

Expedited Review of Research

An Expedited Review is a review of research involving human subjects by the IRB chairperson or by an experienced reviewer designated by the chairperson from among members of the IRB.

Certain types of research protocols may be eligible for review under expedited review procedures. The research must involve no more than minimal risk and fit one or more of the categories for expedited review procedures as specified in the regulations [45 CFR 46.110 and 21 CFR 56.110] and described below.

Categories of Research Eligible for Expedited Review

[63 FR 60364-60367, November 9, 1998]

The activities listed below 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 procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

- The categories in this list apply regardless of the age of subjects, except as noted.
- 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 IRB.

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.
- For classified research involving human subjects
- For research involving prisoner populations
- For research involving deception that will mislead subject about their health status, the researchers, or the research purpose
- For research involving the use of proxy consent or emergency waiver of consent
- For research involving genetic testing of samples that have identifiers and the subject have not been informed of all the risks
- For research that involves the growth of perpetual cell lines that was not disclosed in the consent form

Expedited Research Categories Pertaining to Initial 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 [cannot be under an HDE] 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 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, 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.

Non-invasive procedures will be reviewed in consideration of the impact the testing will have on the population. For example, exercise testing in a debilitated elderly population may exceed the minimal risk threshold.

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 DHHS regulations for the protection of human subjects. See Exempt Categories and 45 CFR 46 101(b)(4). This listing refers only to research that is not exempt.]

Projects that involve the collection of prospective data are reviewed via an expedited mechanism. Projects that collect identifiers, track data extraction through links, or use identification keys also fall under this category. If the information involved is sensitive or could be damaging, a full board review may be required.

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

As above, if the data collection involves sensitive or potentially damaging information, a full board review may be required. The reviewer will request a description of the plan to protect, store, and, in some cases, destroy recordings made for research purposes. This may include a plan for stripping identifiers from the data set or disguising identifying characteristics in recorded voices or images.

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 DHHS regulations for the protection of human subjects. See Exempt Categories and 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.]

If the data collection is studying the traits of specific populations, a full board review may be required if the findings could be stigmatizing to a segment of society. The reviewer will request a description of the plan to protect and store the data. This may include a plan for stripping identifiers from the data set.

Expedited Research Categories Pertaining to Continuing Review

1. 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.

[Note: for categories 8a and 8b the following applicability criteria apply: (1) the remaining activities must be minimal risk, (2) if identification of the subjects or their responses will reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal, and (3) the research may not be classified research. For category 8b the only applicability criterion is that the research may not be classified research.]

For a multi-site protocol, an expedited review procedure may be used by the IRB at a particular site whenever the conditions of category (8)(a), (b), or (c) are satisfied for that site. However, with respect to category 8(b), while the criterion that "no subjects have been enrolled" is interpreted to mean that no subjects have ever been enrolled at a particular site, the criterion that "no additional risks have been identified" is interpreted to mean that neither the investigator nor the IRB at a particular site has identified any additional risks from any site or other relevant source.

2. 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. [Under Category (9), an expedited review procedure may be used for continuing review of research not conducted under an investigational new drug application or investigational device exemption where categories (2) through (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. The determination that "no additional risks have been identified" does not need to be made by the convened IRB.]

If a research protocol meets the requirement for minimal risk research, but does not meet the requirements for one or more of the expedited review categories (1-7), the panel may determine the project is eligible for expedited review and designate all subsequent reviews to be expedited during a full-board review.

If a research protocol has been initially approved through a full-board review procedure, the continuing review may **not** be done by the expedited review procedure unless it falls within Category 8 or 9, above.

Expedited Research Review Pertaining to Changes in Approved Research

1. Minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

A minor change is one which, in the judgment of the COMIRB reviewer, makes no substantial alteration in (i) the level of risks to subjects; (ii) the research design or methodology (e.g., an addition of a procedure which would increase risk to subjects); (iii) the number of subjects enrolled in the research (e.g., increases by more than 10%); (iv) the qualifications of the research team; (v) the facilities available to support safe conduct of the research; or any other change in the research that would otherwise warrant review of the proposed changes by the convened IRB.



COMIRB Expedited Review Process

The Application will be reviewed by one of the IRB Chairs, Expedited/Exempt Manager, or designated IRB member.

The IRB Chair approves the designation of the Expedited/Exempt Manager (also an IRB member) for this role and provide input into the annual performance review of this individual. Designated members of the IRB must be sufficiently experienced. They must have at least one year of IRB review experience and undergo COMIRB Expedited/Exempt training procedures which include mentored reviews.

The reviewer(s) conducting initial or continuing review complete the appropriate Expedited Review Checklist (F-IR-022) or Reviewer Checklist for Expedited Continuing Review (F- IR-053-2) to determine whether the research meets the criteria for expedited review and, if so, whether the research can be approved.

In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. If the reviewer believes that there is reason for disapproval, or the nature of the project is not suitable for expedited review, then the reviewer(s) must defer any decision and refer the application for review at a convened IRB meeting.

In the event that expedited review is carried out by more than one reviewer and the reviewers disagree, the IRB administrative staff will work to obtain a consensus. Upon the discretion of the COMIRB Director, Expedited/Exempt manager or IRB Chair the protocol will be submitted to the IRB for full board review.

Reviewers will indicate approval, require modifications, reclassify the project as Exempt/Not Human Subject Research or request resubmission to full board. If modifications are required the COMIRB will inform the investigator by e-mail and/or letter. The response to modifications will be returned to the Chair, Expedited/Exempt manager or designated IRB member(s) for further review.

Expedited reviews are usually completed within 2-4 weeks. COMIRB will respond in writing via email and letter with the reviewer's determination.

Informing the IRB

The IRB panel will be apprised of expedited review approvals through inclusion of this information on the panel meeting agenda under a section entitled "Staff Report". Expedited review determinations are reported at least quarterly at a designated panel meeting. "Staff Report" Copies of all expedited approvals are available for optional review at the request of any IRB member. An approval of research by expedited procedures does not require any ratification by the convened IRB; however, the IRB has the opportunity and authority to re-review previously approved expedited research at its discretion.