submitting Committee: Institutional Review Board

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

Elizabeth Trias 6/20/05
Manager Date