



POLICY MANUAL

PERSONNEL POLICIES

Number 308

Subject: Human Participants in Research

Effective Date: June 1, 2007

308.1 INTRODUCTION AND DEFINITIONS

- 1.1 The purpose of this policy is to govern the involvement of Human Participants in the conduct of Research at USU. The University is committed to safeguarding the rights and welfare of human participants, and complies with the regulations of the U.S. federal government and the State of Utah.
- 1.2 For the purposes of this policy, Research is defined in harmony with 45 CFR 46 as a systematic investigation, including research development, testing and evaluation designed to develop or contribute to Generalizable Knowledge.
 - 1.2.1 For the purpose of this policy, Generalizable Knowledge is any result of Research that is intended to be extended (or generalized) beyond the population or program being investigated. Such extension shall include public disclosure of such results either in public settings, through publication of a thesis or dissertation, or through other dissemination or publication.
 - 1.2.2 The USU Institutional Review Board (IRB) shall have the sole responsibility, through interaction with the Principal Investigator and review as set forth in this policy, to determine whether an investigation to be conducted constitutes Research in accordance with 45 CFR 46, as illustrated in Decision Chart #1, published as guidance by the Office of Human Research Protections (OHRP), available at:
<http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm>
- 1.3 A Human Participant (“Participant”) in Research is 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.

The terms “Human Participant” and “Participant” are equivalent to the terms “Human Subject” and “Subject” as used in the “Common Rule”, 45 Code of Federal Regulations (CFR) 46.

- 1.4 Human Research, or Research involving Human Participants is any Research, as defined above, that involves Human Participants in accordance with 45 CFR 46 and as illustrated in Decision Chart #1, published as guidance by the OHRP, available at:
<http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm>.
 - 1.4.1 The USU IRB shall have the sole responsibility of determining whether an investigation constitutes Human Research, under the above definition. The following activities, which may found to be exempt from Common Rule (45 CFR 46) requirements, shall nonetheless be included among those to be submitted for IRB review: quality improvement programs and program evaluations carried out for other than exclusive use by the organization sponsoring the evaluation, classroom exercises that are associated with research methodologies courses, public health activities and innovative health care.
- 1.5 Investigator is a person or entity affiliated with USU, whether as an employee, student or otherwise, whose role statement, job description, employment assignment and/or function within the University is, either in whole or in part, to carry out Research. Such Investigators shall include, but not be limited to, USU faculty, professional researchers, research assistants, laboratory and clinical staff, and others as may be designated by the Vice President for Research.
 - 1.5.1 Principal Investigator is an Investigator who is an employee of the university and is authorized by his or her unit and college, or by the Vice President for Research, to take responsibility for Research involving Human Participants. This individual shall have primary responsibility for submitting Research protocols and carrying out Research programs that protect the health and well-being of Human Participants, as set forth in this policy.
- 1.6 Intervention includes both physical procedures, by which data are gathered (for example, venipuncture), and manipulations of the Participant or the Participant's environment that are performed for research purposes.
- 1.7 Interaction includes communication or interpersonal contact between Investigator and Participant.

- 1.8 The IRB gives special consideration to protecting the welfare of particularly vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. A Child is a person under the age of 18 who is not able to legally consent to treatments or procedures involved in the research (see Utah Code Annotated 75-1-201 (29)). A Child's Guardian, according to DHHS regulations, is an individual authorized to consent on behalf of the child to general medical care. A Guardian of an incapacitated adult shall be a person who has qualified as such pursuant to testamentary or court appointment.
- 1.9 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 which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private Information must be individually identifiable (i.e., the identity of the subject is or may be ascertained by the investigator or associated with the information) in order for the obtaining of the information to qualify as Research involving Human Participants.
- 1.10 Minimal Risk means that the probability and magnitude of harm or discomfort anticipated in the Research are not greater, in and of themselves, than those ordinarily encountered in daily life, or during the performance of routine physical or psychological examinations or tests.
- 1.11 Conflict of Interest is a situation in which a University employee owes a professional obligation to the University, which is or can be compromised by the pursuit of outside interests. Conflicts of Interest are further defined and discussed in USU Policy No. 307, "Conflicts of Interest."
- 1.12 Confidentiality is the withholding of certain information as specified under an agreement between USU and another individual or entity (for example, a collaborating institution) wherein the entities agree to maintain as confidential all Private Information regarding the Research, protocol, investigational process, and information discovered during the investigation. Also, the right of a Human Participant to have Private Information protected from disclosure except as allowed under the Privacy Rule (42 CFR 160, 164)

