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Introduction to Version 4.3

The purpose of the Institutional Review Board (IRB) Standard Operating Procedure (SOP) is to provide direction to members of the IRB and the IRB staff in carrying out duties assigned to the IRB, and to provide a “best practices” reference guide. This SOP comprehensively summarizes existing policy as well as the regulatory expectations found in the Common Rule (45 CFR 46). At the time of the release of Version 4.1, USU is not carrying out research on new investigational drugs or biomedical devices. Therefore, these SOPs do not include extensive information concerning the requirements of the Food and Drug Administration (FDA) regulations, found at 21 CRF 56.

Utah State University’s (USU) IRB periodically reviews its local practices and SOPs to maintain procedures tailored to the practices and research programs at USU. The procedures described are also reviewed to ensure compliance with applicable regulations and guidance.

Another purpose of these SOPs is to ensure conformity between written university policies and procedures and operational practices within USU. The SOPs reflect the practices and procedures expected by USU’s IRB at multi-site studies as well, when those studies involve research programs supported by USU. If defined procedures are not found in these SOPs, then research must be suspended in accordance with the provisions set forth in 45 CFR 46 and all its subparts (A, B, C, & D), and to comply with USU’s Federal Wide Assurance (FWA) on file with the Office of Human Resource Protection (OHRP) until the SOPs adequately address all regulatory requirements. USU and its IRB have made important procedural decisions that are documented in these SOPs.

Substantial changes in version 4.3 include revisions to the noncompliance policy, Chapter 5, to more clearly spell out the procedures for investigating and resolving noncompliance. New revisions include a provision allowing researchers the opportunity to present a version of events to the IRB before the IRB determines whether noncompliance occurred and whether it is serious or continuing.

Changes to the SOPs to reflect a long standing practice of obtaining school district approval when working with school districts has also been added to Chapter 10 of the SOPs.

Clarifying statements and examples have been added to Chapter 9 regarding minor and non-minor modifications; the 15% restriction on participant population numbers has been removed in favor of a more nuanced approach to determining what constitutes a substantial change in participant population.

Substantial changes in the previous document, version 4.2, include agency requirements for studies funded or overseen by the Department of Defense, Department of Education, Department of Energy, and Department of Justice.

Maintaining a Current SOP

These SOPs are considered to be a “living document” that will be updated or reviewed annually or more often as changes in statutes, regulation, guidance, practice, or policy occur.

Intended Audience and Distribution

The audience includes the IRB members and alternates, IRB staff and administration, and university administrators. The SOPs will also provide valuable guidance, in conjunction with the Investigator Handbook, to Principal Investigators, research professionals and administrative staff, and anyone else conducting or involved in research.
A. Background

Chapter 1: The Ethical Mandate to Protect Human Subjects

Research must be carried out in an ethical manner (see 45 CFR 46 Subpart A). The basic ethical principles guiding research involving human participants are described in the following nationally and internationally developed and recognized documents.

a. The Nuremberg Code
   The modern history of human subject protections begins with the discovery after World War II of numerous atrocities committed by Nazi doctors in war-related human research experiments. The Nuremberg Military Tribunal developed ten principles as a means of judging their “research” practices, known as The Nuremberg Code. The significance of the Code is that it addressed the necessity of requiring the voluntary consent of the human subject and that any individual “who initiates, directs, or engages in the experiment” must bear personal responsibility for ensuring the quality of consent. Additionally, the Nuremberg Code, more than other counterparts listed here, is a recitation of participants’ legal rights, and has been used as a basis for decisions made in adjudicating some cases involving human research.

b. The Declaration of Helsinki
   Similar principles to The Nuremberg Code have been articulated and expanded in later codes, such as the World Medical Association Declaration of Helsinki: Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects (1964, revised 1975, 1983, 1989, 1996, 2000), which call for prior approval and ongoing monitoring of research by independent ethical review committees.

c. The Belmont Report
   Perhaps the most important contribution of The Belmont Report is its elucidation of three basic ethical principles:
   1. Respect for persons (applied by obtaining informed consent, consideration of privacy and confidentiality, and additional protections for vulnerable populations);
   2. Beneficence (applied by weighing risks and benefits); and
   3. Justice (applied by the equitable selection of subjects).

   Note: The Belmont Report also provides important guidance regarding the boundaries and interface between biomedical research and the practice of medicine.
Chapter 2: The Regulatory Mandate to Protect Human Subjects

Federal regulations require specific protections for human subjects; a brief overview is detailed below.

a. **Department of Health and Human Services (DHHS) Regulations at 45 C.F.R. 46.**
   In May of 1974, the Department of Health, Education, and Welfare (later renamed DHHS) codified its basic human subject protection regulations at 45 CFR 46, Subpart A. Revised in 1981, 1991, 1996 and 2005, the DHHS regulations presently include additional protections for fetuses, pregnant women, and human in vitro fertilization (Subpart B), prisoners (Subpart C), and children (Subpart D). The DHHS regulations are enforced by the Office for Human Research Protections (OHRP). In addition to DHHS regulations, the following federal agencies have specific requirements regarding the review and conduct of human research: Department of Defense, Department of Education, Department of Energy, and Department of Justice. The regulations specific to these agencies are included in Chapter 17 of these SOPs.

b. **Health Insurance Portability & Accountability Act (HIPAA) for the use and disclosure of protected health information in research.**

c. **Research Use/Disclosure without Authorization.**

d. **The Assurance and Registration Process.**
   The Common Rule requires that every institution engaged in federally supported human research file an “Assurance” of protection for human subjects (56 FR 28003). The Common Rule Terms of Assurance are listed on the OHRP website. All Common Rule Agencies must recognize Federal-Wide Assurances (FWAs) approved by OHRP in DHHS. USU conducts human research under FWA #00003308, which document is posted on the IRB website. USU meets the terms required for the FWA as reviewed at the OHRP website located at: [http://www.hhs.gov/ohrp/assurances/](http://www.hhs.gov/ohrp/assurances/)

State and local laws and ordinances affecting the review of proposals include the Governmental Records Access and Management Act (GRAMA), the Family Education Records Protection Act (FERPA), the Utah Governmental Immunities Act, and others. Where laws or regulations differ, the university and the IRB shall make every attempt to adhere to the stricter standard. If laws or regulations come into conflict with one another, USU shall rely upon the Attorney General of the State of Utah, or an authorized representative, to resolve the conflict. USU may also seek legal clarifications from General Counsel as appropriate.
Chapter 3: Types of Human Research and Institutional Review Board Considerations

All USU research involving human participants must be reviewed by the Institutional Review Board (IRB). There are special considerations related to each type of research.

a. Definition of Human Participant and Human Research.

Federal regulations at 45 CFR 46.102 (d) define research as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” Federal regulations at 45 CFR 46.102(f) define Human Subject as “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. Private information includes information that an individual can reasonably expect will not be made public, and information about behavior that an individual can reasonably expect will not be observed or recorded. Identifiable means that the identity of the individual is or may readily be ascertained by the investigator or associated with the information. USU uses the term “Human Participant” as an equivalent to OHRP’s “Human Subject,” and their definitions at USU are identical.

Generalizable knowledge: Knowledge that is “expressed in theories, principles, and statements of relationships” that can be widely applied to our experiences. Generalizable knowledge is usually created to share with other people, such as through presentations and publications. Masters’ theses and Ph.D. dissertations are considered to present generalizable knowledge.

“Generalizable knowledge” would include one or more of the following concepts:

- The knowledge contributes to a theoretical framework of an established body of knowledge
- The primary beneficiaries of the research are other researchers, scholars and practitioners in the field of study
- Publication, presentation or other distribution of the results is intended to inform the field of study
- The results are expected to be generalized to a larger population beyond the site of data collection
- The results are intended to be replicated in other settings
- Web based publication for professional purposes

(Systematic Investigation: A process that involves the formulation of a hypothesis or research question, and that includes the collection and/or analysis of data that will lead to a conclusion that either proves or disproves the hypothesis, or that answers the research question.

b. Examples of Human Research.

The following examples illustrate common types of human research. These are examples only, and are not exhaustive of all human research. They may be conducted at one location or as multi-center projects.

(1) Clinical Research.

Clinical research involves research: (a) to increase scientific understanding about normal or abnormal physiology, disease states, or development and (b) to evaluate the safety, effectiveness or usefulness of a procedure or intervention. Vaccine trials, medical device research, and cancer research are all types of clinical research. At present, USU’s Human Research Protection Program (HRPP) does not allow research on test articles as defined under FDA regulations.
(2) Behavioral and Social Sciences Research.

The goal of social and behavioral research is similar to that of clinical research — to establish a body of knowledge and to evaluate interventions — but the content and procedures often differ. Social and behavioral research involving human participants focuses on individual and group behavior, mental processes, or social constructs and usually generates data by means of surveys, interviews, observations, studies of existing records, and experimental designs involving exposure to some type of stimulus or environmental intervention. For more information concerning Social, Behavioral and Educational Research, refer to Chapter 12.a.

(3) Epidemiological Research.

Epidemiological research targets specific health outcomes, interventions, or disease states and attempts to reach conclusions about cost-effectiveness, efficacy, efficiency, interventions, or delivery of services to affected populations. Some epidemiological research is conducted through surveillance, monitoring, and reporting programs — such as those employed by the Centers for Disease Control and Prevention (CDC) — whereas other epidemiological research may employ retrospective review of medical, public health, and/or other records. Because epidemiological research often involves aggregate examination of data, it may not be research involving human subjects. When this is the case, the PI should submit the research to the IRB to determine whether it is research involving human subjects. For additional information regarding epidemiological research, refer to Chapter 14.a.

(4) Repository Research, Tissue Banking, and Databases.

Research utilizing stored data or materials (cells, tissues, fluids, and body parts) from individually identifiable living persons qualifies as Human Research, and requires IRB review. When data or materials are stored in a bank or repository for use in future research, the IRB should review a protocol detailing the repository’s policies and procedures for obtaining, storing, and sharing its resources, for verifying informed consent provisions, and for protecting participants’ privacy and maintaining the confidentiality of data. The IRB may then determine the parameters under which the repository may share its data or materials with or without IRB review of individual research protocols. For additional information concerning research using data and specimens, refer to Chapter 13.

(5) Quality Assurance/Quality Improvement Activities.

Quality assurance activities attempt to measure the effectiveness of programs or services. Such activities may constitute Human Research, and require IRB review if they are designed or intended to contribute to generalizable knowledge. Quality assurance activities that are designed solely for internal program evaluation purposes, with no external application or generalization, will probably not require IRB review or will qualify for an exemption. In questionable cases, the IRB, not the individual investigator, should determine when IRB review of such activities is required.

(6) Pilot Studies.

Pilot studies involving human participants are considered Human Research and require IRB review and approval before conduct of the research commences.

(7) Human Genetic Research.

Genetic studies include but are not limited to: (a) pedigree studies (to discover the pattern of inheritance of a disease and to catalogue the range of symptoms involved); (b) positional cloning studies (to localize and identify specific genes); (c) DNA diagnostic studies (to develop techniques for determining the presence of specific DNA mutations); (d) gene transfer research (to develop treatments for genetic disease at the DNA level), (e) longitudinal studies
to associate genetic conditions with health, health care, or social outcomes, and (f) gene frequency studies. Unlike the risks presented by many biomedical research protocols considered by IRBs, the primary risks involved in the first three types of genetic research are risks of social and psychological harm, rather than risks of physical injury. Genetic studies that generate information about participants' personal health risks can provoke anxiety and confusion, damage familial relationships, and compromise the subjects' insurability and employment opportunities. For many genetic research protocols, these psychosocial risks can be significant enough to warrant careful IRB review and discussion. Those genetic studies limited to the collection of family history information and blood drawing should not automatically be classified as "minimal risk" studies qualifying for expedited IRB review. Because this is a developing field, there are some issues for which no clear guidance can be given, either because not enough is known about the risks presented by the research, or because no consensus on the appropriate resolution of the problem yet exists. OHRP representatives have advised that "third parties," about whom identifiable and personal information is collected in the course of research, are human participants. Confidentiality is a major concern in determining if minimal risk is involved. The IRB considers if informed consent from third parties can be waived in accordance with Section 46.116 and if so, document the waiver in the IRB minutes. In most cases waiver of consent may be appropriate. For more information concerning genetic research, refer to Chapter 14.b.

c. Determining Whether an Activity is Research Involving Human Participants

Investigators with questions concerning whether an activity constitutes research with human participants should submit a request for clarification to the IRB Office. The request is made using the "Request for Determination of Non-Human Subjects Research." The form is designed to allow the IRB office to make the determination whether the activity constitutes human research by verifying 1) whether the activity meets the definition of research, as set forth in section ‘a,’ above, and if so, 2) whether the individuals involved meet the definition of human participants, as given in section ‘a.’

The IRB office notifies investigators of the decision by e-mail, and if the activity is determined to be human research, provides information to the Investigator to facilitate completion of an appropriate application for IRB review.

Chapter 4: Shared Responsibilities for Protecting Human Subjects

The ethical conduct of research is a shared responsibility. It requires cooperation, collaboration, and trust among the institution, investigators, and their research staff; the participants who enroll in research; and the Institutional Review Board members and staff.


USU’s HRPP is administered on an institutional level. The university as a whole, the IRB, investigators, sponsors and participants all have responsibilities for ensuring that USU’s human research is conducted ethically and that the safety and welfare of human participants are adequately protected. The Human Research Protection Program Statement is available on the web at: https://irb.usu.edu/htm/human-research-protection-program

b. Policies and Procedures Supporting USU’s HRPP.

As part of USU’s FWA, USU has developed policies and the IRB Office maintains these SOPs for conducting human research in a responsible and ethical manner, including how research will be reviewed by the IRB (Chapter 9, below), the reporting of unanticipated problems to the IRB and appropriate regulatory bodies (Chapter 5, below), developing and maintaining educational programs
and other issues (e.g., procedures for communication and correspondence flow between the IRB, the Data and Safety Monitoring Board, and Principal Investigators).

c. Institutional Assurance.
The Vice President for Research is USU’s Institutional Official, signs the university’s FWA, and is ultimately responsible for overseeing the protection of human participants involved in USU’s human research. The Institutional Official must also ensure that open channels of communication are maintained between the IRB, research investigators and staff, and facility management, and that the IRB is provided with sufficient meeting space and staff to support its substantial review and confidential record keeping responsibilities. Appropriate channels of communication are provided through research study teams, the IRB, the Office of Compliance Assistance (OCA), Federal Compliance Manager (FCM) and USU’s Compliance Hotline.

d. Institutional Authority of the IRB.
The Vice President for Research is USU’s Institutional Official (IO), and is responsible for all research activities conducted under the auspices of Utah State University. The IRB is authorized under USU Policy #306, “Research,” and Policy #308, “Human Participants in Research” to carry out review, approval and monitoring of Human Research for USU. See Chapter 5, below, for additional information on the roles and authority of the IRB.

e. IRB Administration Review.
On an annual basis, in conjunction with university performance appraisals, the IRB Chair shall provide to the IO an evaluation of the IRB Director and other staff in the IRB office, indicating areas of strength, accomplishments, weaknesses, and potential areas for improvement in the administration of the IRB. This evaluation shall be used by the IO or other officer with responsibility for the evaluation of the IRB Director and staff in completing the evaluation for IRB personnel. The IRB chair’s evaluation may be attached to the employee’s performance appraisal, or may be retained with the employee’s appraisal file.

The individual with line responsibility for supervision of the IRB Director shall be responsible for requesting an evaluation from the IRB Chair in a timely manner on an annual basis.

f. The Principal Investigator.
As the individual responsible for the implementation of research, the principal investigator bears direct responsibility for ensuring the protection of every research participant. This responsibility starts with protocol design, which must minimize risks to participants while maximizing research benefits (see section I, below). In addition, the Principal Investigator must ensure that all members of the research team always comply with the findings, determinations, and requirements of the IRB. In situations where research is being conducted outside the United States or on tribal lands, the Principal Investigator will have primary responsibility for seeking and receiving approvals from local IRB or other review bodies as may be required by the cognizant foreign (or tribal) government. USU’s IRB maintains OHRP’s International Compilation of Human Research Protections on its website to facilitate the Principal Investigator’s review of local laws.
The Principal Investigator must also ensure the adequacy of both the informed consent document and the informed consent process, regardless of which members of the research team are authorized to actually obtain and document consent.

Principal Investigators are responsible for ensuring that:

1. Any human research that they conduct as employees or agents of USU has received initial prospective review and approval by an authorized IRB;
2. Continuing review and approval of the research has been accomplished within the time frame stipulated by the IRB; and

3. The research is conducted at all times in compliance with all applicable regulatory requirements of all cognizant jurisdictions and the determinations of the IRB (or IRBs).

No changes in approved research may be initiated without prior IRB approval, except where necessary to eliminate apparent immediate hazards to participants; and no research may be continued beyond the IRB-designated approval period.

The principal investigator is required to notify the IRB in writing of **ALL** of the following:

<table>
<thead>
<tr>
<th>Investigator Must Report</th>
<th>Time Frame for Reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deaths</td>
<td>Within 24 hours if the subject is currently enrolled in the research. Otherwise, within 60 days of investigator’s notification of death.</td>
</tr>
<tr>
<td>Protocol Deviations</td>
<td>Immediately, when it represents a significant alteration in the approved protocol and/or if it affects the safety or welfare of the subject.</td>
</tr>
<tr>
<td>Change to the protocol made without prior IRB review in order to eliminate an apparent immediate hazard to participant</td>
<td>Immediately</td>
</tr>
<tr>
<td>Protocol violations</td>
<td>Immediately, when it represents a significant alteration in the approved protocol and/or if it affects the safety or welfare of the subject.</td>
</tr>
<tr>
<td>Allegation or finding of noncompliance with conducting of research protocols</td>
<td>Immediately upon discovery of the noncompliance</td>
</tr>
<tr>
<td>Restrictions, suspension, or termination of study by sponsor or principal investigator</td>
<td>Within 3 days</td>
</tr>
<tr>
<td>Any activity which involves a potential or actual unexpected risk to subjects or others</td>
<td>Within 7 days of activity</td>
</tr>
<tr>
<td>Any harm experienced by a participant which, in the opinion of the investigator, is both unexpected and more likely than not caused by the research procedures</td>
<td>Within 7 days of report by participant</td>
</tr>
<tr>
<td>Complaint of a participant when the complaint indicates unexpected risks or cannot be resolved by the research team</td>
<td>Within 3 days of confirmation the team is unable to resolve the issue</td>
</tr>
<tr>
<td>Information that indicates a change to the risks or potential benefits of the research</td>
<td>Within 10 days of discovery</td>
</tr>
<tr>
<td>Breach of confidentiality</td>
<td>Within 3 days of discovery</td>
</tr>
<tr>
<td>Incarceration of a participant in a protocol not approved to enroll prisoners</td>
<td>Within 10 days</td>
</tr>
<tr>
<td>Any other problem that the investigator considers to be unanticipated and indicates that participants or others are at increased risk of harm</td>
<td>Within 7 days of discovery</td>
</tr>
</tbody>
</table>

The Principal Investigator must follow set procedures to submit protocols to the IRB along with the necessary forms and paperwork. The IRB web address for online submission is [http://protis.usu.edu](http://protis.usu.edu)
g. **Investigators’ Assurances.**

It is the responsibility of each PI to formally “assure” the IRB that it will comply with regulations governing the protection of human participants (Investigator’s Assurance). The assurance is included as part of the IRB Application.

h. **Communicating Findings to Sponsors and Participants.**

It is the moral obligation of investigators to share the findings of their research with participants and sponsors. Investigators shall make the following types of information available to participants:

- **Unexpected findings related to individuals** – Whenever research uncovers an otherwise unknown, but potentially harmful, condition in relation to a participant whose identity is known to the investigator, that individual shall be provided with information concerning the condition in a timely manner.

- **Findings indicating the presence of an unexpected harm associated with an intervention** – Whenever research indicates the probability that an intervention increases risk to participants, the finding shall be reported by the investigator to the institution as an unanticipated problem. All unanticipated problems shall be considered and acted on in accordance with Chapter 9 of these SOPs. If the unanticipated problem occurs in a multi-site study, all sites shall be informed of the occurrence. All unanticipated problems shall be reported to the cognizant agency in accordance with USU’s FWA and to any sponsor of the research. The IRB shall consider risks to the study cohorts and shall provide appropriate information to participants in order for them to make an informed decision about continuing in the study.

- **Findings related to study cohorts** – Whenever research indicates that an intervention has a measurable impact on risks to participants, whether positive or negative, the investigator shall inform research participants of those impacts as soon as it is feasible within the framework of the study. The duty to inform under this procedure may be fulfilled by providing information to study participants through correspondence or on a study website, so long as the participants have agreed to receiving information by these means. Communication of findings may be by the university or by the sponsor.

- **Findings related to a broader population** – Whenever research culminates in significant findings, whether the findings confirm or are contrary to the hypothesis or research objectives of the study, it is the duty of the investigator to make those findings available to the sponsor and to the public. It is the policy of the university to make best efforts to publish and otherwise make research results available to the public. An investigator shall not withhold findings from the public, except to allow for intellectual property protection under Policy #306, “Research,” and Policy #327, “Intellectual Property and Creative Works.”

i. **Other Members of the Research Team.**

Every member of the research team is responsible for protecting human participants. Co-investigators, study coordinators, nurses, research assistants, graduate and undergraduate students, and all other research staff have a strict obligation to comply with all IRB determinations and procedures, adhere rigorously to all protocol requirements, inform Principal Investigators of all adverse participant reactions or unanticipated problems, ensure the adequacy of the informed consent process, and take necessary measures to ensure adequate protection for participants.
Investigators at every level are responsible for notifying the IRB promptly of any serious or continuing non-compliance with applicable regulatory requirements, or determinations of the IRB, of which they become aware, whether or not they themselves are involved in the research.

j. **Processing Participant Feedback.**
Participants in human research conducted at USU are encouraged to provide feedback to the study team and to the university. The Compliance Hotline and website are available for this purpose, but study based suggestions and questions should be directed to and handled by study personnel whenever possible. This process is facilitated by including contact information for appropriate personnel in the Informed Consent document and ensuring that all participants receive a copy of the form, and are actively encouraged to provide feedback to the study team. All feedback shall be summarized in writing by the employee receiving it, and provided to the PI for consideration and timely dissemination as appropriate. Participants providing feedback must be treated with respect, and appreciation for their feedback should be expressed. Study personnel shall be trained to identify situations where a participant should be referred to the PI, and to identify when feedback constitutes a complaint or request for information, which are discussed in the following section “k”.

k. **Processing Participant Complaints and Requests for Information.**
All study personnel shall be adequately trained to be able to refer participant complaints and requests for information in an efficient and timely manner. Training shall include the ability to identify when an unanticipated problem may have occurred, when problems that were anticipated may have occurred, and whether a disposition can be achieved within the lab, at the departmental level, with the IRB or at an institutional level. The following guidelines shall be applied:

1. For requests for information concerning study outcomes
   - PI
2. For requests for information concerning the participant’s health
   - PI
3. For complaints about study personnel
   - PI
4. For complaints about the PI
   - IRB
5. For complaints about other personnel
   - PI or Dept Head
6. For complaints about research-related harm
   - PI and IRB
7. For complaints about coercion or undue influence
   - IRB
8. For requests for information pertaining to HIPAA regulations
   - FCM
9. For complaints or notification of regulatory non-compliance
   - FCM

The worker receiving the request or complaint shall refer it immediately to the PI or other officer as indicated in the guidelines. If the PI is informed of a request or complaint, it shall be his/her responsibility to either determine, based on the guidelines, that he/she is authorized to reach a final disposition of the matter, or that the request or complaint must be referred to others as outlined above. When communicating a problem to the IRB, the contact point shall be the IRB Director or the IRB Chair.

