

**SOP: 403**  
**INITIAL REVIEW - CRITERIA FOR IRB APPROVAL**

**1. POLICY**

All research projects that include human participants must meet certain criteria before the investigator can initiate study-related procedures. The criteria specified in Section 1.1 below are based on the principles of respect for persons, beneficence, and justice as discussed in the Belmont Report. In addition, certain other criteria that are unique to The University of Oklahoma may apply and must be met when applicable.

No investigator has a right to conduct research within this institution. Rather, it is a privilege granted by society as a whole and the Board of Regents of the University of Oklahoma in particular.

The IRB shall evaluate each project on an individual basis in order to assess whether the investigator is providing adequate resources to protect the participant. Such resources may include research staff, social support services, counseling, ancillary care, equipment, and training provided by the investigator to external or internal entities involved in the research project.

This assessment shall be based on the initial IRB application, which includes the protocol, outside IRB approval letters, letters of support, advertisements, and all other supporting documents. The IRB shall consult the investigator for additional information regarding necessary services.

The IRB systematically reviews the IRB application, research protocol, consent forms, and the HIPAA forms, which address the proposed arrangement for protecting privacy and confidentiality of research participants during and after the conduct of the research.

The IRB systematically reviews the IRB application, research protocol, consent forms, and the HIPAA forms, which address the proposed arrangement for storage of identifiable data during and after the conclusion of the study.

**Specific Policies**

**1.1 Minimal Criteria for Approval of Research**

In order for a research project to be approved, the IRB must find that:

- A. Risks to participants are minimized:
- By using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk, and
  - Whenever appropriate, by using procedures already being performed by or on the participants for diagnostic or treatment purposes.
- B. Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and to the importance of the knowledge that may be expected to result.

In evaluating risks and benefits, the IRB shall consider those risks and benefits that may result from the research (as distinguished from risks and

benefits of therapies that participants would receive even if not participating in the research).

C. Selection of participants is equitable:

The IRB shall take into account the purpose(s) of the research, the setting in which the research will be conducted, and the inclusion/exclusion criteria so that fair and equitable burdens and benefits are maximized. The IRB shall evaluate the recruitment and enrollment practices, plus the amount and timing of payments to participants. The IRB should also be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, handicapped or mentally disabled persons, or economically or educationally disadvantaged persons.

D. The investigator will obtain informed consent/assent from each prospective participant or the participant's legally authorized representative, in accordance with and to the extent required by appropriate local, state, and federal laws or regulations.

E. The investigator will document informed consent/assent as required by local, state, and federal laws or regulations.

F. If the protocol is more than minimal risk, the research plan includes adequate provisions for monitoring the data collected to protect participants.

G. Where appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of identifiable data.

H. When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, handicapped or mentally disabled persons, economically or educationally disadvantaged persons, or participants enrolled at international sites, additional safeguards have been included in the study and in the IRB review process to protect the rights and welfare of these participants.

## 1.2 Other Criteria

The IRB reviews the plan for data and safety monitoring when the protocol is submitted for initial review and also requests studies overseen by a Data Safety Monitoring Board (DSMB) to provide a DSMB report at the time of continuing review or as available. The IRB may suggest a data safety monitoring plan (DSMP) to the investigator, if applicable, to protect participants.

The IRB shall conduct continuing review of research projects at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

If any of the following are true, the IRB shall obtain verification from sources other than the investigators that no material changes have occurred since previous IRB review:

- The IRB has doubts about the veracity of the information provided by the investigator.

- The information provided by the investigator is inconsistent with other information known to the IRB, and the inconsistencies are not resolved through communication with the investigator.
- There was previous serious or continuing non-compliance with continuing review requirements.
- There is any other reason for which an IRB member believes that such verification is appropriate.

For VA Research:

The IRB is required to determine whether the medical record must be flagged to protect the participant's safety by indicating participation in the study and the source of more information on the study. The IRB does not require medical records to be flagged if:

- Participation in the study involves only one encounter.
- Participation in the study involves the use of a questionnaire or previously collected biological specimens.
- Identification as a participant in a particular study (if the study is not greater than minimal risk) would place the participant at greater than minimal risk.

