SOP 5.06 – Full Committee Review: Initial IRB Review

1. Objective

The purpose of this SOP is to describe the procedures for reviewing initial study proposals through the convened IRB in accordance with 45 CFR 46.

Procedures for reviewing previously approved studies during continuing review via the convened IRB are discussed in SOP 5.10. Procedures for reviewing previously approved studies for modification via the convened IRB is discussed in SOP 5.08.

2. General Description

The IRB conducts initial review for non-exempt research at convened meetings unless the research is eligible for initial review through the expedited review procedure (SOP 5.05). The IRB approves research that meets the federal criteria for approval as specified in 45 CFR 46.111, 21 CFR 56.111, and 38 CFR 16.111.

Definitions

Research - is "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge." Research includes, but is not limited to, surveys and interviews, behavioral investigations, retrospective reviews of data, experiments with blood and tissue, demonstration and service programs, and clinical trials.

Human Subject - means a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or collects identifiable private information. "Human subject" under FDA regulations includes an individual who is or becomes a participant in research, either as a recipient of a test article or as a control. A "subject" may be a healthy human or a patient.

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.

Quorum – is defined as more than half of the regular voting members. A quorum consists of regular members or their alternate and includes at least one member whose primary concerns are in scientific areas, and one member whose primary concerns are in nonscientific areas. When a protocol is reviewed that contains prisoners, the prisoner representative is present.

3. Roles & Responsibilities

Execution of SOP: Principal Investigator (PI)/ Study Personnel (SP), Office of Research Integrity – Human Subjects (ORI-HS) Director/Staff, IRB Chairs/Co-Chairs, IRB Members

4. Procedures

Determination of review type

In order to determine the type of review necessary, ORI-HS staff/IRB Chair/Co-Chair will screen the application and make determinations as to whether the project constitutes human subjects research and, if so, the type of review required. All protocols are assigned to be reviewed at a convened meeting unless (1) they meet the criteria for expedited review listed in SOP 5.05, (2) they meet the criteria for exempt determination listed in SOP 5.04, or (3) they are deemed not to be human subject research as described in SOP 5.02.

Projects requiring review by the convened IRB

Any study involving greater than minimal risk requires review by the convened IRB. Examples of studies that may involve greater than minimal risk:

- Studies involving vulnerable populations.
- Clinical intervention studies that randomly assign human subjects to alternative experimental or placebo groups.
- Studies involving sensitive information connected to personal identifiers.
- Studies that involve the intentional deception of subjects, such that misleading or untruthful information will be provided to the participants.

Schedule of meetings

Each IRB meets one time per month on a regularly scheduled day, time, and location. Meetings are set in advanced and published on the ORI-HS website. Meetings are closed in that only members and invited guests are allowed to attend.

Protocol Submission and Review

1. The PI completes a protocol package for IRB review and submits it to the ORI-HS. A complete protocol package may contain the following documents:
    - Protocol Proposal Form
    - Informed Consent/Parent Permission/Child Assent
    - Recruitment/advertisement materials
    - Survey/questionnaires
    - Data collection sheets
    - Grant proposals/award document
    - Facility Authorization Letters
    - Investigator's brochure (when one exists)

2. ORI-HS staff screen the application to determine whether it is complete (e.g., includes all pertinent forms and appropriate signatures). If it is not complete, ORI-HS staff returns the application to the investigator with a list of items/revisions needed.

3. ORI-HS staff screens the IRB application to ensure coordination with other university committee reviews as outlined SOP 3.12 or to ensure compliance with pertinent federal requirements.

4. ORI-HS staff completes an administrative review via an administrative review document for the IRB chair/co-chair to review. This review notes adherence to federal regulations, state and local laws, university policy and procedures. The administrative review is provided to the IRB chair/co-chair for review.

5. ORI-HS staff assigns a chair/co-chair to review the initial proposal. If the reviewer determines that the protocol needs to be reviewed by the convened IRB, they complete the 'Chair's Reviewer Form' to "Send to Full Board." Any revisions or clarifications that are noted will be sent to the PI by ORI-HS staff prior to sending the protocol to the convened IRB for review. There are no limits on the number of reviews sent to the convened IRB for review.

6. IRB members and alternates are sent the full protocol materials to review approximately 10 days prior to the IRB meeting date. All IRB members and alternates complete their review on the IRB Protocol Reviewer's Form created for that study. The IRB Protocol Reviewer's Form contains the federal requirements for criteria of approval (45 CFR 46.111). IRB members and alternates have approximately 7 days to complete their review. The due date is given to IRB members and alternates by the ORI-HS staff who assigns the protocol.

7. IRB chair/co-chairs reviews the IRB member reviews prior to the convened IRB meeting in order to prepare for the review at the convened meeting date.

8. The IRB Chair or IRB 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 or IRB related request. 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 chair/co-chair or ORI-HS staff to assess their willingness to serve as a consultant. The consultant will serve in an advisory role only, is not a voting member of the IRB and will not be counted toward quorum. The consultant will receive relevant study materials. They will then provide their assessment at the meeting or via a written document to be considered at the meeting. 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. If a consultant is not available, the protocol may be postponed pending inclusion of this consultant.

