SMANTA FE INSTITUTE
GM11 Protection of Human Subjects in Research Policy

Overview

In order to safeguard the rights and welfare of Human Subjects in Research, the Santa Fe Institute (SFI) ascribes unequivocally to the principles of The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects in Research by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. SFI has established policies to assure full compliance with all federal regulations governing the participation of Human Subjects in Research.

This policy summarizes the responsibilities of SFI administration, Principal Investigators (PI) and other researchers for the appropriate conduct of Human Subjects Research, and for compliance with all related federal regulations and local policies. The SFI recognizes and accepts responsibility, which it shares with its investigators and other researchers, for determining that research involving Human Subjects fulfills the ethical principles set forth in the Belmont Report, applicable federal regulations, local laws, and policies.

SFI has selected the University of New Mexico (UNM) to act as its Institutional Review Board (IRB). An IRB Authorization Agreement and Memorandum of Understanding is entered into with UNM for all project protocols reviewed by UNM's IRB.

Statement

SFI adheres to all federal regulations and SFI policies governing the participation and protection of Human Subjects in Research. Principal from among these policies and regulations are the following:

A. From Federal Policy on the Protection of Human Subjects

Any institution that receives funds from and is accountable to departments and agencies of the federal government for funds awarded for the support of Research using Human Subjects is required to safeguard the rights and welfare of those subjects.

No federal grant or contract for Research involving definite plans for Human Subjects may be made to any institution unless the application for such support has been reviewed and approved by the appropriate IRB. (See Responsibilities below).

Reviews by an IRB must determine that Human Subjects will be adequately protected according to established criteria involving an evaluation of risks and benefits, equity of selection, and the informed consent process and documentation.

Approved studies must be reviewed at least annually by an IRB. Modifications to a study must be approved before they are implemented.

B. From SFI Policies on the Protection of Human Subjects

GUIDING PRINCIPLES

The principles espoused in the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects in Research have been adopted by the SFI for all Research involving Human Subjects.
SFI Policy – Protection of Human Subjects in Research

SCOPE OF AUTHORITY

SFI holds a Federal-wide Assurance of Compliance with DHHS regulations (FWA #00011330) for the protection of Human Subjects (45 Code of Federal Regulations (CFR) 46). This assurance, which is regularly renegotiated and approved, applies to all federally funded Research with Human Subjects (as defined in 45 CFR 46.102(3) and (f)) being conducted by investigators acting as agents of SFI regardless of the site of the activity. The Assurance applies to all human Research involving any SFI facilities, personnel, or students, or Research that is supported either by federal funds granted to, or applied for through, the SFI, or for Research conducted at non-SFI sites.

Commensurate protections are in place for all other human Research conducted at or under the jurisdiction of SFI.

- The UNM IRB has sole authority to grant IRB approval for human Research applications.
- If the UNM IRB does not grant IRB approval or suspends or terminates IRB approval, these decisions may not be overturned at any higher level.
- Implementation of UNM IRB-approved studies may be prevented or terminated by decision at any other level in the institution, although the IRB approval shall not be voided by such action.

JURISDICTION

All faculty and staff who are conducting studies involving Human Subjects within the course and scope of their duties, as well as SFI students who are conducting studies involving Human Subjects within the course of their studies, regardless of the source of the funding, or even in certain cases in which no funds are involved, are required without exception to have prior approval from the UNM IRB before Research is initiated.

Regardless of the percent of effort, prior approval of the IRB is required, without exception, when Human Subjects Research studies conducted by SFI faculty, staff, or students access any SFI facilities, personnel, or students and/or when the human Research is supported either by extramural funds granted to, or applied for through, the SFI, or for Research conducted with SFI funding at non-SFI sites.

Prior approval of the IRB is not required when part-time or unpaid faculty are not acting as staff members, employees, or agents of the SFI, when no SFI facilities, personnel or students are used and when the activity is not represented to subjects as being conducted under the aegis of the SFI. However, in such cases investigators holding SFI appointments nevertheless are required to obtain approval for the use of Human Subjects from a duly constituted IRB.

ACTIVITIES ACCESSING SFI FACILITIES, STAFF, OR STUDENTS BEING CONDUCTED BY A NON-SFI PRINCIPAL INVESTIGATOR (PI)

All non-SFI investigators involved in Human Subjects Research projects that access any SFI facilities, or personnel (faculty or staff) must submit an application for Administrative Review to the SFI Human Research Protection Program (HRPP) for a determination of whether proposed Research involving Human Subjects falls within the SFI HRPP jurisdiction and requires IRB review and approval or Certification of Exemption from IRB review.

