



Protection of Human Research Participants

Policy Number:

Research/Academic Policy

Effective Date:

Responsible University Officer

- Chancellor

Responsible Office and Board

- Office of Research Integrity
- Institutional Review Board

Policy Statement:

University research and teaching activities involving human research participants must be conducted in accordance with basic ethical principles and all applicable federal, state, and university policies, procedures, laws and regulations. These activities, irrespective of purpose or funding source, must be reviewed and approved by the University of Alaska Fairbanks Institutional Review Board prior to commencement. The use of human research participants in research or teaching must be adequately justified, use the most appropriate methods available, and be conducted by knowledgeable individuals who have completed an Institutional Review Board approved educational program on human research protections. The Chancellor or a formally designated senior administrator shall serve as the Institutional Official charged with oversight of the University of Alaska Fairbanks Human Research Protections Program. This includes the establishment and maintenance of the Institutional Review Board which has the authority, described herein, to develop procedures to implement this policy.

Background:

Research involving human participants is essential for the advancement of human health, the advancement of knowledge, the good of society, and may be of direct benefit to individual participants. The university provides a supportive environment for conducting high quality research, education, and service that is built on a foundation of trust. The fundamental ethical principles of respect for persons, beneficence, and justice as described in the Belmont Report are the cornerstone for the UAF Human Research Protections Program. Applicable laws, regulations, policies and guidelines include but are not limited to the Belmont Report, the Common Rule and applicable sections of the Code of Federal Regulations. The IRB may also use guidelines set by professional organizations to establish procedures.

Definitions:

- **Common Rule** – is the common federal policy for protecting human research participants contained in the Code of Federal Regulations.
- **Human Research Participants (HRP)** – includes any living individual about whom a UAF faculty, staff or student conducts research and obtains 1) data through intervention or interaction with the individual, or 2) identifiable private information as defined by 45 CFR 46.102(f). Referred to as *human subject* in the Code of Federal Regulations.
- **Institutional Review Board (IRB)** – is a campus-wide, independent ethics committee tasked with oversight of all university procedures regarding the use of humans as research subjects. Appointments to the Institutional Review Board (IRB) are made by the Institutional Official.
- **Institutional Official** – is the individual authorized to act for the university and obligate the university to the terms of the Federalwide Assurance. The UAF Chancellor or a senior administrator formally designated by the Chancellor serves as the Institutional Official overseeing the UAF Human Research Protections Program.
- **Federalwide Assurance** – is documentation of institutional commitment to comply with federal regulations for the protection of human subjects. This document is signed by the Institutional Official and must be federally approved before an institution may receive funds or engage in research involving human research participants.
- **Office of Research Integrity (ORI)** – the University of Alaska Fairbanks office responsible for ensuring compliance of UAF personnel with internal policies and with local, state and federal regulations governing the conduct of research. Administrative support for the IRB is provided by the ORI.
- **Research** – is defined within the Common Rule to mean “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”
- **UAF Human Research Protections Program** – is a comprehensive university program with the primary objective of protecting human research participants. The basic elements of the program include the activities of the IRB, the UAF ORI, and the Institutional Official.
- **UAF Quality Improvement Program** – is administered by the UAF Office of Research Integrity. As part of this program, routine surveys and internal assessments are conducted for research programs involving human research participants.

Responsibilities:

Obligations of the Administration and University Members

It is the responsibility of the UAF Chancellor, the Institutional Official, ORI, the IRB and all units managing or conducting research activities to support and protect the officially sanctioned involvement of human participants in research and teaching at the university or at off campus sites.

University faculty, staff, and students conducting research and/or instructional activities involving human research participants shall:

1. follow all applicable laws, regulations, policies, procedures, and guidelines governing human participants in research and teaching;
2. be appropriately certified in human research protections, as required by IRB procedures, prior to engaging in research or teaching activities involving HRP;
3. receive and participate in IRB approved in-service training concerning human research protections;
4. fully participate in the UAF Quality Improvement Program managed by ORI;
5. abide by and carry out the decisions of the IRB; and
6. report all concerns, complaints and adverse events regarding HRP to the IRB and/or the ORI.

Institutional Official

The Institutional Official shall:

1. ensure compliance with all applicable laws, regulations, policies, procedures, and guidelines governing human participants in research and teaching;
2. appoint IRB members, in consultation with current members and the ORI;
3. appoint the IRB chairperson;
4. ensure that all IRB members have received formal training in human research protections;
5. implement this policy with the assistance of ORI and the IRB;
6. oversee IRB development of administrative procedures necessary to implement this policy; and
7. perform all necessary reporting requirements including reporting to the appropriate federal governmental and university officials any noncompliance with laws and policies as well as any corrective or remedial action taken.

Institutional Review Board

The IRB shall:

1. in cooperation with UAF ORI and the Institutional Official formulate, review and have final approval authority for procedures related to the implementation and maintenance of this policy and the UAF Human Research Protections Program;
2. review and approve, require modifications to, or withhold approval of university research including the teaching of research techniques and methods involving HRP;
3. at least annually, conduct continuing review of previously approved IRB Protocols which received expedited or full review;
4. evaluate the university's Human Research Protections Program as necessary to ensure compliance with changes in regulations or policy;
5. review allegations of noncompliance;
6. whenever necessary, obtain records, data and other relevant information related to the use of HRP;
7. report any substantiated allegations of noncompliance with federal, state, or university policies, procedures, laws and regulations to the Institutional Official;

8. take any actions, including suspending an activity or protocol, that are in its judgment necessary, to ensure compliance with applicable federal, state, or university policies, procedures, laws and regulations; and
9. report any corrective or remedial actions taken in response to noncompliance to the Institutional Official.

Non-Compliance

Failure to comply with this policy, associated procedures, or to fully participate in the UAF Quality Improvement Program can be grounds for disciplinary action by the university and, if applicable, suspension or termination of research, referral for misconduct proceedings, and/or reporting to state and federal regulatory and/or funding agencies. Any disciplinary action taken by the university will follow the employment rules governing the individual's employment category.

Exclusions:

Exclusions to this policy may only be granted by the IRB.

Approved by:

Steph B Jones

Stephen Jones, UAF Chancellor

4-30-05

Date