

Institutional Review Board (IRB) Policies & Procedures Manual



Document: irbm-004-003-expedited-review.docx

Expedited Review Procedures

Purpose

This policy outlines the types of research that may undergo expedited review and the method used to conduct the expedited review process.

Policy

Boston Children's Hospital permits the review of research protocols through the expedited review process governed by the Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA) federal regulations.

Protocols that may be reviewed under expedited review are limited to:

1. Categories of research listed in 45 CFR46.110 unless the reviewer(s) determines that the study involves more than minimal risk,
2. Minor changes in previously approved research during the period for which approval is authorized,
3. Research for which limited IRB review is a condition of exemption.

Expedited review procedures may not be used for classified research.

The Chair and Vice Chairs of the Institutional Review Board (IRB) are responsible for the final determination as to which protocol revisions/amendments are eligible for expedited review and each has the authority to designate one or more experienced committee members to perform the expedited review.

Procedures

New Submissions

Protocols that may be reviewed under the expedited review process are those listed by the Secretary of DHHS in the Federal Register, 45 CFR46.110(a), and by the FDA in the Federal Register, 21 CFR 56.110(a).

Pre-Review

All protocols considered for expedited review will undergo an administrative pre-review. The IRB administrative staff will pre-review protocols for completeness and consistency and provide the investigator with feedback, questions, or concerns. IRB administrative staff will also provide advice as to what will likely be acceptable within IRB policies and provide input on the protocol and consent document prior to being reviewed. The investigator must respond to the issues raised and changes requested through the pre-review process before protocols are provided to a committee member for expedited review.

IRB administrators also initially determine whether the protocol meets the criteria for expedited review as specified by the regulations, which include the applicability criteria. It is important to recognize that procedures that may be considered minimal risk in adults may not be minimal risk in children. This may be the result of psychological or emotional distress, even if the actual procedures present minimal physical risk to the subject.

The standard requirements for informed consent (or its waiver, alteration, or exception) apply.

After initial screening by the administrative staff of the IRB and the pre-review, the protocols are brought to the attention of the IRB Chair or Vice Chairs. The Chair or Vice Chairs will:

1. Review the protocol or
2. Designate an **experienced IRB member** to do so.
 - a. **Experienced IRB member:** A member who has served on the IRB for at least 6 months and has the knowledge and background to be able to conduct the review.
 - b. In identifying experienced members who may review protocols, the IRB Chair or Vice Chair will consider the discipline of the research and length of service and ask the committee member with expertise in that discipline to review a protocol.
 - c. Members are asked to declare if any conflict of interest exists for any protocol, they are asked to review through expedited review procedures.
 - i. No member with a conflict of interest (COI) may serve as a reviewer for any expedited item.
 - ii. If there is a COI, the protocol will be reassigned.
 - d. Any member may be asked to serve as an expedited reviewer as required, based on their experience and length of service.
 - e. If a protocol involves prisoners and is eligible for expedited review, the prisoner representative will be one of the designated expedited reviewers.
 - f. The IRB Chair or Vice Chairs may also refer any protocol to the full committee for review at a convened meeting.
 - i. Even when expedited review is allowed in accordance with federal regulations, the Chair/Vice Chairs reserve the right to request full committee review.
 - ii. The Chair's/Vice Chair's determination is final.
3. The IRB member who conducts the expedited review will be given access to the electronic submission which includes the following:
 - a. Protocol SmartForms
 - b. Experimental Design
 - c. Consent/Assent Forms
 - d. Consent/Assent Waiver and Alteration Information
 - e. Financial Disclosure and any management plan provided by compliance review
 - f. Information about IT technology and Privacy and Security Provisions
 - g. Recruitment notices, postings, letters
 - h. Complete Department of Health and Human Services (DHHS)-approved protocol (if different from above) and any DHHS-approved sample consents

Materials as pertinent:

- i. Investigational Drug Data

- j. Investigational Device Data
- k. Request for Clinical Imaging Equipment for Research
- l. Radiation Exposure and Radioactive Materials
- m. Supplemental Genetic Information
- n. Pregnant Women and Fetuses information
- o. Prisoners

In addition to the above items, reviewers will have access to the following:

