

Oklahoma State University Institutional Review Board Standard Operating Procedures

Duties of IRB Members

SOP #	OR 203
Effective Date	1/1/2012
Revision Date	08/12/2015
Revision #	1
Approval: IRB	08/12/2015

1. POLICY

Each Institutional Review Board (IRB) member's primary duty is to safeguard the rights and welfare of the individual human beings who are serving as the subjects of research conducted under the auspices of Oklahoma State University (OSU). Each IRB member must understand that he or she is not serving on the IRB in order to expedite the approval of research but to be a fair and impartial link between the Investigator and the research subjects. In order to fulfill their duties, IRB members are expected to be versed in the regulations governing human subjects research and OSU policies germane to research involving human subjects.

Specific Procedures

1.1 Duty to Oklahoma State University

The IRB, which is constituted in accordance with 45 CFR 46.107 and 46.304, is established and appointed as a faculty committee, although not all IRB members are members of the OSU faculty. IRB members serve OSU as a whole, rather than a particular college or department. Therefore, members must not allow their own interests or that of their college or department to supersede their duty to safeguard the rights and welfare of research subjects.

1.2 Term of Duty

Appointed by the Institutional Official (IO), IRB members, including the chair and vice chair, are expected to commit to a 3-year term and to fulfill certain duties. These duties will be shared with prospective members prior to appointment. Each prospective member is expected to fully understand the duties of IRB members prior to conducting protocol reviews. Each appointment may be re-evaluated after one year by the IRB Chair IRB Manager, and the member to determine if the level of commitment remains a good match for both the member and the IRB.

1.3 Specific Duties

1.3.1 Members:

- A. Nonaffiliated member(s): Nonaffiliated members are individuals who are not otherwise affiliated with OSU, except through IRB membership, and are not a member of the immediate family of any individual who is currently affiliated with OSU. Consequently, an individual could not be considered for IRB membership as a nonaffiliated member if he/she is a retiree of the university or has a spouse, parent, child, or sibling currently affiliated with OSU. However, a graduate of OSU from years ago or someone whose family member attended OSU in the past could be considered. The overriding criterion should be that the person represents the local community. As such, nonaffiliated members are expected to provide input regarding their knowledge about the local community and be willing to discuss issues and research from that perspective.
- B. Nonscientific members: Nonscientific members are individuals whose primary concerns are in nonscientific areas. Nonscientific members are expected to provide input on areas germane to their knowledge, expertise, and experience. For example, members who are lawyers should present the legal views of specific areas that may be discussed, such as exculpatory language or state requirements regarding consent. Nonscientific members

advise the IRB if additional expertise in a nonscientific area is required to assess if the protocol adequately safeguards the rights and welfare of subjects.

- C. Scientific members: Scientific members have experience with being actively engaged in research or practice in the physical, educational, social, behavioral, or biological sciences and disciplines. Scientific members are expected to contribute to the evaluation of a research study on its scientific and statistical merits. These members should also be able to advise the IRB if additional expertise in a scientific area is required to assess if the protocol adequately safeguards the rights and welfare of subjects.
- D. All IRB Members: IRB members review proposed, modified, and continuing research projects, which includes protocol materials, to assess the risks posed to subjects in relation to the benefits expected to result from the research. Members approve studies according to ethical standards, OSU requirements, pertinent regulations, and the IRB's standard operating procedures and operational policies. Members serve as primary reviewers at convened meetings; review policies, procedures, and forms on a regular basis; and participate in protocol audits, when needed.
- E. Chair: In addition to the responsibilities noted above, which are germane to all members, the Chair presides over meetings of the IRB, convening special meetings when necessary. The Chair makes decisions in pressing situations in an effort to safeguard the rights and welfare of subjects and others, and to maintain the university's compliance with pertinent regulations. Therefore, the Chair is empowered to suspend the conduct of a research project deemed to place individuals at unacceptable risk, pending IRB review; and to suspend the conduct of a study if he/she determines that an Investigator is not following the IRB's requirements. The Chair leads the IRB in making decisions with fairness and impartiality, ensuring that any member with a conflict of interest recuses him/herself from proceedings as appropriate. The Chair reviews research protocols, including all protocols slated for review at convened meetings of the IRB and protocols qualifying for expedited review for which he/she serves as the designated reviewer. The Chair performs and/or delegates the task of assigning protocols qualifying for expedited review to different designated reviewers from among experienced IRB members. This includes review of protocol modifications, as well as continuing reviews qualifying for expedited review. He/She performs review of minor revisions to protocols that are submitted as a result of full board review, determines or designates the responsibility for determining whether proposed and continuing research qualifies for expedited review, reviews or designates another IRB member(s) to review all submitted investigator reports to determine if there is reason for review at a convened meeting of the IRB, confirms primary reviewer assignments made by the IRB administrative support staff when asked, and reviews IRB policies, procedures, and forms on an ongoing basis. In addition, the Chair reviews or designates IRB committee member(s) to review serious adverse events (SAEs) and unanticipated problems, and decides which ones must be reviewed at a convened meeting of the IRB. Finally, the IRB Chair communicates concerns about the human research protection program and the IRB to appropriate University officials, including the Institutional Official (IO), and acts as a consultant and educator to the OSU research community. The Chair holds regular meetings with the IRB Manager, represents the university in discussions with federal regulators, and represents the IRB in discussions with researchers, other university stakeholders, and community stakeholders. The Chair may delegate any of his/her responsibilities, as appropriate, to another qualified IRB member when necessary or warranted.
- F. Vice Chair: The Vice Chair assists the Chair as needed. In the absence of the Chair, the Vice Chair serves as the IRB Chair. If the Chair is conflicted (i.e. has a conflict of interest), the Vice Chair assumes the duties of the Chair.
- G. Primary and Secondary Reviewers: In addition to the duties described above, each member will be expected to act as a primary reviewer for assigned studies at convened

