TITLE: Initial Expedited Review

POLICY NUMBER: IRB-106

REVISION NUMBER: 1.0

POLICY APPROVAL DATE: 5/13/2026

A. PURPOSE

This policy outlines the requirements and process for conducting initial expedited review of research protocols involving human subjects in accordance with federal regulations.

B. SCOPE

This policy applies to all human subjects research eligible for expedited review conducted under the authority of the Institutional Review Board (IRB) at Oklahoma State University.

C. REFERENCES

45 CFR 46
OHRP Guidance on Expedited Review Procedures
IRB 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 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 initial administrative review of submissions to ensure completeness, determine potential eligibility for expedited review, assigns the protocol to a qualified reviewer, communicates approval status, and issues determination letters.

- **IRB Chair or IRB Members:** Conduct a regulatory and ethical review of the research, providing feedback and comments to the Researcher and IRB Office, as applicable.

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 or is related to topics that requests sensitive private information

G. PROCEDURE

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

- **Review of Application:** The IRB Office will perform an administrative review. Eligible studies are assigned to the IRB Chair or a designated qualified 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 protocols involving multiple subject areas or specialized knowledge. The reviewer(s) will evaluate the protocol 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 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 convened IRB.

- **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

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.

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.

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