Eff. 8-12-15
SFI Policy – Protection of Human Subjects in Research

Responsibilities

*Vice President for Research* has overall responsibility for implementation of and compliance with federal regulations and SFI policy concerning Human Subjects Research at SFI. He or she has delegated the daily operation of the HRPP to the HRPP Administrator.

*The UNM IRB* is obligated and authorized to ensure that:

- Human Subjects are adequately informed of the nature of the study;
- Human Subjects’ participation is voluntary;
- the benefits of a study outweigh its risks; and
- the risks and benefits of the study are evenly distributed among the possible subject populations.

The UNM IRB is obligated and authorized to:

- require necessary modifications of study applications to secure approval;
- observe, or have a third party observe, the consent process and/or the conduct of Research; and
- suspend or terminate any human Research activity that violates regulations, policies, procedures, or an approved protocol, and report such violations, suspensions or terminations to appropriate parties within the institution, appropriate federal agencies and SFI’s HRPP.

**HRPP:**

- develops, coordinates and provides presentations on issues in Human Subjects protection;
- delivers education and training for investigators and their Research staff;
- responds to requests for clarification and provides guidance regarding ethical issues in biomedical and behavioral Research involving Human Subjects; and
- maintains, promulgates, and updates educational and institutional review guidance materials.

PI must submit an application to the UNM IRB for review and approval before initiating, modifying, or extending any Research project using Human Subjects.

The PI for a study must either meet the criteria for PI eligibility as defined in SFI Policy GM02 or identify on the application and include in the project a faculty sponsor who meets the criteria for a PI. Any exceptions to this requirement are also described in SFI Policy GM02, section I.D., Exceptions.

The Principal Investigator:

- shall consider racial, cultural, and gender diversity among the subject populations and be sensitive to community attitudes in both the design and conduct of Research involving humans;
- has the ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of Human Subjects involved in the Research, and strict adherence to any stipulations imposed by the IRB;
- is responsible for ensuring that all personnel performing the project are qualified, appropriately trained, and will adhere to the provisions of the approved protocol;
- shall implement no changes in the approved protocol or consent without prior IRB approval, except in an emergency if necessary to safeguard the well-being of Human Subjects;
SFI Policy – Protection of Human Subjects in Research

- will assure that adequate resources to protect Research subjects are in place before implementing the Research project and that the Research project will stop if adequate resources become unavailable;
- shall report to the IRB any serious or unexpected adverse event on-site related to Research participation experienced by a subject within 10 working days of having become aware of the event (the PI also must report any problems or incidents related to the conduct of a study, including those in the recruitment or consent process); and
- shall report to the IRB any violation of an experimental protocol or any use of subjects not approved by the IRB.

SFI assures the federal government that the campus is in compliance with federal regulations as described in the Section on Responsibilities above, for the use of Human Subject Research and that no Research involving Human Subjects is conducted without prior review and approval.

The SFI is legally responsible for the acts and omissions of its employees acting in the course and scope of their SFI duties. In the event of a suit against an employee in connection with an IRB-approved Research activity using Human Subjects, the SFI assumes the employee’s defense and indemnification.

Definitions

Human Research Protection Program (HRPP) is the global SFI program which oversees the safety and welfare of participants in Human Subjects Research projects in accordance with all applicable federal regulations and institutional policy. At the institutional level, the HRPP includes five areas: SFI as a research institution; the investigators; the study sponsors; and the Research participants themselves. Within the HRPP, the program is responsible for the education and training of the SFI human Research community.

Human Subject generally means an individual who becomes a participant in Research. However, more specific definitions must be applied depending upon the type of Research and its funding source.

As defined in Department of Health and Human Services (DHHS) regulation 45 CFR 46.102, Human Subject means “a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.”

Institutional Review Board (IRB) is the generic name for any board, committee, or other group formally designated by an institution to review the conduct of Research involving Human Subjects.

Research means the systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge, in accordance with the Department of Health and Human Services (DHHS) definition of research (45 CFR 46.102(d)).

References

- Protection of Human Subjects (45 CFR Part 46); Office of Civil Rights Health Insurance Portability & Accountability Act (HIPAA) (45 CFR Parts 160 and 164);
SFI Policy – Protection of Human Subjects in Research

- Federal-wide Assurance of Compliance with DHHS, Institutional Review Boards
- SFI Policy GM02 Principal Investigator Eligibility.
- SFI Policy GM12 - Research Noncompliance
- SFI Policy GM 13 - Suspension or Termination of Approved Research
- SFI Policy 14 - Mandated Reporting to External Agencies

[Signature]
Authorization

[Signature]
President

[Signature]
Title

07/07/15
Date