meetings. Secondary reviewers may also be assigned, at times. The primary reviewer presents his/her findings resulting from review of the application materials and provides an assessment of the soundness of the protocol and the risks posed by the research. The primary reviewer recommends specific actions to the IRB. Initially, he/she leads the IRB discussion of the study. Primary reviewers may be required to review additional material requested by the IRB for the purpose of study approval. The secondary reviewer, if assigned, adds to the discussion, as necessary.

- H. IRB Manager: In addition to the job duties described in the job description, the IRB manager serves as a member of the IRB. This allows the IRB manager to effectively oversee the day-to-day activities of the IRB and efficiently review certain IRB applications, including but not limited to projects qualifying for expedited review, when assigned, and projects that must be reviewed at a convened meeting of the IRB. In addition, he/she facilitates the review process with the IRB Chair and members. Furthermore, he/she assists the Chair by facilitating communication about IRB requirements for approval of research and IRB decisions regarding approval. The IRB Manager interacts with investigators, sponsors, and IRB members. Additional information about the duties of the IRB Manager may be found in this document.
- I. IRB Coordinator: In addition to the job duties described in the job description, the IRB coordinator serves as an alternate member of the IRB and will help make determinations about which human subjects research projects submitted to the IRB qualify for exempt status. Additional information about the duties of the IRB Coordinator may be found in this document.

NOTE: The task of making the IRB a respected part of the OSU community will fall primarily on the shoulders of these individuals. The IRB must be perceived to be fair and impartial, immune from pressure either by the institution's administration, the Investigators whose protocols are brought before it, or other professional and nonprofessional sources.

1.3.2 The Institutional Official (IO):

The IO appoints a Chair and at least one Vice Chair, who must be members of the OSU faculty. As stated previously, in the absence of the Chair, a Vice Chair will act on behalf of the Chair in particular IRB matters and at IRB meetings, either as a general procedure or on a case-by-case basis.

2. SCOPE

These policies and procedures apply to all IRB Members.

3. RESPONSIBILITY

The IRB manager is responsible for clearly articulating all IRB member duties to prospective and current IRB members. The IRB Chair, and/or Vice Chair, assists the IRB Manager as needed.

IRB Members are responsible for fulfilling their duties as specified.

4. APPLICABLE REGULATIONS AND GUIDELINES

OHRP IRB Guidebook

FDA Information Sheets FAQ, section II, question 17.

Title 45 Code of Federal Regulations Part 46 (45 CFR 46) "Basic HHS Policy for the Protection of Human Subjects"

5. REFERENCES TO OTHER APPLICABLE SOPS

This SOP affects all other SOPs.

