

Utah Valley University

Institutional Review Board

**Standard Operating Procedures**

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## **IRB PURVIEW and AUTHORITY**

The Common Rule (45CFR46) is the body of federal regulations for human subject protection for seventeen federal agencies that sponsor human research. The University has signed a Federal Wide Assurance that guarantees that all research conducted at the University, or by faculty or staff employed by the University, will adhere to these standards, whether or not the research is funded by the federal government. It is the responsibility of the University's Institutional Review Board (IRB) to provide peer review for research covered by the assurance and to establish policies and procedures to assure the protection of human subjects in research at the University. University Policy #138 *Institutional Review Board* (Section V, A) states, "all research involving the use of human subjects must be submitted to the Institutional Review Board (IRB) for review prior to the initiation of the project."

An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities that involves human subjects.

In accordance with 45CFR46.111, in order to approve research the IRB shall determine if all of the following requirements are satisfied:

- (1) Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk.
- (2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
- (3) Selection of subjects is equitable.
- (4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, unless the IRB has authorized a waiver or modification of informed consent (see 45CFR46.116 and 117).
- (5) Informed consent will be appropriately documented.
- (6) When appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of subjects.
- (7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- (8) For purposes of conducting the limited IRB review required by §46.104(d)(7), the IRB need not make all determinations of paragraphs (1) through (7) of this section, and shall make the determinations that if there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

In accordance with 45CFR46 and the Belmont Report: If research procedures/methodology can be modified in such a way that it would result in either:

- (1) Increased aspects of informed consent, (autonomy) and/or
- (2) Greater benefits to the subjects, (beneficence) and/or
- (3) Decreased subject risk, (non-maleficence) and/or
- (4) Fairer subject selection, (justice)

then the IRB has the authority to require such changes for research approval.

The IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

The IRB shall conduct continuing review of research covered by federal regulations at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research (45CFR46. 109(e)).

The Common Rule—45CFR46 is a federal minimal standard and the IRB may establish university policies and procedures that are more stringent than those articulated in the Common Rule.

Where federal, state, institutional and/or local 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, UVU shall rely upon the Attorney General of the State of Utah, or an authorized representative, to resolve the conflict. UVU may also seek legal clarifications from General Counsel as appropriate.

## **The Ethical Mandate to Protect Human Subjects**

### ***Background***

All human subject research at Utah Valley University (UVU) must be carried out in an ethical manner (45CFR46 Subpart A). UVU Policy #138 *Institutional Review Board* (Section V, A) states “all research involving the use of human subjects must be submitted to the Institutional Review Board (IRB) for review prior to the initiation of the project. The basic ethical principles guiding research involving human participants are international, national, regional, and local responsibilities.

### ***The Nuremberg Code*** (<http://ohsr.od.nih.gov/guidelines/nuremberg.html>)

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 those “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.

<b>NUREMBERG CODE</b>
1. Consent of Subject: Voluntary, Legal, and Informed.
2. Experiment must provide positive results for the good of society.
3. Experiment must be scientifically designed and supported.
4. Experiment must avoid all unnecessary physical and mental suffering.
5. Experiment must not result in injury, disability, or death.
6. Risk must never exceed the humanitarian importance of the problem to be solved.

7. Protections for even remote possibilities of injury, disability or death.
8. Experiment to be conducted only by scientifically qualified persons.
9. Subject can stop participating at will.
10. Experimenter must terminate experiment if there is probable cause that it will result in injury, disability or death to the subject.

***The Declaration of Helsinki*** (<http://www.wma.net/en/30publications/10policies/b3/>)

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, 2004), which calls for prior approval and ongoing monitoring of research by independent ethical review committees.

