



**TITLE: Criteria for IRB Approval**

**POLICY NUMBER: IRB-105**

**REVISION NUMBER: 1.0**

**POLICY DATE: 5/13/2026**

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### **A. PURPOSE**

This policy establishes the criteria that must be met for the Oklahoma State University (OSU) Institutional Review Board (IRB) to approve research involving human subjects. The policy ensures that human subjects research is conducted in accordance with the ethical principles of respect for persons, beneficence, and justice, as articulated in the Belmont Report, and in compliance with applicable federal and state regulations.

### **B. SCOPE**

This policy applies to all IRB members, IRB staff, investigators, and all human subjects research proposals submitted to the Oklahoma State University IRB.

### **C. REFERENCES**

Belmont Report

45 CFR 46.111

45 CFR 46.116 – Informed Consent

45 CFR 46.117 – Documentation of Informed Consent

### **D. DEFINITIONS**

**Institutional Review Board (IRB):** A committee established to review, approve, and monitor research involving human subjects.

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

**Vulnerable Populations:** Groups that may be at increased risk of coercion or undue influence, including but not limited to children, prisoners, pregnant women, and individuals with diminished decision-making capacity.

**Office for Human Research Protections (OHRP):** Provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the U.S. Department of Health and Human Services.

### **ROLES AND RESPONSIBILITIES**

**IRB Coordinator:** Ensures that IRB reviewers have the appropriate tools, materials, and resources necessary to conduct reviews.



IRB Manager (or Designee): Provides training, guidance, and oversight for IRB members regarding protocol review and approval.

IRB Members: Conduct thorough reviews of research submissions and make determinations or recommendations regarding approval.

### **E. CRITERIA FOR IRB APPROVAL**

1. Risks to subjects are minimized using sound research design and, when appropriate, procedures already being performed for other purposes.
2. Risks to subjects are reasonable in relation to anticipated benefits and the importance of the knowledge expected to result.
3. Selection of subjects is equitable and appropriate to the purpose and setting of the research.
4. Where appropriate, provisions are included for monitoring data to protect the rights and welfare of subjects.
5. Adequate safeguards are in place to protect subject privacy and maintain data confidentiality.
6. Additional safeguards are implemented for populations vulnerable to coercion or undue influence.
7. Sufficient resources are available to support the conduct and completion of the research.
8. Protocol attachments shown to subjects are written at an appropriate reading level applicable to the population. OHRP Guidance states that documents should be written at a 6<sup>th</sup>-8<sup>th</sup> grade reading level for studies targeting the general population.
9. Informed consent is sought and obtained from subjects and documented in accordance with applicable regulatory requirements, unless specifically waived by the IRB.

9.1 Informed consent includes the required following elements:

- a. Study involves research
- b. Voluntary participation
- c. Description of the procedures
- d. How much time can participants expect to spend on the study



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- e. Benefits of participation, if none that are directly related, listing the benefit to society
  - f. Risks and/or discomfort involved in the study
  - g. Confidentiality of records
  - h. Compensation (if there is none, clarification of that to be stated)
  - i. Contact information for PI
  - j. Contact information for the IRB Office
  - k. Notice about possible future research use of information or biospecimens stripped of identifiers
  - l. Treatment of injury (OSU Medical Liability Statement) – Biomedical studies
  - m. Disclosure of alternative procedures/treatments (Biomedical studies)
10. For sponsored research, applicable grant information (scope of work, for example) is included for IRB review.
  11. The IRB may require external verification of information or additional oversight when necessary to protect subjects. (An example of this could include letters of support from outside institutions such as prisons, schools, clinics, other universities, etc.).
  12. If the study involves translations to languages aside from English, the documents that are provided to participants in the other languages are required to be submitted and the Translator Confidentiality Agreement must be included in the application.
  13. The application and the protocol attachments are consistent.
  14. OSU may rely on other qualified IRBs through formal reliance or authorization agreements. Similar arrangements may also be made for other qualified IRBs to rely on the OSU IRB. The Vice President of Research will approve all reliance or authorization agreements.
  15. If a study involves deception, an IRB review will be conducted and then reviewed and approved by the Vice President of Research before final IRB approval is provided to the Researcher.
  16. Research may be subject to continuing annual review appropriate to the level of risk. However, the research may be subject to more frequent review, if the IRB deems necessary.



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<b>Date</b>	<b>Revision Number</b>	<b>Description of Changes</b>
4/20/2026	1	<ul style="list-style-type: none"><li>• Changed document from SOP to a Policy</li><li>• Removed the IRB Member Review Sheets as these are now integrated questions within OneAegis for the IRB Member to review and fill out</li><li>• Added information related to approval for deception studies</li><li>• Add information related to the elements required to be included in informed consent</li></ul>