Expedited Review Categories –
revised Common Rule (1/21/19 effective date)

The revised Common Rule, effective Jan 21, 2019, has 9 federal categories of research activities involving human subjects that can be approved under Expedited review, per the Policy for the Protection of Human Subjects (45 CFR 46). Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the Expedited categories, may be reviewed through the expedited review procedure. This review procedure allows the IRB Chairperson or one or more IRB members designated by the Chairperson to evaluate and approve eligible research.

Categories 1 to 7 pertain to both initial and continuing IRB review. Categories eight (8) and nine (9) pertain only to continuing IRB review.

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. (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.

Examples:

- Analysis of how well standard doses of ibuprofen relieve headache pain in adults.
- Comparing how different brands of Band-Aids, used under their FDA approved indication, affect wound healing.

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.

Examples:

- Analysis of glucose levels in healthy adults using a finger stick glucometer.
- Analysis of human blood interactions with various types of synthetic biomaterials.
  Analysis of venous blood and lung fluid samples to determine concentrations of specific biomarkers and the cells responsible for their production.

Expedited Category 3

Prospective collection of biological specimens for research purposes by non-invasive means such as:

- 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);
- un-cannulated 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: OHRP clarified that it agrees with the FDA's position that the following procedures are considered noninvasive:

- Vaginal swabs that do not go beyond the cervical os;
- Rectal swabs that do not go beyond the rectum; and
- Nasal swabs that do not go beyond the nares.

Examples:

- Collection of buccal swabs to analyze enzyme function.
- Collection of saliva samples to test for markers of environmental sensitivity using genotyping techniques.
- Analyzing the change in composition of the gut microbiome as an effect of immunotherapy treatment.

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, such as:

- 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 subjects 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.

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:

- Analysis of brain activity through Electroencephalogram (EEG) while viewing different media.
- Magnetic Resonance Imaging (MRI) scans used to provide data for investigators to study intervention-related effects on brain morphology.
- Functional Magnetic Resonance Imaging (fMRI} as the instrumentation for recording brain signals from the motor cortex.

Expedited Category 5

Research involving materials (e.g., data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

- 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 category includes materials that were previously collected for either non-research or research purposes, provided that any materials collected for research were not collected for the currently proposed research.
- The phrase "…or will be collected solely for non-research purposes" pertains to the origin of the materials. For example, blood samples that were collected for a clinical test or the results of a course driven exam given in a history class.

Examples:

- Analysis of previously collected specimens that contain identifiable information (e.g. name or medical record number).
- Evaluating whether or not the implementation of a health management program reduced the number of community members who were newly diagnosed with diabetes.
- Analysis of how a hospital personnel's team performance is influenced by individual team members' job experience and technical skills, using previously collected secondary data.

Expedited Category 6

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

Expedited Review does not apply if 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.

Examples:

- Using video recordings to examine communication styles between educators and students.
- Using motion capture to record re-creations of traditional customs of indigenous peoples.
- Using audio recordings to examine subject matter expert's experiences with a specific process.

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.

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).

Examples:

- Interviewing teenagers about the influence of social media on body image.
- Interviewing couples in order to understand the relationship between communication styles and well-being.
- Interviewing formerly incarcerated people about the experience of practicing yoga and meditation during their incarceration.

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.

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.