



This document is intended to provide an overview of the [Expedited Categories](#) of research. If further assistance or clarification is required, please contact the ORIC at 304-293-7073, or at [IRB@mail.wvu.edu](mailto:IRB@mail.wvu.edu).

In general, a research protocol cannot be expedited if any of the following are true:

1. The research is more than minimal risk.
2. The research is classified.
3. The research does not meet the requirements of the following expedited categories.

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## Expedited Category 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.
  - i. 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.

**Note:** The WVU IRB has determined that any research that involves the use of a drug, whether FDA approved or not, must be reviewed at a convened full board IRB meeting.

- 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.

## Expedited Category 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.

## Expedited Category 3

Prospective collection of biological specimens for research purposes by noninvasive means. Examples include:

- /// Hair and nail clippings in a non-disfiguring manner;
- /// Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
- /// Permanent teeth if routine patient care indicates a need for extraction;
- /// Excreta and external secretions (including sweat);
- /// 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;
- /// Placenta removed at delivery;
- /// Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
- /// 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;
- /// Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
- /// Sputum collected after saline mist nebulization.

**Note:** This category includes the prospective collection of specimens by noninvasive methods. This includes methods not involving general anesthesia or sedation. Research involving tissue samples and body fluids require approval from the [WVU Institutional Biosafety Committee \(IBC\)](#).

## 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. 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 include:

- /// 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;
- /// Weighing or testing sensory acuity;
- /// Magnetic resonance imaging;
- /// Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
- /// Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

**Note:** WVU includes physical exercise (i.e. research from C-PASS) and physical measurements (i.e. some engineering studies) as Category 4.

## 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).

- a. 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.

**Note:** Often, this category is used for medical record review when the researchers are recording identifiable information (see the Guidance on HIPAA Identifiers and Data Protection). This category can also be used for social and behavioral studies whenever the investigator wishes to analyze previously recorded data that are identifiable, such as class grades and assignments.

## Expedited Category 6

Collection of data from voice, video, digital or image recordings.

## 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.

- a. 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.

**Note:** Research qualifying for this category of expedited review usually involves an intervention with a pre- and post-test instrument (i.e. survey). Focus groups, surveys, and interviews are also common.

## Expedited Category 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.

## Expedited Category 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.

**Note:** This category applies to protocols which include a device were originally reviewed by the convened full board. At that meeting, should the Board determine that the research presents no more than minimal risk, and no additional risks have been identified, the protocol's continuing review/renewal is eligible to be reviewed using expedited processes.