University Policy 584: Protection of Human Participants in Research

Category: 500, Operating Policies
Sub Category: Research and Sponsored Projects
Covered Individuals: USU Faculty, Staff, and Students Engaged with Human Subjects Research
Responsible Executive: Vice President for Research
Policy Custodian: Office of the Vice President for Research
Last Revised: 2019/05/22
Previous USU Policy Number: 584

584.1 PURPOSE AND SCOPE

Utah State University is committed to the protection of human participants in research. In accordance with the Federal Policy on the Protection of Human Subjects (45 C.F.R. 46) and Utah State University's Federal Wide Assurance, all research involving human participants must be conducted in a manner that prioritizes the rights and welfare of human subjects participating in research. All students, staff, faculty, units, and affiliates of Utah State University share in the responsibility for promoting the welfare of human research participants in research, primarily by adhering to the relevant laws, regulations, and professional and ethical standards governing the conduct of such research.

The Human Research Protection Program at Utah State University is comprised of three primary elements: the institution itself (including units, departments, and centers), the Institutional Review Board, and researchers.

584.2 POLICY

2.1 Applicability & Authority

This Policy applies to all research involving human subjects that is performed by or under the direction of USU faculty, staff, students, trainees, or other affiliates of USU or otherwise conducted under the auspices of USU. All human subjects research conducted under those conditions will be guided by the ethical principles contained in the Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research ("The Belmont Report"), and will be performed in compliance with all applicable federal and state laws. The Utah State University Human Research Protection Program exists to assist researchers and the institution in adhering to the legal and ethical codes governing human subjects research, and to assure the rights and welfare of human subjects participating in those projects.

The Institutional Review Board (IRB), one component of the Human Research Protection Program (HRPP), operates under Federal Wide Assurance #00003308, on file with the U.S. Department of Health and Human Services or relevant successor agency. It will, at all times, maintain the minimum membership requirements specified in the Common Rule. All human subjects research falling under this policy must first be submitted for approval or exemption by the Utah State University Institutional Review Board, or by a research ethics committee designated by the USU IRB. No human subjects research may begin until USU IRB approval, exemption, or reliance is finalized. The Institutional Review Board may approve, approve with modifications, disapprove, suspend, cede review to another IRB, or terminate any research involving human subjects, and it has the sole ability to approve human subjects research or designate the appropriate site for review. Other USU units or officials may disapprove human subjects research, but

human subjects research may not be approved to move forward or continue until IRB approval, exemption, or reliance is in place.

2.2 Approval or Exemption of Research

In its consideration of proposed research, the IRB shall ensure that minimum ethical standards regarding human subjects research are met before the research protocol ("protocol") is approved:

2.2.1 Respect for Persons

The circumstances of recruitment shall be disclosed, and will not be coercive, or present undue influence or inducement, in exchange for participation. When appropriate, participants will receive all relevant information about the study in advance and in a manner that is clear to them. Questions from prospective participants and participants shall be answered truthfully, and information cannot be withheld simply to enhance recruitment. Participants will be fully aware of their rights. Vulnerable and underrepresented populations will receive advanced consideration and protection.

2.2.2 Beneficence

Research will not expose participants to unreasonable risk of harm, including social, legal, economic, psychological, or physical harm. Risks will be minimized and benefits will be maximized. Any risks that can be avoided without undermining the legitimate scientific objectives of the research will be eliminated. Sound research design will be used to ensure the minimization of risk and maximization of benefits. Both the probability and magnitude of harm will be reasonable in relation to the anticipated direct or indirect benefits of participation in all research projects involving human subjects.

2.2.3 Justice

Selection of subjects will be equitable, with the overall goal of ensuring that the benefits and burdens of research participation are fairly distributed. Subjects should be selected based on the research questions, rather than ease of access or vulnerability. Subjects must not be unduly induced to participate in research, and no procedures should be used that undermine the completely voluntary nature of research participation. Enrollment into a study must never be the product of coercion or undue influence.

2.2.4 Qualified Investigators

Research must be performed or closely supervised by individuals who have the expertise, experience, and training to minimize risks and ensure, as much as possible, that no harm comes to human subjects in their research. The Principal Investigator maintains the primary responsibility for the conduct of the research, and must ensure that all study team members are appropriately trained in human subjects research protections, the relevant study procedures, and all applicable laws and regulations impacting the research.