<b>DECLARATION OF HELSINKI</b>
1. Duty of physician: protect life, health, privacy, and dignity of human subject.
2. Research must use scientifically accepted principles, and based on scientific literature.
3. Respect for environment and animals must be provided.
4. Ethical Review Committee: Experimental protocol to be submitted for consideration, comment, guidance, and approval.
5. Protocols: Should always contain a statement of the ethical considerations involved, and indicate compliance with the principles of this Declaration.
6. Research should be conducted only by scientifically qualified persons.
7. Assessment of risks and burdens, in comparison with benefits.
8. Risks must be adequately assessed and satisfactorily managed.
9. Benefits must outweigh burdens.
10. Subject population must benefit from study.
11. Voluntary Informed Consent.
12. Subject's integrity, privacy, and confidentiality must be respected and protected.
13. Subject informed of: aims, methods, funding, conflicts of interest, institutional affiliations, benefits, risks, potential discomforts. Subject also has right to abstain from participation and/or withdraw from participation at any time without reprisal. Written informed consent or non-written consent formally documented and witnessed.
14. Informed consent of a subject that is a dependent should be obtained by a well-informed investigator who is independent of this relationship.
15. Informed consent of legal representative if subject is incompetent.
16. Investigators must obtain assent from incompetent subjects such as minors in addition to informed consent of the legal representative.
17. When consent is not possible, the review committee must approve the experimental protocol.
18. Authors and publishers have the ethical obligation not to publish reports of experimentation which are not in accordance with the principles in this Declaration.

***The Belmont Report*** (<http://ohsr.od.nih.gov/guidelines/belmont.html>)

Revelations in the early 1970s about the 40-year United States Public Health Service Study of Untreated Syphilis in the Negro Male at Tuskegee and other highly unethical government research resulted in the 1974 legislation calling for regulations to protect human subjects and for a national commission to examine ethical issues related to human subject research (i.e., the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research). The Commission’s final report, “The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research,” defines the ethical principles and guidelines for the protection of human subjects.

<b>BELMONT REPORT</b>	
<b>Principles</b>	<b>Applications</b>
<p><b>Respect for Persons</b></p> <ol style="list-style-type: none"> <li>1. Individuals should be treated as autonomous agents.</li> <li>2. Persons with diminished autonomy are entitled to protection.</li> </ol>	<p><b>Informed Consent</b></p> <ol style="list-style-type: none"> <li>1. Information               <ol style="list-style-type: none"> <li>a. Procedures</li> <li>b. Purpose</li> <li>c. Risks and benefits</li> <li>d. Alternatives</li> <li>e. Opportunity to ask questions and to withdraw at any time.</li> </ol> </li> <li>2. Comprehension</li> <li>3. Voluntariness</li> </ol>
<p><b>Beneficence</b></p> <ol style="list-style-type: none"> <li>1. Human subjects should not be harmed.</li> <li>2. Research should maximize possible benefits and minimize possible harms.</li> </ol>	<p><b>Assessment of Risks and Benefits</b></p> <ol style="list-style-type: none"> <li>1. The nature and scope of risks and benefits.</li> <li>2. The systematic assessment of risks and benefits.</li> </ol>
<p><b>Justice</b></p> <p>The benefits and risks of research must be distributed fairly.</p>	<p><b>Selection of Subjects</b></p> <p>There must be fair procedures and outcomes in the selection of research subjects both individually and socially.</p>

**The Regulatory Mandate to Protect Human Subjects**

The IRB operates under four levels of authority. The first level of authority is represented by congressional legislation (5 U.S.C. 301; 42 U.S.C. 289(a); 42 U.S.C. 300v-1(b); Source: 56 FR 28012, 28022, June 18, 1991), which was codified by the Department of Health, Education, and Welfare in 1974 in the Code of Federal Regulations (Title 45, Public Welfare, Part 46 Protection Of Human Subjects; 45CFR46, Subpart A) and later revised in 1981, 1991, 1996, 2005 and 2009 to include Subparts B, C, D and E. Duplicate codes were written by other federal departments and agencies, leading to the designation of 45CFR46 as the “Common Rule”.

Human subject research is also under the purview of other government agencies and federal regulations such as the Federal Drug Administration (21 CFR Parts 1-1499) (FDA; for research using devices and compounds), the Health Insurance Portability & Accountability Act (HIPAA; 45 CFR Parts 160, 162, and 164), and the Family Education Records Protection Act (FERPA; 34 CFR Part 99). Where these laws affect human subject research, the IRB is responsible for

enforcement of these additional regulations. In addition to the 45CFR46 and the OHRP guidelines, UVU is also a state institution and as such comes under the authority of relevant state and local laws and ordinances affecting the review of proposals. 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, Health Insurance Portability and Accountability Act (HIPAA), Utah Public Officers and Employees Ethics Act and others.