308.2 POLICY

USU Investigators must adhere to strict ethical standards when involving Human Participants in their Research. These standards are in place to protect the basic rights of Participants. Any Research that departs from the spirit of these standards violates University policy. All Research performed under the auspices of USU, including collaborative Research conducted with one or more public or private entities, in which Human Participants are involved must be reviewed and approved by the Institutional Review Board (IRB) appointed by the Vice President for Research, or by such other review body as shall be designated by the IRB. USU, through its Human Research

Protection Program, its IRB and other review processes, works together with Investigators, sponsors and Research Participants to uphold ethical standards and practices in its Research.

The IRB review and approval process shall be conducted in accordance with all U.S. federal government and state laws, and all university policies and regulations that govern the use of Human Participants in Research, including the IRB Handbook and the IRB Standard Operating Procedures current at the time of the review. The requirement for IRB review and approval applies to all Human Research involving USU Investigators or Human Participants in all locations, whether funded or not, and whether conducted by faculty, students or other employees. It also applies to persons unaffiliated with the university who wish to investigate Participants who are under the protection of the university, such as students and patients. No such study shall begin before it has been approved by the IRB. Investigators are encouraged to consult with the IRB administrator, or the IRB chair, during preparation of an early draft of proposals to be submitted, at which time concise and current details concerning Human Research can be obtained.

The IRB web site, at <http://www.usu.edu/research/irb> is made available to Principal Investigators, Investigators, Human Participants and others in order to provide ready access to USU's Policies, Standard Operating Procedures, the IRB Handbook and associated information. Interested parties should make use of the information provided electronically, and whenever appropriate they may contact the IRB administrator or chair for additional assistance with the preparation, approval and execution of protocols involving Human Participants.

Investigators are referred to the following documents and regulations, hereby made a part of this policy by reference:

- *Ethical Principles and Guidelines for the Protection of Human Subjects of Research (The Belmont Report)*
- 45 CFR 46 "Protection of Human Subjects," (The "Common Rule")
- 45 CFR 160 and 164A,E "Standards for Privacy of Individually Identifiable Health information," ("The Privacy Rule")
- 42 CFR 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought"
- Department of Health and Human Services guide document: "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subjects Protection."

If an Investigator is unsure of the interpretation of the federal and state statutes and guidelines as listed, or has other questions regarding the applicability or effect of federal, state or local laws or regulations, he/she shall contact University Counsel for advice and direction.

The USU IRB is authorized to approve Research protocols involving Human Participants through the Federal-Wide Assurance # 00003308, dated September 6, 2002. This assurance is on file with the Office of Human Research Protections, U.S. Department of Health and Human Services. USU delegates to the IRB the responsibility for reviewing Research protocols primarily for the purpose of ensuring that Human Research is carried out in accordance with ethical principles, as outlined in the Belmont Report, and for protecting the welfare and rights of Human Participants. The IRB shall act independently in this capacity, but shall coordinate its review with other review bodies – including the Sponsored Programs Office, the Conflicts of Interest Committee, The Office of Compliance Assistance and the Office of the Vice President for Research – whose responsibilities under USU policy include review of the scientific and scholarly validity of the proposed research study, and its freedom from bias introduced because of unmanaged conflicts of interest. The IRB is authorized to:

- approve, require modification to secure approval, or disapprove all Human Research activities overseen or conducted at USU;
- suspend or terminate approval of Human Research not being conducted in accordance with the IRB’s requirements or that has been associated with unexpected serious harm to participants;
- observe, or have a third party observe, the consent process;
- observe, or have a third party observe, the conduct of the Research.
- Authorize a separate IRB or other review body that has a current FWA to provide oversight of a multi-site or specialized study under an authorization agreement, as allowed by federal statute.

308.3 PROCEDURES

3.1 Principles that IRB members consider during their reviews are set forth in the *IRB Protocol Review Standards* document (available at: <http://www.usu.edu/research/irb/forms/IRB%20Protocol%20Review%20Standards%203-19-03.pdf>) current at the time of application. These principles include:

- 3.1.1 Minimizing the risks to Participants.
- 3.1.2 Balancing of risks with the potential benefits from the study.
- 3.1.3 Obtaining informed consent from the Participant or permission from a legal guardian before participation. Such consent or permission must be in writing unless waived by the IRB.
- 3.1.4 Providing adequate detail about the study in language that is understood by the Participant so the Participant can make an informed decision
- 3.1.5 Maintaining Participants’ privacy and Confidentiality.

