National American University

Institutional Review Board (IRB)

IRB Policy

It is morally and ethically imperative that the rights and welfare of research subjects be protected. In accordance with federal, as well as applicable state regulations, National American University has established the Institutional Review Board and the following policies and procedures for research involving human subjects, or data or materials derived from humans. Safeguarding the rights and welfare of human subjects utilized in research protects not only the individual subject but also the researcher and the institution sponsoring the research project.

IRB Mission Statement

The mission of the National American University Institutional Review Board is to assure highest quality research involving human subjects conducted under the auspices of the university. In that regard, safeguarding the rights and welfare of human subjects in research is a general institutional policy delegated by the president through the provost to the Institutional Review Board (IRB). Therefore, any research project involving human subjects which is conducted by National American University faculty, staff, students, or external persons (or that takes place on any National American University campus or as a part of an academic affiliation agreement) is subject to review and approval by the IRB. The IRB's main purpose is to ensure protection of human subjects through the review, approval, modification, or disapproval of research applications submitted by faculty, staff, student, and/or external investigators. The IRB is further responsible for communication, recordkeeping, reporting, monitoring, education of the university community about ethical issues, and oversight of all research activity involving human subjects. The IRB is guided by ethical principles outlined in the Belmont Report (1979) and legal mandates outlined in the Code of Federal Regulations Title 45 Part 46 (1994).

Committee Composition

Federal regulations require that membership of the IRB include, at a minimum, one member whose primary concerns are in scientific areas, one member whose primary concerns are in nonscientific areas, other members representing more than a single profession, and at least one individual not affiliated with the university.

Definitions

For purposes of this policy, "Human Subject/Participant" is defined as "a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information." "Research" is defined as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to general knowledge."

IRB Procedures

In order to approve proposed research protocols, the IRB shall determine if the research is exempt or non-exempt. In the case of non-exempt research the IRB shall ensure that all of the following requirements are satisfied:

- Risks to subjects are minimized by using tests or procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risks, and whenever appropriate, use tests or procedures already being used for learning, diagnostic, or treatment purposes.
- Risks to subjects are reasonable in relation to the anticipated benefits, if any, to subjects, and the importance of knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB shall consider only those risks and benefits that result from the research (as distinguished from risks and benefits of interventions subjects would receive even if not participating in the research).
- Selection of the subjects 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.
- Voluntary informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by Title 45 Code of Federal Regulations, Part 46.116 (see Informed Consent).
- 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 provision for monitoring the data collected to attempt to insure the safety of subjects. If any serious breech in the procedure or harmful event occurs with a subject it should be reported to the IRB as soon as possible.
- Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. Where some or all of the subjects 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 must be included in the study to protect the rights and welfare of these subjects.

In conformity with Federal Regulations, the IRB will determine which of three separate avenues for review of research involving human subjects will be utilized:

- Full IRB Review. Research involving more than minimal risk to the subject requires review by the full IRB using current scientific and ethical standards. All research using children or vulnerable populations requires review by the full IRB.

- Expedited Review. Research involving no more than minimal risk and in which the only involvement of subjects will be in one or more of the categories defined by Federal Policy 46.110 requires review by the Chair and selected members of the IRB.

- Exempt Review. Research of minimal or no risk as defined by Federal Policy 46.101b requires review by the IRB Chair only. Some types of activities are specifically exempt from IRB review. They include:

    - Non-intrusive observation of subjects in public places,
    - Data-gathering from class members for classroom purposes (e.g., class exercises, course evaluations), and
    - Needs assessment or evaluation data intended to remain within the university community.

All persons seeking IRB approval will utilize the same application form. Applications may be obtained from _____.

Reference

The Institutional Review Board Guidebook, published by the federal Department of Health and Human Services, may be used by the NAU IRB to assist it in making determinations within the university's IRB policies and procedures.