The second level is the authority to interpret 45CFR46. This authority was delegated to the Office of Human Research Protection (OHRP; §46.102, 56 FR 28012, 28022, June 18, 1991). The OHRP has established guidelines that represent how the Federal government itself interprets the Common Rule (<http://www.hhs.gov/ohrp/policy/index/index.html>) and compiled an IRB Guidebook ([http://www.hhs.gov/ohrp/archive/irb/irb\\_guidebook.htm](http://www.hhs.gov/ohrp/archive/irb/irb_guidebook.htm)). The OHRP is responsible for enforcing compliance with the Common Rule.

The third level of authority is institutional. Utah Valley University has the right to establish its own policies regarding the ethical conduct and administration of research, including human subject research, provided they meet the minimum standard as articulated by the Federal regulation (45CFR46) and guidelines (OHRP guidelines), state, and local laws.

Under the power of the University president, the Institutional Review Board was constituted as a standing committee in 2002 (UVU Policy #102 *Establishing and Disbanding Committees*). The IRB is an institutional committee that has hybrid authority, federal, state, local, and institutional. This is reflected by the role of the Institutional Official (IO), who can disapprove IRB approved research, but cannot approve research disapproved by the IRB.

The IRB at UVU is regulated by UVU Policy #138 *Institutional Review Board*, which states that, “all research involving the use of human subjects must be submitted to the Institutional Review Board (IRB) for review prior to the initiation of the project.” Those who serve on the IRB are subject to all relevant university policies including the rights and responsibilities of faculty (UVU Policy #635 *Faculty Rights and Professional Responsibilities*). This policy protects the academic freedom of investigators, consistent with the statements on academic freedom and tenure articulated by the American Association of University Professors (1940 Statement of Principles on Academic Freedom and Tenure; AAUP Policy Tenth Ed.2 10/26/06).

#### “Academic Freedom

1. Teachers are entitled to full freedom in research and in the publication of the results, subject to the adequate performance of their other academic duties; but research for pecuniary return should be based upon an understanding with the authorities of the institution.
2. Teachers are entitled to freedom in the classroom in discussing their subject, but they should be careful not to introduce into their teaching controversial matter which has no relation to their subject.[2] Limitations of academic freedom because of religious or other aims of the institution should be clearly stated in writing at the time of the appointment.[3]
3. College and university teachers are citizens, members of a learned profession, and officers of an educational institution. When they speak or write as citizens, they should be free from institutional censorship or discipline, but their special position in the

community imposes special obligations. As scholars and educational officers, they should remember that the public may judge their profession and their institution by their utterances. Hence they should at all times be accurate, should exercise appropriate restraint, should show respect for the opinions of others, and should make every effort to indicate that they are not speaking for the institution.[4]”

The fourth level of authority is exercised by non-profit professional accrediting bodies, such as the Association for the Accreditation of Human Research Protection Programs (AAHRPP) and Public Responsibility in Medicine and Research (PRIM&R). These are professional bodies that articulate the consensus of best practice in the IRB community and provide a forum for discussion of how IRB regulations apply to the many different research contexts. These professional organizations work closely with the OHRP and following IRB best practice as articulated by these organizations is generally considered to be “compliant” by the OHRP.

### ***The Assurance and IRB Registration Process***

The Common Rule—45CFR46, 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 (<http://www.hhs.gov/ohrp/>). All Common Rule Agencies must recognize Federal-Wide Assurances (FWAs) approved by OHRP in the Department of Health and Human Services (DHHS).

UVU has signed a Federal Wide Assurance (number FWA0003308) that commits the University to:

- 1) comply with the appropriate federal regulations for federally funded research;
- 2) have written IRB procedures;
- 3) provide IRB review of human subject research covered by the FWA;
- 4) obtain and document informed consent;
- 5) ensure that all collaborating institutions also operate under an approved FWA;
- 6) have a formal written agreement of compliance from all nonaffiliated investigators: and
- 7) provide the IRB with sufficient resources.