All unanticipated problems, as defined in Chapter 9.j of these SOPs and other matters as set forth in the Table “Reporting Responsibilities of the Principal Investigator to the IRB” in section 4.f, above, must be reported to the IRB within timeframes as indicated in the table.

A report on the disposition of every complaint that is referred to the IRB, the department, college or institution shall be generated, copied to the IO and other administrators as appropriate and placed in the protocol file for the duration of the retention period.
I. Evaluation of Risks and Benefits.
Investigators shall consider risks and benefits to participants when designing the study. Through the Use of the Risk/Benefit Assessment Form the investigator shall demonstrate to the IRB that risks have been minimized; that alternative research methods, if any, have been assessed; that procedures already being performed on the participants could not yield the data necessary to the study; and that risks are reasonable in relation to benefits. This evaluation shall include consideration of additional safeguards required by 45 CFR 46, subparts B,C and D for identified vulnerable populations, and additional safeguards that may be reasonable for other populations that are adjudged by the IRB to be vulnerable.

B. Institutional Review Board (IRB) Administration

Chapter 5: IRB Roles and Authorities

a. Human Subject Protections Regulations.
USU requires protection for human participants in accordance with federal regulations, “Protection of Human Subjects,” at 45 CFR 46 (The Common Rule). The regulations require that the IRB file a written “Assurance” of protection for human participants with DHHS/Office of Human Research Protections (OHRP) to oversee its human research. This Federal Wide Assurance (FWA #00003308) is on file in the IRB Office. The OHRP also requires completion of training for IRB members, signatory officials and Investigators as part of the terms and conditions of the FWA. USU utilizes an on-line training program sponsored by The Collaboration for Institutional Training Initiative (CITI) to acquaint listed individuals with their responsibilities under the FWA. Records of this training are kept in the IRB Office. Additional regulatory requirements under other federal funding agencies are discussed in Chapter 17 of these SOPs.

b. Purpose of the IRB.
An IRB’s primary responsibility is to ensure that the rights and welfare of subjects are protected in USU’s human research programs. In doing so, the IRB ensures that the human research is conducted ethically, and in compliance with Federal regulations, the requirements of applicable state or other local (including applicable foreign) law, the FWA (or other Assurance), and USU’s institutional policies and procedures. While the principal investigator has the primary responsibility for researching and complying with laws in foreign (or tribal) jurisdictions, the IRB provides support when research will be conducted outside the US by interfacing with appropriate IRBs or other review bodies with jurisdiction where the research will be conducted. Where laws and regulations appear not to be harmonized, the IRB shall rely on General Counsel and the Attorney General of the State of Utah to provide legal clarification, as outlined in Chapter 2.e of these SOPs.

c. Scope of the IRB’s Authority (45 CFR 46).
USU’s IRB prospectively reviews and makes decisions concerning all human research conducted at USU or by USU employees or students, or otherwise under the auspices of USU (e.g., research using non-public patient data, from USU records, using USU resources, published or presented with USU cited as supporting or conducting the research, or recruiting USU participants at USU facilities). The IRB has statutory authority to take any action necessary to protect the rights and welfare of human participants in USU's research program. The IRB has the authority to approve, require modifications in, or disapprove USU's human research.
The IRB has authority to suspend or terminate the enrollment and/or ongoing involvement of human participants in USU's research as it determines necessary for their protection. The IRB has the authority to observe and/or monitor USU's human research to whatever extent it considers necessary to protect human participants.

d. **IRB’s Sole Authority to Approve Research.**
   The IRB shall make decisions that are in the best interest of the research participants. The university administration may determine, under USU Policy 306, “Research” or for other reasons that the study may not be conducted. However, no study may be conducted by USU in contravention of a decision by the IRB not to allow the study. At each annual review of the HRPP the ability of the IRB to act independently in its assigned role shall be assessed. This assessment will be based on Section C of the HRPP Annual Review Form & Checklist, and will consider issues such as the appropriateness of the reporting structure, conflicts of interest held by IRB administrators or members, and institutional conflicts of interest that may curtail the independence of the IRB. IRB members and staff are to report undue influence to the Federal Compliance Manager (FCM). The FCM investigates allegations of undue influence, and if true, takes action to eliminate the undue influence.

e. **Harmonization among IRBs in Multi-Site Research.**
   Although it is the preference of the IRB that a single standard consent form is used at all participating research sites in multi-site studies, the ultimate responsibility for the welfare of the participant resides at each individual study-site. If the IRB from a participating site makes suggestions for changes, they will be considered and incorporated if acceptable to the IRB. Similarly, local variations can be incorporated into a standard document for use in all or most multi-sites. When necessary and appropriate, variations across multiple sites will be permitted with the approval of the IRB Chairperson and Principal Investigator. Major changes must have the approval of the IRB.

f. **Relationship of IRB to Other Institutions.**
   USU's IRB may be designated for review of research under another institution’s FWA (or other Assurance) only with the written agreement of USU, using a standard Authorization Agreement, approved by USU’s Institutional Official. Any such agreement must specify the responsibilities of the facility and its IRB under the other institution’s FWA, as well as the responsibilities of USU’s IRB under the agreement. USU’s IRB has no authority over, or responsibility for, research conducted at other institutions in the absence of such a written agreement.

g. **Multi-Site Investigations.**
   USU may participate in studies where investigators and/or study populations are involved at more than one location. An investigator is engaged in a multi-site study when the activity involves multiple entities and meets the definition of Human Research under Policy #584, “Human Participants in Research.” It is possible that a study that is considered Human Research at one site would not be so considered at a different site, as for example, when personal health information is being collected at one site, but de-identified data is being analyzed at a separate site.

The IRB chair and IRB Director shall determine the extent to which USU’s IRB has responsibility for review of multi-site research on a case-by-case basis. The following criteria shall be weighed when making the determination:

1. The level of risk
2. Whether USU is the lead site, and has overall responsibility for the study
3. Whether USU’s IRB has the capability to provide appropriate scientific and ethical review on its own
(4) Whether other institution’s IRBs have the capability to analyze local conditions for populations associated with USU

(5) Whether there is a collaborative agreement among participating institutions’ IRBs to jointly review and approve human research

(6) Whether an outside IRB has been retained by USU to review the type of study under consideration

Based on these factors, the chair and Director may:

(1) Require that USU’s IRB be considered the lead or co-equal IRB of record

(2) Recognize another IRB as being the IRB of record, but require that USU’s IRB retain certain rights to review and approve research involving USU investigators or participants

(3) Assign the responsibility for review to another IRB through the use of an Authorization Agreement

In no case shall a PI make the determination concerning which IRB shall be the IRB of record. See also Chapter 9.c, below, for more information regarding procedures to be followed to determine and document assignment of responsibility for review to another IRB using the “IRB Meeting Preparation Checklist.”

For multi-site research where USU’s IRB is the IRB of record, the PI shall identify each collaborating site in the IRB application, along with contact information for the collaborating institution’s IRB. The PI shall also maintain records of IRB approval notice(s), IRB-approved consent document(s), letter(s) of compliance, and/or letter(s) of permission, including approval for all protocol modifications from all collaborating sites engaged in the research.

For multi-site research where USU’s IRB is not the IRB of record the PI shall provide a copy of the approved research protocol, the approval notice, and such other documentation as may be required by USU’s IRB before the IRB approves Human Research at USU. In cases where an authorization agreement between institutions has been executed, the terms and conditions of the agreement shall take precedence.

In all multi-site research, reportable issues must be shared with all institutions engaged in the study. When USU has responsibility as the IRB of record, the IRB has responsibility for requiring all involved institutions to report unanticipated problems, suspensions, and terminations to USU, and to share the information with all participants. When USU relies on another IRB’s review, that IRB must report all reportable issues to USU’s IRB.

h. Appeal of IRB Determinations.

The IRB must provide the principal investigator with a written statement of its reasons for disapproving or requiring modifications in proposed research and must give the investigator an opportunity to appeal the decision in person or in writing. The IRB must carefully and fairly evaluate the investigator’s response in reaching its final determination. The IRB has defined the process that the investigator must follow to respond appropriately, and how decisions may be appealed with the full IRB. This process is set forth in the Investigator’s Handbook, page 43. Investigators may not appeal the IRB’s final determinations to any other body.

i. Other Review Organizations within Utah State University.

(1) The IRB may require that proposed research be reviewed and approved by USU’s Radiation Safety Committee, Bio-Hazard Committee, Institutional Bio-safety Committee, Conflict of
Interest Committee and/or other relevant committees of USU, or of collaborating institutions.

(2) The IRB must report any serious unanticipated problems involving risks to participants to the Vice President for Research, and to any applicable sponsors or agencies.

(3) All persons conducting research within USU, and all persons acting as employees or agents of USU regardless of location, must comply with all requirements of the Human Research Protection Program and the instructions of the IRB in the conduct of human research. Such persons must provide the IRB with copies of any reports or correspondence to or from any regulatory or compliance enforcement federal agency such as OHRP, that exercises oversight over the protection of human participants in research in which they are involved.

j. Responsibilities to Regulatory Agencies.

The IRB complies with the requirements of all relevant regulatory and compliance enforcement agencies or offices, including OHRP. Copies of any reports or correspondence to or from such agencies concerning the following topic areas shall be processed in accordance with Chapter 16.

k. Researcher Non-compliance: Allegations, Investigation, and Disposition.

Non-compliance is any situation, incident, or process during the conduct of human subjects research that is inconsistent with any of the following: applicable local, state, or federal law; USU Policies; IRB SOPs; approved IRB protocols; or any directive from the USU IRB. Non-compliance may be minor and/or infrequent, or serious and/or continuing.

Serious Non-compliance is any non-compliance which, in the judgment of the IRB Chair or convened IRB, places human subjects at elevated or unreasonable risk; decreases potential benefits to participants; jeopardizes the safety, welfare, or rights of research participants or others; compromises the integrity of the human research protection program; or compromises a research participant’s ability to render informed consent.

Continuing Non-Compliance is any action or omission which, in the judgment of the IRB Chair or convened IRB, demonstrates a pattern of non-compliance over time, and/or across research projects. Such a pattern suggests that the likelihood of non-compliance will continue without intervention.

Reporting & Receiving Allegations of Non-Compliance

When any Utah State University employee or affiliate receives information related to non-compliance and those activities appear to be related to research being conducted by USU personnel or under USU’s purview, those allegations shall promptly be reported to the IRB Staff, Director, or Chair. All allegations of non-compliance received by someone other than the IRB Chair shall be expeditiously reported to the IRB Chair.

The IRB Chair shall receive the non-compliance allegation and, using the information available, make an initial determination of whether (a) the activities constitute human subjects research; and if so (b) whether the substance of the allegation is likely to constitute serious or continuing non-compliance. The IRB Chair may also determine that the activities described in the allegation do not constitute human subjects research non-compliance.

Utah State University does not tolerate retaliation against individuals who come forward in good faith with allegations of non-compliance. Retaliation will be immediately reported to University administration.
Suspension of Research Pending Disposition
The IRB Chair or Institutional Official may take action to suspend the research that is the subject of the non-compliance allegation, pending a formal inquiry and/or determinations by the convened IRB. The IRB Chair or Institutional Official may suspend the research if:

(a) the activities appear to be human subjects research; and

(b) the alleged non-compliance appears to raise the level of risk to the research participants.
Suspension of research should not be implemented if the suspension would cause new or increased risks to participants.

Processing Allegations of Non-Compliance
After the IRB Chair has received the allegation of non-compliance and made the initial determinations described in Section II.B.10.ii, the IRB Chair shall determine:

(a) That sufficient information exists to find that no human subjects research non-compliance has occurred;

(b) That sufficient information exists to find that the non-compliance is not serious or continuing, and develop a corrective action plan for the Principal Investigator;

(c) That more information is needed before findings can be made regarding whether the allegations constitute serious or continuing non-compliance and refer the matter for further inquiry;

(d) That sufficient information exists to find serious or continuing non-compliance and refer the matter for investigation; and/or

(e) That the allegation is sufficiently serious to be turned over to the Institutional Official, cognizant dean, and/or department head for immediate action.

If the IRB Chair determines that the matter should be referred for further inquiry or investigation as described in Sections (c) or (d), above, the IRB Chair shall refer the matter to the Office of Compliance Assistance. When an investigation is requested, the Office of Compliance Assistance shall, in consultation with the Institutional Official or designee, and IRB Chair, identify appropriate membership of the investigative team, which may consist solely of the Federal Compliance Manager. Inquiries shall be conducted by the Federal Compliance Manager, and findings regarding whether an investigation is warranted will be reported to the IRB Chair for further action.

Except when suspension of the research is appropriate under Section II.B.10.iii, the Principal Investigator should not be contacted until the inquiry or investigative team has had an opportunity to sequester documents related to the alleged non-compliant research activities.

Investigations shall be carried out expeditiously and thoroughly, using approved IRB forms and processes. Utah State University’s Scientific Misconduct Guidelines should serve as guidance for carrying out the investigation, especially as to procedures for conducting interviews, appropriate evidentiary standards, standards for notifying parties, and other procedural issues.

During the course of the investigation, additional areas of non-compliance may be uncovered; those areas of non-compliance should be investigated alongside the initial allegations. Investigative findings reported to the convened IRB should include, but are not limited to:

(a) Findings of fact surrounding each allegation;

(b) Any material findings which are inconclusive or where conflicting information is present;

(c) The extent to which research activities were aligned with the approved protocol, if one existed; and

(d) Recommendations to the convened IRB regarding:
   a. Whether the non-compliance is serious or continuing;
b. Whether the non-compliance was willful, knowing, or reckless; and

c. An appropriate corrective action plan.

If an investigation or inquiry uncovers areas of non-compliance that are outside of the purview of the IRB (e.g. is not human subjects research non-compliance), the investigating party shall promptly refer those areas of concern to the appropriate federal or state agencies or administrative unit, and the investigations should be coordinated so as not to hinder any aspect of each investigation.

When the investigation is complete, the parties under investigation shall be made aware of the investigation (if they have not been made aware during the course of the investigation) and preliminary findings. They shall be given an opportunity to respond, in writing, to the allegations and preliminary findings of the investigation prior to the convened IRB meeting where the matter will be presented.

Convened IRB Non-compliance Review
The convened Utah State University Institutional Review Board shall, based on the findings provided by the investigative team and materials provided by the investigator(s), make the final determination of whether the allegations of non-compliance constitute non-compliance, and if so

(a) Whether the non-compliance is serious; and/or

(b) Whether the non-compliance is continuing.

The investigators about whom the allegations pertain shall be notified in writing of the IRB’s determinations regarding the existence and nature of non-compliance. If the non-compliance is not serious or continuing, it shall be handled as outlined in section iv.(b), above. If serious or continuing non-compliance is present, the IRB shall also notify the cognizant Dean and Department Head, as well as the Institutional Official, Associate Vice President for Research, and any other party the IRB deems appropriate (e.g. participants, research staff, etc.). Sponsor notifications are addressed in section viii, below. All notifications should be delivered only after the timeframe for notice of appeal, outlined in section vii below, has passed.

Corrective Action
If the convened Institutional Review Board finds non-compliance, it shall require a corrective action plan. Such plans may include, but are not limited to:

(a) Referral to the IRB Chair and Director for minor corrective action in cases of minor non-compliance;

(b) Referral to the investigator for a proposed corrective action plan;

(c) Temporary suspension of the protocol pending further corrective action;

(d) Temporary suspension of enrollment of new participants pending further corrective action;

(e) Termination of a protocol or all human subjects research activity related to the non-compliance;

(f) Destruction or sequestration of data;

(g) Mandated additional training in the protection of human subjects in research for investigators and research staff;

(h) Required supervision of the research or investigator by a qualified mentor;

(i) Suspension of the individual investigator(s) or staff responsible for the non-compliance from the research activities;

(j) Recommend Suspension or termination of the investigator’s ability to conduct human subjects research;

(k) Notification to research participants of the non-compliance;

(l) Required modifications to the protocol and accompanying documents;

(m) Mandated process for obtaining informed consent again;
(n) More frequent review of one or more of the non-compliant investigator’s protocols;
(o) IRB or third party monitoring of the consent process;
(p) IRB or third party monitoring of the data collection process;
(q) IRB or third party monitoring of data storage and maintenance; and
(r) Recommendation of further action by the Vice President for Research, Dean, Department Head, or Tenure and Promotion Committee, which may include but is not limited to:
   a. Retraction of published or presented work related to the non-compliant research;
   b. Retraction of submitted work related to the non-compliant research;
   c. A letter of reprimand to be placed in the investigator’s or student’s file;
   d. Reporting to the appropriate professional organization regarding the non-compliant behavior of a member.

At all times, the IRB shall act in accordance with its ethical and legal mandate to ensure the protection of human subjects participating in research.

Appeals Process
An investigator wishing to appeal the determination of non-compliance rendered by the convened IRB must notify the IRB Director and Chair of their intent to appeal within five (5) business days of receipt of the written determination. An appeal must be submitted to the IRB Office in writing within ten (10) business days of receipt of the written determination, and will be reviewed at the next convened IRB meeting.

The written appeal must clearly present:
   (a) Which finding(s) of the convened IRB are being disputed;
   (b) All evidence supporting the investigator’s claim that the finding(s) should be overturned; and
   (c) All relevant reasoning supporting the investigator’s claim that the finding(s) and determination(s) should be overturned.

The corrective action plan is not subject to appeal, but will be reconsidered in the event of a successful appeal. The IRB shall notify the investigator and all relevant parties of the outcome of the appeal.

Reporting Non-compliance
In addition to the notifications detailed throughout this Section, in accordance with USU’s Federal Wide Assurance (FWA), USU must promptly report non-compliance with the governing regulations to the Office of Human Research Protections or other cognizant agency within a “reasonable timeframe after discovery.” Federal law and USU Policy requires that any funded research found to be in serious or continuing non-compliance must be reported to the funding sponsor. Reporting shall be completed within 30 days of the convened IRB’s determination or within 30 days of the outcome of the appeal, whichever is later.

I. Responsibility for Human Participant Protection Education Program.
The IRB requires education about human participant protections for research investigators, members of the IRB, and IRB administrators, and has overall responsibility for developing and implementing this education plan in conjunction with USU’s Office of Compliance Assistance. The IRB Chair and Director work in collaboration with the OCA in carrying out their responsibility for education plans. Training records are accurately maintained in the IRB Office.

m. Increasing Level of Understanding and Compliance.
During the process of reviewing, amending, and approving research studies, the IRB Director and chair shall monitor interactions with Investigators to ensure that they correctly understand and are applying principles and procedures that protect the rights and welfare of participants, and that the
Principal Investigator identified for the study provides substantive direction to all personnel under his/her supervision. The Director and chair shall identify:

1. Instances in which individual investigators fail to provide for adequate protection of participants;
2. Instances in which the designated PI is not providing adequate control to ensure compliance with regulations, policies and procedures and appropriate protection of the rights and welfare of participants;
3. Patterns of repeated non-compliance or misunderstanding of principles or procedures by investigators leading to failure to provide adequate protection of participants; or
4. Patterns among the population of USU investigators indicating a broad misunderstanding of principles or procedures designed to protect participants.

When such instances and patterns are identified, the Director and chair shall, in cooperation with the PI, provide appropriate training to individuals as needed to ensure an understanding of, and compliance with, established policies and procedures. If the patterns indicate the need for departmental, college or campus-wide training, the chair and Director shall work with the FCM to provide for appropriate interventions to ensure the safety and welfare of research participants.

Failure on the part of an investigator to comply with, or to show adequate understanding of, policies and procedures related to the protection of human participants shall be grounds for restricting individuals from proposing human research, or for suspending or terminating human research.

n. Determining Adequacy of USU’s Human Participant Outreach Program and Other Aspects of the HRPP.

At each regular review the Human Participant Outreach Program shall be evaluated to make certain that the web-based outreach tools are being appropriately maintained and that other aspects of the program provide prospective participants with adequate information to make a decision concerning their participation, or the participation of their children in USU research. Elements to be considered include education programs, availability of brochures and other informational publications, public relations activities and speaking engagements.

During the review, institutional commitments shall also be assessed, using the AAHRPP Domain I standards and elements as a guide for discussion and deliberation.

Other aspects of the sufficiency of the HRPP are considered as outlined in Section D of the HRPP Annual Review Checklist. During the review institutional commitments shall be assessed, using the AAHRPP Domain I standards and elements as a guide for discussion and deliberation. Any weaknesses that have been identified during the year through review, self-assessment, investigative activities or interactions with researchers, research staff or participants will be reviewed to identify opportunities for improvement.

o. Human Research Quality Improvement Program

The IRB is authorized to observe the consent process and other aspects of research, including interactions and interventions with participants, data security measures, and similar research-related activities. Such monitoring may be employed whenever the IRB deems that it would increase the safety of research participants, either as part of a quality improvement program or on a case-by-case basis. Quality improvement monitoring will be focused on research involving greater than minimal risk, and studies to be monitored and frequency of monitoring shall be determined by the IRB chair.

Whenever a study is chosen for monitoring the IRB Director or designee will review the complete protocol file, in addition to assigning an individual to observe the research or consent process. Prior to observations, the IRB Director or designee will contact the investigator and indicate the activities
The summary report is reviewed with the investigator. The investigator may discuss with the IRB representative any problems s/he has with the report and add comments before the report is finalized. When indicated, the PI will be invited to create a corrective action plan. The summary report, the observation report form, and any corrective action shall be included in the protocol file. The IRB Director and Chair shall review each report, evaluate the need for follow-up, and refer the report to a member of the IRB staff to verify that any issues raised have been resolved and that all corrective actions have been taken.

At least annually the IRB Director will present the monitoring activities under the quality improvement program at a regularly scheduled IRB Meeting. Findings in the summary reports, issues raised through the monitoring process and resolution of corrective action plans shall be discussed. Appropriate modifications to IRB procedures, improvement initiatives and additional training to be introduced shall be discussed and approved by the IRB.

Chapter 6: Institutional Review Board Membership
The Institutional Review Board (IRB) shall have sufficient expertise to review the broad variety of research in which USU commonly becomes involved, shall be knowledgeable about all relevant regulatory requirements, and strive to remain impartial and objective in its reviews.

a. Appointing Members to the Institutional Review Board.
The Common Rule requires that the IRB be comprised of at least five members, with at least one non-scientist and at least one non-affiliated member (defined as a person who has no affiliation with the institution except as a member of the IRB). If research is conducted with prisoners, a prisoner representative must be included on the IRB when such research is under consideration. USU seeks to maintain membership on the IRB that represents a balance of individuals with expertise in research areas commonly pursued at USU. In addition, the IRB shall include at least one individual who represents the interests and general perspective of research participants. Individuals are appointed to the IRB by the Institutional Official (IO). The following criteria are applied when considering prospective members of the IRB:
(1) **For scientist members:**
   
   (a) The individual shall be an established scientist with substantial experience in conducting human research in a discipline commonly practiced at USU.
   
   (b) The individual shall have demonstrated an understanding of the purposes and operations associated with USU’s Human Research Protection Program, and shall have demonstrated an understanding of the Common Rule and USU’s policies and procedures with respect to designing, receiving approval for, and conducting human research.
   
   (c) The individual shall have demonstrated exemplary performance with regard to ethical treatment of research participants and others involved in human research.
   
   (d) The individual shall be available to participate in IRB activities on a regular basis, including attendance at scheduled IRB meetings.

(2) **For non-scientist members:**
   
   (a) The individual shall be in a position to understand and represent the interests of some sector or sectors of USU’s research participant population.
   
   (b) The individual shall demonstrate, through interviews and/or previous experience, that s/he is capable of applying ethical principles to situations involving research participants.
   