### **1.3 Reliance on Other IRBs for Review and Approval of Research Conducted at the University of Oklahoma.**

Under authority granted by the Board of Regents of The University of Oklahoma, the Senior Vice President and Provost of the Health Sciences Center and the Senior Vice President and Provost of the Norman campus may enter into joint review arrangements, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort as allowed and upon modification of the institutional Federal-wide Assurance agreements (FWAs). For example, for projects determined to have a conflict of interest, the University IRB review may be waived and delegated to Western Institutional Review Board (WIRB). NOTE: Review of VA research by a commercial IRB is prohibited.

### **1.4 Reciprocal Review and Approval of Research Conducted at One of the University of Oklahoma Campuses.**

When a research project involves both campuses, a reviewing campus shall be designated. The reviewing campus shall be determined in the following manner:

1. For medical or clinical studies involving human participants, the OUHSC Campus IRB will review for both campuses.
2. For all other research activities, determination of the reviewing campus shall be based on the home campus of the Investigator unless the research involves clinical procedures that are outside of the expertise of the Norman Campus IRB. For example, if a Norman Campus Investigator from the College of Education proposes to conduct a behavioral research project but intends to recruit from the OUHSC campus, the Norman Campus IRB will provide IRB review.
3. For FDA-regulated research involving human participants, the OUHSC Campus IRB shall review for both campuses.

4. For VA research involving human participants, the OUHSC Campus IRB shall review for both campuses.
5. The IRB Chair from either campus shall have the right to require review by its own IRB regardless of this policy, provided that the decision is stated in writing and presented to the IRB Chair of both IRBs.

### **1.5 Review of Research Conducted by Persons with University of Oklahoma Appointments at Non-University Facilities.**

Research carried out by persons with University of Oklahoma affiliations impacts the University, even if it is not conducted at University facilities. Any individual who has a University appointment, whether full- or part-time, salaried or voluntary, staff or faculty, is required to notify the appropriate IRB of his/her plans to conduct research. The IRB Chair or designee shall review such activities and determine whether the rights and safety of the participants have been adequately considered by another IRB. If no IRB review has taken place, or if the IRB Chair or designee has sufficient concerns about the study, the research shall not proceed until those concerns have been adequately addressed by the IRB Chair or the convened IRB.

### **1.6 IRB of Record for Another Site.**

The University may extend the applicability of its FWA to cover two types of collaborating individual investigators: collaborating institutional investigators and collaborating independent investigators.

#### **A. IRB Authorization Agreement (IAA) for Collaborating Institutional Investigators**

Under certain circumstances, OU will accept the responsibility of oversight of the conduct of research for another site. The Director of Compliance and the IRB shall approve arrangements for OU to be the IRB of record for another site. The HRPP Director formalizes the arrangement with the site for accepting this responsibility through an IRB Authorization Agreement signed by both parties. An FWA is required when the site is engaged in research. If the site does not have an FWA, then it must file an FWA. The site must conduct the research in accordance with the IRB Authorization Agreement.

Criteria for OU IRB to serve as the IRB of Record:

- The performance site engaged in research does not have an IRB of Record and agrees to rely solely on the OU IRB for review of human subjects research activities; or
- The performance site engaged in research may or may not have an IRB of Record, but agrees to rely on the OU IRB for a specific research project.

Conditions for OU IRB to serve as the IRB of Record:

- The research shall be conducted in collaboration with OU; and
- The investigator must be a full-time faculty member at OU.

Performance site engaged in research requesting OU IRB to serve as the IRB of Record must:

- File a Federalwide Assurance (FWA); and

- Conduct the research in accordance with the IRB Authorization Agreement.

The OU investigator shall provide to the OU IRB a written justification for the OU IRB to be the IRB of record for the research for the collaborating institutional investigator. The HRPP Director shall consult with legal counsel and present the agreement to legal counsel for review prior to signature by the Institutional Official. The IRB shall make available to OHRP the agreement upon request.

## **B. Individual Investigator Agreement (IIA) for Collaborating Independent Investigators**

Under certain circumstances, OU will accept the responsibility of oversight of the conduct of research for another investigator. The Director of Compliance and the IRB shall approve arrangements for OU to be the IRB of record for another investigator. The HRPP Director formalizes the arrangement with the investigator for accepting this responsibility through the Individual Investigator Agreement signed by both parties. The investigator must conduct the research in accordance with the Individual Investigator Agreement.

A collaborating independent investigator is:

- a. not otherwise an employee or agent of the University;
- b. conducting collaborative research activities outside the facilities of the University; and
- c. not acting as an employee of any institution with respect to his or her involvement in the research being conducted by the University.