6. ATTACHMENTS

OR 203-A	Member Responsibilities -
OR 203-B	Member Responsibilities - Chair
OR 203-C	Member Responsibilities – Vice Chair
OR 203-D	Member Responsibilities - Alternate Member
OR 203-E	Member Responsibilities - Reviewer Duties

7. IMPLEMENTATION OF PROCEDURES

Who	Task	Tool
<i>IRB Manager</i> <i>IRB Chair</i>	Document the expectations for members of the IRB.	Member Responsibilities Member Responsibilities – Chair & Vice Chair Member Responsibilities - Alternate Members Member Responsibilities - Reviewer Duties
<i>IRB Manager</i> <i>IRB Chair</i>	Meet with prospective members to discuss expectations.	
<i>IRB Manager</i>	Maintain up-to-date descriptions of member responsibilities. Answer questions from IRB members as needed.	
	Periodically review members' duties.	
	Ensure that members are carrying out their responsibilities as expected and that there is adequate staff support to ensure that members are able to function as documented.	
	As needed, make recommendations to the Chair, Assistant Vice President for Research Compliance, and/or the IO regarding changes to descriptions, staffing, meeting scheduling, and other factors that affect any member's ability to perform their duties.	

Title	IRB Member
Term	3 years
Responsibilities	<ul style="list-style-type: none">• Regularly attend convened meetings of the IRB• Be familiar with IRB procedures, policies and documents, including applicable Federal, State, and OSU policies• Be familiar with criteria for approval of research applications• Review expedited and full board research applications• Act as primary reviewer at IRB meetings as needed• Act as secondary reviewer at IRB meetings as needed• Consult with Investigators as needed• Obtain continuing education germane to human subject protection• Help publicize the role of the IRB by speaking to colleagues and students
Time Commitments	<ul style="list-style-type: none">• IRB: 8 hours per month• Attend Continuing Education• IRB members are advised to alert the IRB coordinator well in advance, if possible, if they cannot attend an IRB meeting, or will be unavailable for a length of time, so they are not assigned protocols to review.
Other Requirements	<ul style="list-style-type: none">• The following financial relationships must be disclosed annually: any equity interests over \$10,000 to commercial entities that sponsor or conduct research at Oklahoma State University (OSU); significant payments of other types, including honoraria, consultant fees received from commercial entities that sponsor or conduct research at OSU.• A potential for a conflict of interest must be disclosed prior to conducting a review of research. Conflicts of interest could include close personal or professional relationships to an Investigator; interest, financial or otherwise, in the outcome of the research.• Alert the IRB Coordinator well in advance, if possible, when they cannot attend an IRB meeting, so they are not assigned protocols to review. If a member does not alert the IRB Coordinator in a timely manner, and is assigned protocols to review for the next upcoming meeting, then the member is expected to deliver written comments to the IRB Coordinator prior to the beginning of the meeting.
Compensation	<ul style="list-style-type: none">• Faculty: None (an absolutely fabulous line on your vita)• Non-faculty: None other than reimbursement for costs incurred for parking related to IRB roles and responsibilities.

Title	Chair (The Chair must be a current member of the OSU faculty.)
Term	3 years
Responsibilities	<p>In addition to the duties of IRB members, the Chair of the IRB assumes the following duties:</p> <ul style="list-style-type: none">• preside over convened meetings of the IRB;• convene special meetings when necessary;• ensures that any member with a conflict of interest recuses him/herself from proceedings as appropriate;• make decisions in pressing situations in an effort to safeguard the rights and welfare of subjects and others, and to maintain the University's compliance with pertinent regulations;• review all submitted Investigator reports and determine if there is reason for full board review, in consultation with the IRB Manager;• perform or delegate expedited review of research applications, revisions, modifications, and continuations;• review and approve minor revisions to full board applications;• review reports of serious adverse events and unanticipated problems and decide which ones should be reviewed at convened meetings of the IRB;• consult with Investigators as needed;• conduct post-approval monitoring in concert with the IRB Manager and other members of the IRB when deemed appropriate;• conduct training sessions with Investigators and research staff as needed;• review policies, procedures, and forms on an on-going basis;• obtain continuing education germane to IRB responsibilities;• suspend the conduct of a research study deemed to place individuals at unacceptable risk, or that is not following IRB requirements, pending IRB review.• communicate concerns about the human subject protection program and the IRB to University officials, including the Institutional Official (IO);• act as a consultant and educator to the OSU research community;• represent the University in interactions with federal regulators;• represent the IRB in discussions with researchers, other University stakeholders, and community stakeholders;• delegate any of his/her responsibilities as appropriate to other qualified individual(s); (Documentation must be in writing.)

- hold regular meetings with the IRB Manager; and
- confirms primary reviewer assignments made by IRB administrative support staff when asked.