   (c) The individual shall be available to participate in IRB activities on a regular basis, including attendance at scheduled IRB meetings.

The Institutional Official shall consider vacancies created in the IRB based on the profiles of individuals leaving the IRB and on the nature of the human research being performed at USU. Suggestions for prospective members may be sought from the IRB chair, the IRB administrator, current and former members of the IRB or members of the community in a position to identify appropriate individuals. Public solicitation for members may also be made at the discretion of the IO.

Upon identification of appropriate candidates for membership, the IO shall conduct interviews with individuals to ascertain their appropriateness for appointment, based on the above criteria as reflected in the “Member Expectations” document. During the interview, the IO shall explore with the prospective member the requirements of the position and ascertain the individual’s interest and ability to fulfill those requirements. **No individuals with oversight of university business interests shall be appointed to the IRB.**

Terms for members shall normally be a period of three years, and may be renewed indefinitely as mutually agreed by the IO and the member. Renewal of a member’s term should be discussed with and approved by the IRB Chair, and notification of the renewal made by the IO.

b. **Responsibilities and Duties.**
   
   IRB members are responsible for ensuring that the rights and welfare of research participants are protected. Members vote to approve, require modifications in, disapprove, or defer research submitted to the IRB. Members attend IRB meetings on a regular basis, serve as reviewers for research within their areas of expertise, as well as serve as general reviewers on all research discussed at convened meetings. Members may also be asked to conduct expedited reviews when so designated by the IRB Chairperson. Members may be asked to participate in other subcommittees, ad hoc committees, and educational events, as long as there is no conflict of interest with the IRB responsibilities. The IO or IO’s designee reviews with each prospective member the responsibilities of IRB membership, using the IRB Member Responsibilities Agreement, at the beginning of each term. By signing the form, members acknowledge their understanding of the requirements of the position.

c. **Members Approved to Perform Expedited Reviews**
When a protocol may be reviewed under expedited procedures, the IRB chair shall have the
discretion to determine which members of the IRB are qualified to perform reviews independently. A
list, which shall be reviewed and updated by the Chair at least annually, shall list members judged by
the chair to be qualified to independently perform protocol reviews (as set forth in Chapter 9.f), and
disciplinary areas for which each listed member is approved to perform expedited reviews.

Criteria used by the chair in choosing IRB members for the list shall include: knowledge of
regulations, guidance and policies governing human research and IRB review; established expertise as
a reviewer as demonstrated in performance of IRB duties; and demonstrated expertise in disciplinary
fields in which they have been formally trained.

d. Appointment of IRB Chair, Length of Service, and Duties.
The IRB Chair is formally appointed by the IO or IO’s designee. The Chair serves 3-year terms and may
be reappointed. In addition to the responsibilities of IRB membership, the Chair has primary
responsibility for conducting IRB meetings and directing the IRB Director and staff to ensure
operation of the IRB within all applicable regulatory requirements. The IRB Chair works with IRB
members, institutional officials, and investigators to ensure that the rights and welfare of research
participants are adequately protected. As a fair and impartial committee head, the Chair functions as
a role model for how IRB business should be conducted.
On an annual basis, and in conjunction with the Annual Review of the HRPP, the IRB Chair’s
performance shall be evaluated by the IO and others as determined by the IO. The IO and/or the IO’s
designee shall meet with the Chair to provide feedback concerning the Chair’s performance and to
discuss ways to improve IRB performance.

e. Alternate IRB Members.
The IO may appoint one or more alternate members to replace regular IRB members who are, on
occasion, unable to attend convened IRB meetings. Alternate members must be listed on the IRB’s
official membership roster, which must specify which member (or members) the alternate is qualified
to replace. The backgrounds of alternate members should be similar to the member they are replacing or they should be able to represent similar interests. Terms of appointment, length of
service, and duties are exactly as for regular IRB members.
(Note: Although an alternate may be qualified to replace more than one regular member, only one
such member may be represented by the alternate at any convened meeting.)

f. Consultants.
On an as-needed basis the IRB or IRB Director may invite individuals with competence in special areas
to assist in the review of issues that require expertise beyond or in addition to that available on the
IRB for any type of IRB protocol review. These individuals may not vote with the IRB or approve a
protocol. The IRB Chair shall be given the curriculum vitae or qualifications of the consultant in order
to evaluate the weight to be given to the consultant’s recommendations during protocol review.
 Consultants shall complete a Conflict of Interest Disclosure from the IRB Chair, and the disclosure
must indicate that the consultant will have no conflict of interest related to the study to be reviewed.
Selection of consultants shall be as indicated in Chapter 9.c, below.

g. Independent IRB Review.
The IRB Chair may seek an appropriate independent IRB to review a protocol if USU’s IRB lacks
diversity in areas of race, gender, and cultural backgrounds, as well as sensitivity to issues in
community attitudes (45 CFR 46.107(a)), or if USU’s IRB lacks expertise in the type of research to be
reviewed, or if such use is necessary to ensure timely review of a study. An independent IRB will be
selected based on its expertise and knowledge in relation to the research to be reviewed.
h. **IRB Membership Requirements.**

In compliance with the Common Rule, the composition of the IRB must satisfy the following requirements:

1. At least one IRB member shall be a non-scientist.
2. IRB members shall possess varying professional backgrounds to promote complete and adequate review of research activities commonly conducted at USU.
3. The IRB shall include at least one member whose primary concerns are in non-scientific areas.
4. The IRB shall have at least one member whose primary concerns are in non-scientific areas. One non-scientific) member must always be present to have a quorum.
5. The IRB shall include at least one member who is not otherwise affiliated with USU and who is not part of the immediate family of a person who is affiliated with USU.
6. IRB members shall be sufficiently diverse relative to race, gender, cultural background, and sensitivity to community attitudes so as to promote respect for the IRB’s advice and counsel in safeguarding the rights and welfare of human participants.
7. IRB members shall include persons able to ascertain the acceptability of proposed research in terms of institutional commitments, regulations, applicable law, and standards of professional conduct and practice.

*Note: The regulations require an unaffiliated member and a non-scientific member. The positions are frequently filled by one individual, but that may not always be the case.*

i. **Determining Adequacy of the Membership of the IRB.**

On a regular basis, at least annually, the IO, the IRB Chair, the IRB Administrator and others as shall be determined by the IO, shall review the composition of the IRB to evaluate its sufficiency with regard to regulations at 45 CFR 46.107 and USU’s policies and procedures. The IRB’s adequacy shall also be reviewed with regard to USU’s human research portfolio. During this review the following determinations shall be made:

1. Whether an adequate number of members is included on the IRB to meet regulatory requirements and provide an appropriate level of deliberation for research protocols being presented.
2. Whether the IRB has sufficient membership and membership diversity to “promote complete and adequate review of research activities commonly conducted by” USU.
3. Whether the amount of research conducted has grown such that an additional IRB must be established, or the existing IRB must be expanded, in order to meet the demand for timely review.
4. Whether new types of research are being undertaken by USU investigators, requiring the addition of members with expertise in the new disciplines.
5. Whether USU is regularly conducting research with vulnerable categories of participants, so that consideration should be given to including individuals knowledgeable about and experienced in working with those populations.
6. Whether the scientific membership of the IRB appropriately reflects the types of human research being conducted at USU.
7. Whether the non-scientific and non-affiliated membership of the IRB appropriately reflects the make-up of the research participant population at USU.
8. Whether the IRB is competent to “ascertain the acceptability of research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.”
(9) An appropriate prisoner advocate is included on the IRB in order to be able to review human research involving prisoners.

(10) That current members of the IRB have an understanding of their specific role on the IRB and are participating and performing adequately in their roles. During the review, the IO and Chair shall discuss appropriate feedback to be shared with IRB members, and discuss any necessary training interventions than may further improve the IRB.

Note: The HRPP Annual Review Form and Checklist shall be used to ensure that each area of concern has been addressed.

j. Conflict of Interest.

No IRB member may participate in the IRB’s initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. For example, an IRB member may also be a Principal Investigator for a study being reviewed by the IRB. Another example would be a member having a financial interest in a study being reviewed. IRB members, including the Chair, who have conflicting interests, are required to disclose such interests and to absent themselves from deliberations, quorum counts, and votes on the relevant protocol. Such absences are recorded in the meeting’s minutes as absences, or as “excused”, not as abstentions. The IRB must be careful to maintain a quorum if votes are taken during absences.

k. Determining COIs among IRB Members.

Each member of the IRB is responsible for reviewing the IRB packet distributed on a monthly basis by the IRB Office. The member’s review of the packet provides an opportunity to identify any conflict of interest that the member is aware of.

At the beginning of each convened meeting of the IRB, members shall be reminded of the statutes and policies governing conflicts of interest, and shall be asked by the Chair or Administrator (or designated alternate) to disclose any conflicts before deliberations on projects to be reviewed during the meeting. Conflicts may be financial or non-financial in nature. Financial conflicts might include consulting with or holding equity in a company that will sponsor a project to be reviewed. Non-financial conflicts are often relational in nature. For example, an student investigator for whom the IRB member serves on the individual’s thesis committee, or the investigator is a close relative, spouse or partner of the member.

In addition, the agenda for each meeting shall contain the following statement as a reminder to members regarding disclosure of conflicts of interest:

“If you have a conflict of interest regarding any protocol to be reviewed during this meeting, you should disclose your conflict and recuse yourself from deliberations and voting on each project for which you have a conflict. You may be present and answer questions posed by members of the IRB, but you may not vote on any project in which you have a conflict of interest. Conflicts may include, among others, participation as an investigator or mentor in a project, sponsorship in your own lab by an industrial sponsor of a protocol, or sponsorship by a competitor of a protocol’s sponsor.”

The IRB Reviewer Checklist shall also contain a similar statement, allowing a member to disclose any conflict of interest that would preclude her/him from reviewing the protocol.

l. Initial Training, Continuing Education, and Professional Development of IRB Members.

The terms of the Federal-Wide Assurance (FWA) specify that the IRB is required to have a plan to provide education about human research protections for IRB members.
The USU IRB members receive comprehensive reference materials (including these SOPs) necessary to review research from an ethical and regulatory perspective. All members complete the educational modules available on the CITI website, or comparable training. Members are provided with continuing education opportunities within the institution or at neighboring institutions, and resources are made available each fiscal year for one or more IRB members to attend national or regional human subject protection meetings (i.e. PRIM&R/ARENA Annual Conference). Members also receive continuing education materials at regularly held IRB meetings.

The Federal Compliance Manager (FCM) shall have responsibility for delivery of in-service training to members of the IRB. This training shall build upon the basic and recertification training required of members through the CITI Human Research Protection training modules. The following elements may be included in training of IRB members, which shall take place in regularly scheduled IRB meetings, or in special training meetings as may be convened by the IRB Chair:

1. Ethical decision-making
2. Problems with special populations (including vulnerable populations)
3. Privacy issues
4. New or changed criteria or guidance from federal agencies
5. Review of regulations, policies and procedures
6. Conflicts of interest

Training may be delivered in several formats, including:

1. Video productions,
2. Written materials,
3. Updates of human research protection regulations, or
4. Case studies.

The topics, content and method of delivery of training shall be coordinated between the IRB Chair and the FCM. Such training shall be conducted no less than annually.

m. Training of IRB Members for Equitable Selection of Participants.

In addition to required CITI training, the IRB Chair, Administrator or the FCM shall provide training for prospective and existing members of the IRB regarding the equitable selection of participants for research. Such supplementary materials may be delivered at regular meetings of the IRB, in one-on-one meetings, such as new member orientations, or in specially called meetings held either in person or by teleconference. Materials specific to equitable participant selection may also be distributed separately, or as part of the IRB review packet.

Sufficient training shall be provided such that each member of the IRB is competent to determine whether a study within their own disciplinary field meets the regulatory requirement for equitable selection and the foundation principle of justice. Specific objectives of training shall be that members are familiar with and can apply the concepts of:

1. Choosing a study population that is reasonably related to the purpose of the research;
2. Soliciting participation in ways that will provide representative selection among the population;
3. Identifying inclusion and exclusion criteria that do not unnecessarily exclude participants based on gender, race, socioeconomic status, or other differentiators unrelated to the study;
4. Providing safeguards against the inclusion of participants based on convenience;
(5) Providing safeguards against the exclusion of participants when subpopulations they represent could be benefited by inclusion.

Review and discussion of Chapter 5-3, “The Study Population: Women, Minorities and Children” in *Institutional Review Board Management and Function* (Bankert and Amdur, 2006), or other similar materials, could be employed to fulfill this requirement.

n. **Compensation of IRB Members.**

USU generally does not provide monetary compensation to USU employees or non-affiliated members for their service on the IRB. However, it is acknowledged that service on the IRB requires a significant investment of time for all IRB members and especially for IRB Chairs. The IRB Chair shall, on an annual basis, provide each IRB member with a formal letter, to be included in the individual’s personnel file, describing the critical importance and extremely time-consuming nature of their IRB service. IRB members who are not otherwise affiliated with USU are compensated for their service by having all travel costs paid by the university for on-going training. When USU employees serve as IRB members they may be reimbursed only if the IRB meetings take place outside normal duty hours, for example, in the evening, or at a site away from campus.

o. **Liability Coverage.**

IRB appointees acting within the scope of their authority of appointment are protected under the Utah Governmental Immunities Act except in cases of intentional or grossly negligent misconduct.
Chapter 7: Institutional Review Board (IRB) Administrative Support

The Common Rule requires that USU’s Institutional Review Board be provided with sufficient meeting space and staff to support the IRB’s review and recordkeeping responsibilities.

a. Determining Adequacy of Resources for the IRB
The Vice President for Research, as USU’s Institutional Official (IO), is ultimately responsible for ensuring the protection of human participants in any USU research program. At each regular review of the HRPP the human resource and budgetary needs of the IRB shall be considered. Based on a budget presented by the IRB, the IO shall direct adequate resources to the IRB to ensure its ability to carry out its duties in the protection of human participants. The HRPP Annual Review Form & Checklist, Section B, shall be used to make this determination. In consultation together, the IRB Chair, director, staff, and USU’s administration consider processes, workloads, outreach activities and other commitments. Based on this assessment, workloads may be adjusted for the IRB based on human resource allocations, adjusting technical support, or adjusting the types of projects to be reviewed by the IRB. If a limitation of study types is made, adequate measures shall be taken to provide for the use of a qualified outside review unit to provide review as directed by the IRB chair.

The regulatory requirements for records and documentation of the IRB’s actions are such that there shall be at least one full-time staff person with clear responsibility for the overall operations of the IRB.

b. Reporting Lines and Supervision
The IO or the IO’s designee appoints the IRB Director and other staff members. The IRB Director reports to and is supervised by the Associate Vice President for Research, but takes daily direction from the IRB Chairperson. The IRB Director is jointly evaluated by the Associate Vice President for Research and the IRB Chairperson, as outlined in Chapter 4. All other IRB staff report to, are supervised by, and take direction from the IRB Director.

c. Initial Training, Continuing Education, and Professional Development of IRB Staff
The IRB requires continuing education in human participant protections for IRB staff per the terms and conditions of the FWA. All IRB staff must complete the designated educational modules available at the CITI website. This training acquaints them with their responsibilities under the FWA and with the role of the IRB within USU’s HRPP. Other education and training are also required as set forth in Chapter 8.

d. IRB Director Duties
The duties of the IRB Director are defined in a suitable Position Description and career ladder document and shall include responsibility for:

(1) Directing and overseeing all IRB support functions and operations
(2) Serving as a member of the IRB
(3) Developing and implementing procedures to effect efficient document flow and maintenance of all IRB records
(4) Approving exemptions on behalf of the IRB Chairperson or designated staff.
(5) Facilitating and participating in review of expedited protocols and reporting to the IRB.

e. IRB Office Functions
The Director, or an appropriate staff person under the Director’s supervision, shall:
(1) Maintain the official roster of current IRB members on the IRB web page, with contact information and length of IRB term.

(2) Maintain Curricula Vitae or resumes within the IRB Office for each current member of the IRB.

(3) Conduct a review, together with the IO and IRB Chair, of the IRB membership and the composition of the IRB at least annually in order to maintain a diverse spectrum of qualified individuals and to adjust the membership and composition to meet organizational and regulatory requirements.

(4) Schedule IRB meetings.

(5) Distribute pre-meeting materials.

(6) Compile the minutes of IRB meetings in compliance with regulatory requirements as outlined in Chapter 8.

(7) Promptly report changes in IRB membership to the Office for Human Research Protections (OHRP).

(8) Maintain all IRB documentation and records in accordance with regulatory requirements.

(9) Ensure that all IRB records are secured and properly archived.

(10) Facilitate communication between investigators and the IRB.

(11) Track the progress of each research protocol submitted to the IRB.

(12) Maintain a computerized database for tracking purposes.

(13) Serve as a resource for investigators on general regulatory information, and provide guidance about forms and submission procedures.

(14) Maintain training documentation and reference materials related to human participant protection requirements.

(15) Maintain and update the IRB Investigators’ Handbook and IRB forms.

(16) Draft reports and correspondence to investigators on behalf of the IRB or IRB Chair regarding the status of the research, including conditions for approval of research and reporting and resolution of adverse events or unanticipated problems.

(17) Draft reports and correspondence directed to research facility officials, federal officials, and others on behalf of the IRB or IRB Chairperson.

(18) Assist in evaluation, audit, and monitoring of human research as directed by the IRB and the IO.

(19) Maintain and update manuals and Standard Operating Procedures.

(20) Assist with Accreditation Visits.

(21) Coordinate and assist during regulatory inspections and site visits.

The IRB Director is responsible for ensuring that documentation of IRB activities and decisions fully satisfies all regulatory requirements. The IRB Director should have a detailed, working knowledge of relevant regulatory requirements.

f. IRB Staff Duties

IRB staff support the function and operation of the IRB at the direction and under the supervision of the IRB Director.
Chapter 8: IRB Recordkeeping and Required Documentation

The Common Rule requires written policies and procedures to govern the operations and direct the activities of the IRB and the HRPP. These IRB Standard Operating Procedures (SOPs) satisfy this requirement when these procedures are implemented by the institution. Recordkeeping and documentation requirements for IRB operations are as follows:

a. Retention of IRB Documents

Retention of some records is required by 45 CFR 46 for a period of three years after a research project is completed. USU retains the following documents in accordance with this requirement:

1. IRB applications
2. Informed Consent documents
3. DHHS approved sample consent document, if one exists
4. Proposals, or Certifications of Consistency (as part of the Investigator Assurance)
5. DHHS approved protocol, if one exists (usually for multi-site studies)
6. Copies of advertisements
7. Copies of recruitment materials
8. Minutes of convened IRB meetings
9. Documents provided to the IRB for protocol reviews during convened meetings
10. Scientific evaluations, including the “Scientific Validity Review Checklist,” when available
11. For initial and continuing review of research by the expedited procedure:
   - The specific permissible category
   - Description of action taken by reviewer
   - Any findings required under the regulations.
12. For exemption determinations, the specific category of exemption.
13. Unless documented in the IRB minutes, determinations required by the regulations and protocol-specific findings supporting those determinations for:
   - Waiver or alteration of the consent process
   - Research involving pregnant women, fetuses and neonates.
   - Research involving prisoners
   - Research involving children
14. All correspondence between the IRB and the investigators
15. For each protocol’s initial and continuing review, the frequency for the next continuing review.
16. Continuing review applications
17. Records of continuing review activities
18. Statements of significant new findings provided to participants
19. Amendments
20. Reports of unanticipated problems and serious or ongoing non-compliance
21. Reports of injuries to participants
22. Correspondence with government officials concerning unanticipated problems
23. Correspondence with government officials that could reasonably be expected to affect the status of USU’s FWA.
Documents may be retained longer as required by other federal or state laws or regulations, or as directed in University policy.

Final disposition of documents shall take place based on retention as set forth above. Documents shall be destroyed after that date.

b. Access to IRB Records
All IRB records shall be kept secure in locked filing cabinets or locked storage rooms, or on a secure server. Ordinarily, access to IRB records is limited to the IO, the IRB Chairperson, IRB members, IRB Director, IRB staff, authorized USU representatives, and officials of Federal and state regulatory agencies, including the Office for Human Research Protections (OHRP). Research investigators shall be provided reasonable access to files related to their research. All other access to IRB records is limited to those who have legitimate need for them, as determined by the IRB Chairperson, the Federal Compliance Manager, General Counsel and the IO. Appropriate accreditation bodies shall be provided access as needed to assess the HRPP.

c. IRB Records
Generally, IRB records shall include files organized into the following categories:

1. Written standard operating procedures
2. IRB membership rosters (See subsection d, below)
3. Training records (See subsection e, below)
4. IRB correspondence (other than protocol-related) (See subsection f, below)
5. IRB research application (protocol) files (See subsection g, below)
6. Research (protocol) tracking system (See subsection h, below)
7. Documentation of exemptions and exceptions (See subsection i, below)
8. Documentation of expedited reviews (See subsection j, below)
9. Documentation of convened IRB meetings – minutes (See subsection k, below)
10. Documentation of review by another institution’s IRB when appropriate
11. Documentation of cooperative review agreements, e.g., Memoranda of Understanding (MOUs) for multi-site research, or as otherwise appropriate
12. Federal Wide Assurances (FWA)
13. Project tracking documents from automated system

d. IRB Membership Rosters
The IRB Director shall ensure that a current IRB membership roster is maintained and that any changes in IRB membership are reported promptly by the IRB Director to OHRP. All IRB membership rosters shall include the following information required by OHRP:

1. Names of IRB members.
2. Names of alternate members and the corresponding regular member(s) for whom each alternate may serve.
3. Earned degrees of each member and alternate, where applicable.
4. Specific scientific qualifications (such as board certifications and licenses) or other relevant experience sufficient to describe each member’s chief anticipated contribution to IRB deliberations.
5. Status of each member as a scientific or non-scientific member.
(6) The representative capacity of each member or alternate.

(7) The affiliation status of each member, indicating whether the member, or any immediate family member of the IRB member is affiliated with USU.

Any employment or other relationship with USU or with USU’s collaborating institutions (e.g., full or part time employee, stockholder, member of governing board, paid or unpaid consultant).

e. Education and Training Records

The IRB requires a plan for continuing education in human research protections for investigators. The terms of the FWA also require continuing education for IRB members.

All investigators engaged in Human Research at USU must complete training. The training must have a post-test capability, and the investigator must receive a certificate of completion. Training available through CITI shall be considered adequate for fulfillment of the training requirement. IRB members and staff must complete the initial educational modules available at CITI, or comparable training as approved by the IRB Chair and Administrator. Additional campus training is provided from time to time on topics as determined by the IRB Chair and Director.

The IRB Director shall ensure that accurate records are maintained listing research investigators, IRB members, IRB staff who have fulfilled USU human research protection initial and continuing training requirements.

f. IRB Correspondence

The IRB Director shall ensure that accurate records are maintained of all correspondence to or from the IRB. This shall include correspondence in relation to reporting of unanticipated problems or serious or ongoing non-compliance to agencies as required under the FWA.

g. IRB Protocol Application Files

The IRB shall maintain a separate file for each research application (protocol) that it receives for review. Protocols will be numbered sequentially in the order in which they are initially received.