- p. Investigational drug/device brochures or other information provided by the Sponsor
 - q. Assessments, and questionnaires that are not standard
 - r. Additional reference information
 - s. Copies of the scientific reviewers' forms and any correspondence related to the departmental scientific review or other ancillary reviews
4. All the criteria specified in 45 CFR 46 are applied as part of the expedited review process.
- a. In reviewing the research, the reviewers may exercise all the authorities of the IRB except that the reviewers may not disapprove the research.
 - b. The designated IRB reviewer may at any time determine that the protocol be forwarded to the full committee for review.
5. Reviewer and Investigator correspondence: Any questions, comments, or requests for revisions (including any informed consent document concerns) that are received from the reviewer are sent to the investigator through the electronic system. The expedited reviewer will indicate whether they want to receive:
- a. the investigator's response or
 - b. the administrative IRB staff can verify that the changes have been made.
- The investigator must respond through the electronic system, and submit any revised forms, protocols and informed consent documents.
- a. If an investigator is not willing to accept the recommendations and requirements presented as part of the expedited review process, then the protocol and the correspondence to date will be placed on the agenda for the next scheduled meeting of the full IRB.
 - b. If all issues are resolved and the informed consent finalized, approval will be given.
6. The expedited reviewer is required to complete a worksheet which contains all the regulatory criteria for approval and include it in the electronic protocol system.
7. The date the expedited reviewer signs off for final approval of the study is the date the approval period starts.

8. If applicable, the primary expedited reviewer must document rationale for requiring an annual Continuing Review. Otherwise, the protocol requires an annual administrative update.
9. Research activity may be disapproved only after review in accordance with the non-expedited procedures.

A list including the protocol titles, PIs, protocol numbers, and designated expedited review categories is sent to the full committee at its next scheduled meeting.

Categories of Research That May Be Reviewed by the IRB through an Expedited Review

Applicability

1. Research activities that involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review process unless the reviewer(s) determines that the study involves more than minimal risk.
2. The categories in the list below apply regardless of the age of subjects, except as noted.
3. The expedited review process may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability; be damaging to their financial standing, employability, insurability, or reputation; or be stigmatizing, unless reasonable and appropriate protections are implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
4. The expedited review process may not be used in classified research that involves human subjects.
5. Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Research Categories

Category 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. 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.

Category 2

Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture, as follows:

- From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an eight-week period and collection may not occur more frequently than two times per week; or
- 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 eight-week period and collection may not occur more frequently than two times per week.

Category 3

Prospective collection of biological specimens for research Purposes by noninvasive means.

Examples:

1. Hair and nail clippings in a non-disfiguring manner
2. Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction
3. Permanent teeth if routine patient care indicates a need for extraction
4. Excreta and external secretions (including sweat)
5. Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax, or by applying a dilute citric solution to the tongue
6. Placenta removed at delivery
7. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor
8. 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
9. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings
10. Sputum collected after saline mist nebulization

Category 4

Collection of data through noninvasive procedures (that do not involve general anesthesia or sedation) routinely employed in clinical practice, excluding procedures that involve 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:

1. 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
2. Weighing or testing sensory acuity
3. Magnetic resonance imaging
4. Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography

5. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing, where appropriate, given the age, weight, and health of the individual

Category 5

Research that involves materials (e.g., data, documents, records, specimens) that have been collected, or will be collected, solely for non-research purposes (e.g., medical treatment, diagnosis).

Category 6

Collection of data from voice, video, digital, or image recordings made for research purposes.

Category 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 that employs survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Category 8

Continuing review of research previously approved by the convened IRB, as follows:

1. Where
 - the research is permanently closed to the enrollment of new subjects;
 - all subjects have completed all research-related interventions; and
 - the research remains active only for long-term follow-up of subjects; or
2. Where no subjects have been enrolled and no additional risks have been identified; or
3. Where the remaining research activities are limited to data analysis.

Category 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.

Continuing Reviews:

See IRB policy: ***Continuing Review***

Amendments/Revisions/Modifications

See IRB policy: ***Amendments and Revisions*** that discusses the expedited review process.

Related Content

IRB Policies:

Amendments and Revisions

Continuing Review

Document Attributes

Title	Expedited Review Procedures		
Author	Susan Kornetsky	Dates	4/01/2005
Reviewed/ Revised by	Susan Kornetsky	Reviewed/ Revised	6/20/2005 3/15/2007 5/04/2007 3/04/2008 3/25/2008 5/14/2009 3/19/2010 10/29/2010 5/1/2015 4/28/2016
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Approved	<hr/> Susan Kornetsky, MPH Director of Clinical Research Compliance <hr/> August Cervini, MBA Vice President for Research Administration		