



## EXPEDITED REVIEW OF RESEARCH

Research activities may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110.

~~All of~~ the following must be true in order for the application to be eligible for expedited review:

1. The research falls into one or more of the expedited categories below.
2. The research or remaining research involves no more than minimal risk<sup>1</sup> to the participants or the research falls into category 8(b) ~~(see outlined Appendix A) below.~~
3. The research or the remaining research procedures do not involve procedures where the identification of the subjects or their responses will place them at risk of criminal or civil liability or be damaging to their 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 or the research falls into category 8(b) ~~(see outlined Appendix A) below.~~
4. The research is not classified (i.e. research is not subject to government secrecy laws).

~~Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.~~

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 procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects. ~~Below is a snapshot view of the expedited categories (see Appendix A complete regulatory language).~~

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### Research Eligible for Expedited Review (Initial Review)

1. Certain clinical studies of drugs and medical devices.
2. Certain collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.
3. Prospective collection of biological specimens for research purposes by noninvasive means.
4. Collection of data through noninvasive procedures routinely employed in clinical practice.
5. Research involving data, documents, records, or specimens that have been collected (for research or non-research purposes) or will be collected solely for non-research purposes.
6. Collection of data from voice, video digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

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### Research Eligible for Expedited Review (Continuing Review)

<sup>1</sup> Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

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- 8.** Certain continuing review of research including long-term follow up, or only data analysis is remaining, or where no subjects have been enrolled and no additional risks identified.  
Certain continuing review of research, not conducted under an investigational new drug application or investigational device exemption, and not eligible for categories 2-8.

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**Appendix A: EXPEDITED expedited CATEGORIES categories OF OF RESEARCH research (1-9)**

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 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, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml [37 Tbsp] 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 [3.4 Tbsp] or 3 ml per kg [0.28 tsp per lb] 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. 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;
  - 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

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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 non-research purposes (such as medical treatment or diagnosis).**
  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.**
  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; (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.
  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.**

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