

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

SUBJECT: Institutional Review Board (IRB) Expedited Review

POLICY

I. Purpose:

- A. To describe the Children's Hospital of Wisconsin (CHW) IRB's expedited review process and define applicable categories of research studies for review under this process.

II. Policy:

A. Definitions:

1. **Minimal Risk:** 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 or during the performance of routine physical or psychological examinations or tests. [45 CFR 46.102(i)]

B. Review Using Expedited Review Procedures

1. Under federal rules, certain research may not require review by the full board and may be reviewed by the Chair or designee. The results must be reported at the next convened IRB meeting.
2. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that they may not disapprove the research. A research study may be disapproved only after full board review.
3. The IRB may use the expedited review procedure to review either or both of the following:
 - a. Research involving no more than minimal risk and which the only involvement of human subjects will be in one or more categories described in section C. below.
 - b. Minor changes in previously approved research during the period (of one year or less) for which approval is authorized. For purposes of this Section, "minor changes" means any change in the materials or related documents of a research study that (i) would not affect the IRB's assessment of risks and benefits to subjects; (ii) is a specified change in wording that

has been agreed to by the IRB; or (iii) is a change or clarification that has been specifically described by the IRB.

4. Research should not be deemed to be of minimal risk simply because it is included on the list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedures when the specific circumstances of the proposed research involves no more than minimal risk to human subjects.
 5. Expedited review procedures may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
 6. IRB members shall be advised of research studies that have been expedited at the next IRB meeting, and the same will be noted in the IRB meeting minutes along with the regulatory authority justifying the expedited review.
 7. Expedited review procedures may not be used for research involving prisoners.
 8. If there is any doubt about the appropriateness of expedited review, full board review should be performed. [See also, "IRB Initial Review" and "IRB Continuing Review" policies]
- C. Expedited Review Categories (Note: Categories (1) through (7) pertain to both initial and continuing review)
1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.) (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
 2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be

collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, flexibility testing where appropriate given the age, weight, and health of the individual.
5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [See "IRB Exempt Research" policy] This listing refers only to research that is not exempt).
6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [See “IRB Exempt Research” policy] This listing refers only to research that is not exempt).
8. Continuing review of research previously approved by the convened IRB as follows: (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or (b) where no subjects have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

PROCEDURE

- A. If the investigator feels that his/her research project qualifies for expedited review, a completed Request for Expedited Review form and Expedited Review Check List along with the applicable supporting materials shall be submitted to the IRB Coordinator via IRBNet.
- B. The IRB Coordinator shall forward the submission to the IRB Chair or designee. If the IRB Chair or designee determines that the study is not eligible for expedited review, the study will be sent to the full board; there will be no appeal of this decision.
- C. Research studies approved through expedited review will be included in the meeting minutes of the next IRB meeting and will include the regulatory authority justifying the expedited review.

References:

- A. 45 CFR 46.110
- B. 21 CFR 56.110
- C. 63 FR 60364-60367, November 9, 1998

Documentation (Documents & Forms):

- A. IRB Request for Expedited Review
- B. IRB Expedited Review Check List

(signed copy on file)

Peggy Troy, President CHHS