Each IRB research application (protocol) file will contain the following materials:

(1) The IRB Research (Protocol) Application Form.
(2) The IRB-approved informed consent document, with the approval date and dates of each change on the affected page.
(3) Scientific evaluations, if any, of the proposed research by university personnel, the IRB, or approved consultants.
(4) Applications for Federal or other support, if any.
(5) A complete copy of the protocol, or research plan, or investigational plan. (for projects which receive no direct funding, sponsor or cooperative group protocols).
(6) Advertising or recruiting materials, if any.
(7) Applications for protocol amendments or modifications.
(8) Continuing review status reports and related information.
(9) Reports of unanticipated problems involving risks to participants or others and of serious or ongoing non-compliance.
(10) Reports of unanticipated problems occurring within USU (or involving employees or agents of USU) and reported to any regulatory agency.
(11) Reports of external unanticipated problems or adverse events received from sponsors or cooperative groups.
(12) Data and Safety Monitoring Board (DSMB) reports, if any.
(13) Results of any internal quality control and monitoring activities.
(14) Results of any external monitoring activities, including reviews provided to the investigator by sponsors, cooperative groups, or Federal agencies.
(15) All IRB correspondence to or from research investigators.
(16) All other IRB correspondence related to the research.
(17) Documentation of all IRB review and approval actions, including initial and continuing convened (full) IRB review.
(18) Documentation of type of IRB review (exempt, expedited, or convened).
(19) Documentation of project closeout.

h. **IRB Protocol Tracking System**
   The IRB Director shall ensure the maintenance of a reliable, computerized research (protocol) tracking system.

   At a minimum, the system shall include the following information:
   
   (1) Title of the Research (Protocol)
   (2) Names of principal investigator and co-investigators where appropriate
   (3) Funding source (SPO control number is entered into categories: federal, state, and other. Unfunded projects are placed in the “none” category.)
   (4) Date of initial approval
   (5) Date of most recent continuing approval
   (6) End of current approval period
   (7) Type of review (expedited, convened review or exempt)
   (8) Current status (under review, approved, suspended, closed)

i. **Documentation of Exemptions**
   Investigators shall submit a request for exemption to the IRB Office via the Application for Exempt Research. Human research involving prisoners shall not be exempt. For all other studies, the IRB Chairperson has designated the IRB Director or designee to review the exempt status based on the categories listed in 45 CFR 46 and communicate that status in writing to the investigator. The exemption will be valid for three years from the date of certification and the study will be closed and archived thereafter. If the research will extend beyond three years, the PI must notify the IRB prior to the expiration date and submit a new application to continue the research.

   Documentation of verified exemptions consists of the reviewer’s written concurrence in the IRB Research Application File that the activity described in the investigator’s Application for Exempt Research satisfies the conditions of the cited exemption category. Categories of exempt research are stipulated in the Investigators’ Handbook and the Common Rule as follows:
   
   (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
   (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior,
unless: (a) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. (see exceptions below)

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2)(b) of this section, if: (a) The human subjects are elected or appointed public officials or candidates for public office; or (b) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects (see exceptions, below).

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (a) Public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs. For such projects:

• The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act).
• The research or demonstration project must be conducted pursuant to specific federal statutory authority.
• There must be no statutory requirement that the project be reviewed by an IRB.
• The project must not involve significant physical invasions or intrusions upon the privacy of participants.
• The exemption has authorization or concurrence by the funding agency.

(6) Taste and food quality evaluation and consumer acceptance studies, (a) if wholesome foods without additives are consumed or (b) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration (FDA) or approved by the Environmental Protection Agency (EPA) or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Exemptions are not available for all kinds of research (45 CFR 46.101(i)), as indicated below:

(1) No research involving prisoners may be exempted.
(2) Research that falls in category (2) may not be exempted when children are participants if the investigator will interact with the child. This applies to survey or interview research, or observations of public behavior; however, research that is limited to educational testing may be exempted if both federal and state FERPA and PPRA requirements have been met.
(3) Research falling in category (4) must involve only data that is in existence at the inception of the study, at the time that the research (protocol) application is filed.

j. Documentation of Expedited Reviews
Expeditied IRB review procedures may be employed only for:
(1) minor changes (See Chapter 9(f) for definition of minor change) in previously approved research during the specified approval period, or
(2) initial or continuing review of research falling within specific categories published in the Federal Register. Expedited reviews are conducted and approved by two IRB members (from the list of reviewers approved by the Chair as provided for in Chapter 6.a) who are designated at the Director’s discretion, based on the established list of reviewers pre-approved by the IRB Chair.

Documentation for expedited review and approval consists of the reviewer’s written concurrence in the IRB Application File that the activity described in the investigator’s Application for Expedited Review satisfies the conditions (1) for a minor change, or (2) involves minimal risk and is in a cited expedited review category in the Common Rule.

k. Documentation of Convened IRB Meetings in the Minutes
The minutes of IRB meetings shall be compiled by the IRB Director or other qualified IRB staff, following the IRB meeting minutes template. Minutes shall be distributed to members of the IRB and to the IO or IO’s designee following each meeting. Distribution to the IO or IO designee ensures that USU’s administration is aware of decisions and actions taken by the IRB. The following specific information shall be recorded in the meeting minutes:
(1) Attendance recorded by name
(2) Quorum requirements and how they have been met (See section m(1))
(3) All actions taken by the IRB, to include, for example, actions on the initial or continuing review of research; specific measures taken to protect vulnerable populations, for example, children and persons who have impaired decision-making ability; review of protocol or informed consent modifications or amendments; unanticipated problems involving risks to subjects or others; adverse event reports; reports from sponsors, cooperative groups, or DSMBs; reports of continuing non-compliance with the regulations or IRB determinations; waiver or alteration of elements of informed consent and associated justification; justification of any deletion or substantive modification of information concerning risks or alternative procedures contained in any DHHS-approved sample consent document; suspensions or terminations of research; and other actions
(4) Separate deliberations for each action
(5) Votes on these actions categorized by “for, against, abstain”
(6) The basis for requiring changes in or disapproving research. This information shall also be provided in writing to the investigator, who shall be given an opportunity to respond in person or in writing.
(7) Summary of controverted issues. The minutes must contain a written summary of all controverted issues and their resolution.
(8) Required IRB findings and determinations (see discussion section (19), Required IRB Findings and Determinations)
(9) Unless documented in IRB records, determinations required by the regulations and protocol-specific findings justifying those determinations for all research (not just DHHS-supported research) for:
   a. Research involving pregnant women, fetuses and neonates
   b. Research involving prisoners
   c. Research involving children
(10) A list of research approved since the last meeting utilizing expedited review procedures and the specific citation for the category of expedited review of the individual protocol

(11) Persons who recused themselves by name and with name of protocol

I. Attendance at IRB Meetings

IRB minutes shall list attendance as follows:

1. Names of members present
2. Names of absent members
3. Names of alternates attending in lieu of specified (named) absent members. Alternates may substitute for specific absent members only as designated on the official IRB membership roster
4. Names of consultants present
5. Name of investigators present
6. Names of guests present

m. Quorum Requirements and Voting at IRB Meetings

IRB minutes shall include a statement of “Quorum Requirements” based on the following standards:

1. A majority of the IRB members (or their designated alternates), including at least one member whose primary concerns are in nonscientific areas, one unaffiliated member, and one member who represents the general perspective interests of participants, must be present to conduct a convened meeting. The nonscientific, unaffiliated and participant representatives may be the same person or represented by 2-3 different people. The status of quorum will be determined by the Chair following the call to order of the meeting and documented in the minutes. In order for research to be approved, it must receive the approval of a majority of those members present at the meeting.

2. Members may be present in person or audio (telephone) or audio-visual teleconference. Members present via teleconference shall be noted as such in the meeting minutes, which shall also indicate whether the members received all pertinent information prior to the meeting and were able to actively and equally participate in all discussions.

3. IRB minutes shall include documentation of quorum and votes for each IRB action and determination by recording votes as follows: Total Number Voting (); Number voting for (); Number voting against (); Number abstaining (). Names are recorded of those who abstained.

4. Members absenting themselves due to conflicts of interest may not be counted toward quorum requirements (i.e., may not be counted among those voting or abstaining) or be counted as among the majority of members necessary to constitute a quorum.

5. An individual who is not listed on the official IRB membership roster may not vote with the IRB.

6. Any ex-officio member of the IRB may not vote with the IRB.

7. Ad Hoc consultants may not vote with the IRB.

8. A non-scientist member must always be present for a vote to be taken.

9. A non-affiliated member must always be present for a vote to be taken.

Note: When a member and their alternate both attend a meeting, only one may vote.

n. Actions Taken by the Convened IRB
IRB minutes shall include all actions taken by the convened IRB and the votes underlying those actions. These actions shall also be provided in writing to investigators after formal approval from the IRB. IRB actions for initial or continuing review of research include the following:

(1) Approved with no changes (or no additional changes). The research may proceed.

(2) Approvable with minor changes to be reviewed by the IRB Administrator who is designated by the IRB or Chair. Such minor changes must be clearly delineated by the IRB so the investigator may simply concur with the IRB’s stipulations. The research may proceed after the required changes are verified and the protocol approved by the IRB Administrator.

(3) Tabled, requiring substantive changes. The protocol must be revised in a way that will meet the regulatory requirements and be resubmitted for review at a convened IRB meeting. The research may proceed only after the convened IRB has reviewed and approved the required changes to the research.

(4) Deferred, pending receipt of additional substantive information or pending seating of the IRB with appropriate expertise. The IRB determines that it lacks sufficient information about the research to proceed with its review, or determines that it needs additional expertise in order to provide meaningful review. The research may not proceed until the convened IRB has approved a revised application incorporating all necessary information.

(5) Disapproved. The IRB has determined that the research cannot be conducted at USU or by employees or agents of USU.

o. IRB Findings and Determinations Where Documentation is Required by Regulation

While the regulatory agencies agree on what will be documented, the methods of documentation are not regulated, and have received different guidance. The IRB closely follows OHRP methods and guidance. The following IRB findings and determinations are documented in IRB meeting minutes.

(1) The level of risk of the research

(2) The approval period for the research, including identification of research that warrants review more often than annually. All human subjects research shall be reviewed at least annually.

(3) Identification of any research for which there is need for verification from sources other than the investigator that no material changes are made in the research (e.g. Cooperative studies or other collaborative research)

(4) Justification for waiver or alteration of informed consent, addressing each of the four criteria at 45 C.F.R. 46.116(d)

(5) Justification for waiver of the requirement for written documentation of consent in accordance with the criteria at 45 C.F.R. 26.117(c)

(6) For DHHS-supported research, justification for approval of research involving pregnant women, human fetuses, and human in vitro fertilization, addressing each of the criteria specified under 45 C.F.R. 46 Subpart B of the DHHS Human Subjects Regulations.

(7) For DHHS-supported research, justification for approval of research involving prisoners, addressing each of the categories and criteria specified under 45 CFR 46 Subpart C of the DHHS human subject regulations. Generally, the IRB Director is responsible for providing certification of the IRB’s findings to OHRP.

(8) For DHHS regulated research, justification for approval of research involving children, addressing each of the categories and criteria specified under 45 CFR 46 Subpart D of the
C. The Substance of IRB Review

Chapter 9: Types of Institutional Review Board Determinations

Unless determined to be exempt in accordance with criteria at Chapter 10, all human subject research conducted at USU or by USU employees or agents or otherwise under USU auspices must be prospectively reviewed and approved by the IRB. No human subject research may be initiated or continued at USU or by USU’s employees or agents without prospective approval of the IRB. Regardless of the type of review (approved as exempt, expedited or review at a convened meeting), the investigator is notified in writing of the IRB’s determinations.

a. Review by the Convened IRB

Regulations at 45 CFR 46.108(b) (the Federal Policy (Common Rule) for the Protection of Human Subjects) require that the IRB conduct initial and continuing reviews of all non-exempt research at convened meetings at which a majority of the members are present, unless the research falls into one or more of the categories appropriate for expedited review (see item “e” of this chapter).

IRB meetings are scheduled monthly, as needed, and at a minimum of once per fiscal quarter, regardless of whether a meeting is required for review of applications.

If no application is received that requires full board review, then the monthly meeting may be canceled by the IRB Chair or Administrator. During months that no meeting is to be held, the monthly packet is nonetheless distributed to members for their review. Members are expected to review all reports contained in the packet, and provide comments as appropriate to the IRB Chair and Administrator. Reports included in the packet are enumerated in Chapter 10. The IRB may ask for clarification or require convened review of a study approved by the Expedite procedures reported in the monthly packet.

In addition to cancellations made when no applications requiring full board review are pending, the Chair may also, under extenuated circumstances, postpone or cancel meetings at his/her discretion. Such circumstances may include the inability to seat a quorum at the meeting or the unavailability of a member or outside expert with particular knowledge and expertise required for review of a pending application.

When a meeting is held, but no application is pending that requires full-board review, the chair may select applications for review to provide training and opportunities for interaction among members of the IRB. When such applications are reviewed, a quorum of the IRB, in accordance with IRB SOP, Chapter 8.m will be required, and discussion of controverted issues shall be recorded in the minutes as if the application required full-board review.
b. Monitoring Attendance During IRB Meetings

IRB meetings are held in accordance with Chapter 9. During these meetings it shall be the duty of the IRB Director or his/her designee to verify that a quorum is maintained throughout the meeting. The following steps shall be followed to ensure that each protocol is discussed and approved by a qualified quorum of the IRB:

1. Names of voting members of the IRB shall be recorded.
2. The presence of at least one non-scientist and one nonaffiliated member shall be verified. In accordance with the Common Rule, section 46.107(c)(d), the same person may fulfill a dual role with regard to this requirement.
3. Conflicts of interest disclosed according to Chapter 10 shall be noted, and required recusals shall be taken into account in calculating the quorum for each protocol.
4. As established in Chapter 6, a quorum consists of more than half of the members of the full board.

The number of members present who are not conflicted shall be divided by the number of members of the full board. If the number meets the “one-more-than-half” requirement, then a discussion will be allowed and a vote taken, except that the absence of a non-scientist or a nonaffiliated member, or a conflict on the part of a sole non-scientist or nonaffiliated member in attendance, will automatically preclude establishing a quorum for the purposes of deliberating or approving a protocol that requires action by the full board. Similarly, no quorum can be established for deliberation or approval of a protocol involving prisoners without a prisoner advocate being present.

The minutes associated with each protocol requiring review by the full board shall indicate who participated in the deliberation, and shall establish that a quorum of the IRB participated.

c. Initial Review by the Convened IRB

No less than one week prior to the convened meeting, all members of the IRB shall be provided with Protocol Review Packets, as set forth in Chapter 10.a, for each protocol to be reviewed. All members of the IRB are expected to familiarize themselves with materials in the review packet in order to contribute to the IRB’s deliberations. Members of the IRB will be polled in advance of the meeting to provide the Chair with a list of members who are expected to attend. Using the “IRB Meeting Preparation Checklist,” the Chair examines the members to be present and reviews the protocols on the agenda to ascertain that the IRB will have appropriate expertise for the review (e.g., knowledge of local context). If the IRB will not have appropriate expertise, the IRB chair will obtain consultation, defer the protocol to a meeting with appropriate expertise, or assign the review to another IRB with appropriate expertise. Based on expected attendance and expertise, the Chair evaluates the IRB’s ability to appropriately review protocols or the need for consultation and makes assignments for primary reviewers as follows:

1. The IRB Chair selects two primary reviewers for each protocol so that at least one has scientific or scholarly expertise appropriate for the research. If the chair cannot select at least one primary reviewer with appropriate expertise, the IRB chair will obtain consultation or defer the protocol to a meeting with appropriate expertise.
2. If the protocol involves populations vulnerable to coercion or undue influence, the IRB chair selects a primary reviewer who is knowledgeable about or experienced in working with such participants. If the chair cannot select at least one primary reviewer with appropriate expertise, the IRB chair will obtain consultation or defer the protocol to a meeting with appropriate expertise.
The primary reviewers receive and review the complete Protocol Review Packet, prepare to present their reviews to the convened IRB and make a recommendation to the IRB for action. The convened IRB deliberates and determines whether the regulatory criteria for approval, as contained in the IRB Review Checklist have been met, and takes actions as appropriate.

In situations where appropriate expertise is not available among the members of the IRB expected to attend the meeting, the Chair will seek consultation from outside the IRB membership. The scientific, scholarly or other knowledge or expertise needed is identified by the IRB chair, and qualified individuals are identified through inquiries to administrators, faculty or others either from within or outside USU. When consultants participate in IRB meetings, the curriculum vitae of the consultant is sent with all other review materials for the meeting so that IRB members can evaluate the weight to place on the consultant’s input. Consultants never vote with the IRB.

d. Continuing Review by the Convened IRB
The IRB conducts substantive and meaningful continuing review of research at intervals appropriate to the degree of risk, but not less than once per year. Continuing review continues as long as:
   a. Research remains active for long-term follow-up of participants, even when the research is permanently closed to the enrollment of new participants and all participants have completed all research related interventions, or
   b. The remaining research activities include collection of analysis of private identifiable information.

Expiration of approval for protocols is set forth in subsection ‘m’ of this chapter.

Continuing reviews shall be conducted by the convened IRB unless the research qualifies under the eligibility criteria as set forth in section 9.e, below, and falls into one or more of the categories appropriate for expedited review (as set forth in 9.e).

The same considerations for IRB review as described in Chapter 10 should be applied for continuing review. At least one week prior to the convened meeting, all members of the IRB shall be provided with the Protocol Review Packet (see Chapter 10.a) including the IRB Continuing Review Protocol Status Report form, which contains a summary of the research, a status report on the progress of the research, number of subjects enrolled and withdrawn, relevant recent literature, and other relevant information as the number of subjects accrued; a description of any unanticipated problems involving risks to subjects or others; information about any withdrawal of subjects from the research or complaints about the research; findings obtained thus far; amendments or modifications to the research since the last review; reports on multi-center trials and any other relevant information, especially information about risks associated with the research.

Primary reviewers may be chosen to review continuing protocols if review by the convened IRB is needed. Primary reviewers are appointed by the IRB Chair as outlined in 9.c, above. The Protocol Review Packet would be sent to the primary reviewers along with the initially approved protocol. Criteria to consider for these reviewers would be if there are no changes in the methods or objectives, advertising or consent documents. Any changes that were prospectively requested or promptly reported throughout the year shall be reviewed (i.e. advertising, consent documents, unanticipated problems). The IRB Reviewer Checklist shall guide the preparation of the primary reviewers’ presentation to the convened IRB. The convened IRB deliberates based on the information distributed to them and information that has been presented by the primary reviewers. The convened IRB then takes action, approving research that meets the requirements set forth in the IRB Review Checklist and taking other actions as appropriate.
e. **Expedited Review**

The IRB may utilize an expedited procedure for the initial or continuing review of research that meets eligibility criteria, as set forth below and falls within the categories published in the November 9, 1998, Federal Register 63 FR 60364-60367; 63 FR 60353-60356 DHHS-FDA list of research eligible for expedited IRB review, also set forth below.

**Eligibility requirements:**

(a) The research presents no more than minimal risk to subjects. (Not applicable for category (8)(b))

(b) The identification of the subjects or their responses will not reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal. (Not applicable for category (8)(b))

(c) The research is not classified.

(d) The category or categories of research allowing review using the expedited procedure (1)-(9). When using category (8), have the reviewer document whether category (8)(a), (8)(b), or (8)(c) applies.

**Categories in the Common Rule that allow use of the expedited procedure during Initial and Continuing Review:**

1. Clinical studies of drugs and medical devices only when 1 of 2 conditions is met:

   (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review), or

   (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

   *NOTE: USU does not currently allow research falling in this category to be undertaken at USU.*

2. Collection of blood samples by finger stick, heel stick, ear stick or venipuncture as follows:

   (a) From healthy, non-pregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week.

   (b) From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means.

   Examples:
   - Hair and nail clippings in a non-disfiguring manner
   - Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction
• Permanent teeth if routine patient care indicates a need for extraction
• Excreta and external secretions (including sweat)
• Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue
• Placenta removed at delivery
• Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor
• Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques,
• Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings,
• Sputum collected after saline mist nebulization

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications. USU does not currently allow studies focused on medical devices. Examples:
   • Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject’s privacy
   • Weighing or testing sensory acuity
   • Magnetic resonance imaging
   • Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity
   • Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where weight and health of the individual are appropriate

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (Some research in this category may be exempt from the federal regulations).

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not limited to: research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

8. Continuing review of research previously approved by the convened IRB as follows:

   (a) Where research is permanently closed to the enrollment of new subjects, all subjects have completed all research-related interventions and the research remains active only for the long-term follow-up of subjects, or
   (b) Where no subjects have been enrolled and no additional risks have been identified, or
   (c) Where the remaining research activities are limited to data analysis.

Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB
has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

f. **Process for Assigning Reviewers for Expedited Reviews**

When the IRB Director or authorized staff representative has determined that a protocol is qualified for expedited review as set forth in 9.e, qualified reviewers shall be chosen from the membership of the IRB to complete the expedited review as set forth in Chapter 9.f. Primary reviewers are appointed by the IRB Chair as outlined in 9.c, above. Two reviewers shall be assigned to each expedited review. One shall be the IRB Director or Chair. The second shall be chosen by the IRB Director from a list of IRB members who have been pre-approved by the IRB chair to act as reviewers as provided for in Chapter 6.c.

The two assigned reviewers shall complete their reviews in accordance with IRB SOPs Chapter 10, using materials provided to them in the Protocol Review Packet (see Chapter 10.a), and shall exchange Reviewers Checklists and other review materials in order to reach consensus regarding the protocol. Either reviewer may request that the protocol be presented to the full IRB for review. Approval or other action taken shall be consistent with IRB SOPs Chapter 9.k, and both reviewers must agree on the action recommended. If the reviewers are unable to agree on the correct action, or if denial is recommended, the protocol shall be submitted to the full IRB for review. Only the convened IRB can deny a continuation of a previously approved protocol.

IRBs shall keep all IRB members advised of research that has been approved under expedited procedures (45 CFR 46.110(c)). This is documented by listing the research in the monthly Continuing Review Report distributed to members of the IRB.

Documentation for expedited reviews maintained in IRB records shall include the category and circumstances that justify using expedited procedures. Further guidance on documentation is available at Chapter 10.

g. **Expedited Review of Minor Changes in Previously Approved Research (45 CFR 46.110(b)).**

Investigators must request, via submission of an Amendment/Modification form, any proposed changes in IRB-approved research, including proposed changes in informed consent process or documents. No changes may be initiated without prior approval of the IRB, except where necessary to eliminate apparent immediate hazards to participants.

The IRB may utilize expedited procedures to review a proposed change to previously approved research if it represents a minor change to be implemented during the previously authorized approval period.

1. **Definition of a minor modification.** A minor modification is one which, in the judgment of the IRB reviewer, makes no substantial alteration in (1) the level of risks to participants; (2) the research design or methodology; (3) the number of participants enrolled in the research; (4) the qualifications of the research team; (5) the facilities available to support safe conduct of the research; or (6) any other factor which would warrant review of the proposed changes by the convened IRB. In addition, added procedures must (7) involve no more than minimal risk, and (8) fall into categories 1-7 of research that would allow review using the expedited procedure.

2. **Process for Making Minor Modifications to Approved Protocols.** Minor modifications may be made to protocols upon submission of a Request for Amendment/Modification form, and may be reviewed on an expedited basis. Minor modifications are reviewed and approved by
a qualified member of the IRB as they are received by the IRB Office, using materials provided in the Protocol Review Packet (see Chapter 10.a).

h. Non-Minor Modifications to Approved Protocols
Any change that does not meet the criteria for minor modifications, as set forth above, will be considered a non-minor modification for which a new application will be required. New applications will be considered by the IRB under initial review, however, investigators are encouraged to delineate in the application what modifications have been made to the previously approved protocol. Criteria that should be evaluated include:

1. Level of risk compared to benefit: Any modification that would result in a change to the Risk Benefit Checklist indicating an increase in risk or a decrease in benefit shall require submission of a new application.

