

# General Information for Expedited Research

An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.

## Expedited Research Categories

Research categories that may be reviewed using expedited review procedures by the University of Tennessee at Martin Institutional Review Board (IRB) match federal guidelines and include:

**Category G:** Clinical studies of drugs and medical devices only when condition (a) or (b) are 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 (1) an investigational device exemption application (21 CFR Part 812) is not required; or (2) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

**Category H:** 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 amount 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<sup>2</sup> 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.

<sup>2</sup>Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." 45 CFR 46.402 (a).

**Category I:** Prospective collection of biological specimens for research purposes by noninvasive means.

**Category J:** Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwave. 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:

- (a) 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;
- (b) weighing or testing sensory acuity;
- (c) magnetic resonance imaging;
- (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography; or
- (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

**Category K:** 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. 45CFR 46.101 (b)(4). This listing refers only to research that is not exempt.

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

**Category M:** Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identify, 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 for 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.

**Category N:** 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 remains active only for long-term follow-up of subjects; or
- (d) no subjects have been enrolled and no additional risks have been identified; or
- (e) the remaining research activities are limited to data analysis.

**Category O:** Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where the following conditions apply:

- (a) Categories two (2) through eight (8) do not apply; and
- (b) 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.

## **Applicability of Expedited Review Categories**

Research activities may be eligible for expedited review if they present no more than minimal risk to human subjects, and involve only procedures listed in one or more of the nine listed categories. The nine categories activities listed should not be considered to be of minimal risk simply because they are listed, Inclusion on this list means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

- (a) The categories in this list apply regardless of the age of subjects, except as noted.
- (b) 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.
- (c) The expedited review procedure may not be used for classified research involving human subjects.
- (d) IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review-expedited or convened-utilized by the IRB.
- (e) Categories G through O pertain to both initial and continuing IRB review.

## **Additional Expedited Review Categories**

- The Federal policy concerning expedited review categories is contained in the Federal Register (Volume 63, Number 216: pages 60634-60367).
- Sources of Categories: Department of Health and Human Services-Office for Protection from Research Risks (OPRR), National Institutes of Health, HHS. OPRR and the Food and Drug Administration (FDA) have identical lists of categories of research activities that may be reviewed by the IRB through the expedited review procedure.
- Historical Information: The Federal Policy (Common Rule) for the Protection of Human Subjects was published in the Federal Register on June 18, 1991 (56 FR 28003) and is employed by 17 Executive Branch agencies. This Federal Policy requires adherence to certain requirements by Federal agencies\* and institutions receiving support from those agencies for research activities involving human subjects. The Federal Policy has three cornerstones: review of any research involving human subjects by an IRB with limited exceptions, informed consent of all

research subjects; and informal, written assurance of institutional compliance with the Policy. The Department of Health and Human Services' (DHHS) codification of the Federal Policy can be found at 45 CFR Part 46, Subpart A.

- Section 56-110 of the Federal Policy provides for expedited review procedures for certain categories of research involving no more than minimal risk, and for minor changes in approved research. This same section gives the Secretary, HHS, the authority to amend and republish the expedited review list as needed after consultation with the departments and agencies that are subject to the Federal Policy. The expedited review list that is referenced in the Federal Policy was originally published by the Secretary, HHS in 1981 (46FR 8392, 46 FR 8980). It listed categories of research that could be reviewed by the IRB through an expedited review procedure. The FDA also references an expedited review list (21 CFR Part 56) for matters under FDA's jurisdiction. The HHS and FDA lists have differed slightly, in that item nine (9) on the 1981 HHS expedited review list regarding certain types of behavioral research is not included in the list referenced in 21 CFR 56.110.

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\*The following agencies adopted the Common Rule: Department of Agriculture; Department of Energy; National Aeronautics and Space Administration; Department of Commerce; Consumer Product Safety Commission; International Development Cooperation Agency-Agency for International Development, Department of Housing and Urban Development; Department of Justice, Department of Defense; Department of Health and Human Services; Department of Education; Department of Veterans Affairs; Environmental Protection Agency; National Science Foundation; Department of Transportation; Central Intelligence Agency; and the Social Security Administration.

## **Expedited Review Procedures**

Once the applicant has completed the IRB application, the application will move through the following steps on its way toward approval.

**Please keep in mind that the review process takes time, and research may not be initiated until the application is approved.**

The IRB application should include the following items:

- (a) The original IRB application with original signature
- (b) A copy of the IRB Application with original signatures
- (c) Copies of all instruments (e/g., questionnaires, test, etc.) that will be used in the project. If qualitative research will be conducted, include a list of expected questions or topic areas that may be addressed.
- (d) Copies of all informed consent forms or procedures
- (e) Copies of all applicable letters of permission or cooperation, and approvals from other IRBs
- (f) Copies of applicable technical sections of grant applications or contracts
- (g) Copy of Principal Investigator(s) vitae showing qualifications to perform this research