The terms required for the FWA as reviewed at the OHRP website located at:

<http://ohrp.osophs.dhhs.gov/humansubjects/assurance/filasurt.htm>

The FWA document will be given to all those engaged in human research as well as training materials for investigators and IRB members, or posted on the University’s IRB website.

In addition, UVU has committed to extend the compliance to all human subject research conducted at the University, regardless of the funding source. Failure to comply with the commitments of the FWA has the potential to result in loss of federal funding to the University.

## **Institutional Review Board (IRB) Membership**

The Institutional Review Board (IRB) membership shall have sufficient diversity of expertise to review the broad variety of human subject research in which UVU commonly becomes involved, shall be knowledgeable about relevant regulatory requirements, and participate in and strive to remain impartial and objective in its reviews and to act independently of all external factors other than the protection of human subjects.



### ***Appointing Members to the Institutional Review Board***

In compliance with the Common Rule, membership of the IRB must satisfy the following requirements [45CFR46. 107 (a-e)]:

- (a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.
- (b) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
- (c) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.
- (d) No IRB may have a member 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.
- (e) An IRB may, in its discretion, 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. These individuals may not vote with the IRB.

Upon identification of appropriate candidates for membership, the IO, or the IRB Chair as designee, shall conduct interviews with individuals to ascertain their appropriateness for appointment. During the interview, the IO, or the IRB Chair as designee, shall explore with the prospective member the requirements of the position and ascertain the individual's interest and ability to fulfill those requirements. Appointment of IRB members will occur in consultation with the relevant department chair and/or dean.

Terms of service for members shall normally be for a period of three years, and may be renewed as mutually agreed by the IO, or designee, 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.

Termination of a term of service before the end of a three year term shall occur in consultation with the IO, and/or the IRB chair as designee, and the IRB member. This could be initiated for reasons such as increased service, scholarly activity or teaching commitments, conflicts of interest, or failure to adequately participate in the IRB committee and review processes. The primary responsibility for determining whether external commitments impede the ability of a member to participate in IRB activities belongs with the IRB member, Chair and IO alone.

Removal from service as a member of the IRB may occur only through due process as defined in relevant university policy for either of the following reasons:

1. Serious violation of University policy.
2. Failure to perform the duties of an IRB member.

#### ***Appointment of IRB Director, Length of Service, and Duties***

The IRB Director (institutional position) is formally appointed by the IO. A Director serves a 5-year term and may be reappointed. The Director has primary responsibility to ensure that the rights and/or welfare of research participants are adequately maximized at UVU. The Director serves as the University's expert and oversees and manages the operations of the IRB at UVU pursuant to all UVU policies and in compliance of all federal, state, and local regulations. In closely working with the IRB Chair/Vice-Chair, members, institutional officials, and investigators, the Director ensures the working operation of the IRB within all applicable regulatory requirements while furthering ethical human subject research. The Director provides all related training on regulations, administration, and logistics to all potential investigators and IRB board members and serves as the main institutional liaison.

#### ***Appointment of IRB Chair/Vice-Chair, Length of Service, and Duties***

The IRB Chair is formally appointed by the IO. A Chair/Vice-Chair serves a 3-year term and may be reappointed. In addition to the responsibilities of IRB membership, the Chair/ Vice-Chair has primary responsibility for determining the type of review for each proposal, dealing with non-compliance, conducting IRB meetings, and collaborating with the IRB Administrator and staff to ensure operation of the IRB within all applicable regulatory requirements. The IRB Chair/Vice-Chair works with IRB members, institutional officials, and investigators to ensure that the rights and/or welfare of research participants are adequately maximized. As a fair and impartial committee head, the Chair/Vice-Chair functions as a role model for how IRB business should be conducted. On an annual basis, and in conjunction with the annual review process, the IRB Chair/Vice-Chair's performance shall be evaluated by the IO or designee and others as determined by the IO. The IO or designee shall regularly meet with the Chair/Vice-Chair to provide feedback concerning the Chair/Vice-Chair's performance and to discuss ways to improve IRB performance.

