TITLE: Exempt Review
POLICY NUMBER: IRB-104
REVISION NUMBER: 2.0
APPROVED 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 exempt status under applicable federal regulations and institutional policy.

B. SCOPE

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

C. REFERENCES

OSU Policy 4-0115, Policy for the Protection of Human Subjects in Research
45 CFR 46 Subpart A
45 CFR 46.104 Exempt Categories

D. DEFINITIONS

- **Exempt Review: Review of** research involving no more than minimal risk human subjects activities that fall within specific categories outlined in 45 CFR 46.104.

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

- **Minimal Risk:** The probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during routine examinations.

E. ELIGIBILITY CRITERIA

Research may be eligible for exempt 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 exempt review categories,
- The research does not involve procedures or populations that require IRB Committee Member review (e.g., more than minimal risk),

- The research does not involve vulnerable populations 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+).
    - Children under 18 is only acceptable to fall under the exempt category 1 if procedures involve normal educational practices.

F. 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, determines potential eligibility for exempt status, reviews submitted revisions, conducts review for exempt status, communicates approval status, and issues determination letters.
- **IRB Chair or IRB Members:** Performs exempt determinations as needed.

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. Exempt research must be of minimal risk to the subjects, have a sound research design, and be conducted ethically, meaning that at a minimum the principles of respect of persons, beneficence and justice must be met. The reviewer making the exemption determination may require protection to meet these principles, including informed consent is appropriate to the research. If the reviewer feels that the protocol does not meet the criteria for exemption, the review level will be changed, and the application will be processed at the new level (expedited or full board). 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 approval.
- **Determination of Exempt Status:** The IRB makes the final determination regarding exempt 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 exempt. The approval period for exempt studies is 3 years, with the researcher being able to extend after that point, on an annual basis, by simply notifying the IRB Office they plan to continue the research.

- **Modifications to exempt 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 review criteria may be reviewed through exempt procedures, while modifications that increase risk or otherwise do not qualify for exempt review shall be referred to the expedited review process. If you are unsure whether your proposed changes require modification, you may contact the IRB for determination.

H. REVISION HISTORY

Date	Revision Number	Description of Change
3/31/2026	1	• Changed document from SOP to Policy to clarify scope and applicability. • Minor formatting updates and wording updates. • Add that policy will be reviewed every 3 years. • Revise IRB Manager to OneAegis as the system name is changed.
7/27/2026	2	• Revise language in the Purpose section and IRB Staff Role/Responsibility to ensure consistency between Exempt/Expedited/Full Board review policies • Add Eligibility Criteria section ensuring similar language used between Exempt/Expedited/Full Board policies