

Proposed UAF Policy 05-002

Original Adoption: April 30, 2005

Revised: February 27, 2024

Responsible Chancellor's Cabinet Member: Chancellor

Responsible Department/Office: Office of Research Integrity
Institutional Review Board



Protection of Human Research Participants Policy

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 (IRB) before 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 IRB-approved educational program on human research protections. The Institutional Official (IO) is charged with oversight of the University of Alaska Fairbanks Human Research Protections Program (HRPP). This includes establishing and maintaining the IRB, which has the authority described herein to develop procedures to implement this policy.

BACKGROUND & JUSTIFICATION

University of Alaska Fairbanks is committed to ensuring all human participants' welfare, safety, and rights in research conducted at or by the university. Research involving human participants is essential for the advancement of human health, the advancement of knowledge, and 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. All research, funded or not funded, involving human participants conducted by the university community (employees, students, agents, volunteers) or using university facilities or resources will be governed by the HRPP. As described in the Belmont Report, the fundamental ethical principles of respect for persons, beneficence, and justice are the cornerstone of the UAF HRPP. 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 professionals or organizations to establish procedures.

DEFINITIONS

Common Rule: the common federal policy for protecting human research participants contained in the Code of Federal Regulations.

Human Research Participants: includes any living individual about whom a UAF community member conducts research and obtains 1) information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or 2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable

biospecimens as defined by 45 CFR 46.102(e(1)). Referred to as human subject in the Code of Federal Regulations.

Institutional Review Board (IRB): a campus-based, multi community, and independent ethics board tasked with oversight of all university procedures regarding using humans as research participants. The IO makes appointments to the Institutional Review Board (IRB).

Institutional Official (IO): 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 IO overseeing the UAF HRPP.

Federalwide Assurance: documentation of institutional commitment to comply with federal regulations for the protection of human participants. The IO signs this document 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 is responsible for ensuring compliance of UAF personnel with internal policies and with local, state, and federal laws, and regulations governing the conduct of research. The ORI provides administrative support for the IRB.

Research: 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 (HRPP) is a comprehensive university program that aims to protect human research participants. The basic elements of the program include the activities of the IRB, the UAF ORI, and the IO.

UAF Research Integrity Committee (RIC): appointed by the Vice Chancellor of Research and is administered by the ORI. A charge of this committee is to conduct routine surveys and internal assessments for research programs involving human research participants.

University Community Member: Employees (which include faculty members), students, agents, and volunteers at or under the sponsorship of the university.

REFERENCES RELIED UPON

Belmont Report: <https://www.hhs.gov/ohrp/regulations-and-policy/index.html>

Federal Policy for the Protection of Human Subjects ('Common Rule'):

<https://www.hhs.gov/ohrp/regulations-and-policy/index.html>

National Health Institute Protecting Human Research Participants:

https://grants.nih.gov/sites/default/files/PHRP_Archived_Course_Materials_English.pdf

The Research Integrity Committee Charter

RESPONSIBILITIES

Obligations of the Administration and University Members

It is the responsibility of the UAF Chancellor, the IO, ORI, the IRB, university community members 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 off-campus sites.

University Community Members

University Community Members 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 human research participants;
3. receive and participate in IRB-approved in-service training concerning human research protections;
4. fully abide by and comply with directives set forth by the RIC.
5. abide by and carry out the decisions of the IRB; and
6. report all concerns, complaints and adverse events regarding human research participants to the IRB and/or the ORI.

Institutional Review Board (IRB)

The IRB shall:

1. in cooperation with UAF ORI and the IO formulate, review and have final approval authority for procedures related to the implementation and maintenance of this policy and the UAF HRPP;
2. review and approve, require modifications to, or withhold approval of university research including the teaching of research techniques and methods involving human research participants;
3. at least annually, conduct continuing review of previously approved IRB protocols which received expedited or full review;
4. evaluate the university's HRPP 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 and action related to the use of human research participants;
7. report any substantiated allegations of noncompliance with federal, state, or university policies, procedures, laws, and regulations to the IO;
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 IO.

Research Integrity Committee (RIC)

The RIC shall:

1. regularly review risk assessments and recommend appropriate steps be taken to design, implement, or modify research compliance activities to reduce compliance risks identified by such assessments;
2. enable mechanisms to allow for anonymous reporting and appropriate safeguards to protect against potential retaliation;
3. take such other actions, or make such other recommendations as are necessary to promote ethical organizational research culture.

Institutional Official (IO)

The IO 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 RIC members;
4. appoint the IRB chairperson;
5. ensure that all IRB members have received formal training in human research protections;
6. implement this policy with the assistance of ORI and the IRB;
7. oversee IRB development of administrative procedures necessary to implement this policy; and
8. perform all necessary reporting requirements, including reporting to the appropriate federal government and university officials any noncompliance with laws and policies as well as any corrective or remedial action taken.
9. appoint the ORI to provide an administrator to act as an advisor and guide university community members.

NON-COMPLIANCE

Failure to comply with this policy, associated procedures, or to fully comply with the directives set forth by the RIC 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.

EXCEPTIONS

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

PROCEDURES

ORI establishes processes consistent with applicable laws, regulations, policies, procedures, and guidelines governing human participants in research and teaching.

All university community members are required to secure approval from the IRB before conducting human participant research and to abide by all processes established by the ORI

Procedures that support this policy will be updated as needed.

POLICY APPROVED BY:



Daniel M. White, Chancellor
University of Alaska Fairbanks

Signed: **2/28/2024**