



POLICY TITLE	Institutional Review Board	Policy Number	138
Section	Governance, Organization, and General Information	Approval Date	June 11, 2008
Subsection	Publications, Reports, Research, and Records	Effective Date	June 11, 2008
Responsible Office	Office of the Vice President of Finance and Administration		

1.0 PURPOSE

1.1 It is the general concern of the University that research done under its jurisdiction does not expose persons who participate as subjects or respondents to unreasonable risks to their health, general well-being, or privacy.

1.2 The Institutional Review Board (IRB) at the University is committed to working with faculty to conduct human subject research in an ethical manner.

1.3 The legal basis for review and approval of Human Subject Research is detailed in Title 45 Code of Federal Regulations Part 46 (45 CFR 46) and succeeding regulations. While these regulations apply specifically to research funded by federal agencies (i.e., NIH, NSF, DOD, DOE, FDA, Veterans Administration) the University will conform with these regulations in all research involving human subjects, regardless of funding source (i.e., federal, departmental, university funding, or no funding at all). This requirement is codified in the University's approved "Federal-wide Assurance of Protection for Human Subjects" document on file with the federal Office for Human Research Protections.

2.0 REFERENCES

2.1 21 CFR Part 50 *Protection of Human Subjects*

2.2 21 CFR Part 56 *Institutional Review Boards*

2.3 45 CFR Part 46—Code of Federal Regulations *Public Welfare: Protection of Human Subjects*

2.3.1 Subpart A *Federal Policy for the Protection of Human Subjects*

2.3.2 Subpart B *Additional Protections for Pregnant Women, Human Fetuses, Neonates Involved in Research*



2.3.3 Subpart C Additional DHHS *Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects*

2.3.4 Subpart D Additional DHHS *Protections for Children Involved as Subjects in Research*

2.4 UVU Policy 371 *Corrective Actions and Termination for Staff Employees*

2.5 UVU Policy 541 *Student Code of Conduct*

2.6 UVU Policy 635 *Faculty Rights and Professional Responsibilities*

3.0 DEFINITIONS

3.1 Assurance: A formal written, binding commitment that is submitted to a federal agency in which an institution promises to comply with applicable regulations governing research with human subjects and stipulates the procedures through which compliance will be achieved.

3.2 Human subject: A living individual about whom an investigator (whether professional or student) conducting research obtains:

- 1) Data through intervention or interactions with the individual, or
- 2) Identifiable private information (45 CFR 46.102 Definitions (f)).

3.3 Informed consent: "Informed" means that the subject knows what a reasonable person in the same situation would want to know before giving consent. "Consent" means explicit agreement to participate and requires the subject's signature. Informed consent must comply with the required elements as outlined in the Code of Federal Regulations (45 CFR 46.116).

3.4 Principal investigator: A principal investigator is the person(s) designated as the individual(s) responsible for the administrative and programmatic aspects of the proposed project. The principal investigator must have the technical competence and substantive capabilities (scientific, administrative, and otherwise) to carry out a sponsored project. A faculty, staff, or a faculty sponsored student may be a principal investigator.

3.5 Research: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR part 46.102 Definitions (d)).



4.0 POLICY

4.1 In compliance with federal regulations, the IRB is responsible to ensure protection of human subjects in research conducted at, or on behalf of, the University.

4.2 No human subject research may be conducted at, or on behalf, of the University without Institutional Review Board (IRB) review and approval.

4.3 All research involving the use of human subjects must implement procedures to ensure that: 1) the rights and welfare of the individuals involved are adequately protected; 2) the participation of the subjects is based on freely given, legally effective informed consent; and 3) the risks to the subjects are reasonable in relation to the sum of the benefit to the subjects and/or the importance of the knowledge to be gained as to warrant a decision to allow the subjects to accept these risks.

5.0 PROCEDURES

5.1 All research involving the use of human subjects must be submitted to the IRB for review prior to the initiation of the project.

5.2 Primary responsibility for ensuring that the rights and welfare of research subjects are protected continues to rest with principal investigators conducting the research. Others engaged in the conduct of research share this responsibility. All faculty and staff members who assign or supervise research conducted by students have an obligation to consider carefully whether those students are qualified to adequately safeguard the rights and welfare of subjects.

5.3 The University provides the federal government with a formal commitment to ethical and appropriate review and conduct of human subject research in a document entitled "Federal-wide Assurance of Protection for Human Subjects." The detailed university procedures for conducting research involving human subjects are described in a manual entitled "Investigator's Handbook for Research Involving Human Subjects" The handbook is available online on the University's web site or in hard copy from the IRB office.

5.4 Faculty, staff, and students who engage in research involving human subjects must complete the University-approved online certification course prior to submitting a research proposal to the IRB and prior to beginning any research activity. The certification is effective for a period of two years, after which the researcher must complete a refresher course. Subsequent training will be required every two years in order for the researcher to remain certified. The University's approved online training is available on the University's web site.

5.5 The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent provided the IRB finds and documentation is shown that:



- 1) The research involves no more than minimal risk to the subjects;
- 2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- 3) The research could not practicably be carried out without the waiver or alteration; and
- 4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

5.6 Federal requirements mandate that no IRB decision can be reversed by any individual, official, or agency. An appeal of an IRB decision may be appropriate after there has been extensive correspondence between the IRB and the researcher as part of the normal IRB process, and an IRB decision has been communicated to the researcher.

5.6.1 If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

5.6.2 The details of the disapproval should indicate that the principal investigator has a right to appeal in person at the next scheduled meeting of the original IRB that reviewed the research or to respond in writing to that panel.

5.6.3 The full IRB Committee will review an appeal. Per federal regulations and guidance, the appeal request cannot be reviewed by another IRB Committee.

5.6.4 After an in-meeting appeal or the receipt of a written appeal, the panel will vote again. The second vote of the IRB panel is final.

5.6.5 It is the responsibility of the IRB Chairperson to ensure that a fair hearing of the appeal is permitted.

5.7 Failure to conduct research ethically and in compliance with university policy, as well as all applicable state and/or federal regulations, will subject a principal investigator (faculty, staff, or student), and/or others involved in human subject research, to appropriate discipline, dismissal, and/or termination of employment in compliance with relevant university policy (i.e., UVU Policy 371 *Corrective Actions and Termination for Staff Employees*; UVU Policy 541 *Student Code of Conduct*; UVU Policy 635 *Faculty Rights and Professional Responsibilities*).

5.8 Ethical treatment of human subjects in classroom assignments is the responsibility of the supervising faculty.



UTAH VALLEY UNIVERSITY

Policies and Procedures

POLICY HISTORY		
June 11, 2008	Approved for Policy Manual	UVU Board of Trustees
November 29, 2018	Non-substantive changes made in sections 2.5 and 5.7 to update the title of Policy 541 from <i>Student Rights and Responsibilities</i> to <i>Student Code of Conduct</i> .	UVU Policy Office