

## Conducting IRB Reviews

### **A. Initial Review.- the process for the commencement of an initial review is as follows:**

1. The Principal Investigators/IRB Agreement Form and the Application for Approval of a Research Project Involving Human Subjects (must be completed by the Principal Investigator and submitted to the Chairperson of the IRB Review Committee.
2. The application must be accompanied with a (i) defined protocol Explaining how human subjects will be used, (ii) three copies of the proposed research,(iii) Informed Consent Document, (iv) all recruitment materials (e.g. letter of invitation, recruitment script, advertisement flyer), (v) all surveys, questionnaires, instruments used in research project, (vi) letter(s) of permission from each site of performance (if applicable), (vii) a copy of grant application (if applicable) and (viii) HIPPA authorization, waiver of authorization or de-identification form (if applicable).
3. The Chairperson will give notice to the Members of the IRB Review Committee, via a Proposal Routing Form that a proposal has been submitted and needs to be reviewed.
4. The IRB Review Committee will assemble and review the proposed research project according to Federal and Institutional Policies on Research Involving Human Subjects.
5. The Review Committee may then (i) approve the proposal (ii) request for further explanation, (iii) recommend augments to the proposed research, or (iv) deny the request on the grounds of the relative risks/noncompliance with Federal/Institutional policies or inadequate safeguards.
6. Once the Review Committee comes to an agreement that the proposed research is compliant with Federal and Institutional policies on research involving human subjects, the Principle Investigator is granted permission to commence his/her research project.
7. Approval of research is by a majority vote of a quorum (except where expedited review is appropriate), no vote of approval/disapproval will be taken unless the quorum is present.

### **B. Continuing Review. All IRB approved research projects will undergo annual (from the date research commences) reviews by the Institutional IRB. The following steps will be taken for continuing reviews:**

- I. The Principle Investigator is to submit to the IRB Chairperson, an annual report clearly identifying changes and/or problems that have occurred with the original approved project. If there have been no changes or problems, the annual report should reflect this. Included in the annual report there should be a progress report stating the development of the research project. The principle investigator must address the required information noted below in #4 and #5.
- II. The Chairperson of the IRB Review Committee will give notice to the members of the IRB Review Committee, via a Proposal Routing Form that an approved research project is currently

undergoing a “continuing review”. Members of the IRB Review Committee will receive a copy of the submitted annual report and/or continuing review form/termination form (from the chairperson).

1. All research protocols (except protocols determined by the IRB to qualify for administrative review) must be periodically reviewed, including research for which data analysis is the only on-going research activity.

a. Research Closed to Accrual of New Subjects. A research protocol for which no new subjects will be enrolled must be periodically reviewed until such time that:

i. analysis of the data has concluded that no new information needs to be provided to enrolled subjects; and/or

ii. there is no need to re-contact enrolled subjects to obtain additional research information.

2. Based on its review, the IRB may require that the research be restricted, modified or halted altogether. Alternatively, special precautions or IRB imposed restrictions may be relaxed.

3. Type of Review. Review by the full IRB, with recorded vote, is required unless the research is otherwise appropriate for expedited review.

a. Full Board Review. The full IRB must conduct a continuing review of a protocol using standard review procedures when that protocol was originally reviewed using standard review procedures, unless the protocol has been modified such that it can be reclassified as eligible for expedited review. Alternatively, research activities that have previously been judged as exempt, or were qualified for expedited review, may change such that full board review would be required for the continuing review.

i. Primary Reviewer System. When conducting continuing review by full board (*i.e.*, when the protocol may not be reviewed using an expedited review procedure), the IRB may use a primary reviewer system for continuing review. Primary reviewers should receive and review a copy of the complete protocol including any modifications previously approved by the IRB. Even when using a primary reviewer system, the full, convened IRB must discuss the protocol and make a determination with recorded vote.

b. Expedited Review. A protocol that was originally reviewed using expedited review procedures may receive its continuing review on an expedited basis. Additionally, a Full Board reviewed protocol that had no subject accrual during the previous period, has not been awarded funding, or remains open only to data analysis may be reviewed using an expedited review.

i. When conducting continuing review under an expedited review procedure, the IRB Chair or designated IRB member conducts the review on behalf of the full IRB.

c. Exempt Research Activities. Once a research protocol has been determined by the IRB to qualify for review by the IRB Chair or designee, that protocol need not be periodically reviewed by the IRB.

4. Criteria. Continuing review must be substantive and meaningful. The criteria for continuing review are the same as those for initial review. Therefore, the IRB (or the reviewer for protocols reviewed under an expedited procedure) must determine:

- a. that the risks to subjects continue to be minimized and reasonable in relation to the anticipated benefits;
- b. that the selection of subjects continues to be reasonable in relation to anticipated benefits;
- c. that informed consent continues to be appropriately documented;
- d. that there are:
  - i. provisions for safety monitoring of the data,
  - ii. protections to ensure the privacy of subjects and confidentiality of data, and
  - iii. appropriate safeguards for vulnerable populations.

5. Materials to be Reviewed.

- a. The full IRB should receive and review, at a minimum, the principle investigator's annual report and the current consent form being used.
- b. Primary reviewers should also receive a copy of the complete protocol and supporting documentation including any modifications previously approved by the IRB.

6. Consent Document. Review of the currently approved consent document must ensure that the information is still accurate and complete. Any significant new findings that may relate to the subject's willingness to continue participation should be provided to the subject in an updated consent document. Review of currently approved or proposed consent documents must occur during the scheduled continuing review of research by the IRB but may be done more frequently if new information becomes available.