#### ***Alternate IRB Members***

The IO, or the IRB Chair as designee, 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 to replace. The backgrounds of alternate members should be similar to the member they are replacing. 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.)

### ***Consultants***

On an as-needed basis the IRB may, at its discretion, 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. These individuals may not vote with the IRB. The IRB shall have available 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 form for submission to the IRB Chair, and the disclosure must indicate that the consultant will have no conflict of interest related to the study to be reviewed (45CFR46.107 (f)).

### ***Independent IRB Review***

The IRB Chair may seek an appropriate independent IRB to review a protocol if UVU's IRB lacks diversity or expertise to appropriately evaluate (45CFR46. 107(a,e)), or if 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.

### ***Determining Adequacy of the Membership of the IRB***

The Institutional Review Board (IRB) membership shall have sufficient diversity and expertise to review the broad variety of human subject research in which UVU commonly becomes involved. To ensure complete independence of IRB review, viewpoints from a variety of academic backgrounds and experience in different research methodologies shall be maintained.

The IO, or the IRB Chair as designee, shall consider vacancies created in the IRB based on current IRB needs. Suggestions for prospective members may be sought from the IRB Chair, the IRB Administrator, and 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.

On a regular basis, at least annually, the IO, the IRB Chair, the IRB Administrator, and others as determined by the IO, shall review the members and alternates of the IRB to determine its sufficiency with regard to regulations at 45CFR46.107 and UVU's policies and procedures. The IRB's adequacy shall also be reviewed with regard to UVU's human research portfolio.

### ***Board Member 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 the Chair as designee, reviews with each prospective member the responsibilities of IRB membership at the time of appointment.

### ***Conflict of Interest of Board Members***

The primary concern of IRB members is to comply with the Federal Code of Regulations (45CFR46). A conflict of interest occurs whenever additional considerations are involved in the independent review and evaluation of human subject research. 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. These additional considerations can be both positive and negative such as deference to colleagues and perceived departmental interest, or bias against a particular type of research methodology.

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. IRB members, including the chair, who have conflicting interests, are required to disclose such interests and to recuse 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.

### ***Determining Conflict of Interests among IRB Members***

The primary responsibility for determining whether a conflict of interest exists lies with each IRB member. Each member of the IRB is responsible for reviewing the IRB packet distributed prior to each IRB full-Board meeting by the IRB office. The member's review of the packet provides an opportunity to identify any conflict of interest concerns.

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."

The IRB Review 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.

### ***Role of IRB Members in the Development of IRB Proposals***

It is natural for IRB members to be called upon by colleagues to provide advice on, or assist in the development of IRB proposals. This activity is beyond the official role of an IRB member. Nevertheless, there are distinct benefits from this activity. Primarily, investigators are trained about the protection of human subjects and considerations of IRB best practices. Unfortunately, prior involvement in individual proposals raises the possibility of a conflict of interest. Members would naturally be inclined to support a proposal in which they have been involved. Evaluating

whether the role in the project affects the member's independence is primarily the responsibility of the member concerned. At a minimum, members when evaluating a proposal should disclose their prior role in the development of the proposal.

### ***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 for IRB members about human research protections.

The UVU IRB members receive comprehensive reference materials (including these SOPs) necessary to review research from an ethical and regulatory perspective. All members must complete the IRB Members & Staff 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 such as Public Responsibility in Medicine & Research (PRIM&R) Annual Conference, the Association for the Accreditation of Human Research Protection Programs (AAHRPP), Society of Research Administrators (SRA), etc. Members shall also receive continuing education materials at regularly held IRB meetings.

The IRB Director or designee will have responsibility for delivery of in-service training to members of the IRB. The following elements should be included in training of IRB members, which will take place in regularly scheduled IRB meetings, attending national or regional conferences, participating in training sessions at other institutions, or in special training meetings as may be convened by the IRB Director or designee;

- Training for review of expedited and full board proposals
- The Belmont Report (autonomy, beneficence & justice)
- Problems with special populations (including vulnerable populations)
- Privacy issues
- New or changed criteria or guidance from federal agencies (45CFR46, DHHS, FDA, etc.)
- Review of regulations, policies and procedures
- Informed consent
- Conflicts of interest
- Equitable selection of participants

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

### ***Compensation of IRB Members***

UVU generally does not provide monetary compensation to UVU employees or nonaffiliated members for their service on the IRB. However, it is acknowledged that service on the IRB requires a significant investment of time.