2. Research design or methodology: Surveys, focus groups, interviews, observations, and other accepted research designs shall not be considered interchangeable. Methods of delivery shall also not be viewed as equivalent. For example, a survey delivered over the internet shall not be considered equivalent to a survey delivered by written instrument. A downward change in the ability to protect privacy or confidentiality shall constitute a non-minor change, requiring submission of a new IRB application.

3. Number of participants enrolled: Any change in the total number of participants to be enrolled in a study that exceeds 15% shall constitute a non-minor change, requiring submission of a new IRB application. Lesser changes may also be considered non-minor at the discretion of the IRB or the authorized IRB reviewer.

4. Qualification of the research team: Any change in the training methodology for researchers, and any downward change in the level of education required for a researcher to participate shall constitute a non-minor change, requiring submission of a new IRB application.

5. Facility availability: Any change in the facilities that could, in the opinion of the IRB or the authorized IRB reviewer, limit the privacy or safety of a research participant, or limit the degree of confidentiality afforded data regarding a research participant, shall constitute a non-minor change, requiring submission of a new IRB application.

6. Other changes: The IRB or the authorized IRB reviewer shall consider any other change proposed in the addendum request by the PI, and shall determine whether the change is minor or non-minor consistent with regulations, policies and the best interest of the research participants.

7. Documentation: The IRB or the authorized IRB reviewer shall document findings that either: a) a minor modification may be made based on an addendum request, or b) that a new application must be submitted. The decision made shall be communicated to the PI. If a PI believes a finding has been reached based on erroneous information, s/he may consult with the IRB Chair and the reviewer to explain the basis of the error. The decision of the IRB Chair shall be final.

i. Use of Subcommittees to Support IRB Activities
The IRB Chair may appoint subcommittees on an ad hoc basis to perform non-review functions as needed, such as monitoring compliance to IRB regulations.

j. Review of Reports of Unanticipated Problems Involving Risks to Participants or Others
Investigators are required to report to the IRB issues as set forth in the table “Reporting Responsibilities of the Principal Investigator to the IRB” in Chapter 4.f, above. These issues constitute unanticipated problems involving risks to participants or others, as defined below, and timeframes
An unanticipated problem involving risks to participants or others is any incident, experience, or outcome that meets both of the following criteria:

1. Is unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied; and

2. Is related or possibly related to the research

3. Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Reports to the IRB should contain enough information for the IRB Chair, administrator or any designated primary reviewer to judge whether the event raises new questions about risks to participants. When the study is part of a multi-site effort, a standard form may already be in use to provide details of the event to the sponsor. If the event occurred at a different site, the information may also be in a standard format. These reports can be forwarded to the IRB to provide information about the event.

All such reports are reviewed by the IRB Chair, who may form a subcommittee at the Chair’s discretion. Based on prompt deliberation, the Chair shall determine whether to refer the problem to the IRB as an unanticipated problem involving risks to participants or others according to the above definition.

- If not referred, no further action is taken under this policy.
- If referred, the Chair shall form a recommendation to be presented to the IRB for action.
- The unanticipated problem involving risks to participants or others is placed on the agenda for review by the convened IRB.
- The Unanticipated Problem Report Form shall be included in the Protocol Review Packet (see Chapter 10.a) which is received by all members of the IRB. The discussion may be led by the Chair or a member of the subcommittee appointed by the chair.
- The convened IRB meets as soon as possible to consider the unanticipated problem, the Chair’s recommendation, and determine what actions shall be required. Actions which may be incorporated include the following elements:
  - Requirement for specific corrective action for the study
    - Require a plan for corrective action, based on the type and nature of the issues
    - Require education of the investigators and research team
    - Modify the protocol
    - Modify inclusion/exclusion criteria (e.g., to mitigate newly identified risks
    - Modify the informed consent process or documents (e.g., include a description of newly recognized risks, or additional information to be disclosed during the consent process)
    - Require that subjects be re-contacted and provided with updated information or consent
    - Require current participants to re-consent to participation
    - Provide additional information to past participants
    - Notify current participants when new information may relate to participants’ willingness to continue to participate in the research
- Suspend enrollment of new participants
- Suspend research procedures among currently enrolled participants
- Suspend the research
- Terminate the research
- Modify the continuing review schedule
- Provide additional monitoring or routine audits
- Refer the incident to other organizational entities (e.g., the Federal Compliance Manager)
- Take additional steps as needed
- Decide to take no action, if appropriate
  - Communicate required actions to investigator, IO and others as appropriate

Following review by the convened IRB, reporting to regulatory agencies and appropriate organizational officials takes place according to Policy #308, Human Participants in Research, Section 3.12.

k. **Data Safety Monitoring Plans and Review of Reports**

Projects that are found, through completion of the Reviewer’s checklist, to pose greater than minimal risk to participants must provide a data safety monitoring plan for monitoring and facilitating the reduction of risk. The IRB has the responsibility, in compliance with 45 CFR 46.111(a)(6), to provide for monitoring to ensure participant safety.

The IRB may require monitoring by the PI or another USU department or college-appointed individual or board for projects for which risks are judged by the IRB to be moderate or higher. The IRB may require monitoring by a Data Safety and Monitoring Board (DSMB) made up primarily of individuals outside the university when the risk to participants is judged by the IRB to be high. USU may hire an outside entity to provide or manage a DSMB to fulfill this requirement. The IRB shall have the authority to approve the appointment of the board, whether organized by USU or an outside entity.

The data and safety monitoring plan shall provide for at least the following elements:

(1) Monitoring the progress of trials and the safety of participants

(2) Plans for assuring compliance with requirements regarding the reporting of unanticipated problems (UPs)

(3) Plans for assuring that any action resulting in a temporary or permanent suspension of a study is reported to the agency responsible for the grant

(4) Plans for assuring data accuracy and protocol compliance

Investigators are required to forward reports produced by DSMBs or others designated in their plans to the IRB within 5 working days of receipt. The review of data and safety monitoring reports is handled in the same manner as internal reports of unanticipated problems or adverse events.

When DSMBs or other outside monitoring are used, IRBs conducting continuing review of research may rely on a current statement from the DSMB or reviewing individual indicating that it has reviewed study-wide UPs, interim findings, and any recent literature that may be relevant to the research, in lieu of requiring that this information be submitted directly to the IRB. The IRB shall receive and review reports of local, on-site unanticipated problems involving risks to participants or others and any other information needed to ensure that its continuing review is substantive and meaningful.

l. **Outcomes of IRB Review**
IRB actions upon research reviewed include the following:

1. Approved with no changes (or no additional changes). The research may proceed.

2. Approvable with non-substantive changes to be reviewed by the IRB Administrator (designated by the IRB Chairperson). Such changes must be clearly delineated by the IRB or designated reviewer so the investigator may simply concur with the IRB’s stipulations. The research may proceed after the required changes are verified and the protocol is approved by the designated reviewer.

3. Approvable with substantive changes to be reviewed at the level stipulated by the designated reviewer or by the IRB if originally reviewed at that level. The research may proceed only after the convened IRB has reviewed and approved the required changes to the research, unless, at a convened meeting where the study has been discussed, the IRB determines that the protocol meets established criteria for expedited review. In that case the Chair may refer the protocol to an approved reviewer for review and approval under the expedited procedure.

4. Deferred (or tabled) pending receipt of additional substantive information. The designated reviewer or IRB determines that it lacks sufficient information about the research to proceed with its review. The research may not proceed until the convened IRB – or, if it is found to meet established criteria for expedited review, by approved reviewers – has approved a revised application incorporating necessary information.

5. Disapproved. The IRB has determined that the research cannot be conducted at USU or by employees or agents of USU or otherwise under the auspices of USU.

The IRB, through the IRB Administrator or Chair, shall provide written notification of its determinations to investigators. Notification shall include:

1. The IRB’s decision to approve, disapprove, or require modifications to secure approval of research.

2. Any modifications or clarifications required by the IRB as a condition for IRB approval.

3. When the research is disapproved or approved with modifications, adequate information for the investigator to understand the reasons for the IRB’s decision.

4. A statement that the investigator has the opportunity to respond to the IRB in person or in writing.

**m. Expiration of Approval Period**

The Common Rule requires that the IRB conduct substantive and meaningful continuing review of research not less than once per year. Thus, the IRB approval period for research may extend no more than 365 days (or 366 days when affected by a leap year) after the convened IRB meeting at which the research was last approved or the date of the expedited review process if expedited review was performed (see Continuing Review). The regulations permit no grace period to this 1-year requirement. For example, a study approved on July 1 would expire on June 30, and no work could continue on that project beyond the end date of the approval period (June 30) without a continuing review having been completed and new approval having been given by the IRB.

If the continuing review is not approved by the date specified, the study approval automatically expires and the study is closed. All research must stop including recruitment, advertisement, screening, enrollment, consent, interventions, interactions, and collection of private identifiable information. Interventions and interactions on current participants may continue only when the IRB finds an over-riding safety concern or ethical issue involved such that it is in the best interests of
individual participants. Under no circumstances can enrollment of participants occur. A new application will be required before work can commence again.

Upon closure of the study, a letter is sent to the PI with copies distributed to the Vice President for Research, Dean, Department Head, the IRB Committee, and funding agency if applicable.

n. Suspension or Termination of IRB Approval of 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. Either the IRB Chair or the Institutional Official (IO) may temporarily suspend research when circumstances indicate the presence of additional risk to participants or others in relation to a research study.

The initial recommendation of the appropriate action shall be made by the IRB Chair, either alone or in conjunction with a subcommittee appointed by the 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. Recommendations shall be considered and actions to be taken shall be determined by the membership of the IRB as outlined in the procedure for Section j, above (Review of Reports of Unanticipated Problems Involving Risks to Participants or Others), and shall be reported to the OCA, IO, University Counsel and the appropriate funding agency as set forth in Policy #584, Research with Human Participants, section 3.12. A timeline for reporting of suspensions, terminations, serious and continuing noncompliance, unanticipated problems involving risks to participants and other reportable events is contained in the Investigator Handbook, Chapter 9. Once an event has been discovered by the institution, the IRB will gather information as necessary, assess the situation, and make a timely report to USU administration and to involved funding agencies through the Vice President for Research. Specific agency requirements shall be met, as may be contained in Chapter 17 of these SOPs; however, in no case shall an initial report be made to funding agencies more than 30 days from the discovery of a reportable event.

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. In some cases, protection of the rights and welfare of the research participants may require the transfer of the study to a different researcher, the transfer of participants to a different study, or continuation of the protocol under separate monitoring.

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

- Enrolled participants will be notified by the IRB.
- 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.
- The IRB shall be convened as soon as reasonably possible to consider the suspension, non-compliance, or other unanticipated problems that may have led to the suspension, and made a decision regarding the need for continued suspension, reinstatement, or other alternatives.

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.

o. Continuing Review of Exempt Research
Chapter 10: IRB Review and Approval Considerations

a. Documentation Required for Review.

Whether a protocol is being submitted to IRB members for full-board review or for expedited review, as set forth under IRB SOPs, Chapter 9.e, the following documents shall be delivered to all members who will be charged with reviewing the protocol:

1. An IRB Application
2. A copy of the full proposal or dissertation (if a multi-site study funded by DHHS, the complete DHHS-approved protocol)
3. The proposed Informed Consent document (if a multi-site study funded by the DHHS, the DHHS-approved informed consent form)
4. Any proposed privacy authorization
5. Any advertisement to be used for recruitment
6. Any brochures to be used during the study
7. Any survey instrument to be administered
8. Proposed types and amounts of compensation for participation
9. If for continuing review, the IRB Protocol Status Report Form
10. If for a minor modification, the Amendment/Modification Form
11. If for review of an unanticipated problem, the Unanticipated Problem Report Form
12. If for review of serious or continuing noncompliance, a summary of the allegation and of a copy of the IRB Noncompliance Report concerning the alleged noncompliance
13. A Reviewer’s Checklist, to be used by primary reviewers and reviewers assigned to conduct review under expedited procedures

When assembled, these documents comprise the Protocol Review Packet. Protocol Review Packets are distributed to members of the IRB (in the case of reviews by the convened IRB) at least 7 days prior to convened meetings of the IRB at which the protocol is to be discussed – whether for initial review, continuing review, review of unanticipated problems or review of serious or ongoing noncompliance. IRB members assigned to conduct reviews using expedited procedures also receive the Protocol Review Packet.

Reviewers shall complete a thorough review of the Protocol Review Packet, and based on the review shall make recommendations to protect the safety and welfare of human participants and comply with applicable regulations and policies. The reviewer may communicate with investigators through the IRB Office as necessary to gain clarification of written materials. However, no materials in the Protocol Review Packet may be directly altered by the reviewer in order to make the material conform to regulations or policies.
The IRB office, upon action by the IRB, or in the case of expedited review, authorized members of the IRB, shall communicate to the PI the outcome of the review and provide written guidance to PIs for resubmitting protocols requiring modification.

b. Compliance with Regulatory Requirements.

Regulations at 45 CFR 46.111 (Common Rule) delineate specific criteria for the approval of research. The IRB shall determine that all of the following requirements are satisfied before approving proposed research.

(1) Levels of Risk.

The IRB shall consider the overall level of risk to participants in evaluating proposed research. The regulations require that the IRB distinguish research that is greater than minimal risk from research that is no greater than minimal risk when considering proposals for expedited review. However, the IRB should assess the risk/benefit in all research protocols. Under specific circumstances listed under Expedited Review in the Common Rule Regulations at 45 CFR 46.110, research that is no greater than minimal risk may be eligible for expedited review, waiver or alteration of informed consent requirements, or waiver of the requirement to obtain written documentation of consent.

Under the Common Rule at 45 CFR 46.102(i) “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.”

(2) Risks Minimized (45 CFR 46.111(a)(1)).

To approve research, the IRB must determine that risks are minimized by using procedures that are consistent with sound research design and do not expose participants to unnecessary risks. Whenever appropriate, the research should utilize procedures that are already being performed on the participants for diagnostic or treatment purposes. The IRB verifies that the research plan, including research design and methodology, will not place participants at unnecessary risk. This may include research that is inadequately designed or is lacking in statistical power, such that meaningful results cannot be obtained. The IRB verifies this through the use of the Scientific Validity Review Checklist, and in accordance with Chapter 9 above.

In the first section of the IRB Application – Scientific Review – one of the five options must be checked. A check on any of the first four items will indicate the proposal has received an adequate scientific review. If the fifth item is checked, indicating that a scientific review has not yet been performed, the IRB reviewer, if qualified, shall complete the Scientific Validity Review Checklist.

To qualify as a reviewer, the reviewer shall have sufficient depth of knowledge and expertise in the discipline of the proposal to allow the reviewer to provide adequate review. In addition, the reviewer may have no conflict of interest in either the project or with the PI or other investigator on the project. If the reviewer is not qualified, s/he shall contact the IRB administrator or chair so that a qualified reviewer can be appointed.

When performing the scientific validity review, the reviewer shall ascertain and indicate that each of the listed elements in the checklist is adequately addressed. The reviewer may also check the “Other” item, and provide specific information regarding any scientific shortcomings identified in the proposal.
No protocol may be approved unless its scientific validity has been ascertained and documented using the Scientific Validity Review Checklist.

The IRB shall also consider the professional qualifications and resources of the research team. Investigators are expected to maintain appropriate professional credentials and licensing privileges.

(3) **Risks Reasonable Relative to Anticipated Benefits (45 CFR 46.111(a)(2)).**

To approve research, the IRB must determine that the risks of the research are reasonable in relation to the anticipated benefits (if any) to participants, and the importance of the knowledge that may reasonably be expected to result.

The IRB develops its risk/benefit analysis, using the Risk/Benefit Assessment provided by the investigator (see Chapter 4.I), by evaluating the most current information about the risks and benefits of the interventions involved in the research, in addition to information about the reliability of this information. The IRB will consider only those risks that result from the research, and should not consider long-range effects (e.g., public policy implications) of applying the knowledge gained in the research.

(4) **Equitable Selection of Subjects (45 CFR 46.111(a)(3)).**

To approve research, the IRB must determine that the selection of participants is equitable. This reflects USU’s adherence to the concept of “Justice” as set forth the Belmont Report. In making this determination, the IRB should evaluate the purposes of the research, the research setting, and the inclusion/exclusion criteria. The IRB should be especially cognizant of the problems of research involving vulnerable participant populations. Generally, a population that stands no chance of benefiting from the research should not be selected to assume the risk.

The IRB should be mindful of the importance of including members of minority groups in research, particularly when the research holds out the prospect of benefit to individual subjects or the groups to which they belong. Non-English speaking participants should not be systematically excluded because of inconvenience in translating informed consent documents. The IRB should also ensure that participants are not taken from one group of people because it is convenient.

The IRB should be mindful of the desirability of including both women and men as research participants and should not arbitrarily exclude the participation of persons of reproductive age. Exclusion of such persons must be fully justified and based on sound scientific rationale.

Determination that participants will be selected equitably shall be made according to the process outlined in subsection g, below.

(5) **Determining Equitable Recruitment.**

The IRB shall have responsibility for approving appropriate recruiting practices for research studies. The SOPs, Chapter 8.g, require the investigator to submit to the IRB any recruitment advertisements or other recruiting materials as well as the Informed Consent document and the procedures to be used in obtaining informed consent. Under expedited review, an IRB reviewer shall review the recruiting material and the proposed informed consent process if the documents are easily compared. The Chair or the assigned reviewer
may, however, choose to have the recruitment procedures reviewed by the full board if complicating issues are involved.

The IRB shall have responsibility to determine that payment levels are reasonable, and that advertisements and recruiting techniques are not coercive. They shall review advertisements in final form for appropriateness of language, font sizes and visual effects. Audio advertisements shall be reviewed in final form for similar criteria. Any advertisement to recruit participants should be limited to the information the prospective participants need to determine their eligibility and interest. When appropriately worded, the following items may be included:

(a) The name and address of the investigator and/or research facility.
(b) The condition under study and/or the purpose of the research.
(c) In summary form, the criteria that will be used to determine eligibility for the study.
(d) The time or other commitment required of the participants.
(e) The location of the research and the person or office to contact for further information.
(f) A clear statement that this is research and not treatment.

Recruitment procedures should be designed to assure that informed consent is given freely and to avoid coercion or undue influence. To evaluate this, the IRB should know from what population the participants will be drawn, what incentives are being offered, and the conditions under which the offer will be made.

An advertisement may not:
(a) State or imply a certainty of favorable outcome or other outcome,
(b) Differ materially from the informed consent document,
(c) Promise free treatment when referring to an investigational intervention, or
(d) Emphasize the payment or amount to be paid.

The IRB shall be provided with adequate information to verify that:
(a) Incentive payments, in addition to being reasonable and non-coercive, are available, at least on a pro-rated basis, for participants who withdraw from the study;
(b) That bonuses for completing the study are not coercive;
(c) That information about the amount and schedule of payments is included in the informed consent form and process; and
(d) Recruitment procedures used in the study are fair and equitable.

(6) **Payment to Research Participants.**

The IRB shall review any proposed payments to research participants associated with the research that it overseas. Payments to research participants may not be of such an amount as to result in coercion or undue influence on the participant’s decision to participate. Payments may not be provided to participants on a schedule that results in coercion or undue influence on the participant’s decision to continue participation. For example, payment may not be withheld as a condition of the participant completing the research. If the participant withdraws early, payment should be prorated to reflect the time and inconvenience of the participant’s participation up to that point.

Payment may be permitted, with prior approval of the IRB, in the following circumstances:
(a) No direct participant benefit. When the study to be performed does not directly enhance the quality of life to the participant.

(b) Others being paid. In multi-institution studies, where participants at a collaborating non-USU facility are to be paid for the same participation in the same study at the same rate proposed.

(c) Comparable situations. In other comparable situations in which, in the opinion of the IRB, payment of volunteers is appropriate.

Investigators who wish to pay research participants must indicate in their proposal the justification for such payment with reference to the criteria listed and, in addition, must:

(a) Substantiate that proposed payments are reasonable and commensurate with the expected contributions of the participant;

(b) State the terms of the participant participation agreement and the amount of payment in the informed consent form; and

(c) Substantiate that participant payments are fair and appropriate, and that they do not constitute (or appear to constitute) undue pressure to volunteer for the research study.

The IRB shall review all proposals involving the payment of participants in the light of these guidelines.

(7) Review of the Informed Consent Requirements (45 CFR 46.111(a)(4)).

To approve research, the IRB must determine that legally effective and voluntary informed consent shall be sought from each prospective participant or the participant's legally authorized representative (see 45 CFR 46.116) unless a waiver of consent is approved by the IRB. Any such waiver must be consistent with Common Rule guidelines and applicable state law regarding participation in research, which may be different from law governing clinical care. The specific elements required for informed consent are discussed in Chapter 11.

For research conducted in the state of Utah, when the participant is not capable of providing informed consent (such as children or incapacitated adults), consent or permission may only be given by parents with custodial rights (if participants are children) or by a legal guardian appointed by the court.

Informed consent may only be sought under circumstances that provide the participant (or the legally authorized representative) with sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence (45 CFR 46.116). For example:

(a) Informed consent information must be presented in language that is understandable to the participant (or the legally authorized representative).

(b) No informed consent process may include any exculpatory language (a) through which the subject is made to waive, or appear to waive, any of the subject’s legal rights; or (b) through which the investigator, the sponsor, the USU employees or agents are released from liability for negligence, or appear to be so released.

(c) Informed consent must be obtained prior to initiation of any clinical screening procedures that are performed solely for the purposes of determining eligibility for research.
(8) **Waiver or Alteration of Informed Consent Requirements.**

Minimal Risk Research. The Common Rule regulations at 45 CFR 46.116(d) permit the IRB to approve a consent procedure which does not include or which alters some or all of the required elements of informed consent, or to waive the requirement to obtain informed consent altogether. To approve such a waiver or alteration, the IRB must find and document that:

(a) The research involves no more than minimal risk to the participants.

(b) The waiver or alteration shall not adversely affect the rights and welfare of the participants.

(c) The research could not practicably be carried out without the waiver or alteration.

(d) Whenever appropriate, the participants shall be provided with additional pertinent information after participation.

These findings and their justifications shall be clearly documented in IRB minutes when the IRB exercises this waiver provision.

(9) **Documentation of Informed Consent.**

To approve research, the IRB must determine that informed consent will be appropriately documented, unless documentation can be waived under the Common Rule. The Common Rule at 45 CFR 46.117 provides two methods for documenting informed consent:

(a) Consent may be documented through use of a written consent document that embodies all of the required elements of informed consent (these elements will be discussed in detail in Chapter 11). The consent document form shall be signed by the participant (or the participant’s legally authorized representative), and a copy must be given to the person signing the form.

(b) Consent may also be documented through use of a short form consent document which states that the elements of informed consent have been presented orally to the participant (or the legally authorized representative). When this method is used the following is necessary:

1) There must be a witness to the oral presentation,

2) The IRB must approve a written summary of what is to be presented orally,

3) Only the short form must be signed by the participant or the representative,

4) The witness must sign both the short form and the summary,

5) The person actually obtaining consent must sign the summary, and

6) A copy of the summary and the short form must be given to the participant or the representative.

(c) The original signed consent document must remain with the Principal Investigator for three years after the research is completed.

(10) **Waiver of Documentation of Consent.**

Regulations at 45 CFR 46.117(c) permit the IRB to waive the requirement to obtain written documentation of informed consent. *(Note: This provision can be used only for the waiver of documentation of consent, not for waiver or alteration of consent itself.)* To approve such a waiver, the IRB must find and document either of the following conditions:
(a) The only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. In this case, each participant shall be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern. OR

(b) The research presents no more than minimal risk of harm to participants and involves procedures or activities for which written consent is not normally required outside of the research context. In cases in which the documentation requirement is waived, the IRB may require the principal investigator to provide participants with a Letter of Information regarding the research.

