

Categories Qualifying for Expedited Review

Category 1—Drugs, IND not required Device, IDE not required

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.
- research on medical devices for which
 - investigational device exemption application (21CFR Part 812) is not required
 - medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

Category 2—Blood, healthy adults and children, others

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

- 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.)
- 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.)

Category 3—Biological specimens, noninvasive collection

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);
- 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 removal at delivery;
- amniotic fluid obtained at the time of rupture of the membrane before or during labor;
- supragingival 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—Routine clinical data

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. 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 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. (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.)

Category 5—Materials collected for non research purposes

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

Category 6—Voice, video, digital, image

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

Category 7—Individual or group behavior

Research on 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.

Category 8—Renewal: no research-related interventions

Renewal of research previously approved by a convened IRB as follows:

- where
 - the research is permanently closed to the enrollment of new subjects;
 - all subjects have completed all research-related interventions;
 - the research remains active only for the long term follow-up of subjects;

or

- where no subjects have been enrolled and no additional risks have been identified;
- remaining research activities are limited to data analysis.

Category 9—Renewal of minimal risk study

Renewal of research not conducted under an investigational new drug application or investigational drug 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. Such a determination documented at a convened meeting of the IRB can be implemented when minor modifications are required and no additional risks are identified with this decision.

References

Code of Federal Regulations: Title 45, Part 46

Bankert/Amdur *Institutional Review Board Management and Function, Second Addition*, Sudbury, Massachusetts, Jones and Bartlett Publishers 2006