3.1.6 Informing Participants that their participation is voluntary and that they are free to withdraw from the study at any time without consequence.

3.2 Protocols submitted to the IRB are categorized as follows:

3.2.1 Exempt from further review. Determination of exempt status shall be made in accordance with the Standard Operating Procedures of the IRB, and shall in no case be made by an individual who might have a conflict of interest concerning the study. All Research adjudged to be exempt shall nonetheless be subject to monitoring and continued review by the institution through the IRB so that the health, well-being and privacy of Human Participants involved in such Research are adequately protected. Such review shall require an annual update confirming that the then-current activities qualify for exemption, outlining any changes made in the protocol or indicating that the project has been completed and/or terminated.

3.2.1.1 Certain Human Research shall be exempt from review under the following circumstances, in accordance with 45 CFR 46.101(b), subsections:

- (1) Educational settings (see Decision Charts 2 & 3. All decision charts referred to in this subsection are available at: <http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm>). For certain activities, such as classroom activities, the USU IRB provides a Classroom Research Assignment Application, which may be submitted by an investigator to determine whether a classroom activity may be exempt, and for which a full application may not be required. See USU IRB Standard Operating Procedures for further information.
- (2) Or (3) Tests, Surveys, Interviews, Public Behavior Observations (see Decision Charts 2 & 4.)
- (4) Existing Data, Documents Records or Specimens (see Decision Charts 2 & 5)
- (5) Public Benefit or Service Programs (see Decision Charts 2 & 6)
- (6) Food Taste and Acceptance Studies (see Decision Charts 2 & 7)

3.2.2 Subject to expedited review. If the IRB administrator finds that a protocol involves no more than Minimal Risk, expedited review may be conducted by the IRB administrator and a limited number of board members with expertise in the Research activity being conducted. Selection of IRB

members to conduct expedited reviews shall be by the IRB Chair, and expedited reviews shall be performed in accordance with the Standard Operating Procedures of the USU IRB. This process generally requires a period of four to six weeks to complete.

- 3.2.3 Subject to full review. In cases where more than Minimal Risk is involved, and where expedited review is deemed by the IRB administrator to be insufficient or inappropriate, the protocol is subject to review by the full board. Such reviews typically require a period of four to six weeks to complete.
- 3.3 Protocols submitted to the IRB for review shall be presented by a Principal Investigator, and shall consist of three components. (Forms and information can be found at <http://www.usu.edu/research/irb>):
- 3.3.1 IRB Application Form – Completion of this form will allow the IRB Administrator to quickly place the protocol in the appropriate review category (exempt, expedited, or full board review). These forms have been developed to minimize the response time of the IRB. All sections of the application must be completed in order for the IRB to begin its review. Information should be written in lay language, avoiding jargon and acronyms.
 - 3.3.2 A copy of the grant, thesis or dissertation upon which the project is based. If a project has none of the above documentation, a description of methods and objectives, and a clear, concise description of procedures to be used in the project shall be submitted.
 - 3.3.3 Informed Consent Form - This document must conform to the requirements of the IRB Standard Operating Procedures as reflected in the *Informed Consent Checklist* (available at: <http://www.usu.edu/research/irb/forms/InformedConsentChecklist.doc>) and be approved for use in the study by the IRB. It contains the following elements as required under 45 CFR 46.116:
 - 3.3.3.1 A statement that the study involves Research
 - 3.3.3.2 A statement of the Research to be performed and the purpose of the Research
 - 3.3.3.3 Reasonably foreseeable risks or discomforts
 - 3.3.3.4 Reasonably foreseeable benefits to participants and others
 - 3.3.3.5 Appropriate alternatives to the study that may benefit the participant
 - 3.3.3.6 A statement of Confidentiality

3.3.3.7 Availability of compensation or treatment for injury

3.3.3.8 Contact information

3.3.3.9 A statement explaining that participation is voluntary and that there is no penalty for withdrawal.

3.3.4 The Informed Consent form shall contain adequate information, written in plain language familiar to the participant, so that s/he can make an informed decision regarding participation.

3.4 IRB applications shall be completed on line in accordance with the IRB Standard Operating Procedures. Incomplete packages will be returned to the Investigator without review. The IRB administrator and staff work with Investigators to verify completeness of submissions and identify concerns or needed clarifications. Reviews are then conducted as described above. If full board review is required, the Investigator will provide ample copies of packets for each board member (as directed by the IRB administrator) no later than two weeks before the monthly IRB meeting.