Note: IRB minutes shall clearly reflect this waiver provision and the justification for its use.

To approve research, the IRB must determine that, where appropriate, the research plan makes adequate provision for monitoring the data to ensure the safety of participants. For research in which risks are substantial, a general description of the data and safety monitoring plan must be submitted to the IRB as part of the protocol. Development of a plan to monitor data and safety is accomplished in accordance with Chapter 9.I. Expertise of the IRB Chair, Administrator, or another appointed member of the IRB may be necessary for the PI to develop the data and safety monitoring plan.

(12) Privacy of Participants and Confidentiality of Data.
To approve research, the IRB must determine that, where appropriate, there are adequate provisions to protect the privacy of subjects and the confidentiality of data. Persons not employed at USU can only access IRB records within the restrictions of the Federal Privacy Act and other statutes. Requests for such documents must be submitted to the IRB Chair or Vice President for Research Office at least 60 days before access is desired.

In reviewing confidentiality protections, the IRB shall consider the nature, probability, and magnitude of harms that would be likely to result from a disclosure of collected information outside the research. It shall evaluate the effectiveness of proposed anonymizing techniques, coding systems, encryption methods, storage facilities, access limitations, and other relevant factors in determining the adequacy of confidentiality protections.

(13) HIPAA. USU may be a “covered entity” under the Health Insurance Portability and Accountability Act (HIPAA).
As such, it is required to protect information that is designated as Personal Health Information (PHI) under HIPAA. In order for information to be designated as PHI, the information must be of such a nature that a reasonable person would have an expectation that the information would be private, and must be tied to information that would be a personal identifier.

PHI may be used in research, and may be released by other covered entities for the purpose of conducting research. PHI may also be de-identified by a covered entity so that the information is no longer qualified as PHI. Such information may also be released for research purposes.
When USU uses PHI, it is obligated to protect the information as confidential, and USU investigators shall follow all applicable regulatory guidelines concerning the use and storage of the data under the HIPAA Privacy Rule and the HIPAA Security Rule.

When USU generates PHI, it is obligated to receive authorization from the individuals about whom the data provides information prior to using or releasing such information in research. Investigators using PHI in research shall submit a completed IRB Checklist for HIPAA for each project being proposed that uses PHI. IRB reviewers shall verify that the checklist is completed and that all information needed by the reviewer is available to make a determination.

(14) **FERPA and PPRA.**
USU may gather data from educational institutions for use in research studies. Such data is subject to the Family Education Records Protection Act (FERPA) and the Protection of Pupils’ Rights Amendment (PPRA) and to equivalent state laws. Whenever an investigator proposes the use of educational records, or the gathering of sensitive data from schools or pupils within schools, the investigator shall complete the “IRB Checklist – Children” Part D, and submit it to the IRB with other review materials. The checklist provides guidance on the appropriate steps to be taken to meet the regulatory requirements under FERPA and PPRA. IRB reviewers shall verify that the checklist is complete and that all information needed by the reviewer is available to make a determination.

(15) **Additional Safeguards for Vulnerable Subjects (45 CFR 46.111(a)(3)).**
The IRB must be cognizant of the vulnerable nature of many human participants. To approve research, the IRB must determine that, where appropriate, additional safeguards have been included to protect the rights and welfare of participants who are likely to be vulnerable to coercion or undue influence, such as children (45 CFR 46 Subpart D), prisoners (45 CFR 46 Subpart C), pregnant women (45 CFR 46 Subpart B), persons with diminished decision-making capacity, or economically or educationally disadvantaged persons.

Should the IRB find that they regularly review research involving such vulnerable participants, the IRB shall include among its members persons who are knowledgeable about and experienced in working with these vulnerable participants (45 CFR 46.107 (a)). The IRB shall take particular care to protect participants from such potentially coercive influences in all research that they review.

Determination that adequate safeguards exist to protect the rights and welfare of vulnerable participants, shall be made in accordance with subsection 16, below.

(16) **Determining Additional Safeguards for Vulnerable Populations.**
It shall be the responsibility of the IRB to consider and provide for appropriate additional safeguards for populations that are considered to be vulnerable, including but not limited to, pregnant women, human fetuses, neonates, prisoners, children, and adults unable to provide informed consent.

In general, such additional safeguards shall be developed considering possible consent protections, additional structural protections in the consent and monitoring process, and other procedural protections that may be afforded vulnerable populations.

Additional safeguards shall be considered through the use of the Reviewer’s Checklist and other checklists (e.g., the Prisoner’s Checklist, the Children’s Checklist or the Pregnant
Women’s Checklist) which identify vulnerable populations and guide consideration of the provision of additional safeguards in the conduct or research, the obtaining of informed consent, and the procedures for approving and monitoring research by the IRB.

(17) **Actions to be Taken when Research Participants are Incarcerated.**

Subpart C of 45 CFR 46 sets forth conditions that must be met when conducting research with participants who are prisoners. During the course of otherwise approvable research, a participant may become a prisoner through an adjudicative process. When this takes place it shall be reported by the PI to the IRB, and the IRB shall consider steps to be taken to remain in compliance with federal regulations. In general, two options are available:

(a) If the detention of the individual who has become a prisoner is expected to be reasonably short and will terminate during the period that the study is being conducted, the participant may be allowed to withdraw from the study during the period that they remain a prisoner, and continue as a participant after the detention has ended.

(b) If the period of detention shall be extensive and the purpose of the study does not conform to one of the four categories of approved research with prisoners, or other conditions as outlined in the “Investigator Checklist for Studies Involving Prisoners” cannot be met, then the participant shall be withdrawn from the study.

When a participant is withdrawn from a study due to incarceration, the IRB shall ensure that any follow-up available to non-prisoner participants shall be delivered as needed to the participant.

If a participant becomes a prisoner after all data has been collected from him/her, the investigator may utilize such data, except as restricted through federal or state regulations or laws (such as the withdrawal of authorization under HIPAA).

(18) **Criteria for Requiring Review More Often Than Annually (45 CFR 46.103(b)(4)(ii)).**

The IRB must recognize that protecting the rights and welfare of participants sometimes requires that research be reviewed more often than annually. For example, when a new intervention is being tested, the risks may not be completely known. The IRB shall monitor the research project closely, and require more frequent review as circumstances may warrant, based on the following criteria:

(a) Probability and magnitude of anticipated risks to participants.

(b) Likely medical condition of the proposed participants.

(c) Overall qualifications of the principal investigator and other members of the research team.

(d) Specific experience of the principal investigator and other members of the research team in conducting similar research.

(e) Nature and frequency of unanticipated problems observed in similar research at this and other facilities.

(f) Vulnerability of the population being studied.

(g) Other factors that the IRB deems relevant.

In specifying an approval period of less than 1 year, the IRB may define the period with either a time interval or a maximum number of participants (i.e., after 3 months or after
three participants). The minutes of IRB meetings must clearly reflect these determinations regarding risk and approval period.

(19) **Independent Verification from Sources Other than the Investigator that No Material Changes Have Occurred Since the Previous IRB Review.**
Obtaining verification that the approved research plan is being followed may be necessary at times, for example, in cooperative studies, or other multi-center research. The IRB recognizes that protecting the rights and welfare of participants sometimes requires that the IRB verify independently, utilizing sources other than the investigator, that no material changes occur during the IRB-designated approval period.

The IRB shall consider the following factors in determining which studies require such independent verification:

(28) Probability and magnitude of anticipated risks to participants.
(28) Likely medical condition of the proposed participants.
(28) Probable nature and frequency of changes that may ordinarily be expected in type of research proposed.
(28) Prior experience with the principal investigator and research team.
(28) Other factors that the IRB deems relevant.

In making determinations about independent verification, the IRB may prospectively require that such verification take place at predetermined intervals during the approval period, or may retrospectively require such verification at the time of continuing review.

(20) **Obtaining Consent from Non-English Speakers.**
The Common Rule regulations at 45 CFR 46.116 requires that informed consent be obtained in language that is understandable to the participant (or the participant’s legally authorized representative).

In accordance with these regulations, the IRB may require that Informed consent conferences include a reliable translator when the prospective participant does not understand the language of the person who is obtaining consent.

When a full-length form embodying all required elements is required by the IRB to document consent, that form must be written in a language understandable to the participant. The IRB shall require that appropriately translated consent documents be submitted to the IRB for review and approval prior to their use in enrolling participants.

The IRB may utilize expedited review procedures in approving such documents if the English language consent document has already been approved, and the investigator attests in writing to the accuracy of the translation.

When a short-form consent document is used, the short form itself must be written in a language understandable to the participant, although the summary may be in English. The translator who took part in the informed consent conference may serve as the witness.

(21) **Compensation for Injury.**
The IRB shall ensure that participants are provided with accurate information about the availability of compensation and/or treatment for injury occurring in the research that it reviews. However, this requirement does not apply to (1) treatment for injuries due to
noncompliance by a participant with study procedures; or (2) research conducted for USU under a contract with an individual or a non-USU facility.

(22) **Process for Determination of Medical Treatment.**
In each case where a study is determined to pose greater than minimal risk, it is required that the informed consent document provide the prospective participant with 1) information concerning availability of compensation and treatment for injuries or harms sustained as a result of participation; 2) where additional information about such compensation or treatment may be obtained; and 3) contact information to allow for reporting of research-related injuries or other harms.

It shall be the responsibility of the IRB Administrator to submit to USU Risk Management Services (RMS) each protocol that represents greater than minimal risk, using the “Determination of Coverage” form. Each such protocol shall be submitted to the Risk Management Division of the State of Utah in order to determine if the study will be included as a defined contract under USU’s policy. RMS shall make a recommendation to the IRB based on the determination made by the State.

If the determination is that the study will be covered under USU’s policy, then the informed consent document shall include this information, and indicate how the participant or the participant’s legal representative shall notify USU of a study-related injury, and where to obtain further information concerning compensation and/or treatment.

If the determination is that the study will not be covered, then the informed consent process shall indicate that “no funds have been set aside for compensation for, or medical treatment of, injuries or harms that may be sustained as a result of participation in the study.” The informed consent process shall ensure that participants are aware of how to obtain appropriate treatment for injuries or harmed sustained. The informed consent form shall provide contact information for reporting of injuries or harms sustained as a result of participation in the study.

(23) **The Operation of Tissue or Cell Repositories.**
Tissue repositories and associated data management centers that support activities that are considered non-exempt human research and are housed at USU shall be subject to oversight by the IRB. The conditions for operation of such repositories and centers shall be set by the IRB. The IRB shall consider how specimens are to be collected and shared, and shall consider how best to protect the identities of participants whose samples are being shared. Certificates of confidentiality shall be obtained by investigators from agencies as a condition of operating a repository.

Investigators collecting specimens that will be included in the repository shall agree in writing to obtain informed consent from participants providing samples that meet the criteria outlined below, and shall acknowledge that they may not release identities of participants to other investigators except as shall be reviewed and permitted by the IRB as provided in the following subsection 25.

(24) **Informed Consent for Sharing Repository Information.**
The IRB shall consider how informed consent is to be obtained from prospective participants for use of tissue specimens and data gathered from such specimens in repositories that are accessible by third parties. The information shared in obtaining
informed consent shall include a description of the operation of the repository, the types of research to be conducted, the conditions under which data and specimens will be released to investigators and procedures for protecting privacy and maintaining confidentiality of data.

A checklist of options or other similar method shall fulfill the requirement on the informed consent document. The method used shall indicate clearly that the participant understood risks associated with tissue repositories and chose: 1) to allow tissue samples taken during the study to be used without further consent, 2) to allow samples to be used only with consent, or 3) not allow samples to be placed in the repository for future uses.

In addition to informed consent, the investigator shall also obtain authorization for release of personal health information (PHI) as necessary when tissue samples that have not (or cannot, because of genetic identification) been de-identified are to be shared. The IRB shall have responsibility to oversee authorization under HIPAA for research involving human participants.

(25) Certificates of Confidentiality.
Where research involves the collection of highly sensitive information about individually identifiable participants, the IRB may determine that special protections are needed to protect participants from the risks of investigative or judicial processes. In such situations the IRB may require that an investigator obtain a Department of Health and Human Services (DHHS) Certificate of Confidentiality (CoC). The CoC was developed to protect against the involuntary release of sensitive information about individual participants for use in Federal, state, or local civil, criminal, administrative, legislative, or other legal proceedings.

The CoC does not prohibit voluntary disclosure of information by an investigator, such as voluntary reporting to local authorities of child abuse or of a communicable disease. In addition, the CoC does not protect against the release of information to DHHS or other agencies for audit purposes. Consequently, the IRB shall require that these conditions for release be stated clearly and explicitly in the informed consent document.

(Note: OHRP guidance also requires a CoC for repositories and tissue banks. See http://www.hhs.gov/ohrp/policy/certconf.html)

(26) Compliance with All Applicable State and Local Law.
All human subject research conducted at USU or by USU employees or agents or otherwise under the auspices of USU must comply with applicable state and local laws.

When research is to be conducted outside of Utah, the investigator will be requested to provide an opinion by USU’s general counsel or another attorney acceptable to general counsel clarifying which individuals meet certain definitional qualifications. When research involves children, counsel shall provide an opinion about which individuals meet the DHHS definition of “child,” “legal representative” and “guardian.” When research involves adults unable to consent, counsel shall provide an opinion about which individuals meet the DHHS definition of “legally authorized representative.”

(27) Transnational Research.
All human research conducted outside the United States or on tribal lands shall be conducted in a manner consistent with the ethical principles outlined in USU policies and procedures, and provide equivalent levels of protection to research participants as a participant at USU would receive. Reviewers of research shall possess or have access to
appropriate expertise with respect to local context and laws in order to assure that appropriate protections are provided. Specific elements that should be considered include:

- Compliance with local regulations, as may be available from the OHRP International Compilation of Human Research Protection Programs or other sources
- Adequacy and appropriateness of the consent process to the population to be studied
- Adequacy of a system to receive and address participant complaints
- Post-approval review procedures adequate to protect participants

These elements should be given weight in accordance with the size, duration and level of risk associated with the study.

Reviewers shall work together with investigators to identify and respond to issues specific to the laws and cultural values of the study population. Where possible, the IRB shall coordinate with an IRB at the locality of the research to assure that equivalent protections are established and maintained.

(28) Schools in Research
All human subjects research conducted in or using the resources of a K-12 educational institution (including facilities, electronic systems, and personnel in their employment roles) shall require documentation that the school district or other governance body is aware of the procedures, level of risk, consent procedures, and benefits of the proposed research. Investigators shall provide the USU IRB with a letter on appropriate letterhead by an individual authorized to give permissions related to research stating that the school district or other governing body supports the conduct of this research in the named district, and has adequately reviewed the factors listed above. Protocol approval from the USU IRB shall not be finalized until school district or governance approval is in place.

Chapter 11: Required Elements of Informed Consent
One overarching requirement of research involving human participants is that investigators must obtain the informed consent of prospective participants before they can be included in research. Informed consent presumes two simultaneous concepts: informed decision-making and voluntary participation. Prospective participants must be given sufficient information about the research and its risks and benefits to reach an informed decision as to whether they will voluntarily participate.

To ensure an effective informed consent process, regulations at 45 CFR 46.116(a) mandate the inclusion of eight basic informed consent elements. Six additional elements may be required as set forth in subsection I, below, depending on the nature of the research (45 CFR 46.116(b)).

The informed consent templates provide specific guidance on how elements of informed consent should be worded and ordered.

a. Research Statement (Required Element #1).
Informed consent information must include the following:

1. A statement that the study involves research.
2. An explanation of the purposes of the research.
3. An explanation of the expected duration of participants’ participation.
4. A description of what procedures will be followed.
(5) Identification of any procedures those are experimental.

If the research is medical in nature and if the treating physician is also the research investigator, some participants may not realize they are participating in research, but believe they are just being treated for their condition. By specifying the purpose of the research and describing experimental procedures, it is intended that participants will be able to recognize the difference between research and treatment.

b. Reasonably Foreseeable Risks or Discomforts (Required Element #2).

Informed consent information must describe any reasonably foreseeable risks or discomforts associated with the research. Risks should be listed in descending order of probability and magnitude (risk of death (even if remote) before risks associated with blood draw, for example).

c. Reasonably Expected Benefits to Participants or Others (Required Element #3).

Informed consent information must describe any benefits to participants or to others that may reasonably be expected from the research. However, care must be taken not to overstate the benefits and create an undue influence on participants. Payment for participant’s participation in a research project is not to be considered as a benefit of the research.

d. Appropriate Alternatives (Required Element #4)

Informed consent information must include a disclosure of any appropriate alternative procedures or courses of treatment that may be advantageous to the participant. Enough detail must be presented so that the participant can understand and appreciate the nature of any alternatives.

e. Extent of Confidentiality (Required Element #5).

Informed consent information must describe the extent to which confidentiality of records identifying the participant will be maintained (or not maintained). Research often poses the risk of loss of confidentiality to participants. Many persons who would not otherwise have access to identifiable, private information about the participant may be involved in the research process. Consent information should describe any procedures that the research team will use to protect participants’ private records. In some research, loss of privacy may be the greatest risk of participation.

For any research that is subject to audit or inspection by any funding agency or sponsor, include a statement indicating that the sponsor may choose to inspect and copy medical or research records that identify individual research participants.

f. Compensation or Treatment for Injury (Required Element #6).

Informed consent information for research involving more than minimal risk must include explanations regarding:

(1) Whether any compensation is available if injury occurs.
(2) How participants can receive medical care and treatment for injuries suffered as a result of participating in a research program. And whether any medical treatments are available if injury occurs.
(3) A description of any such compensation or treatments or where more information about them is available.
(4) A description of any applicable state law.

g. Contact Information (Required Element #7).

Informed consent information must include details, including telephone numbers, about whom to contact for three specific situations:
(1) For answers to questions about the research. The principal investigator and other members of the research team are appropriate contacts for this information.
(2) For answers to questions about participants’ rights. The IRB Office telephone number should be provided for this information.
(3) In the event of a research-related injury occurs. The principal investigator along with other research assistants may serve as appropriate contact for this information.

h. Voluntary Participation Statement (Required Element #8).
Informed consent information must contain clear statements of the following:
(1) Participation in the research is voluntary.
(2) Refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled.
(3) The participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

i. Additional Elements Where Appropriate.
Where appropriate, the regulations allow the IRB to require that one or more of the following six additional elements be included in the informed consent information:
(1) Unforeseeable Risks to Participants, Embryos, or Fetuses.
Some research involves particular procedures or interventions that may result in unforeseeable risks to participants, to the embryo, or the fetus (if the participant is or may become pregnant). For research of such a nature, the informed consent information must warn participants that some risks are currently not known or not foreseeable.
(2) Investigator-Initiated Termination of Participation.
There may be instances that would require investigators to terminate the participation of particular participants (e.g., participant noncompliance with research, participant not benefiting from research). The informed consent information must specify these circumstances.
(3) Additional Costs.
If participants must bear any additional costs, (transportation, time away from work, health costs, etc.), these must be disclosed in the informed consent information.
(4) Early Withdrawal/Procedures for Termination.
Participants have the right to withdraw from the research. However, some studies involve medications or procedures that would be dangerous for participants to discontinue abruptly. For studies of this nature, the informed consent information must provide participants with knowledge of the consequences affecting a decision to withdraw. In addition, if there are procedures regarding how to withdraw safely from the research, these must also be described. It is not appropriate for research staff to administer any additional research-oriented questionnaires or interventions that do not affect the safety of participants who have decided to withdraw.
(5) Significant New Findings.
During the course of research, significant new knowledge or findings under study may develop. Since the new knowledge or findings may affect the risks or benefits to participants or participants’ willingness to continue in the research, the informed consent
information must detail the procedures for contacting participants regarding this new information and for affirming their continued participation.

(6) **Approximate Number of Participants.**
For certain types of research, the informed consent information should disclose the approximate number of participants to be enrolled.

j. **Monitoring & Observations**
In considering the adequacy of informed consent procedures, the IRB may require special monitoring of the consent process by an impartial observer (consent monitor) in selected studies to reduce the possibility of coercion and undue influence or whenever the IRB has concerns that the consent process may not be administered appropriately. Such monitoring may be particularly warranted where: a) the research presents moderate to high risks to participants or to vulnerable populations, b) if participants are likely to have difficulty understanding the information to be provided, d) when the procedures or interventions are particularly complicated.

Monitoring may also be appropriate as a corrective action where the IRB has identified consent-related problems associated with a particular investigator, a research project or where research staff are less experienced.

The IRB may also require that investigators include a “waiting period” within the consent process or use devices such as audio-visual aids or tests of comprehension.

Observations under this section shall be carried out using the “Monitoring Observations Report Form,” available on the IRB website, and shall follow the procedures set forth in Chapter 5.q, above.

D. Special Considerations in Institutional Review Board (IRB) Review

Chapter 12: Behavioral and Social Sciences Research
Behavioral and Social Sciences research often involves surveys, observational studies, personal interviews, or experimental designs involving exposure to some type of stimulus or intervention. This section also discusses when exemption and expedited review are appropriate for this type of research.

a. **Social and Psychological Harms.**
When evaluating behavioral and social science research, the IRB carefully examines the research to determine the probability of risk of harm to subjects.

(1) The IRB considers the potential for participants to experience stress, anxiety, guilt, or trauma that can result in genuine psychological harm.

(2) The IRB also considers the risks of criminal or civil liability or other risks that can result in serious social harms, such as damage to financial standing, employability, insurability, or reputation; stigmatization; and damage to social or family relationships.

(3) If information is being collected on living individuals other than the primary “target” subjects the IRB considers the risk of harm to those “non-target” individuals, as well.

To mitigate such risks, the IRB reviews the proposal for appropriate preventive protections and debriefings, adequate disclosure of risks in the informed consent information, and mechanisms to protect the confidentiality and privacy of persons participating in or affected by the research.
b. Privacy and Confidentiality Concerns.

The use of confidential information is an essential element of much social and behavioral and educational research.

(1) It is important to ensure that the methods used to identify potential research subjects or to gather information about subjects do not invade the privacy of the individuals. In general, identifiable information may not be obtained from private (non-public) records without IRB approval and the informed consent of the participant. This is the case even for activities intended to identify potential participants who will later be approached to participate in research. However, there are circumstances that are exempt from the regulations, and circumstances in which the IRB may approve a waiver of the usual informed consent requirements. These have been discussed previously in Chapters 9 and 11, and will also be discussed briefly in following sections of this chapter.

(2) It is also important to ensure that adequate measures are taken to protect individually identifiable private information once it has been collected to prevent a breach of confidentiality that could lead to a loss of privacy and potentially harm participants.

c. Safeguarding Confidentiality.

When information linked to individuals will be recorded as part of the research design, the IRB ensures that adequate precautions are taken to safeguard the confidentiality of the information. The more sensitive the data being collected, the more important it is for the researcher and the IRB to be familiar with techniques for protecting confidentiality.

(1) The IRB that reviews research in which the confidentiality of data is a serious issue should have at least one member (or consultant) familiar with the strengths and weaknesses of the different mechanisms available.

(2) The IRB that reviews survey and interview research should be particularly aware of the regulatory provision at 45 CFR 46.117(c)(1) for waiving documentation of consent when a signed consent form constitutes the only link between the research and the participants and would itself be a risk to the participants (Chapter 10).

(3) Among the available methods for ensuring confidentiality are coding of records, statistical techniques, and physical or computerized methods for maintaining the security of stored data.

(4) The 45 CFR 16.116(a)(5) regulations and the Common Rule require that subjects be informed of the extent to which confidentiality of research records will be maintained.

(5) The IRB is aware that Federal officials have the right to inspect and copy research records, including consent forms and individual medical records, to ensure compliance with the rules and standards of their programs. Identifiable information obtained by Federal officials during such inspections is protected by the provisions of the Privacy Act of 1974.