7. Modifications to Protocol. Modifications and addenda to a research protocol may be submitted at the time of continuing review. A modification form describing the change and all appropriate documentation (approved consent form) must accompany the continuing review/termination application. The amendments may not be implemented by an investigator prior to review and approval by the IRB.

8. Review Must Occur Not Less Than Once Per Year. The IRB must conduct continuing review of protocols at intervals appropriate to the degree of risk, but not less than once per year. "Not less than once per year" means that the research must be reviewed on or before the one-year anniversary date of the previous IRB review, even though the research activity may not begin until some time after the IRB has given approval." All human subjects research activities are subject to audit at anytime by the IRB

a. Grace Period. There is a no grace period.

9. Timing of Continuing Review. The IRB Office must make every effort to link as closely as possible:

a. the receipt by the IRB Office of continuing review materials;

b. the review of those materials by the convened IRB; and

c. the beginning of the subsequent approval

10. IRB Review in Emergency Situations: 45 CFR 46.103

([subjects/guidancewww.hhs.gov/ohrp/human](http://www.hhs.gov/ohrp/human)) permits human subject research activities to be started even in an emergency without IRB review and approval, however the client may not be considered a research subject, the emergency care cannot be claimed as research or any data. If emergency care involves investigational drugs, devices or biologics U.S. Food and Drug Administration (FDA) (<http://www.fda.gov/oc/ohrt/irbs/>) requirements must be satisfied

11. IRB approval may be deferred when substantive clarification or modifications regarding protocol or informed consent documents that are directly relevant may occur according to 45 CFR 46.111 ([www.hhs.gov/ohrp/humansubjects/guidance](http://www.hhs.gov/ohrp/humansubjects/guidance))

12. No IRB member may participate in the IRBs initial or continuing review of a project in which the member has conflicting interest except to provide information requested by the IRB.

**C. Approval of Research. The IRB Review Committee, with the guidance of OHRP and Oakwood University policies on research involving human subjects, will determine if a proposed research meets these requirements. The following criteria shall be used in determining whether to approve or disapprove a proposal:**

1. Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the preview of its responsibility.

3. Selection of subjects is equitable. In making this assessment the IRB should take in to account the purposes of the research and the setting in which the research will be conducted and, should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disable persons, or economically or educationally disadvantaged persons.

4. Informed Consent will be sought from each prospective subject or subject's legally authorized representative.
5. Informed Consent will be appropriately documented.
6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

**D. Reporting of IRB Findings.** The Chairperson of the IRB shall notify the Principal Investigator, in writing, of the committee's decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research proposal, it shall include in its written notification a statement of the reasons for its decision and give the Principal Investigator an opportunity to respond in writing.

**I. RESEARCH PROJECTS REQUIRING MORE THAN ANNUAL REVIEWS, AND RESEARCH PROJECTS NEEDING VERIFICATION FROM NON-INVESTIGATORS.**

**A. Requirements of more than annual reviews.** reviews conducted by the IRB, which occur more frequently than annually are determined at the time of initial approval. This may occur in the following situations:

1. If it is determined that the proposed research project proposes a high risk or danger to the human subjects
2. If the Review Committee is unsure with the possible risk factors which may occur during the duration of the research

**B. Research projects needing verifications.** the IRB Review Committee may determine at the time of initial approval, that a research project may need verification from sources other than the Principle Investigator. Outside verification may occur when:

1. The approved research project involves more than one site of work
2. The approved research project involves more than one Investigator
3. The IRB Committee has just reason to question the integrity of the primary source.
4. The IRB randomly selects projects for review
5. The approved research project is complex and involves unusual levels or types of risk to subjects
6. The project is conducted by investigators who previously have failed to comply with the requirements of the HHS regulations or the requirements or determinants of the Oakwood IRB.

7. The project entails possible material changes which have occurred without IRB approval based upon information provided in continuing reviews or from other sources.

### **III. ENSURING CHANGES IN APPROVED RESEARCH PROJECTS ARE PROMPTLY REPORTED.**

It is the policy of Oakwood University IRB, that if there are any changes in approved research, all work involving that particular research project must immediately cease. It is the responsibility of the Principle Investigator to immediately contact the IRB Chairperson and notify him/her of the changes. This is crucial in eliminating apparent and non-apparent immediate hazards to human subjects and will be addressed through training and Specific directives included in application and approval documentation.

### **IV. CHAIN OF COMMAND AND PROMPT REPORTING OF UNANTICIPATED PROBLEMS, SERIOUS NONCOMPLIANCE AND/OR SUSPENSION OR TERMINATION OF IRB APPROVAL**

Unanticipated problems involving risks to subjects or others in any covered research, serious or continuing noncompliance with Federal, Institutional or IRB requirements and suspension or termination of IRB approval for federally funded research.

Members of Oakwood University will follow the following chain of command when approving or disapproving a protocol in addition to the reporting if any of the cited situations should occur. For cited situations:

The Principle Investigator will immediately notify

- a.) The Chairperson of the IRB
- b.) The Investigator will also inform his/her Department Chair

The IRB Chair will without delay

- a.) Follow-up with the respective Department Chair
- b.) Notify the Human Research Protection Administrator (Chairperson of the Research Council)

The Human Research Protection Administrator will notify

- a) The Official Legally Authorized Individual to represent the Institution (Vice President Of Academic Affairs)
- b) Chairperson of the Research Council

The Vice President for Academic Affairs will notify the Office of Human Research Protection in a timely manner. Consultation with the Office of the Vice President for Academic Affairs will occur regarding response to reports of unanticipated problems involving risks to subjects or others or serious or continuing noncompliance.

The identified chain of command for approvals and disapproval of research protocols ultimately falls to the Vice President of Academic Affairs designated as the institutional person responsible for the Federal Wide Assurance.