**TITLE: Full Board Review**

**POLICY NUMBER: IRB-107**

**REVISION NUMBER: 1.0**

**APROVED DATE: 8/12/2026**

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## A. PURPOSE

To describe the process and procedures by which the Oklahoma State University Institutional Review Board (IRB) reviews and determines research activities involving human subjects to qualify for full board status under applicable federal regulations and institutional policy; whereas the research involved poses greater than minimal risks or does not qualify for expedited status.

## B. SCOPE

This policy applies to all OSU investigators, IRB staff, and IRB members involved in the submission, review, determination, and documentation of full board status human subjects research.

## C. REFERENCES

45 CFR 46.108
45 CFR 46.111
45 CFR 46.116
45 CFR 46.117
45 CFR 46 Subparts B, C, and D
OSU Policy 4-0115, Policy for the Protection of Human Subjects in Research
IRB Post-Approval Monitoring Policy

## D. DEFINITIONS

- **Full Board Review:** Review of research involving more than minimal risks human subjects activities conducted by the IRB at a convened meeting with a quorum present.
- **Quorum:** A majority of IRB members, including at least one non-scientific and community member. The non-scientific member can also be the community member.
- **Protected/Vulnerable Populations:** Groups requiring additional regulatory protections, including but not limited to prisoners, pregnant women, fetuses, targeting specific native populations, LGBTQ+, children (Under 18), invisible and apparent disability, and unable to read/understand English, economically disadvantaged, terminally ill/very sick, and older adults (65+).

- **Institutional Biosafety Committee (IBC):** A review committee that ensures research involving engineered genetic material and biohazards remains safe for staff and the environment.
- **Environmental Health and Safety (EHS):** The university department responsible for ensuring campus regulatory compliance, promoting workplace safety, and protecting the environment and the health of students, faculty, staff, and visitors.
- **Radiation Safety Office (RSO)**: A review official that ensures research involving radioactive materials and machines are used in accordance with applicable and state federal regulations.
- **OneAegis:** OSU's electronic IRB submission and tracking system.
- **IRB Reviewer Submission Checklist:** The list of questions that an IRB Committee Reviewer completes to ensure that all questions have been answered appropriately.

## E. ROLES AND RESPONSIBILITIES

1. **Investigator**

- Submit complete applications and revisions as requested and ensure compliance with the determination.

2. **IRB Coordinator**
   - Conducts an administrative review of applications to ensure completeness and determines eligibility for full board status,
   - May assist in preparing review materials and correspondence with Investigators and Committee Members,
   - Assign IRB Committee Member Reviewer(s) to review the application,
   - Assists with documenting IRB decisions and IRB meeting minutes,
   - Assists with issuing approval and other determination letters, as applicable.

3. **IRB Manager**
   - Can conduct or assist with all responsibilities of the IRB Coordinator, as listed above,
   - Identifies need for outside consultants and ensures no conflicts of interest,
   - Notifies the IRB Committee of meeting time and coordinates schedule to ensure quorum for meeting,
   - Reviews agendas and ensures appropriate materials are available to members in advance,

- Documents IRB decisions and maintains complete and compliant IRB meeting minutes in accordance with institutional and regulatory requirements,
- Assists in addressing noncompliance, unanticipated problems, complaints, or allegations related to human subjects research.

4. **IRB Chair**
   - Provides oversight of the full board review process,
   - Makes IRB determinations on behalf of the convened IRB when authorized (e.g., minor clarifications, administrative approvals),
   - Facilitates balanced discussion, encourages participation from all members, and manages conflicts of interest,
   - Calls for votes and confirms that IRB decisions are clear and properly recorded,
   - Assists in addressing noncompliance, unanticipated problems, complaints, or allegations related to human subjects research.

5. **IRB Committee**
   - Provides feedback and identifies revisions, clarifications, or additional information the researcher must address before approval may be granted,
   - Makes final decision regarding review level and determinations,
   - Reviews and approves IRB meeting minutes for accuracy and regulatory completeness,
   - Assists in addressing noncompliance, unanticipated problems, complaints, or allegations related to human subjects research.

## F. ELIGIBILITY CRITERIA

Research is eligible for full board review when the research involves greater than minimal risks to human subjects. Criteria of research that qualify for full board review involve, but are not limited to, any of the following:

- Blood samples exceeding 550ml or samples drawn more than 2 times per week,
- Biomedical data collected through invasive procedures such as x-rays .or sedation,
- Vulnerable populations designed in 45 CFR 46, Subparts B, C, and D,
- The service or consumption of alcohol,
- Any other procedure(s) that presents greater than minimal risk or would benefit from review by the convened IRB to ensure safety and protection of human subjects.

## G. FULL BOARD REVIEW PROCEDURES

### 1. Submission

- The Investigator or other research personnel will make the submission for the project in OneAegis.

