



Expedited Review Procedures

Policy

Children's Hospital permits the review of research protocols through the expedited review process governed by Food and Drug Administration (FDA) and Department of Health and Human Services (DHHS) federal regulations. Protocols that may be reviewed under expedited review are limited to 1) categories of research listed in 45 CFR46.110 if the research involves no more than minimal risk and meet the applicability criteria and 2) minor changes in previously approved research during the period for which approval is authorized. Expedited review procedures may not be used for classified research. The Chair and Vice Chair of the Committee on Clinical Investigation (CCI) is responsible for the final determination as to which protocols, revisions/amendments are eligible for expedited review and has the authority to designate one or more experienced Committee members to perform the expedited review.

Purpose

The Purpose of this policy is to outline the types of research that may undergo expedited review, and the method used to conduct the expedited review.

Procedures

New

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) (see below). To be eligible for expedited review, all procedures performed for research must be included in the expedited procedure categories, must be considered minimal risk as defined in the regulations and must meet all of the applicability criteria. Classified research is not eligible for expedited review.

Any protocol that fits the criteria for expedited review with the exception of research that only involves the use of excess/ discarded specimens or the review of existing records and databases only must be submitted on the Children's Hospital Protocol Application Form. There is a separate form for discarded specimens and existing records. All required documents (e.g., questionnaires, informed consent documents, advertisements) are to be submitted as applicable for the review.

All protocols considered for expedited review will undergo an administrative –pre review. The IRB administrative staff will review all protocols for completeness and consistency and provide the investigator with feedback, questions or concerns to be

addressed. 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 .

Administrators also initially determine whether the protocol meets the criteria for expedited review as specified by the regulations which include the applicability criteria. In addition to meeting one of the categories on the expedited review list, the protocol, in total, must fall under the criteria for minimal risk. 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 CCI chair and Vice Chair designate which protocols and which revisions/amendments may undergo expedited review and may designate any IRB member as an expedited reviewer or review it themselves.

The standard requirements for informed consent (or its waiver, alteration, or exception) apply, regardless of the type of review --expedited or convened -- utilized by the CCI.

After initial screening by the administrative staff of the CCI and the pre-review , the protocols are brought to the attention of the CCI Chair or Vice Chair . The Chair or Vice Chair will either review the protocol or designate an experienced Committee member to do so. An experienced member is 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. In identifying experienced members who may review protocols, the CCI 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 particular protocol. The roster of the CCI indicates the discipline for each member. Members are asked to declare if any conflict of interest exists for any protocol they are asked to review through expedited review procedures. If this is the case it will be reassigned. Any member may be asked to serve as an expedited reviewer, based on his or her experience, as required and length of service. If a protocol involves prisoners and is eligible for expedited review, the prisoner representative must be designated one of the expedited reviewers. The CCI Chair or Vice Chair may also refer any protocol to the full Committee for review at a convened meeting. Even when expedited review is allowed in accordance with federal regulations, the Chair/Vice Chair reserves the right to request full Committee review. The Chair's/Vice Chair's determination is final. No member with a conflict of interest may serve as a reviewer for any expedited item.

The CCI member who conducts the expedited review will be sent :

- i) Protocol application
- ii) Attached protocol (Experimental Design)
- iii) Consent/Assent/HIPPA Form and Process information
- iv) Financial Disclosure
- v) Investigational Drug Data (as pertinent)
- vi) Investigational Device Data (as pertinent)
- vii) Request for Clinical Imaging Equipment for Research (as pertinent)
- viii) Radiation Exposure and Radioactive Materials (as pertinent)

Document: CIPP 051.004

- ix) Supplemental Genetic Information (as pertinent)
- x) Waiver of Parental Permission (as pertinent)
- xi) Pregnant Women and Fetuses (as pertinent)
- xii) Prisoners (as pertinent)
- xiii) Any proposed informed consent/assent documents
- xiv) Recruitment notices, postings, letters
- xv) Complete Department of Health and Human Services (DHHS)-approved protocol (if different from above), and any DHHS-approved sample consents

In addition to the above items, reviewer will receive the following:

- A copy of the DHHS grant if funded by DHHS
- Investigational drug/device brochures or other information provided by the sponsor
- Assessments, and questionnaires that are not standard
- Additional reference information
- Copies of the scientific reviewers' forms and any correspondence related to the departmental scientific review

All of the criteria specified in 45 CFR 46 are applied as part of the expedited review process. The expedited reviewer is required to complete a worksheet which contains all of the regulatory criteria for approval. Any questions, comments, or requests for revisions (including any that concern the informed consent document) that are received from the reviewer are sent to the investigator in writing. The investigator must respond in writing, and submit any revised forms, protocols, and informed consent documents. The expedited reviewer will indicate whether they want to receive the investigator's response or whether the administrative IRB staff can verify that the changes have been made. If an investigator is not willing to accept the recommendations and requirements presented as part of the expedited review process, the protocol and the correspondence to date will be placed on the agenda for the next scheduled meeting of the full CCI. Once all issues are resolved and the informed consent finalized, approval will be given.

The designated CCI reviewer may at any time determine that the protocol be forwarded to the full Committee for review. The CCI reviewer may not disapprove an expedited protocol.

A summary of each protocol that undergoes expedited review, including a designation of expedited review categories, is to be prepared for the full Committee at its next scheduled meeting.

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

Applicability

1. Research activities that
 - present no more than minimal risk to human subjects, and

- involve only procedures listed in one or more of the following categories, may be reviewed by the CCI through the expedited review process. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review process when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.
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 CCI 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 nondisfiguring 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 nonresearch 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 CCI 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 the Policy and Procedure for Continuing Review.

Activities Limited to the Use of Excess/Discarded Human Biological Specimens and Existing Records and Databases

For those activities that are determined to require expedited review see the Policy and Procedure:

“Medical Record and Database Review Requests”

“Excess/Discarded Human Biological Specimen Use”

Amendments/Revisions/Modifications

See the Policy and Procedure “Amendments and Revisions” that discusses the process for expedited review.

**Related Content
Document Attributes**

Title	Expedited Review Procedures		
Author	Susan Kornetsky	Dates Reviewed/ Revised	04/01/05, 06/20/05 03/15/07 05/04/07 03/04/08 03/25/08 05/14/09 03/19/2010
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