Guidance: Expedited categories

Expedited review is a review category for protocols and modifications to approved protocols that qualify as minimal risk research or are considered minor changes to approved research. These submissions may be reviewed outside an IRB meeting allowing for an expeditious process that decreases turnaround time. Under expedited review the designated reviewer applies all applicable regulations (e.g., Common Rule, FDA, etc.) including the seven criteria for approval and the requirements for informed consent. The IRB member has the authority to either approve the submission or require modification. Submissions may not be disapproved through expedited review. If the reviewer determines they cannot approve the research as is, it must be referred to an IRB meeting so the convened board can review.

> Minimal risk is defined by the federal regulations as the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

The expedited review procedure may not be used where 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 risk.

Category 1: Clinical studies of drugs and medical devices only when condition are met.

1. 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.)
2. 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.

** Given the nature of most clinical investigation of FDA regulated drugs and devices, there are few submissions that qualify for category one expedited review.

Category 2: Collection of blood samples by finger stick, heel stick, ear stick, venipuncture in certain populations are within certain amounts.

1. 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
2. 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.

** It is important to pay careful attention to the proposed volume and frequency in which blood will be collected to ensure the protocol remain within the limits of the category. Special expertise may be needed to confirm that the collection of samples is minimal risk given the specifics of the circumstances in which samples are obtained and the subject population.

Category 3 Prospective collection of biological specimens for research purposes by noninvasive means

Examples:

- hair and nail clippings in a nondisfiguring 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 gum base 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.

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:

- 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.

Recent devolving materials (data, documents, records are specimens) that have been collected or will be collected solely for non research purposes (e.g., for medical treatment or diagnosis)

- Some research in this category may be exempt from the HHS regulations for the protection of human subjects (45 CFR 46.104(d))
- 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.

This category applies to research using retrospectively or prospectively collected materials that were obtained for non research purposes. When the materials will be maintained in an identifiable manner, the IRB reviewer should ascertain that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data, to the extent that the risk to subjects is not greater than minimal risk.

Examples:
When the investigator's only role is to analyze existing research data. For example: If a researcher receives materials from colleagues with a separate IRB approval to collect them and the materials are handled using sound data security methods, protections for privacy and

confidentiality, then the researcher may apply for expedited review for the analysis. Materials in this review category can also include:

- Blood samples collected for other health purposes;
- Academic exams;
- Program evaluations

Category 6: Collection of data from voice, video, digital, or image recordings made for research purposes.

The IRB reviewer should be satisfied that the proposed use of the information does not expose subjects to risks that are greater than minimal. When the materials will be maintained in an identifiable manner, the reviewer should ascertain that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data to the extent that the risk of subject is not greater than minimal risk.

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.

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 social practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

The IRB reviewer should determine that the collection and use of the data remains minimal risk. When information will be collected in a group setting, e.g., focus group, one should consider whether subjects are being asked to disclose information that could reasonably place the subjects at risk of criminal or civil liability are be damaging to the subject financial standing, employability, or reputation.

Categories 8 & 9 only apply to continuing review of approved protocols and are detailed on the following page.

Category 8
Continuing review of research previously approved by the convened IRB as follows where:

(a) The research is permanently closed to the enrollment of new subjects;
(b) all subjects have completed all research related interventions; and
(c) The research remained active only for long-term follow-up of subjects; or where no subjects have been enrolled and no additional risks have been identified; or were the remaining research activities are limited to data analysis.

Clarifiers regarding category (a):

- Closure of enrollment only has to apply to the local site, not to all sites,
- Long-term follow-up may include research interactions (as opposed to intervention) that involve no more than minimal risk to subjects (e.g., quality of life surveys);
- Long-term follow-up may include collection of follow-up data from procedures or interventions that would have been done as part of routine clinical practice to monitor a subject for disease progression or recurrence, regardless of whether the procedures or interventions are described in the research protocol.

Clarifiers regarding category (b):

- "no subjects have been enrolled" means no subjects enrolled at the local site
- "no additional risks have been identified" means no additional risks identified at the local site or any other institution engaged in the research project or from any other relevant source since the IRB's most recent prior review.

Clarifiers regarding category (c):

- The only remaining human subjects research activity is the analysis of data that includes identifiable private information and the IRB reviewer has determined that this activity involves no more than minimal risk.
- Simply maintaining individually identifiable private information without using, studying, or analyzing such information is not human subjects research and thus does not require continuing review.

Category 9: continue review of research not conducted under 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 convenient meeting that the research involves no greater than minimal risk no additional risks have been identified

This category is typically employed with protocols that are clearly minimal risk but did not fit an existing expedited category at the time of initial review. For example, a study assessing perceptions of individuals who hands are exposed to cold stimulation may be minimal risk, but there is no category for the exposure to cold stimulation.