9. When the IRB reviews research that involves categories of participants vulnerable to coercion or undue influence, one or more individuals who are knowledgeable about or experienced I working with such participants are present.

10. All IRB members attending the meeting have the opportunity to discuss each research protocol during the convened meeting, and participate in the determination of whether the research meets the regulatory criteria for approval. The discussion of controverted issues and their resolutions are documented with IRB minutes according to SOP 12.02.

Meeting Administration

1. The IRB meeting may not convene until quorum is established. It is the responsibility of the ORI-HS staff to inform the IRB chair when quorum has been established. Quorum is documented in the IRB minutes according to SOP 12.02.

2. The ORI-HS staff is responsible for monitoring the meeting for late arrivals and departures of members.

3. It is the responsibility of the IRB staff to inform the IRB chair when quorum is lost during the meeting. If quorum is lost during the course of a meeting, the IRB chair will not allow any further discussion, action or votes to be taken until quorum is restored.

4. Each IRB meeting will have an agenda, which provides the framework for the IRB meeting. It is a critical tool used by the IRB to provide the meeting content and establish a sequence of review. In addition, it provides a report of the protocols reviewed through the expedited review procedure. The agenda is prepared by the ORI-HS staff and posted prior to protocols being sent for convened review.

5. IRB members do not participate in the review of any component of a project in which the member has a conflict of interest, except to provide information requested by the IRB. The IRB chair will request disclosure of conflicts of interest at the beginning of each meeting.

Procedures for Voting

1. A majority of the members must vote in favor of a review decision for that decision to be accepted by the IRB. Majority is defined as more than half of the total number of IRB members attending the meeting at which the vote takes place. Only regular and alternate members acting in place of absent regular members may vote.

2. The IRB staff is responsible for counting and documenting all decisions.

Review Decisions

The IRB makes one of the following determinations:

1. *Approved*: The submission meets the requirements for approval. ORI-HS staff sends the PI an approval letter noting the date of the approval as the IRB meeting date and the study expiration date.

2. *Revisions Requested*: The submission requires revision or additional information in order for the IRB to approve. ORI-HS staff sends the PI a letter with the requested revisions or information. Once the IRB chair/co-chair confirms that the revisions have been completed, that date is used as the approval date for the proposal.

3. *Tabled*: The submission does not meet the criteria for approval in 45 CFR 46.111. Major revisions are needed in order for the IRB to consider this study for approval. Concerns are communicated to the PI regarding this decision. The protocol must be resubmitted and reviewed by the convened IRB. The steps that need to be taken to continue the review at the next convened meeting are provided to the PI.

4. *Disapproved*: The submission does not meet the criteria for approval in 45 CFR 46.111 as written. The IRB sends the PI documentation describing the reason for the disapproval. The study is closed, but the PI may resubmit the proposal for reconsideration. This new submission is treated as a new study.

If the protocol is approved, the IRB decides on the risk level of the study. They also consider whether any requests made by the PI (e.g., request for waiver of informed consent, waiver of documentation of consent, waiver of HIPAA authorization, etc.) is acceptable with respect to meeting federal requirements.

The IRB determines the approval period, as appropriate to the degree of risk but not less frequently than once per year. The IRB may set a shorter approval period for high risk protocols or protocols with high risk/low potential benefit ratios. The study expiration date is one year minus one day from the approval date of the protocol. For example, a study that is approved on July 2, 2016 has an expiration at 11:59 pm on July 1, 2017.

If the research involves prisoners, ORI-HS staff check to determine whether the PI submitted the protocol for funding to any DHHS agency. If this is the case and the protocol involves prisoners, ORI-HS staff, with input from the PI, prepares and submits a prisoner certification report to the Office for Human Research Protection (OHRP) in accordance with OHRP requirements and the Mandated Reporting to External Agencies SOP.

Once the IRB approves a protocol, ORI-HS staff send an approval letter to the PI, which includes the approval period, a reminder to use only the approved consent/assent form, and a reminder that the IRB must approve any changes to the protocol prior to initiation of the changes.

All IRB findings are documented in the IRBNet system where the UNLV Office of Research Integrity (ORI) Executive Director and Associate Vice President of Research have access and may review as needed. Other UNLV officials may contact the UNLV ORI Executive Director for information.

If the PI has concerns regarding the IRB decision/recommendations for changes in the study, he/she may submit them to the IRB via a written document that includes a justification for changing the IRB decision.

5. References

45 CFR 46.111
21 CFR 56.111
38 CFR 16.111

UNLV ORI-HS SOP 3.12, 5.02, 5.04, 5.05, 5.08, 5.10, 12.02

Chair's Reviewer Form
IRB Protocol Reviewer's Form
IRBNet IRB Member Quick Start Guide

AAHRPP Tip Sheet #16: Review of Research by the Convened IRB or EC