### 2. Administrative Review

- The IRB Coordinator or Manager performs an administrative review and makes a pre-determination that the application meets full board status,
- If the application is submitted well in advance of the published submission deadline, the IRB Office may return the application for revisions and/or clarifications to provide a more straightforward review process for the IRB Committee Reviewer(s), The IRB confirms any additional need for review and/or approval with other compliance groups or institutional officials,
    - Research involving Dual-Energy X-ray Absorptiometry (DEXA) scans must be reviewed by the RSO. Although DEXA scans are generally considered low risk, they expose participants to ionizing radiation. Full Board review allows the IRB and RSO to evaluate the scientific justification for the radiation exposure, assess whether the radiation dose is minimized and reasonable in relation to the anticipated benefits and knowledge to be gained, and ensure that appropriate safeguards and informed consent language regarding radiation exposure are included in the protocol. This includes pregnancy tests for female participants.
    - Research involving prisoners, as defined by applicable federal regulations, must be reviewed by a prisoner representative as a voting member or consultant participating in the review in accordance with regulatory requirements.
    - Research involving the service or consumption of alcoholic beverages must be reviewed and approved by the OSU Vice President for Research and the OSU Provost. IRB approval cannot be provided until both parties have confirmed permissions/approval.
- The application is scheduled for the next available convened IRB meeting, provided all submission deadlines have been met.

### 3. Pre-Review

- IRB Committee Reviewers are selected based on their expertise. A primary reviewer is always assigned, and a secondary reviewer is

added if the applications involves multiple subject areas or expertise. The reviewer(s) will evaluate the application using the same regulatory criteria applied during convened IRB review, including risk minimization, equitable subject selection, informed consent, and data protection. The reviewer may provide feedback and comments to the Investigator and/or IRB Staff. The reviewer will complete the IRB Reviewer Submission Checklist to ensure that all required review criteria have been adequately addressed and documented. The reviewer(s) also confirms the determination that the application meets eligibility for full board status,

- Review materials are distributed to IRB Committee members at least a week prior to the meeting.

4. Full Board Review
    - A convened meeting is held with a quorum present,
    - The primary reviewer presents the study and provides any comments, concerns, or questions they have related to the project. If applicable, the secondary reviewer may also present additional comments, concerns, or questions,
    - The full board committee conducts a collaborative review of the project to discuss feedback, address concerns, and propose revisions,
    - The investigator and other researchers, as deemed appropriate, may be invited to address questions from the IRB Committee,
    - Committee members who are involved in the project as an investigator or research personnel must withdraw themselves from committee discussion and the voting process to avoid a conflict of interest,
    - Outcomes are discussed by the committee to reach a decision and, when appropriate, may also be discussed with the Investigator.

5. **Review Outcomes**

*Approval periods are determined based on risk and may not exceed one year. If deemed appropriate, the board may vote to move a protocol to expedited category 9. Approval is formally documented via an approval letter.*

6. **Modifications to full board studies:** All proposed modifications to previously approved research must be submitted to the IRB, through the OneAegis system, for review and approval prior to implementation, except where necessary to eliminate apparent immediate hazards to participants.

Minor changes that meet expedited review criteria may be reviewed through expedited procedures, while modifications that increase risk or otherwise do not qualify for expedited review shall be referred to the full convened IRB. Modification submissions must adhere to the published Full Board submission deadlines.

7. **Continuing Review**: All research falling under Full Board status is subject to continuing review and approval as per the IRB Continuation Review policy. Continuing review submissions must adhere to the published Full Board submission deadlines.

## H. QUALITY CONTROL

**Post Approval Monitoring:** Full Board protocols are subject to be selected for post-approval monitoring. Refer to the IRB Post-Approval Monitoring Policy for further information.

**Internal IRB Compliance Audit:** An annual audit shall be conducted by the Data Compliance Analyst within University Research Compliance using a random sample of studies approved through full board review to verify compliance with applicable regulatory requirements and IRB Policy.

- Verification of quorum and non-scientific membership at convened meetings.
- Documentation of discussions, votes, and determinations in IRB minutes.
- Use of electronic tracking system.

## I. REVISION HISTORY

| Date | Revision Number | Description of Changes |
|---|---|---|
| 07/27/2026 | 1 | • Changed document from SOP to a Policy<br>• Revised language of the Purpose and Scope sections to ensure consistency between Exempt/Expedited/Full Board policies<br>• Updated roles and responsibilities and incorporated IRB Committee member roles and responsibilities |

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| | | • Revised language to remove references to submitting an application form, as submissions are completed through the OneAegis online system<br>• Removed references to IACUC review, as it is no longer applicable. Protocols involving animals must be submitted to the IACUC for review<br>• Added Environmental Health and Safety (EHS) and radiation/laser safety as supplemental reviews, as applicable.<br>• Added definitions to clarify what the Institutional Biosafety Committee, Environmental Health and Safety, and Radiation Safety groups are<br>• Added Eligibility Criteria ensuring similar language used between Exempt/Expedited/Full Board policies<br>• Update and revise Review Procedures<br>• Add Quality Control section regarding post-approval monitoring and internal IRB compliance audit |