

Institutional Review Board Policy of the University of North Alabama

1. Purpose

The University of North Alabama's Institutional Review Board (IRB) declaration of principles ensures that all human subjects research complies with ethical principles and federal regulations, including the revised 2018 Common Rule (45 CFR 46), and protects participants' rights and welfare.

The IRB also fosters a culture of ethical research and academic integrity, supporting researchers in navigating ethical challenges.

The 2018 Common Rule is the revised version of the federal regulations governing the ethical conduct of research involving human subjects in the United States. Officially known as the [Federal Policy for the Protection of Human Subjects](#), it was originally issued in 1991 and revised in January 2017, with implementation required by January 21, 2019.

2. Definitions

- Human Subjects Research: Research involving living individuals about whom an investigator obtains data through intervention or interaction, or identifiable private information.
- Informed Consent: The process by which a participant voluntarily confirms their willingness to participate in a study after being informed of all relevant aspects.
- Risk-Benefit Assessment: Evaluation of potential risks to participants against anticipated benefits.
- Vulnerable Populations: Groups with diminished autonomy such as children, prisoners, and individuals with cognitive impairments.

3. Scope

UNA's IRB Policy applies to all faculty, staff, students, adjuncts, visiting faculty, visiting scholars, and other affiliates conducting human subjects research at or sponsored by UNA, regardless of funding source. This includes research conducted off-campus, in online environments, classroom-based research, and pilot studies. Classroom-based projects intended solely for educational purposes and not designed to contribute to generalizable knowledge may be exempt from IRB review, subject to faculty oversight and ethical standards. Student research intended for dissemination beyond the classroom must undergo IRB review.

4. Governance and Oversight

- The IRB is composed of members from diverse disciplines, including at least one member not otherwise affiliated with UNA.
- Members are appointed by the university administration and serve staggered terms.
- The IRB meets regularly to review submissions and conducts expedited and full board reviews as appropriate.
- Researchers denied IRB approval may request reconsideration through notice to the IRB chair within 30 days of the decision notice they wish to have reconsidered. Requests for reconsideration must include a clear statement of the decision the researcher seeks to have reconsidered and justification for reconsideration, including any supporting evidence or clarifications. All requests for reconsideration will be evaluated as a full board review.

5. Compliance and Enforcement

- All researchers must complete CITI or equivalent training prior to IRB submission and include evidence of completion with proposals.
- Non-compliance may result in suspension of research activities and institutional disciplinary action.

- Ethical concerns or violations can be reported confidentially to the IRB using the required mechanism as outlined in consent forms or via other methods.
- The IRB may authorize reciprocity agreements with external Institutional Review Boards.
- The IRB conducts periodic audits and continuing reviews to ensure ongoing compliance.

6. Ethical Principles

Research at UNA adheres to the three core principles of the [Belmont Report](#):

A. *Respect for Persons*

- i. Recognizes the autonomy of individuals.
- i. Requires informed consent and voluntary participation.
- ii. Participants have the right to withdraw at any time without penalty.
- iii. Provides additional protection for those with diminished autonomy (e.g., children, prisoners, individuals with cognitive impairments).

B. *Beneficence*

- i. Obligation to maximize possible benefits and minimize potential harms.
- ii. Requires a risk-benefit assessment to ensure participants are not exposed to unnecessary risks.
- iii. Examples, although not exhaustive, include anonymization of data, secure data storage, and minimizing psychological stress.

C. *Justice*

- i. Ensures fair distribution of the burdens and benefits of research.
- ii. Requires that research participants are equitably selected, avoiding exploitation of vulnerable populations.
- iii. Recruitment strategies must ensure diversity and fairness.

7. International Research Standards

- UNA research complies with applicable international standards, including the [Declaration of Helsinki](#).
- Ethical standards must be upheld in international collaborations, with appropriate local IRB or ethics board approvals.
- Researchers must comply with all applicable local laws, regulations, and cultural norms when conducting research in international settings. In addition, all such activities remain subject to the Institutional Review Board oversight of the University of North Alabama.

8. Digital Research Ethics

- Researchers must consider the ethical implications of digital research, including studies involving social media, AI tools, and biometric data.
- Data privacy, consent in digital environments, and algorithmic bias must be addressed.

9. Community Engagement

- For participatory research, researchers should engage community partners respectfully and transparently.
- Community input should be incorporated into the study design and the dissemination of results.