The extension of the University's FWA to cover a collaborating individual investigator shall be documented using an Individual Investigator Agreement (IIA).

Conditions for OU IRB to serve as the IRB of Record:

- The research shall be conducted in collaboration with OU; and
- The principal investigator must be a full-time faculty member at OU.

The individual investigator must conduct the research in accordance with the Individual Investigator Agreement.

The OU investigator shall provide to the OU IRB a written justification for the OU IRB to be the IRB of record for the collaborating independent investigator. The HRPP Director shall consult with legal counsel and the agreement shall be reviewed by legal counsel prior to signature by the Institutional Official. The IRB shall make available to OHRP the agreement upon request.

### **1.7 Length of Approval**

The approval period for research is based on the date of the convened meeting at which the IRB approved the protocol or approved the research with modifications. Length of IRB approval is typically one year. However, the IRB may require more frequent reviews.

- A. If any of the following are true, the IRB will require review more often than annually:

- There is a high degree of risk.
  - The stage of the research is such that many of the risks are unknown.
  - Any other reason an IRB member believes that more frequent review is required.
- B. The IRB will consider review of research more often than annually when any of the following are true:
- Proposed procedures have not been used in humans.
  - More than minimal risk to vulnerable populations with no prospect of direct benefit.
  - A high likelihood that participants will die due to the research procedures.
  - There have been confirmed instances of serious or continuing non-compliance.
  - Any other reason for which the IRB requests closer monitoring.

### **1.8 Scientific Review**

The IRB shall evaluate proposed research for scientific or scholarly validity. The scientific/scholarly review is documented on the New Study Reviewer Checklist. The IRB will not rely upon other committees for scientific/scholarly review. The IRB shall evaluate the following:

- Whether the research uses procedures consistent with sound research design, which do not unnecessarily expose participants to risk.
- Whether the research is designed to answer the proposed question.
- The importance of the knowledge reasonably expected to result from the research.

### **1.9 Multi-Site Management**

Refer to SOP 801 Investigator Qualifications and Responsibilities, Section 1.5 for information regarding multi-site management.

### **1.10 Pre-review of Research**

The IRB may elect to conduct a pre-review of research prior to review at the convened meeting. All changes will be reviewed and approved by the convened IRB.

### **1.11 Transfer of Research**

The investigator must submit human subject research for IRB review and approval when transferring research to the University. The application shall include all the documents reviewed by the original IRB. Note: the research is considered ongoing if the investigator is in the process of data analysis and this activity will require IRB approval.

The investigator is responsible to obtain a memorandum of understanding (or other similar agreement) allowing the investigator to remove the data from the previous institution and continue the research at OU.

## **2. SCOPE**

These policies and procedures apply to all IRB staff and IRB members and to research submitted to the IRB.

## **3. RESPONSIBILITY**

The IRB Administrator is responsible for providing or obtaining the tools and resources the IRB members need to complete their research reviews.

The IRB Chair or designee is responsible for providing IRB members adequate submission review training and ongoing guidance and for selecting one primary and one secondary reviewer with the relevant expertise to perform reviews and make necessary recommendations on approval decisions by the IRB. If the IRB Chair or designee cannot select primary and secondary reviewers with the relevant expertise, the IRB Chair or designee shall defer the review to another IRB with Primary and Secondary Reviewers with the relevant expertise or obtain consultation for that expertise.

The IRB Chair or designee and the IRB Administrator are responsible to check each item on the agenda to determine whether a consultant is needed for additional expertise, such as scientific or scholarly expertise in a particular field, expertise regarding the local context, or knowledge or experience in working with vulnerable populations.

Primary and Secondary reviewers are responsible to conduct an in-depth review of all materials.

All other IRB members are responsible to review all provided materials in enough depth to be prepared to discuss the information at the convened meeting.

The IRB Education Coordinator is responsible for the initial and continuing education of the IRB members.

## **4. APPLICABLE REGULATIONS AND GUIDELINES**

45 CFR 46.111

21 CFR 56.108, 56.111

## **5. REFERENCES TO OTHER APPLICABLE SOPS**

SOP 301, Research Submission Requirements,

SOP 402, Expedited Review.

