Human Research Protection Committee

Expedited Status

The regulations allow for Expedited review procedures for certain kinds of research; this standard will outline what types of projects qualify for expedited review. Regulations FDA 21 CFR 56.110 and DHHS 45 CFR 46.110 are followed.

Requirements that must be met for research activity to qualify for expedited review

A. Research involving no more than minimal risk
    1. The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations
B. Minor changes in previously approved research during the period for which approval is authorized
C. Appear on specific category list below
D. 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, or reputation.
E. The study does not involve intentional deception such that misleading or untruthful information is provided.
F. The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review utilized by the HRPC.

II. Categories eligible for expedited review (pertain to both initial and continuing review)

A. Clinical studies of drugs and medical devices only when condition (1) or (2) is 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.
B. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
    1. from healthy, non-pregnant adults who weigh at least 110 pounds. 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
    2. from 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. 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.
C. Prospective collection of biological specimens for research purposes by noninvasive means. Examples:
    1. hair and nail clippings in a non-disfiguring manner;
    2. deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
    3. permanent teeth if routine patient care indicates a need for extraction;
    4. excreta and external secretions (including sweat);
    5. 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;
    6. placenta removed at delivery;
    7. amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;

8. 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;
9. mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
10. sputum collected after saline mist nebulization;
11. swabs – vaginal that do not go beyond the cervical os, rectal that do not go beyond the rectum, and nasal that do not go beyond the nares.

D. 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:
   1. 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 participant or an invasion of the participant's privacy;
   2. weighing or testing sensory acuity;
   3. magnetic resonance imaging;
   4. electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
   5. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

E. 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). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46, 10 l(b)(4). This listing refers only to research that is not exempt.)

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

G. 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). This listing refers only to research that is not exempt.)

H. Continuing review of research previously approved by an IRB or the HRPC as follows:
   1. where (a) the research is permanently closed to the enrollment of new participants; (b) all participants have completed all research-related interventions; and (c) the research remains active only for long-term follow-up of participants; or
   2. where no participants have been enrolled and no additional risks have been identified; or
   3. where the remaining research activities are limited to data analysis.

I. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories B through H 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.

J. Continuing review of Humanitarian Use Device. Because a HUD is a legally marketed device and no safety and effectiveness information is being collected systematically, FDA allows for expedited review.

K. Approval of minor changes to the protocol or Informed Consent. Minor changes are defined as those that do not substantially change the research project or increase risk, this may include minor changes to the risk section such as removing duplicates.

L. Amendments of multiple studies as a result of an updated Investigator's Brochure or Action letter if the source document (e.g. Action letter) is first reviewed and approved by the Full Committee and there are no other changes that would necessitate a Full Committee review.
    1. As part of initial Full Committee review of source document Committee should grant approval for proceeding documents to be reviewed through the expedited process.
    2. Approval letters should reflect date of source document Full Committee approval.

III. Persons allowed to conduct Expedited Review
A. The HRPC will convene to consider a project for expedited review.
B. HRPC members with knowledge based on the area of study may review the project in depth to assist fellow committee members to evaluate a project for expedited review.

IV. Committee notification of reviewed project
A. All projects under review will be noted on the monthly meeting agenda.
B. Projects approved by the Committee for expedited review will be sent to the Institutional Official for final approval.
C. A letter will be sent to inform the investigator of the decision within the month following the Committee meeting.
D. Documentation of reviewed items is provided and maintained electronically. All HRPC members and the Institutional Official for ethical research will have access to all files.