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Subject: Types of IRB Review
Division: IRB
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IRB Policy 105.4: EXPEDITED REVIEW

Policy

An expedited review procedure consists of a review of research involving human subjects by the Chairperson or by one or more experienced reviewers designated by the Chairperson from among members of the IRB (may also include contracted consultants). These policies and procedures apply to all research submitted to the IRB that qualifies for expedited review.

The categories of research that may be reviewed by the IRB through an expedited review procedure include research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the specific categories listed in the regulations at Federal Register Volume 63, No 216. In addition, an expedited review procedure can be used to review minor changes in previously approved research during the period for which approval is authorized.

Definition of Minimal Risk

HHS regulations define minimal risk as 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 or tests (45 CFR 46.102(i)).

Cautions

1. The activities listed should not be deemed to be of minimal risk simply because they are included on the list of eligible research. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure. The IRB reserves the right to require full board review of any application.

2. 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. Lastly, the expedited review procedure may not be used for classified research involving human subjects.

Categories of Research That May Be Reviewed Via the Expedited Review Procedure

Categories one through seven pertain to both initial and continuing IRB review.

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is 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 (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.

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

   a) 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

   b) 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.

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

   Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) 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; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) 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; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

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: (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; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. 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). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

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

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, 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.)

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

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

   **Category (8) identifies three situations in which research that is greater than minimal risk and has been initially reviewed by a convened IRB may undergo subsequent continuing review by the expedited review procedure.*

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.

Minor Changes to Previously Approved Research During the Period for which Approval is Authorized

The IRB may also use the expedited review procedure to review minor changes, which do not change the level of risk, in previously approved research during the period (of 1 year or less) for which approval is authorized.

At FRI, minor changes include the following:

1. Informational revisions to the protocol or consent form, including but not limited to the following:
   a) changes in telephone/contact numbers
   b) addition or deletion of associates or staff
   c) changes to correct informational errors
   d) changes to correct typographical or grammatical errors
   e) changes to improve the clarity of statements
2. Deletion of questions in a questionnaire
3. Addition of non-sensitive questions to a questionnaire
4. Addition of a standardized test/questionnaire
5. Minor changes to the number of study participants
6. Decrease in the amount of blood that is drawn or the frequency
7. Decrease in the drug dosage or the frequency of drug administration
8. Minor changes to the recruitment plan, or the inclusion/exclusion criteria
9. Addition of, or changes to advertisements/recruitment letters
10. Extension of the time period of the study to allow for follow-up interviews, or data analysis
11. Extension of the time period for recruiting subjects
12. Changes to the study title
13. Minor procedural changes that do not impact participants
14. Minor procedural changes that impact participants, but do not change the risk/benefit ratio

Any protocol revision that entails more than a minimal risk to the subjects must be reviewed by the full IRB at a convened meeting.

Authority of the IRB Chairperson

The IRB Chairperson (or designated reviewer) may exercise all of the authorities of the IRB, except that he/she may not disapprove the research. A research proposal may be disapproved only after review by the full IRB. For protocols involving vulnerable populations, the IRB Chairperson may consult with expert reviewers, or appropriate members of the IRB (such as the Children's Advocate or the Prisoner's Advocate), or designate the review to an appropriate IRB member.

Notification of the IRB

When the expedited review procedure is used, all regular members shall be informed of actions taken by the IRB at the next convened meeting. IRB members will be informed of expedited reviews with a summary of the review and a copy of the approval letter.

Documentation

If the study qualifies for expedited review, the IRB Chairperson or designee will document his/her determination of risk. The minutes of the next convened meeting will include documentation of the studies that were reviewed via expedited review and any issues discussed regarding questions that an IRB member had concerning the research reviewed.

Additional Items That May be Reviewed by the Chairperson or Designee

Approval of pending minor revisions, clarification: Revisions to consent documents and other documentation or clarifications submitted as a result of full IRB review and as a condition to final approval may be reviewed by the IRB Chairperson or his/her designee. Final approval will be issued providing the revisions, documentation or clarifications do not indicate or result in a change to the study or change the risk/benefit ratio.

Responsibility

The IRB Administrator is responsible for identifying submissions that qualify for expedited review, and for providing a summary of expedited reviews performed to IRB members at convened meetings. The IRB Chairperson or designee is responsible for conducting expedited reviews.

Applicable Regulations and Guidelines

45 CFR 46.102(i), 46.110
21 CFR 56.102(i), 56.110
OHRP IRB Guidebook
OHRP Guidance on the Use of Expedited Review Procedures (August 11, 2003)
November 9, 1998 Federal Register list of research eligible for expedited IRB review