(6) The IRB may require that an investigator obtain a Department of Health and Human Services (DHHS) Certificate of Confidentiality (CoC). The CoC protects against the involuntary release of sensitive information about individual participants for use in Federal, state, or local civil, criminal, administrative, legislative, or other legal proceedings. CoCs are discussed in Chapter 10.

d. Research Involving Deception or Withholding of Information.
The IRB reviewing research involving incomplete disclosure or outright deception will apply both common sense and sensitivity to the review.

Where deception is involved, the IRB needs to be satisfied that the deception is necessary and that, when appropriate, the participants shall be debriefed. (Debriefing may be inappropriate, for example, when the debriefing itself would present an unreasonable risk of harm without a corresponding benefit.) The IRB will also make sure that the proposed subject population is suitable.

Deception can only be permitted where the IRB documents that a waiver of the usual informed consent requirements is justified under the criteria present in the Common Rule and 45 CFR 46.116(d). Specifically, the IRB must find and document that all four of the following criteria have been satisfied (see Chapter 11):

1. The research presents no more than minimal risk to participants.
2. The waiver or alteration shall not adversely affect the rights and welfare of the participants.
3. The research could not practicably be carried out without the waiver or alteration.
4. Where appropriate, the participants shall be provided with additional pertinent information after participation.

In making the determination to approve the use of deception under a waiver of informed consent, the IRB will consider each criterion in turn, and document specifically (in the minutes of its meeting and/or in the IRB protocol file) how the proposed research satisfies that criterion. Approval by the IRB of deception research shall be guided using the Deception Research Checklist. *(Note: The regulations make no provision for the use of deception in research that poses greater than minimal risks to participants.)*


Many studies combine characteristics of behavioral and social research with characteristics of biomedical research. There are many interdisciplinary combinations of behavioral and medical research. They often use or create tissue, specimen, or data repositories (banks).

a. **Prospective Use of Existing Materials.**

Prospective studies are designed to observe outcomes or events (e.g., diseases, behavioral outcomes, or physiological responses) that occur subsequent to identifying the targeted group of participants, proposing the study, and initiating the research.

1. Prospective studies using materials (data, documents, records or specimens) that will "exist" in the future because they will be collected for some purpose unrelated to the research (e.g., routine clinical care) do not qualify for exemption under regulations at 45 CFR 46.101(b)(4) and the Common Rule because the materials in these studies are not in existence at the time the study is proposed and initiated.

2. However, the IRB may utilize expedited procedures (under expedited category #5, see Chapters 10 and 14) to review research that proposes to use materials (i.e., data, documents, records, or specimens) that will be collected in the future (i.e., after the research has been proposed and initiated) for non-research purposes (e.g., clinical observations, medical treatment, or diagnosis occurring in a non-research context).

b. **Retrospective Use of Existing Materials.**
Research Utilizing Large Existing Data Sets.

Biosocial and bio-behavioral research often involves the use of large, existing data sets. When the data sets are publicly available (i.e., available to the general public, with or without charge), their use is exempt, whether or not they contain sensitive, identifiable information (see Chapter 9 and item “2” above).

The use of large, existing data sets requires IRB review when they contain identifiable private information about living individuals. In such cases, the IRB will determine whether the information can be used without additional informed consent and/or permission from the participants.

1. In making this determination, the IRB will first examine the conditions of informed consent under which the data were originally obtained. It may be that the proposed research is permissible under the original terms of consent.

2. If this is not the case, then the IRB will consider whether it is permissible to waive the usual informed consent requirements in accordance with 45 CFR 46.116(d).

3. In other cases, the IRB may determine that the research can proceed only if the investigator obtains and uses “anonymized” data. Under this scenario, codes and other identifiers are permanently removed from the data set before the data are sent to the investigator, and the removal is accomplished in such a manner that neither the investigator nor the source maintaining the data set can re-establish participants’ identities.

4. An alternative to anonymizing data is to maintain the data set as a data repository under the guidelines established by the Office for Human Research Protections (OHRP).

d. Research Using Data or Tissue Banks (also called Repositories).

Human data repositories collect, store, and distribute identifiable information about individual persons for research purposes. Human tissue repositories collect, store, and distribute identifiable human tissue materials for research purposes.

Tissue and Data Bank activities involve three components: (a) the collectors of data or tissue samples; (b) the bank/repository storage and data management center; and (c) the recipient investigators. Under a repository arrangement, the IRB formally oversees all elements of repository activity, setting the conditions for collection, secure storage, maintenance, and appropriate sharing of the data and/or tissues with external investigators. Specifically, the IRB determines the parameters for sharing...
data and/or tissues (which are identifiable within the repository) including whether additional informed consent of subjects is required. Typically, these parameters involve formal, written agreements stipulating conditions as follows:

(1) The repository shall not release any identifiers to the investigator.

(2) The investigator shall not attempt to recreate identifiers, identify participants, or contact participants.

(3) The investigator shall use the data only for the purposes and research specified.

The investigator shall comply with any conditions determined by the repository IRB to be appropriate for the protection of participants.
Chapter 14: Institutional Review Board (IRB) Considerations about Ethical Study Design

a. Epidemiological Research.
   Epidemiological research often makes use of sensitive, individually identifiable, private information (usually obtained from medical or other private records), and links this information with additional information obtained from other public or private records, such as employment, insurance, or police records. Epidemiological research may also combine historical research with survey and interview research. Epidemiological studies often present significant problems regarding both privacy and confidentiality.
   (1) The IRB must first consider privacy issues, and must satisfy itself that the research does not constitute an unwarranted invasion of the participants’ privacy. In doing so, the IRB shall seek to establish that the investigator has legitimate access to any identifiable information that is to be utilized. For example, if state disease registry information is to be utilized, the IRB will need to examine state law relative to the legitimate release of such information for research.
   (2) Once the IRB’s privacy concerns have been resolved, the IRB will examine mechanisms for maintaining the confidentiality of data collected. The IRB shall seek to establish that confidentiality protections are appropriate to the nature and sensitivity of the information that has been obtained.
   (3) Because epidemiological research typically requires large numbers of participants, investigators almost always request that the IRB waive the usual requirements for informed consent. To approve such a waiver in epidemiological research, the IRB must find and document that the criteria for a waiver of informed consent have been met (45 CFR 46.116(d); specifically that (a) the research presents no more than minimal risk to participants; (b) the waiver will not adversely affect the rights and welfare of the participants; (c) the research could not practicably be carried out without the waiver, and (d) whenever appropriate, the participants will be provided with additional pertinent information after participation.

b. Issues in Genetic Research.
   Information obtained through genetic research may have serious repercussions for the participant or the participant’s family members. Genetic studies that generate information about participants' personal health risks can provoke anxiety and confusion, damage familial relationships, and compromise the participants’ insurability and employment opportunities. For many genetic research protocols, these psychosocial risks can be significant enough to warrant careful IRB review and discussion. Those genetic studies limited to the collection of family history information and blood drawing will not automatically be classified as "minimal risk" studies qualifying for expedited IRB review. The addition of the genetic analysis can radically alter the level of risk.

   The protection of private information gathered for and resulting from genetic research is a major concern. The IRB will expect the investigator to describe in detail how individual privacy will be protected and how the confidentiality of obtained information will be maintained. (See Chapter 3. Types of Research.)

c. Family History Research.
   Family history research is a common technique used in bio-social and bio-behavioral research. Family history research typically involves obtaining information from one family member (called a proband) about other family members (third parties).
(1) It is important to recognize the regulations at 45 CFR 46.102 (f)(2) and the Common Rule which include in the definition of human subject a living individual about whom an investigator obtains “identifiable private information.”

(2) Thus, the family members identified and described by the proband may be human participants under the regulations if the investigators obtain identifiable private information about them.

(3) The IRB shall determine whether family members (third parties) are human participants in such research, and if so, consider the possible risks involved, and determine whether their informed consent is required or can be waived (see Chapter 10) under the conditions specified at 45 CFR 46.116(d). OHRP representatives have advised that “third parties” about whom identifiable and private information is collected in the course of research are human participants. Confidentiality is a major concern in determining if minimal risk is involved. IRB's can consider if informed consent from third parties can be waived in accordance with Section.116 and if so, document that in the IRB minutes.

d. Research Involving Potentially Addictive Substances.
Research involving potentially addictive substances often involves the use of what may be termed “abuse-liable” substances. Abuse-liable substances are pharmacological substances that have the potential for creating abusive dependency. Abuse-liable substances can include both legal and illicit drugs. The following are among the issues that the IRB will consider when reviewing research involving potentially addictive substances:

(1) When this type of research is proposed, the IRB will consider the participants’ capacity to provide continuous informed consent, ensuring that participants are competent and are not coerced.

(2) If such research involves participants that are institutionalized, the participants’ ability to exercise autonomy could be impaired.

(3) The IRB shall also consider the requirements for equitable selection of participants and protections for maintaining confidentiality, as such a population may be at risk for being discriminated against, or over-selected.

(4) The IRB shall be sensitive to the ethical context of the research, in that there may be moral dilemmas associated with the use of placebos, or in cases where addicts are presented with alcohol and/or drugs.

(5) The IRB shall focus on the considerations of risk and benefit of such research.
Chapter 15: Potentially Vulnerable Populations

Regulations at 45 CFR 46.111(b) (the Common Rule) require the IRB to give special consideration to protecting the welfare of particularly vulnerable participants, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

The IRB shall ensure that it has adequate representation on the Board to consider specific kinds of research in which it is regularly involved involving these vulnerable populations in a satisfactory manner.

a. Elements to Consider in Reviewing Research Involving Vulnerable Participants.

The IRB shall pay special attention to specific elements of the research plan when reviewing research involving vulnerable participants.

1. Strategic issues include inclusion and exclusion criteria for selecting and recruiting participants; informed consent and willingness to volunteer; coercion and undue influence; and confidentiality of data.

2. The IRB should carefully consider group characteristics, such as economic, social, physical, and environmental conditions, to ensure that the research incorporates additional safeguards for vulnerable participants.

3. Investigators should not be permitted to over-select or exclude certain groups based on perceived limitations or complexities associated with those groups. For example, it is not appropriate to target prisoners as research participants merely because they are a readily available population.

4. The IRB must be knowledgeable about applicable state or local laws that bear on the decision-making abilities of potentially vulnerable populations. State statutes often address issues related to competency to consent for research, emancipated minors, legally authorized representatives, the age of majority for research consent, and the waiver of parental permission for research.

5. Research studies that plan to involve any potentially vulnerable populations must have adequate procedures in place for assessing and ensuring participants’ capacity, understanding, and informed consent or assent. When weighing the decision whether to approve or disapprove research involving vulnerable participants, the IRB shall look to see that such procedures are a part of the research plan. In certain instances, it may be possible for researchers to enhance understanding for potentially vulnerable participants. Examples include requiring someone not involved in the research to obtain the consent, the inclusion of a consent monitor, a participant advocate, interpreter for hearing-impaired participants, translation of informed consent forms into languages the participants understand, and reading the consent form to participants slowly and ensuring their understanding paragraph by paragraph.

6. The IRB may require additional safeguards to protect potentially vulnerable populations. For instance, the IRB may require that the investigator submit each signed informed consent form to the IRB, that someone from the IRB oversee the consent process, or that a waiting period be established between initial contact and enrollment to allow time for family discussion and questions.

b. Pregnant Women, Fetuses, and Human In-Vitro Fertilization.

Research involving individuals in this category shall be reviewed and approved in accordance with guidelines as set forth on the USU Form "IRB Checklist for Research Involving Pregnant Women."

c. Research Involving Prisoners.
DHHS regulations at 45 CFR 46, Subpart C detail special protections for research involving prisoners, who due to their incarceration may have a limited ability to make truly voluntary and uncoerced decisions about whether or not to participate in research. In addition to requirements under 45 CFR 46, the Department of Justice regulations at 28 CFR 512 also govern human research with the Bureau of Prisons. These requirements are discussed in Chapter 17 of these SOPs.

1. A prisoner is defined as any individual involuntarily confined or detained in a penal institution.

2. In order to consider research involving prisoners, the IRB shall:
   (a) Have a majority of its members not otherwise associated with the prison.
   (b) Include a prisoner or a prisoner advocate, who can adequately represent the interests of the prisoners, unless the research has already been reviewed by an IRB that included a prisoner advocate.

3. The IRB uses the criteria outlined in the “Investigator Checklist for Prisoners” to review research involving prisoners. As required in the checklist, the IRB shall:
   (a) Make the seven additional findings set forth in 45 CFR 46.305
   (b) Determine which category in 45 CFR 46.306 permits the research to go forward
   (c) If the research is DHHS-supported, certify these findings to the Office for Human Research Protections (OHRP). Certification to OHRP is not required for research not supported by DHHS. However, OHRP recommends that the IRB apply the standards of Subpart C to all prisoner research. Should non-DHHS research fall outside the category stipulations under 45 CFR 46.306, OHRP recommends that the IRB consult with appropriate experts before approving the research. (See “5” below)

4. Under DHHS regulations, prisoners may participate in the following categories of research:
   (a) Studies (involving no more than minimal risk or inconvenience) of the possible causes, effects, and processes of incarceration and criminal behavior.
   (b) Studies (involving no more than minimal risk or inconvenience) of prisons as institutional structures or of prisoners as incarcerated persons.
   (c) Research on particular conditions affecting prisoners as a class (providing the Secretary of HHS has consulted with appropriate experts and published the intent to support such research in the Federal Register).
   (d) Research involving practices that have the intent and reasonable probability of benefiting the prisoner participant. If the research involves possible assignment to a control group that may not benefit from the research, the Secretary of HHS must also consult with appropriate experts and publish the intent to support the research in the Federal Register (45 CFR 46.306).

5. The following additional determinations shall be made by the IRB before research involving prisoners goes forward (45 CFR 46.305):
   (a) The research under review represents one of the categories of research listed above.
   (b) Any possible advantages accruing to the prisoner through his or her participation in the research, when compared with the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the...
value of such advantages in the limited choice environment of the prison is impaired.

(c) The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers.

(d) Procedures for selecting participants within the prison are fair to all prisoners, and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the IRB justification in writing for following some other procedures, control participants must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project.

(e) The information is presented in language that is understandable to the participant population.

(f) Adequate assurance exists that parole boards will not take into account a prisoner’s participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole.

(g) Where the IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoner’s sentences, and for informing participants of this fact.

d. Research Involving Children.

DHHS regulations at 45 CFR 46, Subpart D require special protections for research involving children. Under the regulations, children are persons who have not attained the legal age for consent to treatments or procedures involved in the research under the applicable jurisdiction in which the research will be conducted.

There are three main issues to consider when reviewing research involving children: (1) risk-benefit analysis; (2) parental permission; and (3) assent of the child.

(1) The IRB shall make certain findings and determinations when reviewing research involving children. IRB records must reflect the IRB’s understanding and justification for the risks and benefits posed by approved research involving children. Proposed research must fall within one of the following four categories:

(a) Research not involving greater than minimal risk.

(b) Research involving greater than minimal risk, but presenting the prospect of direct benefit to the individual participants.

(c) Research involving greater than minimal risk and no prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant’s disorder or condition.

(d) Research not otherwise approvable, which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

Each category stipulates specific conditions that must be met before the proposed research can be approved. These conditions are summarized in the Table in Chapter 7 of the Investigator Handbook, p27.
(2) Provisions must also be made to obtain the child’s assent when the IRB has determined that the child is capable of giving assent. The IRB shall consider the age, maturity, and psychological state of the child involved. The IRB may determine that the assent of the child is not necessary if and only if all three of the following conditions are satisfied:
   (a) The research offers the child the possibility of a direct benefit.
   (b) The benefit is important to the health or well-being of the child.
   (c) The benefit is available only in the context of the research.

(3) The IRB shall take great care in approving research where the child is suffering from a life-threatening illness with little real chance of therapeutic benefit from the research. The IRB shall also be cautious in allowing the parents to overrule the child’s dissent where experimental therapy has little or no reasonable expectation of benefit. The justification for exposing the child to extreme discomfort, with little possibility for benefit, may be tenuous.

(4) If it is deemed appropriate that the child’s assent should be solicited, the IRB should ensure that the assent form is tailored for the child, with respect to his or her level of understanding. For young children especially, the assent form should be designed as a one-page document, with simple, age-appropriate language, and presented in a manner understandable to the child.

The IRB may expedite protocols involving children when (a) the risk involved is deemed to be minimal and (b) when the research involves only those procedures which can otherwise be expedited, according to 45CFR 46.110. However, even if the protocol is considered minimal risk and the research is eligible for expedited procedures, the IRB may still require full-board review.

e. Research Involving Decisionally Impaired Subjects.

Decisionally impaired persons are individuals who have a diminished capacity for judgment and reasoning due to a psychiatric, organic, developmental, or other disorder that affects cognitive or emotional functions. Other individuals who may be considered decisionally impaired, with limited decision-making ability, are individuals under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps.

There are no regulations specific to research involving cognitively impaired persons. In all cases, the IRB shall take special care to consider issues such as the selection of participants, privacy and confidentiality, coercion and undue influence, and risk-benefit analysis. Decisions should be made with the utmost deference to the ethical principles underlying human research as set forth in the Belmont Report. Capacity should be evaluated on an individual basis to avoid incorrect assumptions as to an individual’s ability to make decisions. In cases where research involving cognitively impaired individuals is approved, IRBs should require additional safeguards (e.g., involvement of participant advocates, independent monitoring, formal capacity assessment, waiting periods) as part of the research plan to protect participants.

The National Bioethics Advisory Commission (NBAC) has issued 21 recommendations for IRBs, the research community, and Federal regulators to consider regarding the decision-making capacity of particularly vulnerable participants. The complete report, “Research Involving Persons with Mental Disorders That May Affect Decision Making Capacity” (December 1998), can be found on-line at http://www.bioethics.gov/.
f. **Surrogate Permission with Subjects Judged Incompetent to Consent.**

For research conducted in the state of Utah, when the participant is not capable of providing informed consent (such as children or incapacitated adults), consent or permission may only be given by parents with custodial rights (if participants are children) or by a legal guardian appointed by the court.

Surrogate consent may be used only when the prospective participant is incompetent as determined by a medical or psychological authority, as appropriate, who is not otherwise associated with the study, after appropriate mental or medical evaluation, and there is little or no likelihood that the participant will regain competence within a reasonable period of time, or as established by legal determination. This definition of incompetence is not limited to the legal definition but also may also be a clinical judgment that a person lacks the capacity to understand the circumstances of participating in research and to make an autonomous decision to take part.

Before incompetent persons may be involved in any research, the IRB must find and document in writing that the proposed research meets all of the following conditions:

1. Only incompetent persons are suitable. Competent persons are not suitable for the proposed research. The investigator must demonstrate that there is compelling reason to include incompetent persons as participants. Incompetent persons must not be involved as participants simply because they are readily available.

2. Favorable Risk/Benefit Ratio. The proposed research entails no significant risks, or if the research presents risk of harm, there must at least be a greater probability of direct benefit to the participant than of harm.

3. No Resistance. Participants do not resist participating. Under no circumstances may participants be forced or coerced into participating.

4. Well-Informed Representatives. Procedures have been devised to ensure that participants’ legally authorized representatives are well informed regarding their roles and obligations to protect the rights and welfare of the participants they represent. Representatives must be informed in writing that their obligation is to try to determine what the participant would do if competent, or if the participant’s wishes cannot be determined, what is in the participant’s best interests.

**g. Research Involving Other Potentially Vulnerable Adult Subjects.**

Employees, students, and trainees at USU should also be considered vulnerable participants. Thus, the IRB shall uphold the same standards in approving research involving these groups as other vulnerable populations.

The context of the research is an important consideration for the IRB when reviewing research that involves other potentially vulnerable participants. Research involving homeless persons, members of particular minority groups, or the economically or educationally disadvantaged pose significant challenges. Research involving significant follow-up procedures or offering significant monetary compensation may unduly influence certain types of participants, and the IRB shall take such considerations into account. Nevertheless, research involving these individuals is socially important for understanding and eventually improving adverse health in these populations.

**h. Human Fetal Tissue Transplantation Research.**

Public Law 103-43 governs human fetal tissue transplantation research supported by DHHS as follows:
(1) Human fetal tissue may be used only if the women providing the tissue declare in a signed written statement that she is donating the tissue without any restrictions regarding the identity of the transplant recipients and without being informed of the identity of the recipients.

(2) If the tissue is obtained pursuant to an induced abortion, the attending physician must declare in a signed written statement that the consent of the women for the abortion was obtained prior to requesting or obtaining consent for the donation of the tissue; no alteration of the timing, method, or procedures used to terminate the pregnancy was made solely for the purpose of obtaining the tissue; and the abortion was performed in accordance with applicable State law.

(3) The attending physician must declare in a signed written statement that the tissue was donated by the woman as described in item “a” and with full disclosure with regard to the physician’s interest in the research and any known medical or privacy risks associated with the research.

(4) The principal investigator for the research must declare in a signed written statement that the tissue is human fetal tissue; the tissue may have been obtained pursuant to a spontaneous or induced abortion or stillbirth; the tissue was donated for research; the investigator has provided this information to other individuals involved in the research; the investigator shall require written acknowledgement of receipt of this information by the recipient; and the investigator has had no part in decisions as to the timing, method, or procedures used to terminate the pregnancy solely for the purposes of the research.

(5) It is unlawful for any person to knowingly acquire, receive, or transfer any human fetal tissue for valuable consideration.

(6) It is unlawful for any person to solicit or knowingly acquire, receive, or accept a donation of human fetal tissue for transplantation if the tissue is obtained pursuant to an induced abortion and the donation is made pursuant to a promise that it will be transplanted to any specified individual, to a relative of the donating individual, or in valuable consideration for the costs associated with the abortion.

i. **Research Involving Deceased Persons.**

Research involving deceased persons is not covered by the Common Rule. However, such research may be covered under applicable state law.

**Chapter 16: Managing Conflicts of Interest**

AT USU, a Conflict of Interest is defined as the co-existence of two interests, where the primary interest is in the institution and the secondary interest is outside the university. Any conflict of interest that may compromise or present the appearance of compromising an individual’s or group’s professional judgment in conducting, reviewing, or reporting research shall be disclosed and reduced managed or eliminated.

