# Expedited Review

## What is expedited review?

Expedited review does not mean faster review. Expedited review is review of a proposed research study by the Institutional Review Board (IRB) Chair (or Vice-Chair) on behalf of the full board. Federal regulations allow the IRB to review certain applications on an expedited basis only if they meet strict specified criteria. These criteria can be found in 45CFR46.110 and are also listed on the following pages.

## How to submit a study for expedited review

All studies, regardless of the type of review, should be submitted using an Initial Study Submission Form with the appropriate study materials included, as outlined in the research submission requirements. Expedited review applications should be submitted to the Human Protections Administrator (HPA) who will review for qualification of expedited review criteria and completeness of the submission. If the submission is incomplete, the HPA will notify the investigator of any missing requirements and will not forward the study for Research and Development Committee (R&D) review and subsequent IRB review until the submission is complete. Once the submission is complete, the HPA will forward to the R&D Committee for review, and the R&D review assessment will be included in the submission to the IRB Chair.

## Expedited review of a proposed study

The IRB Chair will make the final determination that the study qualifies for expedited review and will review the study for approval on behalf of the IRB. The IRB Chair will be experienced in terms of professional competence to conduct expedited review. If the IRB Chair is unable to conduct the review for any reason, including conflict of interest, the IRB Vice-Chair may conduct the review. In reviewing the research, the IRB Chair will use the same criteria for approval as is used by the full board, and may exercise all of the authorities of the IRB, except disapproval. The IRB Chair may also request in writing any necessary additional information from the investigator. The IRB Chair (or Vice-chair) may request additional expertise when conducting the expedited review. The Chair may also determine that the study will require full board review. If the IRB Chair approves the expedited request, IRB members will be notified of the approved review on the next IRB meeting agenda or at the next full board meeting. The IRB Chair may approve the study (initial or continuing review) or approve with minor modifications (initial or continuing review). The investigator shall also be notified in writing of the outcome of the review and the required modifications, if applicable.

If the IRB Chair cannot approve the request, the application will be referred to the IRB for full board review. Disapproval of a study via expedited review is not allowed. The study may be sent for full board review if expedited review is not allowable, if major, substantive changes are requested, or if the study warrants continuing review more frequently than annually. If the application is referred for full board review, the principal investigator will be notified in writing. Whenever possible, the proposal will be automatically included on the agenda for the next regularly scheduled meeting. The IRB Chair may also request additional information to be included for the full board to review.

The expedited review procedure 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. Additionally, the expedited review procedure may not be used for government-classified research involving human subjects. The criteria for initial and continuing review under expedited review procedures is the same as those listed for full board review.

If the IRB Chair or other reviewer of the expedited submission deems the research greater than minimal risk, the rationale for the assessment will be documented and the study will be referred to the full board for review. When the research involves vulnerable populations, the reviewer will confirm that additional protections and safeguards have been included in the protocol to protect the rights and welfare of participants.

In cases where a new research study was initially approved through expedited review and subsequently discussed under full board continuing review, any decisions reached at the convened IRB meeting shall supersede any decisions made through the expedited review process. If revisions were requested at the convened meeting, approval may be made by the IRB Chair; if the requested revisions are substantive, they may need to be submitted to the full board.

## Categories of research eligible for expedited review

Use of expedited review is restricted to those applications that BOTH:

a). present no more than minimal risk; AND

b). fulfill one of the nine specific categories described below. The categories apply regardless of the age of subjects, except as noted.

2). Specific categories

These nine categories should not be deemed to be of minimal risk simply because they are included on the list. Inclusion on the list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to subjects.

The following expedited categories pertain to both initial and continuing IRB expedited review:

1. Clinical studies of drugs and medical devices only when the following conditions are met:

a. Research on drugs for which an investigational new drug application (see 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. a. Research on medical devices for which (i) an investigational device exemption application (see 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, non-pregnant 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 non-disfiguring 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. Un-cannulated saliva collected either in an un-stimulated 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 of acceptable procedures are: 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, and echocardiography; e. Moderate exercise, muscular strength testing, body composition assessment, and 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 non-research purposes (such as medical treatment or diagnosis). Note: Some research in this category may be 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.

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; and (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.

Note: For multi-center studies, an expedited review procedure may be used when the three conditions listed above have been satisfied for Woman's Hospital. In such cases, the second condition shall be interpreted to mean that no subjects have been enrolled at this site and neither the investigator nor the IRB has identified any additional risks from any other site or relevant source.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two through eight 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.

NOTE: Studies reviewed using expedited categories 8b or 9 require continuing review. The IRB has elected to follow guidance issued by the Office of Human Research Protections, and under this guidance continuing review is required for these two categories.