TITLE: Expedited Review

POLICY NUMBER: IRB-106

REVISION NUMBER: 2.0

POLICY APPROVAL DATE: 8/12/2026

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 expedited status under applicable federal regulations and institutional policy; whereas the research involved poses no more than minimal risks or does not qualify for exempt status.

B. SCOPE

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

C. REFERENCES

45 CFR 46

OHRP Guidance on Expedited Review Procedures

OSU Policy 4-0115, Policy for the Protection of Human Subjects in ResearchIRB Post-Approval Monitoring Policy

D. DEFINITIONS

- **Expedited Review:** Review of research involving no more than minimal risk conducted by the IRB chair or designated reviewer.

- **IRB Reviewer Submission Checklist:** The list of questions that an IRB Committee Reviewer completes to ensure that all questions have been answered appropriately.

- **OneAegis:** OSU's electronic IRB submission and tracking system.

E. ROLES AND RESPONSIBILITIES

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

- **IRB Staff**: Conducts an administrative review of applications to ensure completeness, determines potential eligibility for expedited status, reviews submitted revisions, assigns the application to a qualified IRB Committee

Member to conduct review for expedited status, communicates approval status, and issues determination letters.

- **IRB Chair or IRB Committee Members:** Conducts a regulatory and ethical review of the application, provides feedback and comments to the Investigator and/or IRB Staff,, reviews submitted revisions, and submits review determination to the IRB Staff.

F. ELIGIBILITY CRITERIA

Research may be eligible for expedited review when all of the following conditions are met:

- The research involves no more than minimal risk to participants
- The research falls within one or more of the federally defined expedited review categories
- The research does not involve procedures or populations that require convened IRB review (e.g., greater than minimal risk or disallowed categories)
- The research involves vulnerable populations (excluding prisoners and pregnant individuals) or is related to topics that requests sensitive private information.
- Vulnerable populations include 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+).

G. PROCEDURES

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

- **Review of Application:** The IRB Office will perform an administrative review. The IRB Office may return the application for multiple rounds of revisions and/or clarifications if the submitted changes are deemed inappropriate or insufficient, until the application is considered ready for expedited review. Applications are assigned to the IRB Chair or a designated qualified IRB Committee Member reviewer. When appropriate, more than one reviewer may be assigned to an expedited review. In such cases, a primary and secondary reviewer may be designated to ensure adequate expertise for applications involving multiple subject areas or specialized knowledge. 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 will complete the IRB Reviewer Submission Checklist to ensure that all required review criteria have been adequately addressed and documented. The reviewer and/or IRB Office may

return the application for multiple rounds of revisions and/or clarifications if the submitted changes are deemed inappropriate or insufficient, until the application is considered ready for approval.

- **Determination of Expedited Status:** The IRB makes the final determination regarding expedited status. Only the IRB Manager, IRB Coordinator, or IRB Chair (or committee member) may make this determination. Investigators or departments may not self-determine the research as expedited.

- **Modifications to expedited 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 exempt criteria may be reviewed through exempt review procedures, while modifications that increase risk or otherwise do not qualify for expedited review shall be referred to the full convened IRB. Modifications that qualify for expedited review under federal rules are sent to an IRB reviewer instead of the full committee.

- **Continuing Reviews and Check-ins:** Continuing annual review of eligible research may be conducted using expedited procedures when permitted by applicable regulations. For studies that do not meet criteria for continuing review, as determined by the reviewer, approval will be granted for a period of up to three years, after which the study will be subject to annual administrative check-ins to ensure ongoing compliance.

H. QUALITY CONTROL

Post Approval Monitoring: Expedited 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 Compliance Analyst within University Research Compliance using a random sample of studies approved through expedited review to verify compliance with applicable regulatory requirements and IRB Policy.

I. REVISION HISTORY

Date	Revision Number	Description of Change
4/22/2026	1	• Changed document from SOP to Policy to clarify scope and applicability • Revised approval period to be consistent with the 2018 Common Rule Guidance • Removed the research categories as these can be found on the OHRP Guidance webpage and are listed on the IRB Reviewer Submission Checklist • Removed language related to research conducted under an investigational drug or device as these are related to a separate IRB of record with OSU Center for Health Sciences • Include information related to that fact that more than one reviewer may be assigned to an expedited review • Added language outlining quality control procedures, including that the Compliance Analyst will conduct random reviews of selected studies to verify compliance
7/27/2026	2	• Revise language in the Purpose, Scope, and Role/Responsibilities sections to ensure consistency between Exempt/Expedited/Full Board review policies • Add language to the "Review of Application" section indicating that applications may undergo multiple rounds of review, revisions, and clarification requests prior to receiving IRB approval. • Revise the "Modifications" section to define the review process for proposed changes at the exempt, expedited, and full board levels, including

		the requirement for full board review when modifications increase the level of risk. • Add information in the quality control section related to post-approval monitoring and title for the Internal IRB Compliance Audit.