Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 108	
CHAPTER: Institutional Review Board	ISSUED: 2/2000	LATEST REVIEW/REVISION: 4/2019
POLICY: Expedited Categories	PAGE 1 OF 6	

1. PURPOSE

This policy/procedure provides guidelines for investigators to determine whether submitted studies qualify for expedited review, and under what conditions renewals and/or modifications for previously approved projects qualify for expedited review. Federal guidelines (45 CFR 46 and 21 CFR 56.110) categorize those research activities that may be reviewed by an expedited review process and, therefore, may not require full IRB review. If the proposed research presents no more than minimal risk to subjects and appears to fall under one of the expedited categories described in this policy, the Principal Investigator may submit the protocol to be reviewed using the expedited process.

2. RESEARCH CATEGORIES FOR EXPEDITED REVIEW (FROM 45 CFR 46 AND 21 CFR 56.110)

2.1. Clinical studies of drugs and medical devices only when one of the following is met:

2.1.1. Research on drugs for which an investigational new drug application (21 CFR 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

2.1.2. Research on medical devices for which: 1) an investigational device exemption (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

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

2.2.1. From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an eight-week period and collection may not occur more frequently than two times per week; or

2.2.2. From other adults and children (anyone under the age of 19 years) 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 eight-week period and collection may not occur more frequently than two times per week

2.3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples include:

2.3.1. hair and nail clippings collected in a non-disfiguring manner

2.3.2. deciduous teeth collected at time of exfoliation, or if routine patient care indicates a need for extraction

2.3.3. permanent teeth, if routine patient care indicates a need for extraction

2.3.4. excreta and external secretions (including sweat)

2.3.5. uncannulated saliva collected either in an un-stimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue

2.3.6. placenta removed at delivery

2.3.7. amniotic fluid obtained at the time of rupture of the membrane prior to or during labor

2.3.8. supra- and sub-gingival dental plaque and calculus, provided that the collection procedure is not more invasive than routine prophylactic techniques

2.3.9. mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washing

2.3.10. sputum collected after saline mist nebulization

2.4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. (When medical devices are used, they must be cleared/approved for marketing.) **Note:** 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 of data collected through noninvasive procedures routinely employed in clinical practice include:

2.4.1. 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 subject or an invasion of the subject's privacy

2.4.2. Weighing or testing sensory acuity

2.4.3. Magnetic resonance imaging

2.4.4. Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography

2.4.5. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing when appropriate given the age, weight, and health of the individual

2.5. 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). **Note:** Some research in this category may be exempt from the Department of Health and Human Services (DHHS) regulations for the protection of human subjects (45 CFR 46.104) (see IRB Policy, "Exempt Research"). This listing refers only to research that is not exempt.

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

2.7. 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, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. **Note:** Some research in this category may be exempt from the DHHS regulations for the protection of human subjects (45 CFR 46.104) (see IRB Policy, "Exempt Research"). This listing refers only to research that is not exempt.

2.8. Continuing review of research previously approved by the convened IRB as follows:

2.8.1 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

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

2.9. 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.

3. APPLICABILITY

3.1. Research activities that present no more than minimal risk to human subjects and involve only procedures listed in one or more of the "Research Categories for Expedited Review" may be reviewed by the IRB through expedited review.

3.2. The activities listed shall not be deemed to be of minimal risk simply because they are included on the list above. Inclusion on this list merely 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.

3.3. The categories listed herein apply regardless of the subject's age, except as noted.

3.4. The expedited review procedure shall not be used when 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, or reputation, or when they would 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.

3.5. The expedited review procedure shall not be used for projects that are collecting material for genetic testing. Projects using stored specimens may be expedited if the subject originally consented to future research that includes genetics. The Principal Investigator shall clearly state in the protocol the specific IRB-approved project (including assigned IRB number) from which the specimens were collected and stored. A statement of the condition for release and testing in the original storage consent signed by enrolled subjects should be included (condition would include request to be re-contacted, use in specific types of research, or general use if project receives IRB approval).

3.6. The expedited review procedure shall not be used for initial review of a project that involves prisoners (see IRB Policy, "Prisoners in Research"), exempt for archival research that is not funded by PHS.

4. SUBMISSION REQUIREMENTS

4.1. Initial Review

4.1.1. See requirements for review (IRB Policy, "IRB Review Process," and the online application available through the electronic system

5. REVIEW PROCESS

5.1. The IRB administrative staff shall do the initial review and assign IRB members to review the research protocol. The reviewers shall receive the entire IRB submission. In reviewing the research, the reviewers may exercise all authorities of the IRB, except the reviewers may not disapprove the research. A research activity shall be disapproved only after review in accordance with the non-expedited review procedure set forth in 45 CFR 46.108(c). See IRB Policy, "IRB Review Process," and document *Checklist for Board members (Board Review – full and expedited).*

5.2. After the Board reviewers have reviewed the project and made recommendations, the IRB Administrator shall review the submission and shall notify the investigator in writing of the official determination of the project. The letter will include the required determinations and protocol-specific findings justifying those determinations for: Waiver or alteration of the consent process; research involving pregnant women, fetuses, and neonates, research involving children, prisoners (data collection only) and those with diminished capacity.

6. MODIFICATIONS TO PREVIOUSLY APPROVED PROJECTS

6.1. Submission Requirements

6.1.1. See IRB Policy, "Modification of Approved Research."

6.2. Review Process

6.2.1. The IRB Administrator shall initially review the submission, assuring all documents are in place, and then assign it to the Chair or designee. In reviewing the research, the Chair or designee may exercise all authorities of the IRB, except the Chair or designee may not disapprove the research. A research activity shall be disapproved only after review in accordance with the non-expedited review procedure set forth in 45 CFR 46.108(c)

6.2.2. After the Chair or designee has reviewed, the investigator shall be notified in writing of the official determination of the modification

7. CONTINUING REVIEW OF ONGOING PROJECTS

7.1. Continuing review for expedited studies, that are non-FDA regulated, post January 21, 2019 (compliance date of the revised Common Rule) includes a new subsection (46.109[f][1][i]) that eliminates continuing review submissions unless the reviewer explicitly justifies why continuing review would enhance protection of research subjects.

7.1.1. An “Annual Review Form” must be submitted to the IRB on a yearly basis, by the anniversary of the project approval, with the primary intention of capturing data corresponding with IRB metrics and AAHRPP accreditation tracking until study closure