3.5 Upon completion of the IRB review, notification of decision regarding the protocol is sent by the IRB administrator to the Investigator. Revisions are sometimes needed, and when the protocol is considered to meet acceptable standards, the Research protocol will be approved for one year (beginning on the date the protocol was approved), or such other term (never greater than one year) as shall be determined by the IRB.

3.6 For those protocols that require an extension beyond the one-year limitation of the IRB approval, a Status Report will be mailed to the Investigator by the IRB Office one month before the anniversary approval date. The Investigator will have ten working days from the date of receipt to submit the Status Report form. A memo shall be attached to the Status Report form stating the Investigator's intention to continue the Research and document any modification to the experimental protocol. The memo shall contain a concise overview of the Research to date (i.e., current copy of the informed consent, number of subjects involved, summary of any recent significant findings, adverse events, etc.). If the protocol is acceptable, an approval letter will be sent to the Investigator, extending the project for an additional year. Continuing review may occur more than once a year depending on the level of risk.

The Investigator will maintain a current file for each protocol s/he submits and have a copy of all records relating to the research protocol (IRB application form, data derived from the study/case report forms/computer data/adverse events, correspondence with the IRB/sponsor/funding sources/FDA/others, sponsor's protocol—if applicable, original Informed Consent and Assent forms).

- 3.6.1 Retention of Records – Records shall be retained by the P.I. for all protocols for three years from the date the study is completed, terminated, or discontinued. Federally-funded Research may require a longer record retention period.
- 3.6.2 The IRB shall retain for at least three years the following records in accordance with 45 CFR 45 Section 115:
 - 3.6.2.1 Minutes of IRB meetings
 - 3.6.2.2 Records of continuing review activities
 - 3.6.2.3 Copies of all correspondence between the IRB and Investigators
 - 3.6.2.4 A list of IRB members
 - 3.6.2.5 The Standard Operating Procedures of the IRB
- 3.6.3 Investigators will notify the IRB office if they either leave the university before the Research is completed, or complete the Research and leave the institution before the end of the three-year record retention date. If the Investigator desires to take copies of the research records to another institution, additional issues may need to be resolved related to the Health Insurance Portability and Accountability Act (HIPAA, 45 CFR 160).
- 3.7 IRB Training in the Protection of Human Participants in Research – USU requires Investigators, co-investigators, and any research personnel who interact with Participants in Research to be trained in the ethical protection of Human Participants. Certification achieved by completion of prescribed training shall be valid for three years from the date when training was completed.
- 3.8 Conflicts of Interest – The IRB Application Form shall include questions designed to identify any potential individual conflicts of interest that may arise in connection with the study. Positive disclosures of conflicting interests shall be referred by the IRB administrator to USU’s Federal Compliance Manager so that the conflict of interest can be fully disclosed and managed or eliminated, as required under federal guidelines and in accordance with USU Policy # 307, “Conflicts of Interest.”. No Research for which a conflict of interest has been disclosed shall be conducted under an IRB-approved protocol until a Conflict of Interest Management Plan has been approved for the work by the USU Conflict of Interest Committee. In addition, members of the IRB shall be queried at the beginning of each IRB review meeting concerning potential conflicts of interest they may have in connection with protocols to be reviewed. Members of the IRB that disclose such conflicts may provide information to the Board as requested, but shall recuse themselves from voting for approval or disapproval of the protocol in question.