Research personnel, IRB members, IRB Chairpersons, the Institutional Official, and research sponsors may all have certain conflicts of interest. Such conflicts of interest may arise because of the intellectual property involved in research discoveries or industry-academic partnerships, from financial incentives offered to researchers, or due to particular role relationships within the governance structure of organizations or institutions.
a. **Research Personnel.**
For researchers, financial or other incentives may negatively impact the collection, analysis and interpretation of data, scientific objectivity and integrity, and ultimately the public trust in the research enterprise. In addition, a researcher may unwittingly exert coercion or undue influence on prospective participants to participate in research.

b. **IRB Chairpersons and Members.**
IRB chairpersons and IRB members may find themselves in any of the following conflicts of interest when reviewing research:
   (1) Where the IRB Chairperson or member is listed as an investigator on the research.
   (2) Where any investigator must report to or is under the supervision of an IRB chairperson or member.
   (3) Where the IRB Chairperson or member competes for research grants or contracts in the same or similar field as an investigator whose research is scheduled for review.

c. **IRB Administrator.**
If the Administrator has other duties in the research arena, there is a possibility of a conflict, which shall be reported to the IRB Chairperson and the institution.

d. **Institutional Officials.**
To avoid possible conflict of interest among institutional officials, OHRP guidance is that those who administer the research programs have the ability to influence programmatic and budgetary decisions, and are in a position to exert undue influence on the IRB. Systemic internal controls should be provided at the institutional level to ensure that the IRB can function independently in its oversight role.

e. **USU IRB Regulations and the Common Rule.**
The regulations at (45 CFR 16.107(e)), the Common Rule, prohibit IRB members, chairs, or staff who have a conflicting interest from participating in the IRB’s initial or continuing review of research.
   (1) Such conflicts must be disclosed, and the IRB member, chairperson, or staff member must not take part in the discussion or voting of such research, except to answer questions from the IRB. The IRB Chairperson shall remind the board of USU’s policies at the outset of each meeting and incorporate this reminder in the minutes of the meeting. The IRB minutes shall specifically reflect such recusals as they occur during meetings.
   (2) The IRB shall consider any matter that raises the possibility of coercion or undue influence in the consent process. The existence of an investigator conflict of interest would fall within this category.
   (3) As a matter of policy, USU requires disclosure of any potential conflicts of interest to the Conflict of Interest Committee established for this purpose. Adherence to disclosure requirements is a routine condition for IRB approval of research.
   (4) IRB members and staff shall participate in education and training activities related to financial conflict of interest issues. (References the HHS August 2000 conference website (OHRP) where PHS policies, requirements, guidelines, and guidance may be found at [http://www.hhs.gov/ohrp/archive/coi/index.htm](http://www.hhs.gov/ohrp/archive/coi/index.htm) or from [http://www.hhs.gov/ohrp/archive/humansubjects/finreltn/finguid.htm](http://www.hhs.gov/ohrp/archive/humansubjects/finreltn/finguid.htm)
f. **The Department of Health and Human Services Public Health Service (DHHS-PHS) Requirements for Grantee Institutions.**

DHHS requires that PHS grantee institutions have a written policy and guidelines on conflicts of interest. USU's Conflict of Interest Committee (COIC) is responsible for reviewing all financial disclosures, and determining if a conflict of interest exists. If one exists, the COIC must determine what actions should be taken to manage, reduce, or eliminate the conflicting interest. Review of conflicts of interest occurs before review by the IRB. COIC reports are submitted to the IRB, and the convened IRB has sole authority to decide whether the management plan is sufficient to allow a human research study to be approved.

The PHS requirements call for grantee institutions to:

1. Maintain a written, enforced policy on conflicts of interest
2. Review all financial disclosure statements (listings of significant financial interests for investigators and immediate family members) for all investigators participating in PHS-funded research
3. Report to PHS the existence of a conflicting interest found by the institution and ensure that it has been managed

Under this regulation, an “Investigator” means the principal investigator and any other person who is responsible for the design, conduct, or reporting of the research. For purposes of determining financial interests, the Investigator’s interests include those of his/her spouse and dependent children.

“Significant financial interest” means anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). Financial interests which are subject to reporting for any given research proposal include those which would reasonably appear to be affected by the specific research proposed; and/or are interests in entities whose financial interests would reasonably appear to be affected by the research.

When engaged in Human Research, "Significant financial interest" does not include:

1. Salary, royalties, or other remuneration from the applicant institution.
2. Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities.
3. Income from service on advisory committees or review panels for public or nonprofit entities.
4. An equity interest that when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both of the following tests: (a) Does not exceed $10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and (b) does not represent more than a five percent ownership interest in any single entity.
5. Salary, royalties or other payments that when aggregated for the Investigator and the Investigator's spouse and dependent children over the next twelve months, are not expected to exceed $10,000.

Examples of conditions or restrictions that might be imposed to manage conflicts of interest include, but are not limited to:
g. The Disclosure Process.
As one method of preventing, monitoring, managing, and resolving conflicts of interest, USU requires full disclosure of conflicts of interest by investigators.

Full disclosure of conflicting information demonstrates good faith and protects the integrity of the research and the reputation of the institution. Disclosure is made to the USU’s conflict of interest official, and where deemed appropriate by that official to the IRB Chairperson.

Where appropriate, and as determined by the IRB or the conflict of interest official, disclosure to the human participants involved in the research may be warranted via the informed consent document.
Chapter 17: Requirements for Research Under Department of Defense, Department of Education, Department of Energy and Department of Justice Regulations

The Common Rule (45 CFR 46) has been adopted by several department of the Federal Government. However, some government agencies have promulgated additional regulations and policies that guide human research when those agencies sponsor research or when specific populations are involved in research. The following sections reflect the additional requirements that apply when human research is sponsored by one of the following agencies:

- The Department of Defense
- The Department of Education
- The Department of Energy
- The Department of Justice, including the Bureau of Prisons

This chapter focuses on procedural requirements associated with agency-specific regulations from the above agencies. Additional information concerning the requirements may be found in Chapter 12 of the Investigator Handbook, “Regulatory Requirements Associated with Human Research Sponsored by Certain Agencies.” Additional requirements contained in these sections shall be reflected in the Supplemental Reviewer Checklist, which will be distributed to IRB reviewers by the IRB Office for each project required to follow any of these regulations.

a. The Department of Defense

(1) Ethics Training. Initial and continuing ethics training is required for all personnel who conduct, review, approve, oversee, support or manage human research. Training is provided using CITI’s human protection training modules. In addition, when human research is sponsored by the Department of Defense (DOD), it is also required that investigators and research staff become familiar with DOD regulations and requirements regarding human protections. These regulations and requirements are contained in this section. Prior to beginning work on a study under DOD regulations, Investigators and staff shall complete USU’s DOD training module, included in USU’s training site maintained by CITI, and shall complete with a passing grade (80%) the competency test given at the end of the module. Investigators and staff are expected to be familiar with the requirements set forth. Individuals who have questions regarding this information may contact the IRB Office for clarifications and assistance.

(2) Scientific Validity. Under DOD regulations substantive amendments are required to undergo scientific review before being approved; however, USU procedures do not allow anything other than minor changes to be included in an amendment. Any substantive change to a DOD-sponsored protocol will therefore require a new application and review by the IRB, including the need for a new scientific review. The IRB Office shall ascertain that a review of the modified protocol has either been conducted as required under these SOPs, or will ensure that the IRB or another appropriate reviewer or review body completes such a review. IRB members will use the Supplemental Reviewer Checklist to verify that this requirement has been met.

(3) Transnational research. When conducting DOD-sponsored human research with international populations, USU must have permission to conduct the research in that country either by receiving a certification from an authorized agent of the government or through a review and approval process with a local IRB or other ethics review body that is recognized by the government. Identifying and completing this process, and understanding
and following all local laws, regulations, customs and practices is the primary responsibility of the PI. Investigators with questions regarding transnational research may contact the USU IRB Office. The IRB shall have responsibility for verifying that appropriate permission has been obtained and record its findings using the Supplemental Reviewer Checklist.

(4) **Reporting of noncompliance.** When a finding of serious or continuing noncompliance is made on a project funded by DOD, USU must report the noncompliance to the Department of Defense. The same information that is outlined in this Handbook and in the SOPs regarding reporting noncompliance would be submitted to DOD under these circumstances.

(5) **DOD review of survey instruments.** As an additional determination that must be made by the IRB, surveys performed on DOD personnel must be submitted, reviewed, and approved by the DOD after the research protocol is reviewed and approved by the IRB. This determination is recorded using the Supplemental Reviewer Checklist.

(6) **Data and Safety Monitoring.** Under DOD regulations, the IRB must appoint a research monitor for studies involving greater than minimal risk. The research monitor is appointed by name. The monitor has authority to:

- suspend the research
- remove individuals from the study
- take any steps to protect the safety and well-being of participants until the IRB has been able to assess the situation and determine corrective actions to be taken.

For studies involving no greater than minimal risk, and for portions of studies not involving greater than minimal risk (though some portions may involve greater than minimal risk) the IRB may, at its discretion, appoint a data and safety monitor. This additional determination by the IRB shall be documented using the Supplemental Reviewer Checklist.

(7) **Multisite research.** When conducting multisite investigations under DOD regulations a formal agreement between organizations is required to specify the roles and responsibilities of each party. The IRB shall determine that this agreement is in place and that its terms and conditions provide adequate protections to human participants. The IRB’s determination will be recorded using the Supplemental Reviewer Checklist.

(8) **Research involving U.S. military personnel.** Human research involving U.S. military personnel must include provisions of additional protections to minimize undue influence:

- Officers are not permitted to influence the decision or their subordinates.
- Officers and senior non-commissioned officers may not be present at the time of recruitment.
- Officers and senior non-commissioned officers have a separate opportunity to participate.
- When recruitment involves a percentage of a unit, an independent ombudsperson is present.

Human research involving U.S. military personnel must include provisions to limit dual compensation as follows:

- Individuals are prohibited from receiving payment of compensation for research during duty hours; however, military personnel may be compensated for research if the participant is involved in the research when not on duty.
• All requirements for additional protections as contained in DOD regulations shall be reviewed by IRB reviewers and, if subject to a full-board review, by the IRB. The requirements are included on the Supplemental Reviewer Checklist.

(9) **Informed consent.** When DOD regulations are being followed, the following requirements must be included pertaining to informed consent, required elements of disclosure, and waiver of consent:

• The definition of “experimental subject” shall be: a human being involved in an activity for research purposes, where there is an intervention or interaction for the primary purpose of obtaining data regarding the effect of the intervention or interaction.

• This definition is equivalent to USU’s definition of a “human participant,” or “human subject.”

• When an individual meets the definition of “experimental subject”, a waiver of the consent process is not allowed unless the waiver is obtained through the Secretary of Defense. When an individual does not meet this definition, the IRB may waive the consent process.

• Provisions for research-related injuries in the informed consent disclosure must include requirements of the Department of Defense component(s) involved.

• Requirements for informed consent under the DOD regulations shall be included on the Supplemental Reviewer Checklist.

(10) **Prisoners of War.** When following DOD regulations, research involving prisoners of war is prohibited. The Supplemental Reviewer Checklist provides a definition for the term “prisoner of war.” The IRB shall verify that no individuals that are prisoners of war will be included in research.

(11) **Access to IRB records.** The DOD may require submission of records for archival purposes. Releases of such records shall be coordinated with the IO, the Federal Compliance Manager and General Counsel.

**b. The Department of Education**

(1) **Working with the National Institute on Disability and Rehabilitation Research (NIDHR).** Whenever a project is funded through the NIDHR, if the research purposefully requires inclusion of children with disabilities or individuals with mental disabilities as research participants, the IRB must include at least one person primarily concerned with the welfare of these research participants. This requirement is reviewed prior to IRB meetings using the IRB Meeting Preparation Checklist.

(2) **Release of student records for research.** The USU IRB, in consultation with the Office of General Counsel, may allow for release of student records without receiving parental/student consent for the release. The following conditions must be met:

The disclosure must be to an organization conducting studies for, or on behalf of, educational agencies or institutions for the purpose of:

• Developing, validating or administering predictive tests
• Administering student aid programs
• Improving instruction
A written agreement between USU and any school district or a post-secondary institution desiring such a release must be in place prior to USU releasing information, indicating:

- That USU has determined, through the IRB and General Counsel, that the exception will be allowed
- The purpose, scope and duration of the study
- The specific identifiable information that may be disclosed under the agreement
- That information released may only be used for allowable purposes that are specified in the written agreement
- That the requirements in 34 CFR 99.31(a)(6) on re-disclosure and destruction of information will be followed
- That the study will be conducted in a manner that does not permit personal identification of parents and students by anyone other than representatives of the organization entering into the agreement
- That the receiving organization will destroy or return to USU all personally identifiable information when no longer needed for the purposes of the study
- The time period during which the organization must either destroy or return the information

(3) Educational records may be released without consent under FERPA if all personally identifiable information has been removed from the record set. The investigator shall have primary responsibility for ascertaining that identifiers have been removed, and shall notify the IRB office of its intent to release de-identified data sets. The following identifiable information must be removed before release:

- Student’s name and other direct personal identifiers, such as the student’s Social Security Number or student number.
- Indirect identifiers, such as the name of the student’s parent or other family members, the student’s or family’s address, and personal characteristics or other information that would make the student’s identity easily traceable, date and place of birth and mother’s maiden name
- Biometric records, including one or more measurable biological or behavioral characteristics that can be used for automated recognition of an individual, including fingerprints, retina and iris patterns, voiceprints, DNA sequence, facial characteristics, and handwriting
- Other information that, alone or in combination, is linked or linkable to a specific student that would allow a reasonable person in the school community who does not have personal knowledge of the relevant circumstances to identify the student with reasonable certainty

All requirements under FERPA for release of student records as outlined above shall be included in the Supplemental Reviewer Checklist.

(4) Compliance with the Protection of Pupil Rights Amendment (PPRA). The statutory requirements of the PPRA have been established to protect children and families from harms potentially associated with release of private and individually identifiable
When a study is funded by the Department of Education the following requirements apply:

- No student shall be required, as part of any research project, to submit without prior consent to surveys, psychiatric examination, testing, or treatment in which the primary purpose is to reveal information concerning one of more of the following:
  - Political affiliations
  - Mental and psychological problems potentially embarrassing to the student or his or her family
  - Sex behaviors and attitudes
  - Illegal, anti-social, self-incriminating and demeaning behavior
  - Critical appraisals of other individuals with whom the student has close family relations
  - Legally recognized privileged and analogous relationships, such as those of lawyers, physicians and ministers
  - Religious practices, affiliations, or beliefs of the student or student’s parent
  - Income, other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under a program.

Prior consent, as used in the subsection above, shall mean:

- Prior consent of the student if the student is an adult or emancipated minor (so long as state law in the location where the research is conducted recognizes such status); or
- Prior written consent of the parent or guardian, if the student is an un-emancipated minor. Schools and contractors obtain prior written parental permission before minor students are required to participate in any Department of Education funded survey, analysis or evaluation.

(5) PPRA compliance when no funding from the Department of Education is involved. The PPRA protects student records and privacy whether the research is sponsored by the Department of Education or not. The USU IRB must verify with schools in these instances that the schools have policies and procedures that comply with the following PPRA requirements:

- The right of a parent of a student to inspect, upon the request of the parent, a survey created by a third party before the survey is administered or distributed by a school to a student.
- Any applicable procedures for granting a request by a parent for reasonable access to such survey within a reasonable period of time after the request is received.
- Arrangements to protect student privacy that are provided by the agency in the event of the administration or distribution of a survey to a student containing one or more of the following items (including the right of a parent of a student to inspect, upon the request of the parent, any survey containing one or more of such items:
  - Political affiliations or beliefs of the student or the student’s parent.
  - Mental or psychological problems of the student or the student’s family
• Sex behavior and attitudes
• Illegal, anti-social, self-incriminating, or demeaning behavior.
• Critical appraisals of other individuals with whom respondents have close family relationships
• Legally recognized privileged or analogous relationships, such as those of lawyers, physicians and ministers
• Religious practices, affiliations, or believers of the student or the student’s parents
• Income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program)
• The right of a parent of a student to inspect, upon the request of the parent, any instructional material used as part of the educational curriculum for the student
• Any applicable procedures for granting a request by a parent for reasonable access to instructional material received
• The administration of physical examinations or screenings that the school or agency may administer to a student
• The collection, disclosure or use of personal information collected from students for the purpose of marketing or for selling that information (or otherwise providing that information to other for that purpose), including arrangements to protect student privacy that are provided by the agency in the event of such collection, disclosure or use
• The right of a parent of a student to inspect, upon the requires of the parent, any instrument used in the collection or personal information before the instrument is administered or distributed to a student
• Any applicable procedures for granting a request by a parent for reasonable access to such instrument within a reasonable period of time after the request is received.

(6) Providing access to instructional materials

• Access to instructional material used in a research or experimentation program:
• All instructional material--including teachers’ manuals, films, tapes, or other supplementary instructional material--which will be used in connection with any research or experimentation program or project must be available for inspection by the parents or guardians of the children engaged in such research.
• Research or experimentation program or project means any program or project in any research that is designed to explore or develop new or unproven teaching methods or techniques.
• Children are persons enrolled in research not above the elementary or secondary education level, who have not reached the age or majority as determined under state law.

All requirements under PPRA as outlined above shall be included in the Supplemental Reviewer Checklist.

c. The Department of Energy
Checklist for Department of Energy (DOE) confidentiality regulations. When human research is funded by the DOE, the IRB will require submission of the document “Checklist for IRBs to Use in
Verifying that HS Research Protocols are in Compliance with DOE Requirements.” This form is listed at the IRB website at this address: https://irb.usu.edu/htm/applications-forms or at: http://humansubjects.energy.gov/other-resources/documents/Researcher-template-for-reviewing-PII-protocols-2010a_ac.pdf.

This checklist verifies compliance with the DOE requirements for the protection of personally identifiable Information.

(1) **Reporting requirements.** When conducting research under DOE requirements, the researcher must cooperate with the IRB and the OCA in promptly reporting to the DOE human subject project manager:
   
   • Any significant adverse events, unanticipated risks, and complaints about the research, with a description of any corrective actions taken or to be taken
   
   • Any suspension or termination of IRB approval of research
   
   • Any significant noncompliance with HRPP procedures or other requirements

   The compromise of personally identifiable information shall be reported immediately to the DOE human subject project manager.

   For purposes of this procedure, “promptly” shall mean within seven working days of the identification of the event being reported, and “immediately” shall mean within three working days of the identification of the event.

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d. **The Department of Justice**

(1) The following requirements identified in 28 CFR 512 and elsewhere shall be included on the Supplemental Reviewer Checklist. The checklist shall be provided to reviewers by the IRB Office whenever the requirements apply to the research to be conducted.

(2) The definition of “Research.” When a project is governed by the regulations of the Department of Justice, within the Bureau of Prisons (BoP) implementation of BoP programmatic or operations initiatives made through pilot projects shall not be considered to be research.

(3) **Allowable research within the BoP.** Research to be conducted within the BoP must fall within regulations at 28 CFR 512, as follows:
   
   • The project must not involve medical experimentation, cosmetic research or pharmaceutical testing.
   
   • The research design must be compatible with both the operation of prison facilities and protection of human participants. The investigator must observe the rules of the institution or office in which the research is conducted.
   
   • Any investigator who is a non-employee of the BoP must sign a statement in which the investigator agrees to adhere to the provisions of 28 CFR 512
   
   • All research proposals must be reviewed and approved by the Bureau Research Review Board

(4) **Scientific Validity of research within the BoP.** Research conducted within the BoP must be determined to have a research design adequate to contribute to the advancement of knowledge about corrections.
(5) **Adequate qualifications of the investigator for research within the BoP.** Investigators involved in research within the BoP must have and be able to demonstrate appropriate academic preparation or experience in the area of study of the proposed research.

(6) **Submissions of proposed research to the BoP.** In coordination with USU's IRB, the applicant shall provide the following information to the BoP:

- A summary statement, which includes:
  - Names and current affiliations of the investigator
  - Title of the study
  - Purpose of the study
  - Location if the study
  - Methods to be employed
  - Anticipated results
  - Duration of the study number of participants (staff or inmates) required and amount of time required from each
  - Indication of risk or discomfort involved as a result of participation

- A comprehensive statement, which includes:
  - Review of related literature
  - Detailed description of the research methods to be utilized
  - Significance of anticipated results and their contribution to the advancement of knowledge
  - Specific resources required from the Bureau of Prisons
  - Description of all possible risks, discomforts, and benefits to individual participants or classes of participants, and a discussion of the likelihood that the risks and discomforts will actually occur
  - Description of steps taken to minimize risks

- Description of physical or administrative procedures to be followed to:
  - Ensure the security of any individually identifiable data that are being collected for the study
  - Destroy research records or remove individual identifiers from those records when the research has been completed.

- Description of any anticipated effects of the research study on organizational programs and operations

- Relevant research materials such as vitae, endorsements, sample consent statements, questionnaires and interview schedules; and

- A statement meeting the assurance and certification requirements at 28 CFR 46, if applicable.

(7) **Selection and recruitment of participants for research within the BoP.** The following criteria shall be met when research is to be carried out within the BoP:

- The selection of participants within any one organization must be equitable.
- Incentives may not be offered to help persuade inmate participants to participate. However, soft drinks and snacks to be consumed at the test setting may be offered.
Reasonable accommodations such as nominal monetary recompense for time and effort may be offered to non-confined research participants who are both:
  - No longer in BoP custody, and
  - Participating in authorized research being conducted by BoP employees or contractors.

(8) Investigator responsible for staff and subcontractors. When conducting research within the BoP the Principal Investigator shall assume responsibility for actions of any person engaged to participate in the study as an associate, assistant or subcontractor to the PI. The PI shall ensure that all staff involved shall be adequately trained to perform the work and shall be familiar with all Department of Justice regulations regarding human research performed within the BoP.

(9) Confidentiality of data. For research conducted with the BoP:

- A non-employee of the BoP may receive records in a form not individually identifiable when advance adequate written assurance that the record will be used solely as a statistical research or reporting record is provided to the agency.
- Except as noted in the consent statement to the participant, the investigator must not provide research information that identifies a participant to any person without the participant’s prior written consent to release the information. For example, research information identifiable to a particular individual cannot be admitted as evidence or used for any purpose in any action, suit or other judicial, administrative, or legislative proceeding without the written consent of the individual to whom the data pertain.
- Except for computerized data records maintained at an official Department of Justice site, records that contain non-disclosable information directly traceable to a specific person may not be stored in, or introduced into, an electronic retrieval system.
- If the investigator is conducted a study of special interest to the Office of Research and Evaluation (ORE) but the study is not a joint project involving ORE, the investigator may be asked to provide ORE with the computerized research data, not identifiable to individual participants, accompanied by detailed documentation. These arrangements must be negotiated prior to the beginning of the data collection phase of the project.

(10) Required elements of disclosure for informed consent. For research conducted within the Bureau of Prisons required elements of disclosure include:

- Identification of the investigators.
- Anticipated uses of the results of the research.
- A statement that participation is completely voluntary and that the participant may withdraw consent and end participation in the project at any time without penalty or prejudice (the inmate will be returned to regular assignment or activity by staff as soon as practicable).
- A statement regarding the confidentiality of the research information and exceptions to any guarantees of confidentiality required by federal or state law. For example, a investigator may not guarantee confidentiality when the participant
indicates intent to commit future criminal conduct or harm himself or herself or someone else, or, if the participant is an inmate, indicates intent to leave the facility without authorization.

• A statement that participation in the research project will have no effect on the inmate participant’s release date or parole eligibility.

(11) Progress reporting and publication. For research conducted within the BoP:

• No less than annually, the investigator shall provide the Chief, Office of Research and Evaluation, with a report on progress of the research.

• At least 12 working days before any report of findings is to be released, the investigator shall distribute one copy of the report to each of the following:
  o The chairperson of the Bureau Research Review Board, the regional director and the warden of each institution that provided data or assistance.

• The investigator shall include an abstract in the report of findings.

• In any publication of results, the investigator shall acknowledge the Bureau’s participation in the research project.

• The investigator shall expressly disclaim approval or endorsement of the published material as an expression of the policies or views of the BoP.

• Prior to submitting for publication the results of a research project conducted under Department of Justice regulations, the investigator shall provide two copies of the material, for informational purposes only, to the Chief, Office of Research and Evaluation, Central Office, Bureau of Prisons.

(12) Research for the National Institute of Justice (NIJ). For all research sponsored by the NIJ:

• A copy of all data must be de-identified and submitted to the National Archive of Criminal Justice Data, including copies of the informed consent document, data collection instruments, surveys, and other relevant materials.

• All projects are required to have a privacy certificate approved by the NIJ Human Subjects Protection Officer.

• All investigators and research staff are required to sign employee confidentiality statements, which are maintained by the responsible investigator.

• The confidentiality statement on the consent form must state that confidentiality can only be broken if the participant reports immediate harm to participants or others.

• Under a privacy certificate, investigators and research staff do not have to report child abuse unless the participant signs another consent form to allow child abuse reporting.