2.2.5 Informed Consent

All participants will first be given the opportunity to receive complete information about the research and its risks, procedures, and benefits before freely giving their consent to participate. Participants or their legally authorized representatives should provide informed consent prior to participation; in cases where a participant cannot render legally effective informed consent, they should still be given a separate opportunity to assent to the research procedures. Coercion or undue influence must never be present in a participant's decision-making process. All information should be made available in a manner easily understood to the participants. Informed consent is an ongoing process, and investigators are responsible for ensuring comprehension and continued consent throughout the life of a research project. The IRB may waive some or all of these requirements when appropriate, and in accordance with its operating procedures and federal law.

2.3 Research Activities

Ongoing human subjects research activities should be carefully overseen by the Principal Investigator. The PI has ultimate responsibility for ensuring compliance of the research with all applicable ethical and legal standards. If, during the conduct of the research, activities occur which were not a part of the approved protocol, the Principal Investigator has responsibility for ensuring prompt reporting to the IRB. This might include deviations from approved procedures, unanticipated adverse events, increased risks, new alternatives to participation, mistakes on behalf of the research team, or unexpected incarceration, injury, or death of a participant.

All persons acting under the auspices of the HRPP have a responsibility to report reasonably suspected or known noncompliance to the IRB Chair or Institutional Official. The IRB Chair and Institutional Official each have the authority to suspend any human subjects research activity if they suspect that the risks to participants are greater than those reviewed and approved by the IRB.

2.4 Training, Education, & Quality Assurance

Utah State University requires that investigators, IRB members, and HRPP staff be competent in the legal and ethical standards governing human subjects research. HRPP staff will make training available to all persons operating under this Policy, and will maintain records of that training. Continuous education is critical to a successful HRPP. HRPP leadership should assess training needs periodically, and ensure that training on specific topics is provided as needed. It should also work with other institutional research leaders to review its own activities, resource levels, and areas of improvement. Seeking and maintaining external accreditation is encouraged as a manner of ensuring a well-functioning HRPP. USU Investigators, IRB members, research participants, and external sponsors are encouraged to bring forward concerns and suggestions regarding improvement of the HRPP.

2.5 Researcher Conflict of Interest

Per USU Policy 307, University employees may experience a conflict of interest when they owe a professional obligation to the University which is or can be compromised by outside interests or conflicts of commitment/allegiance. Any person involved in the design, conduct, or reporting of human subjects research with a conflict of interest must disclose this conflict and may not proceed with human subjects research until the conflict has been managed or eliminated in line with the university's policies and procedures for conflict of interest management.

No IRB member may review, request revisions in, approve, disapprove, grant exemption, or otherwise take action on any protocol with which they have a conflict of interest. Members of the IRB must not also have roles in which business interests or development feature prominently. Any conflicts of interest that arise during the IRB member's term of service must be immediately disclosed to the IRB Chair or Institutional Official.

2.6 Institutional Conflict of Interest

Identification of potential Institutional Conflicts of Interest, as defined below, shall trigger initiation of an ICOI assessment procedure managed by the Office of Research Integrity and Compliance. A potential institutional conflict of interest arises for sponsored projects in which there is an external, non-governmental sponsor or where an outside entity's product or service is used. If the assessment procedure indicates an institutional conflict of interest, the Institutional Conflict of Interest Committee shall meet to review the ICOI and adopt a management plan or identify existing internal controls that provide adequate management of the ICOI. The IRB has the final authority to accept, reject, modify, or specify methods of implementation of the management plan in the context of the proposed research.

584.3 RESPONSIBILITIES

3.1 Human Research Protection Program Leadership

Human Research Protection Program leaders (The Institutional Official, IRB Chair(s), and HRPP Director) and staff are responsible for the day-to-day enforcement and guidance regarding this Policy. They are responsible for being knowledgeable regarding requirements touching on human subjects research protections, and supporting the research community in prioritizing the protection of human subjects in research.

3.2 The Institutional Review Board

The Institutional Review Board is the body charged with the ethics review and disposition of human subjects research. Its primary focus must always be the protection of human participants who may become involved with the research it reviews. The Board must avoid conflicts of interest, undue influence from external pressures, or prioritization of any consideration unrelated to protection of human participants in research. It is comprised of members with scientific expertise, regulatory expertise, and individuals with non-scientific interests. The IRB delegates certain approval and exemption functions to the HRPP staff for more efficient review and approval of human subjects research, but only the convened

IRB can disapprove of human subjects research. No research with human subjects may proceed absent IRB approval or exemption.

3.3 Investigators and Researchers

Investigators, Principal Investigators, and researchers are responsible for compliance with this policy, including: the submission of all human subjects research to the Institutional Review Board in advance of beginning the research; ensuring adherence to approved protocols and best practices; reporting deviations and problems regarding human subjects research to the IRB in a timely manner; and maintaining appropriate training and expertise surrounding the safe and responsible conduct of research involving human subjects.