Time Commitment

IRB: 20 additional hours per month
Participate in continuing education
Instruction: As needed

Other Requirements

The task of making the IRB a respected part of the institutional community will fall primarily on the shoulders of the Chair. The IRB must be fair and impartial, immune from pressure either by the institution's administration, the Investigators whose protocols are brought before it, or other professional and nonprofessional sources.

The following financial relationships must be disclosed annually: 1) any equity interests over \$10,000 to commercial entities that sponsor or conduct research at Oklahoma State University (OSU); and 2) significant payments of other types, including honoraria and consultant fees received from commercial entities that sponsor or conduct research at OSU.

A potential for a conflict of interest must be disclosed prior to conducting a review of research. Conflicts of interest could include close personal or professional relationships to an Investigator; interest, financial or otherwise, in the outcome of the research.

Compensation

Reimbursement to the Chair's department for teaching expenses (release time) or one month's summer salary.

Title	Vice Chair (The Vice Chair must be a member of the OSU faculty.)
Term	3 years
Responsibilities	In addition to the duties of IRB members, in the absence of the chair, or if the chair has a conflict of interest, the Vice Chair of the IRB assumes the Chair's duties. The Vice Chair will assist the Chair, as needed.
Time Commitment	IRB: 2 additional hours per month Participate in continuing education Instruction: As needed
Other Requirements	<ul style="list-style-type: none">• The task of making the IRB a respected part of the institutional community will fall primarily on the shoulders of the Chair. However, the Vice Chair can help the IRB be as fair and impartial, immune from pressure either by the institution's administration, the Investigators whose protocols are brought before it, or other professional and nonprofessional sources.• The following financial relationships must be disclosed annually: 1) any equity interests over \$10,000 to commercial entities that sponsor or conduct research at Oklahoma State University (OSU); and 2) significant payments of other types, including honoraria and consultant fees received from commercial entities that sponsor or conduct research at OSU.• A potential for a conflict of interest must be disclosed prior to conducting a review of research. Conflicts of interest could include close personal or professional relationships to an Investigator; interest, financial or otherwise, in the outcome of the research.
Compensation	None

Title	Alternate Member
Term	3 years
Responsibilities	Attend convened meetings of the IRB as needed. Review submitted research as needed.
Time Commitments	IRB: 8 per month Participate in continuing education
Other Requirements	<ul style="list-style-type: none">• The following financial relationships must be disclosed annually: 1) any equity interests over \$10,000 to commercial entities that sponsor or conduct research at Oklahoma State University (OSU); and 2) significant payments of other types, including honoraria and consultant fees received from commercial entities that sponsor or conduct research at OSU.• A potential for a conflict of interest must be disclosed prior conducting a review of research. Conflicts of interest could include close personal or professional relationships to an Investigator; interest, financial or otherwise, in the outcome of the research.• Alert the IRB Coordinator well in advance, if possible, when the alternate member cannot attend an IRB meeting, so he/she is not assigned a protocol(s) to review. If an alternate member cannot alert the IRB Coordinator in a timely manner, and is assigned a protocol(s) to review for the next upcoming meeting, then he/she is expected to deliver written comments to the IRB Coordinator prior to the beginning of the meeting.
Compensation	Faculty: None Non-faculty: None other than reimbursement for costs incurred for parking related to IRB roles and responsibilities.

Non-affiliated reviewer	Nonaffiliated members are expected to provide input regarding their knowledge about the local community and be willing to discuss issues and research from that perspective.
Nonscientific reviewer	Nonscientific members are expected to provide input on areas germane to their knowledge, expertise and experience, professional and otherwise. For example, members who are lawyers should present the legal views of specific areas that may be discussed, such as exculpatory language or state requirements regarding consent. Nonscientific members should advise the IRB if additional expertise in a nonscientific area is required to assess if the protocol adequately safeguards the rights and welfare of subjects.
Scientific reviewer	Scientific reviewers are expected to contribute to the evaluation of a study on its scientific and statistical merits. These members should also be able to advise the IRB if additional expertise in a nonscientific area is required to assess if the protocol adequately safeguards the rights and welfare of subjects.
Primary reviewer	In addition to the duties described in SOP OR 203, section 1.3.1, each member, or alternate member when called upon, will be expected to act as a primary reviewer for assigned studies at some convened meetings. The primary reviewer presents his or her findings resulting from review of the application materials and provides an assessment of the soundness and safety of the protocol and recommends specific actions to the IRB. He or she leads the IRB discussion of the study. The primary reviewer may be required to review additional material requested by the IRB for the purpose of study approval.