- 3.9 Allegations and findings of non-compliance. Incidents of non-compliance shall be handled by the IRB unless the nature or duration of non-compliance indicates the need for institutional intervention.
- 3.9.1 Non-compliant activities may be identified through IRB oversight, self-reporting, or reporting from employees, Human Participants or others. Reports should be made to the chair of the IRB, and any report of non-compliant behavior involving Research under the oversight of the IRB shall be reported to the IRB chair at the earliest opportunity. Sufficient information shall be submitted to identify who exhibited the non-compliant behavior, when it took place, and any other pertinent details to allow for determination of non-compliance.
- 3.9.2 The IRB chair shall make the initial determination if the allegation is non-compliance involving Human Research. If non-compliance is suspected, but does not involve Human Research, the chair shall provide all pertinent information to the Office of Compliance Assistance for further action.
- 3.9.3 Upon making a finding of non-compliance that is neither serious nor continuing, the IRB Chair shall take steps to correct the non-compliant behavior with the investigator. The IRB Chair shall also notify the Department Chair, Dean, the Office of Compliance Assistance (OCA) and the Responsible Institutional Official of the circumstances surrounding the behavior and corrective actions taken.
- 3.9.4 In cases of serious non-compliance (defined as non-compliant activities that could jeopardize the rights or safety of Human Participants) or continuing non-compliance (defined as non-compliant activities that recur either on the same project or by the same investigator after the IRB chair has taken corrective action), the IRB chair shall notify the OCA for further action. The OCA has been established to provide support to the IRB, Investigators, Human Participants, and other individuals and entities with regard to adherence to federal and state statutes, regulations and guidelines. In conjunction with USU's Responsible Institutional Official (RIO) and others, the OCA receives and processes allegations of misconduct and non-compliance arising from Research activities of the university, and facilitates any associated inquiries and investigations. Information about and contacts for the OCA are available at: http://www.usu.edu/aia/academic/c_overview.cfm. Allegations of non-compliance may be presented to the IRB administrator, the Federal Compliance Manager at the OCA, USU's Internal Audit Services (IAS) either through the hotline or with a representative of IAS, or to University Counsel.
- 3.10 Adverse events and unanticipated problems. Investigators shall follow the procedures contained in the IRB Standard Operating Procedures and IRB Handbook whenever an adverse event or another unanticipated problem arises

having to do with risks to Human Participants or others. The P.I. shall have responsibility for identifying and reporting unanticipated risks, submitting information to the chair of the IRB in sufficient detail for the chair to draft the report as required in 3.12, below, and otherwise as required by the SOPs. If the adverse event or unanticipated risk is life-threatening, emergency services shall be summoned and all reasonable steps shall be taken to ensure the safety and well-being of the Participants or any others affected.

3.11 Suspensions and Terminations of previously approved Research. The IRB is authorized to suspend (defined as temporarily discontinuing) or terminate (defined as permanently discontinuing) Research in order to protect the rights and welfare of Research Participants and others.

3.11.1 The determination of the appropriate action shall be made by the IRB chair, based on non-compliance with the IRB-approved protocol for the Research, or on the association of the Research with an unexpected serious harm to Participants or others. Determinations shall be ratified by the membership of the IRB, and shall be reported to the OCA, RIO, University Counsel and the appropriate funding agency as set forth in 3.12, below.

3.11.2 Suspensions may be lifted if an investigation determines that the harm was not associated with the Research, or if compliance with the approved protocol is re-established, and is determined to be sufficient to protect the rights and welfare of Human Participants.

3.11.3 When a termination or suspension involves the withdrawal of current Participants from a study:

3.11.3.1 Enrolled participants will be notified by the IRB.

3.11.3.2 Participants to be withdrawn will be informed by the IRB of any unexpected risks to which they may have been subjected, and shall be provided with support in understanding and ameliorating those risks.

3.11.3.3 Participants to be withdrawn will be informed by the IRB of any follow-up that is required or offered, and will be informed that any adverse event or unanticipated problems involving risks to them or others should be reported to the IRB and others as appropriate.

3.12 Reports of unanticipated problems, terminations, suspensions and serious or continuing non-compliance shall be submitted to federal agencies in compliance with applicable regulations.

3.12.1 The IRB chair shall have responsibility for coordinating with the P.I., gathering any additional required information and writing the initial report, which shall include:

3.12.1.1 the nature of the event or problem,

3.12.1.2 the findings of USU,

3.12.1.3 the action taken by the IRB and USU

3.12.1.4 the reasoning underlying the actions taken,

3.12.1.5 any plans or recommendations for a continuing inquiry or investigation.

3.12.2 The chair shall submit the draft report in a timely manner to the OCA and the RIO for review. The RIO shall have responsibility for final approval and signature of the report, and for its submission to the appropriate agency.

3.13 Continuous improvement of the Human Research Protection Program.

3.13.1 The IRB and OCA shall work together to measure and report the performance of the Human Research Protection Program to USU's administration. Annual and unannounced reviews of the IRB's operating and review procedures shall be carried out in order to assess the effectiveness and quality of the processes; and to assure compliance with USU's policies and procedures, and with applicable federal, state and local laws and guidelines.

3.13.2 USU Investigators, other USU employees, Human Participants and sponsors of Research are encouraged to bring forward concerns and suggestions regarding improvement of the Program, including the IRB review process.

[BACK TO TABLE OF CONTENTS](#)