584.4 REFERENCES

The following laws, regulations, and ethical treatises are hereby incorporated into this policy by reference:

- 45 C.F.R. 46 – Federal Policy for the Protection of Human Subjects ("The Common Rule")
- 42 U.S.C. ch. 6A – National Research Act
- 21 C.F.R. 50, 56 – Food and Drug Administration Policy for the Protection of Human Subjects
- The 21st Century Cures Act, Pub. L. No. 114-255 (2016)
- *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects in Research* ("The Belmont Report"), National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1976.
- *World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*, as amended October 2000.

Key personnel in the Human Research Protection Program at USU should be familiar with these legal and ethical standards and conduct their work in compliance with their provisions.

584.5 RELATED USU POLICIES

- 307: Conflict of Interest
- 583: Research

584.6 DEFINITIONS

- **Conflict of Interest**: A conflict of interest exists when a University employee owes a professional obligation to the University, which is or can be compromised by the pursuit of outside interests.
- **Human Subject**: A living individual about whom an investigator or other USU affiliate (whether professional or student) conducting research: (i) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. Human subjects are often referred to as "participants."
- **Human Research Protection Program**: The Human Research Protection Program ("HRPP") is the institutional-level framework for the protection of the rights and welfare of human research participants involved in USU's research activities. It encompasses the organizational structure for the oversight of human subjects research, the Institutional Review Board, and all researchers (faculty, student, and otherwise) and their staff.
- **Institutional Conflict of Interest**: An institutional conflict of interest exists whenever the financial interests or holdings of the institution or the personal financial interests or holding of institutional leaders might affect or reasonably appear to affect the design, conduct, reporting, review or oversight of human subjects research.
- **Institutional Leaders**: Those with direct authority over the allocation of institutional resources, including, but not limited to: President, Provost, Vice Provost, Vice Presidents and Associate Vice Presidents, Deans, Department Heads, Center Directors; including those holding positions in an interim capacity who are able to directly influence salaries, appointments, resource allocation or oversight of human participant research, including chairs and directors of the Institutional Review Board, Conflict of Interest Committee, and other committees designated by the Director of Research

Integrity and Compliance (DRIC). Members of the USU Board of Trustees are governed by a separate conflict of interest policy and are not governed by this policy.

- **Institutional Review Board**: An Institutional Review Board ("IRB") is a body established under the requirements of 45 C.F.R. 46 to, first and foremost, protect the rights and welfare of human participants in research. It accomplishes this by reviewing or appropriately delegating the review of each research protocol to ensure the protection of the participants involved. The IRB is an independent entity that must operate without influence from other units within Utah State University, especially those with business interests. The IRB has the sole authority to approve human subjects research conducted by Utah State University affiliates. IRBs are required to have (as a part of its regular membership) or gain (by the addition of members or use of consultants) scientific expertise in the areas of research it is responsible for reviewing.
- **Investigator**: An individual involved in the performance of human subjects research activities who performs one or more of the following: (i) obtaining information about or biospecimens from living individuals by intervening or interacting with them for research purposes; (ii) obtaining identifiable biospecimens or private, identifiable information about a living individual for research purposes; (iii) obtaining the voluntary informed consent of individuals participating in research; (iv) studying, interpreting, or analyzing identifiable biospecimens or identifiable, private information for research purposes; or (v) communicating with the IRB or other institutional review entity regarding the performance of the research project. An investigator's primary concern must be the protection of the rights and welfare of human subjects in all research activities.
- **Principal Investigator**: In addition to the above, an investigator whose training, expertise, qualifications, and role with the institution demonstrates that they are able to take full responsibility for research involving human subjects. The Principal Investigator ("PI") must be a benefited employee of the institution whose job functions allow them to ensure the presence of appropriate resources for the safe and effective conduct of human subjects research, have an oversight role over others carrying out responsibilities for the research, and be knowledgeable about the professional and ethical codes of conduct which should govern the research. Students may not serve as a Principal Investigator on human subjects research projects. In general, adjunct professors, instructors, and others whose job functions do not meet the aforementioned requirements may not serve as Principal Investigators absent additional Institutional Leadership approvals.
- **Research**: A systematic investigation (including research development, testing, and evaluation) designed to develop or contribute to generalizable knowledge.

Information below is not included as part of the contents of the official Policy. It is provided only as a convenience for readers/users and may be changed at any time by persons authorized by the President, subject to review by the USU Policy Committee.

RESOURCES

Procedures

- Utah State University Institutional Review Board Standard Operating Procedures

Related Forms and Tools

- Kuali Research - Protocols

POLICY HISTORY

Original issue date: 2009/04/07

Last review date: 2019/05/22

Previous revision dates: 2016/03/04