What is an Expedited Review Process?

An expedited review procedure consists of a review by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among the members of the IRB.

What Qualifies for Expedited Review?

Expedited review procedures may be considered for use when the research activities:

A. Involve no more than minimal risk to the participants

B. Involve only procedures that are listed in one or more of the following categories:
   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
         (1) an investigational device exemption application (21 CFR Part 812) is not required; or
         (2) 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:**
EXPEDITED REVIEW SUBMISSIONS

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.

*Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." 45 CFR 46.402(a). Source: 63 FR 60364-60367, November 9, 1998.

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.

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. 45 CFR 46.101(b)(4). 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.**
EXPEDITED REVIEW SUBMISSIONS

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. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

Expeditied Categories for Continuing Review Only

8. Continuing review of research previously approved by the convened IRB as follows:
   a. where
      (1) the research is permanently closed to the enrollment of new subjects;
      (2) all subjects have completed all research-related interventions; and
      (3) 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.
EXPEDITED REVIEW SUBMISSIONS

When can expedited review not be used?

Expedited review procedures can NOT be used in either of the following is true:

A. The research is classified
B. The research is such that 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.

Please remember that the standard requirements for informed consent (or its waiver, alteration, or exception) apply to studies reviewed by the expedited process.

How Do I Submit a Request for Expedited Review?

In IRBManager, submit a complete, new protocol submission xForm. There is no submission deadline.