

101 Mission & Scope

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Standard Operating Procedure 101: Mission & Scope of the Human Research Protection Program

The mission of Utah State University's Human Research Protection Program (HRPP) is to protect the rights and welfare of participants in research that occurs under Utah State University (USU) oversight. All students, staff, faculty, units, and affiliates of Utah State University share in the responsibility for promoting the welfare of human research participants in their research. The success of the HRPP depends on all stakeholders – institutional leadership, the Institutional Review Board, and researchers themselves – working together toward the shared goal of performing sound research in ways that emphasize care and respect for research participants.

I. Authority for Human Subjects Research Oversight

Human subjects research oversight is a shared responsibility between the institution's leadership, the Institutional Review Board, and researchers and their staff. In order to ensure that applicable laws, regulations, ethical codes, institutional policies, and other regulatory structures are being consistently adhered to in the conduct of USU's human subjects research portfolio, all human subjects research that will be carried out by any USU student, staff, faculty, unit, and/or affiliate must first be approved, exempted, or delegated to another IRB or Ethics Committee by Utah State University's Institutional Review Board.

Utah State University maintains a Federalwide Assurance, on file with the U.S. Department of Health and Human Services (FWA#00003308). The terms of this Federalwide Assurance states that the USU Institutional Review Board (IRB) will conduct ethics reviews of all human subjects research, regardless of funding source, in accordance with the principles articulated in the Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research ("The Belmont Report"). The USU IRB utilizes the following other laws, ethical codes, and/or guidance documents as guidance for its ethics and regulatory review activities:

- 45 C.F.R. Part 46 – Federal Policy for the Protection of Human Subjects as amended January 2019 ("The Common Rule")
- 42 U.S.C. ch. 6A – National Research Act
- 21 C.F.R. 50, 56 – Food & Drug Administration Policy for the Protection of Human Subjects
- World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects, as amended October 2000.
- Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10, Nuremberg Military Tribunals (1949) ("The Nuremberg Code")

Additionally, other laws, ethical codes, and or guidance documents are implicated when the circumstances of the research warrant (e.g. international work, projects involving indigenous populations, etc.).

II. Scope of the IRB and HRPP

The Human Research Protection Program at Utah State University is overseen by the Vice President for Research, the signatory on USU's Federal Wide Assurance. The Vice President for Research, having an institutional mandate to oversee USU's research activities and portfolio, is also the Institutional Official (IO) for human subjects research oversight.

Consistent with the IO's responsibilities outlined in USU's FWA as well as to meet the requirements at 45 C.F.R. 46, USU's IO provides support for an Institutional Review Board, and oversees its Human Research Protection Program.

The Institutional Review Board shall have the authority to approve, disapprove, exempt, require revisions for approval, or delegate the review of all human subjects research conducted by USU students, staff, faculty, departments/units, and affiliates. It may also suspend or terminate a previously-approved human subjects research project. The IRB has the sole authority to approve or exempt human subjects research, and/or to designate an appropriate site for review prior to the start of the research. Other campus units may disapprove or suspend proposed research as appropriate (e.g. Risk Management, the Office of General Counsel, Department Heads, etc.), but no other unit may authorize research involving human participants to begin or resume until the Institutional Review Board has done so.

III. Research with Human Subjects

Research with Human Subjects is the IRB's primary area of responsibility. Those terms are defined as follows:

- A. **Research** means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research whether or not they are conducted or supported under a program that is considered research for other purposes.
- B. **Human Subject** means a living individual about whom an investigator (whether professional or student) conducting research: a) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or b) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. At Utah State University, language that centers human subjects' autonomy is generally preferred, and so terms including (but not limited to) participant, human participant, research participant, study participant, etc. will be used in place of human subject, but the meaning described here is always intended.
- C. **Intervention** includes both physical procedures by which information or biospecimens are gathered (e.g. venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
- D. **Interaction** includes communication or interpersonal contact between investigator and subject.
- E. **Private Information** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public. This provision applies regardless of whether information *will* be made public; it regards a participant's reasonable expectation that a record would not be made public.
- F. **Identifiable Private Information** is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
- G. **An Identifiable Biospecimen** is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.
- H. **Identifiable, Sensitive Information** is information that is about an individual and that is gathered or used during the course of research where the following may occur: a) through which an individual is identified; or b) for which there is at least a very small risk that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual.