Institutional Review Board (IRB) - Authority and Guiding Principles

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Policy 1.01

Topic: Institutional authority of the IRB and reporting lines
Date of implementation: March 2, 2009
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It is the general institutional policy to safeguard the rights and welfare of human subjects in research and other activities under the authority of the President of the University. From the Office of the President, the authority to review, approve, or deny research involving human subjects is passed to the Institutional Official. The Institutional Official or the Vice President for Research designates a board (i.e., the Institutional Review Board) made up of scientists, non-scientists, and community representatives as described in 45 CFR 46. The board is managed by a Human Protections Coordinator, supervised by the Institutional Official or Vice President for Research.

All projects involving human subjects research and that originate at Northern Arizona University, are conducted on an NAU campus, OR involve NAU students, faculty, or staff are subject to review and approval by the NAU IRB. Notwithstanding, the following shall not be subject to NAU IRB review: (1) human subjects research that is conducted by NAU researchers acting in their individual capacity; and (2) research conducted solely by non-NAU researchers, provided the research is currently approved by the researcher’s home institution IRB; and does not involve NAU other than as the location where the research is being conducted.

The IRB has the authority to disapprove, modify, or approve studies based on consideration of human subject protection. The IRB also has the authority to put a stop to all research that is not in compliance with the rules and regulations of 45 CFR 46.
Policy 1.02

Topic: Purpose of the IRB
Date of implementation: March 2, 2009

The purpose of the IRB is to ensure the protection of human subjects in research. Its primary mechanism for doing so involves the review of all research involving human subjects. Projects requiring review by the IRB must both be research and involve living human subjects. “Research,” as defined by 45 CFR 46, means “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” Also according to 45 CFR 46, “human subject” means “a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual, or identifiable private information.”

In order to determine if a proposed project qualifies as research, the IRB must know the intent of the researcher. Will findings be published or presented to external audiences? Will any outcome of the study, whether in the form of data analysis or methodological advances or anything else, be reported as a means to disseminate knowledge and advance the given field? These possibilities are considered when determining if a project needs to be reviewed by the IRB. If a researcher is unsure about whether or not a project qualifies as research under the authority of the IRB, the researcher should contact the IRB office.

Research collecting private information about individuals must be reviewed by the IRB. Private information can cause the identity of the participant to be associated with the information provided or allow the participant’s identity to be ascertained by the researcher. Researchers unsure about whether or not a project involves living human subjects should contact the IRB office.

Policy 1.03

Topic: Primary foci of the IRB review
Date of implementation: March 2, 2009

In the review of proposed research involving human participants, the IRB and Human Protections Coordinator seek to ensure the following:
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- Risks to participants are minimized by using procedures that are consistent with sound design and do not unnecessarily expose participants to risk, and whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.
- Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB shall consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of interventions participants would receive even if not participating in research).
- Selection of participants is equitable. In making this assessment the IRB shall take into account the purposes of the research and the setting in which the research will be conducted.
- Informed consent will be sought from each prospective participant or the participant’s legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116.
- Informed consent will be appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117.
- Where appropriate, the research plan makes adequate provisions for monitoring the data collected to insure safety of participants.

Where appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data. Where some or all of the participants are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, or persons who are economically or educationally disadvantaged, appropriate additional safeguards have been included in the study to protect the rights and welfare of these participants.

Policy 1.04

Topic: Statement of ethical principles
Date of implementation: March 2, 2009

Northern Arizona University is committed to excellence in teaching, research, and public service, and to the conduct of these activities under the highest possible ethical standards. For projects involving living humans as subjects of research and research-related projects, Northern Arizona University is guided by the ethical principles regarding all research involving human subjects set forth in the
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In addition, the requirements set forth in Title 45, Part 46 of the Code of Federal Regulations will be followed for all applicable Department of Health and Human Services (DHHS) funded research and, except for the requirements for reporting information to DHHS, for all other research without regard to source of funding.

Thus, the following broad principles are the basis for development of Northern Arizona University’s policies concerning review of research involving humans:

• Whereas, the participation of humans in research and training projects may raise fundamental ethical and civil rights questions, no distinctions in the monitoring of projects will be drawn between funded and unfunded projects, sponsored and unsponsored projects, or between projects carried out by students, faculty, or other University employees, on campus or off campus.
• All activities involving humans as subjects must provide for the safety, health, and welfare of every individual. Rights, including the right of privacy, must not be unduly infringed upon.
• The direct or potential benefits to the subject, and/or the importance of the knowledge gained, must outweigh the inherent risks to the individual.
• Participation in projects must be voluntary and informed consent must be obtained from all subjects, unless this requirement is waived by the Institutional Review Board.
• An individual does not abdicate any rights by consenting to be a research subject. A subject has the right to withdraw from a research project at any time or may refuse to participate without loss of benefits to which the subject would be otherwise entitled.
• Safeguarding information about an individual that has been obtained in the course of an investigation is a primary obligation of the investigator.

Principles that assist the IRB in protecting the rights and welfare of human subjects include the following existing codes:

• The Declaration of Helsinki: recommendations guiding physicians in clinical research adopted by the World Health Organization, 1964
• Ethical Principles in the Conduct of Research with Human Participants: adopted by the American Psychological Association, 1973
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*The Belmont Report—Ethical Considerations and Principles for the Protection of Human Subjects of Research*

These policies and related procedures are described here in compliance with the Code of Federal Regulations, Title 45, Part 46.103(b)(4) and 46.103(b)(5).