## **6. ATTACHMENTS**

203-A New Study Reviewer Checklist – Full Board (HSC)

203-A-1 New Study Reviewer Checklist – Full Board (NC)

203-B New Studies Reviewer Checklist – Expedited (HSC)

203-B-1 New Studies Reviewer Checklist – Expedited (NC)

203-BB Expedited Categories Checklist (HSC)

203-BB-1 Expedited Categories Checklist (NC)

203-D VA Research Reviewer Checklist

203-E Reviewer Checklist for Research Involving Pregnant Women, Fetuses & Neonates (HSC)

203-E-1	Reviewer Checklist for Research Involving Pregnant Women, Fetuses & Neonates(NC)
203-F	Reviewer Checklist for Research Involving Prisoners (HSC)
203-F-1	Reviewer Checklist for Research Involving Prisoners (NC)
203-G	Reviewer Checklist for Research Involving Children (HSC)
203-G-1	Reviewer Checklist for Research Involving Children (NC)

## 7. PROCESS OVERVIEW

- 7.1 The IRB Staff makes sure all documents are reviewed for submission, per SOP 301, Research Submission Requirements.
- 7.2 The IRB Administrator provides to the IRB Chair or designee or IRB the item to be reviewed and the tools to conduct the review.
- 7.3 The IRB staff conducts preliminary data entry, assigns the appropriate Board, and forwards the item to the IRB Administrator for processing. The IRB Administrator checks the new research project application documents for accuracy of information and to verify that all required documents are submitted. An initial assessment of the research project is conducted to determine if it requires review by expedited procedures or a convened IRB. The research project is either assigned to the next appropriate agenda or given to the IRB Chair for review
- 7.4 The IRB Chair or designee reviews the content with respect to the risk/benefit analysis, study design, selection of subjects, and the inclusion of required elements in the informed consent according to federal law or regulations, the Belmont Report, and local and state requirements. If the research project requires convened IRB review, the IRB Chair forwards the documents to the IRB Administrator who assigns the research project to the next appropriate IRB agenda.
- 7.5 The IRB Chair may require verification of information submitted by an investigator. This information may be obtained from third parties such as the sponsor, other institutions participating in the research, and other IRBs reviewing the research. The IRB Chair will document this verification in the file.
- 7.6 Prior to the meeting, the IRB Chair designates the Primary and Secondary reviewers for each pending item indicated on the agenda. The IRB Administrator inserts the name of each Primary and Secondary reviewer in the agenda and forwards the agenda to each assigned reviewer.
- 7.7 The IRB Administrator provides an agenda for each IRB meeting, copies of the previous IRB meeting minutes, and copies of all pending agenda items to be reviewed at the meeting to the IRB.
- 7.8 The IRB reviewer examines each assigned agenda item and summarizes findings on the appropriate reviewer checklists provided. The IRB reviewer determines whether special considerations exist that may influence the review of a project and whether evidence exists for third party verification of submitted information is needed. The IRB reviewer presents a summary of findings and recommendations at the assigned convened IRB meeting. The IRB Administrator records the conclusions in the IRB meeting minutes.

7.9 All expedited proposals follow the expedited process outlined in SOP 402, Expedited Review.

7.10 Reliance on Another IRB

For projects determined to have a conflict of interest, IRB review and approval may be waived and delegated to another relied-upon IRB. The University must approve arrangements to rely on another IRB.

To maintain a system for protection of participants, the HRPP follows the process outlined below:

- A. The HRPP makes certain that human participant research is reviewed and approved by an IRB registered with OHRP that has an OHRP-approved assurance of compliance with the HHS regulations ([45 CFR 46.103](#)) for the protection of human subjects.
- B. The HRPP makes certain that the IRB relied upon is guided by the ethical principles of (a) The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research; or (b) other appropriate ethical standards recognized by federal departments and agencies that have adopted the Federal Policy for the Protection of Human Subjects, known as the Common Rule.
- C. A copy of the annual review and approval of the research provided by an outside IRB shall be provided to the IRB, until the study is closed.

7.11 Responsibilities

- A. The HRPP is responsible for periodically reviewing the policies and procedures of the relied-upon IRB to make certain that the rights and welfare of participants are protected. The periodic review is conducted by the HRPP Director every three years.
- B. The HRPP documents the reliance of another IRB by a written agreement with the IRB organization. The agreement describes the commitment that the relied-upon IRB will adhere to the requirements of the FWA. This agreement is signed by the Institutional Official and maintained on file and made available to OHRP upon request.

**APPROVED BY:** \_\_\_\_\_ **DATE:** 09/01/2009

**NEXT ESTABLISHED REVIEW DATE:** MAY 2012