SOP 5.05 – Expedited Review: Initial IRB Review

1. Objective

The purpose of this SOP is to describe the procedures for reviewing initial study proposals via the Expedited review process and in accordance with 45 CFR 46.110.

Procedures for reviewing previously approved studies during continuing review using the expedited review process are discussed in SOP 5.10. Procedures for reviewing previously approved studies for modification using the expedited review process is discussed in SOP 5.08.

2. General Description

Expedited review is a specific type of IRB review that can be conducted by an IRB Chair, or designated (voting) experienced IRB member. In this instance, the IRB chair or designated IRB member acts on behalf of the full IRB and can exercise authority of the full committee to review, but does not have authority to disapprove a study. A decision to disapprove must go to the Full Board (FB) for disposition.

Definitions

Expedited Review – is a particular process of IRB review delineated in 45 CFR 46.110 and following specific criteria. The Expedited review process may be used to review some or all research activities found by the reviewer(s) to be no more than minimal risk and appearing on the predetermined list of Expedited review categories (see below).

Minimal Risk – the probability and magnitude of the harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in the daily life, or during performance of routine physical or psychological examination of healthy persons.

Experienced IRB member – a member who has served for three months as a UNLV IRB member qualifies as an experienced member.

3. Roles & Responsibilities

Execution of SOP: Office of Research Integrity –Human Subjects (ORI-HS) Director/Staff, IRB Chairs/Co-Chairs, Designated voting IRB Members

A voting IRB member may be designated as an expedited reviewer by an IRB Chair/Co-Chair.

4. Procedures

Submission Intake

Upon receipt of an application for initial review, ORI-HS staff screen it for completeness and accuracy and make a preliminary determination that the application meets the criteria for expedited review (as outlined below), including a preliminary assessment that the request meets the minimal risk requirement. The request is either returned to the PI so that they may provide additional information prior to IRB review, or forwarded to an expedited reviewer(s).

Considerations for Children

All expedited protocols involving children as subjects are reviewed by no less than two IRB members prior to initial approval of the study.

IRB Review

The expedited reviewer(s) uses the criteria outline below in addition to applicable regulatory requirements discussed in 45 CFR 46, other relevant local, state, or agency requirements to conduct their review. All decisions are recorded on the 'Chair's Reviewer's Form.' The reviewer(s) reviews all information in the submission in enough depth to be familiar with the protocol, to determine whether the submission is eligible for expedited review, and to determine whether the submission meets the regulatory, and/or any relevant additional, criteria for approval.

The IRB reviewer may procure, for the purposes of providing expertise or special knowledge surrounding a topic or issue of concern, an outside consultant(s) to advise an IRB review of a protocol. An IRB members' CV or comprehensive IRB roster is used to assess for scientific and scholarly knowledge and expertise; knowledge or expertise involving specific populations; and organizational affiliation of IRB members when deciding if additional expertise/consultant will be needed to review the protocols. The consultant will be approached by the IRB reviewer or ORI-HS staff to assess their willingness to serve as a consultant. The consultant will serve in an advisory role only and provide their opinion surrounding the topic of need. The consultant will receive relevant study materials. They will then provide their assessment via a written document to be considered by the reviewer. Any consultant(s) will be free of conflict of interest and will be asked to provide acknowledgment that the review of study or study related materials are of a private nature, and that confidentiality of any shared information will be maintained.

Applicability

A. 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 following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. 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.
B. The categories in this list apply regardless of the age of subjects, except as noted.

C. 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.

D. The expedited review procedure may not be used for classified research involving human subjects.

E. 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 fully convened, utilized by the IRB.

F. Categories one (1) through seven (7) pertain to both initial and continuing IRB review, and procedures for reviewing previously approved studies during continuing review are discussed in SOP 5.10.

Allowable Research Categories

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
    a. (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. (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[2], 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.)

Review Outcomes

The reviewer(s) makes one of the following three determinations:

1. Approved: The submission meets the requirements for approval. The reviewer(s) sends their review to ORI-HS staff. ORI-HS staff sends the PI an approval letter noting the date of the approval issued by the reviewer(s) and the study expiration date.

2. Revisions or Additional Information Required: The submission requires revision or additional information in order for the reviewer(s) to make an approval. The reviewer(s) sends their review to ORI-HS staff outlining the requested revisions or information. ORI-HS staff sends the PI a letter with the requested revisions or information.

3. Full Board Review Required: The reviewer(s) determines that the submission requires review by the FB. The reviewer sends their determination along with any requested revisions or requests for information to ORI-HS staff. ORI-HS staff sends the PI a letter indicating that the submission will be reviewed by the FB along with any requested revisions or requests for information as dictated by the expedited reviewer(s). The letter includes the date of the FB meeting where the submission will be reviewed along with a deadline date (prior to the meeting) for submitting any requested revisions or additional information.

Reporting Expedited Approvals to the Full Board

The FB is notified of all research approved using the expedited review process via reports contained within a FB meeting agenda. All actions approved using the Expedited review process are tracked (within

IRBNet) and placed on a meeting agenda that is published and viewable by all members of the appropriate IRB. Agendas are created/published prior to predetermined board meeting dates.

5. References

45 CFR 46.101
45 CFR 46.110
21 CFR Part 312
21 CFR 56.110

Institutional Review Board Management and Function, Bankert & Amdur – Chapter 4-2
List of Expedited review categories: http://www.hhs.gov/ohrp/policy/expedited98.html
UNLV Rules and Procedures for Conducting Human Subject Research, 4.1

UNLV ORI-HS SOP 5.08 and 5.10