



Expedited Research Categories

1.0 What is Expedited Research?

Expedited research is human participant research of minimal risk where the entire research project falls within one or more of the 9 specific regulatory categories defined below. IRB submissions that qualify for an expedited review as described below are reviewed by a single experienced IRB member designated to review expedited IRB submissions. Expedited submissions are not reviewed by a fully convened IRB meeting therefore submission deadlines and meeting dates do not apply.

2.0 The expedited review process can be used for the following types of IRB submissions:

1. New study submissions that meet the following criteria:
 - Minimal risk (research in which risks to participants do not exceed the risks that individuals would ordinarily encounter in their every-day life)
 - Falls within one or more of the expedited review categories described below.
 - Does not qualify for exempt review (See the [WSU IRB Exempt Research Guidance and Instructions tool](#))
 - Does **not** involve any of the restrictions described below.
2. Continuing Review/Renewal or Status Update submissions of expedited studies.
3. Continuing Review/Renewal submissions of previously approved full board protocols under certain circumstances described by expedited categories 8 & 9.
4. Amendments to approved expedited research when changes do not involve an increase in risk to participants or changes that would otherwise disqualify the study from expedited status.
5. Amendments to previously approved full board studies when proposed revisions are minor, do not exceed minimal risk to participants, or any increase in risk, or newly identified risks, and/or the proposed revision is not a significant alteration of the study design. Examples of revisions to full board studies that can be submitted for expedited review include:
 - Increase or decrease to enrollment.
 - Adverse events added to the pkg insert (medical), but risks are already listed on the consent or they do not apply to the study (pediatric info., but only adults are enrolled in this study)
 - Protocol, Investigator Brochure (IB), or package inserts with updated risk or safety info that was not already listed on the consent, but it does not pertain to the WSU site or the WSU site is permanently closed to accrual, and no one is receiving treatment/active, and no one is in followup.
 - Administrative changes to the consent, such as moving sections, changing personnel names, formatting, etc.

- Administrative changes to the IB (medical), such as moving sections, clarifying language, formatting, etc.
- Alteration in oral forms of administration of a drug (e.g., tablet to capsule or oral liquid) provided the dose remains constant.
- A change that does not substantially alter the specific aims or design of the study.
- Addition or deletion of data collection instruments as long as they pose no more than minimal risk.
- Change in data collection points or amount of data collected as long as it does not alter safety evaluations.
- Increase in the length of confinement or number of study visits for the purpose of increased safety monitoring.
- Alteration in the participant compensation or liberalization of the compensation schedule.
- Changes to improve clarity of statements or correction of typographical errors provided that such a change does not alter the content or intent of the statement.
- Addition or deletion of study sites
- A change that does not involve adding vulnerable participants.

2.1 Restrictions for Expedited Research:

Research may be either restricted or not eligible for expedited review if any of the following are involved:

- The research involves procedures which expose participants to more than minimum risk (greater than ordinarily encountered in daily life)
- Research involving prisoners (Unless incidentally included in secondary research aimed at a broader subject population) or participants with impaired decision-making ability.
- The nature of the research is such that potential identification of the research participants/subjects and/or their responses could 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.**

3.0: Expedited Review Categories:

3.1: Expedited Category 1:

Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

- 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).
- 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.

- **Note:** Most research that falls within this review category is FDA regulated. The FDA regulations require all research including expedited research to undergo annual continuing review. Therefore, renewal of expedited category 1 research cannot be reviewed under the flexible review policy or via status update submission.

3.2: Expedited Category 2:

Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

- a) Participants are healthy, non-pregnant adults who weigh at least 110 pounds.
 - I. For these participants, 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) All other adults and children, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected.
 - I. For these participants, 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.

3.3: Expedited Category 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.

3.4: Expedited Category 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. If 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.

3.5: Expedited Category 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).

- This category refers only to research that does not qualify for exempt review (See the [WSU IRB Exempt Research Guidance and Instructions tool](#)).

3.6: Expedited Category 6:

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

- This category refers only to research that does not qualify for exempt review (See the [WSU IRB Exempt Research Guidance and Instructions tool](#)).

3.7: Expedited 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 employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

- This category refers only to research that does not qualify for exempt review (See the [WSU IRB Exempt Research Guidance and Instructions tool](#)).

Expedited Categories for Research Previously Approved by the IRB at a Convened Meeting:**3.8: Expedited Category 8:**

Continuing review of research previously approved by the IRB at a convened meeting when the following criteria applies to the conduct of the research during the entire approval period under review:

- a) The research is permanently closed to the enrollment of new participants; or
- b) All enrolled participants have completed all research-related interventions; and the research remains active only for long-term follow-up of participants that is minimal risk and/or standard of care follow-up; or
- c) There have been no participants enrolled and no additional risks have been identified; or
- d) All remaining research activities are limited to data analysis.

3.9: Expedited Category 9:

Continuing review of FDA regulated research previously approved by the IRB at a convened meeting when **ALL** the following conditions apply.

- a) The research is not conducted under an investigational new drug application (IND) or an investigational device exemption (IDE);
- b) Expedited review categories (2) through (8) do not apply to the research;
- c) The IRB has determined and documented at a convened meeting that the research, or the remaining research activity involving human subjects, involves no greater than minimal risk to the subjects;
- d) No additional risks of the research have been identified.
 - **Note:** “no additional risks have been identified” means that neither the investigator nor the IRB has identified any additional risks from any institution engaged in the research project or from any other relevant source since the IRB’s most recent prior review.