The IRB director/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.

When UVU employees serve as IRB members, they may be reimbursed if the IRB meetings take place outside normal duty hours, for example, in the evening, or for travel costs to and from a

site away from campus.

The increased responsibilities and time commitment of the IRB chair/vice-chair should be reflected in UVU providing compensation, preferably no less than a two/one course reduction per semester and a stipend. The precise level of compensation for the chair shall occur at the discretion of the IO.

### ***Liability Coverage***

IRB appointees acting within the scope of their authority of appointment are protected under the Utah Governmental Immunities Act (see Appendix) except in cases of intentional or grossly negligent misconduct.

## **Definition of Research and Human Subjects**

Federal regulations at 45CFR46.102 () defines research as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research:

- (1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
- (2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
- (3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
- (4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

Research that does not meet the definition of research involving human subjects must be determined by the IRB staff, not an individual investigator. Investigators must complete and submit an application along with any applicable documents.

### ***Definition of Human Subjects***

Federal regulations at 45CFR46.102 (e) defines Human Subject as “a living individual about whom an investigator (whether professional or student) conducting research:(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. ...Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).”

Utah Valley University defines research involving human subjects as any one of the following:

- (1) Human subject research that meets the DHHS definition of research, regardless of the source of funding.
- (2) Human subject research subject to FDA regulation;

Utah Valley University’s IRB will review all research conducted at the institution and its affiliates when it meets this definition.

### ***Definition of Minimal Risk***

Federal regulations at 102 (i) defines minimal risks as “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.”

### ***Definition of Generalizable Knowledge***

The CFR does not define “generalizable knowledge.” For the purposes of the IRB, UVU considers generalizable knowledge to be one or more of the following:

- Results of the study are communicated either by presentation and/or publication in order to illuminate some topic/issue within one’s field of study.
- Results from the study are applied to some population in addition to the sample.
- The results add to, verify, or refute the body of knowledge in some field.

(Adapted from the University of Michigan)

### ***Determining Whether an Activity is Research Involving Human Participants***

The IRB office as the sole arbitrator makes the determination whether the activity constitutes human research by verifying: 1) whether the activity meets the definition of research and if so, 2) whether the individuals involved meet the definition of human participant.

### ***Types of Human Research and Institutional Review Board (IRB) Special Considerations***

In compliance with UVU Policy #138 *Institutional Review Board* (Section V, A), “all research involving the use of human subjects must be submitted to the Institutional Review Board (IRB) for review prior to the initiation of the project.” No applications will be considered for review if any research activities have commenced. Any human subject research activities in the

absence of a completed IRB review will be considered a violation of policy. There are special considerations related to each type of research.

### ***Quality Assurance and 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.

### ***Pilot Studies***

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

### ***Exemption for Internal Classroom Exercises Involving Human Subjects***

Internal classroom exercise refers to any class related project or assignment that involves human participants conducted primarily for the purpose of evaluating learning (a grade) or teaching students to do research. Even though this work is not defined as research (defined in the federal regulations as a “systematic investigation designed to contribute to generalizable knowledge”) the Institutional Review Board must verify submissions of Request for Class Project Waivers of IRB Application before the exercise begins to ensure that the exercise falls within the parameters given below and does not require IRB oversight. The purpose of this exemption is to improve communication between the instructor and the IRB to determine which projects shall require IRB oversight, and to assist the student in completing his or her project in an efficient and effective manner.

### ***Parameters for Classroom Projects***

1. **No minor or vulnerable populations.** The project cannot include minors or any other vulnerable populations such as pregnant women, prisoners, and those who lack the capacity to give consent.
2. **No more than minimal risk.** The project does not involve any risks of harm greater than might normally be encountered in the daily lives of healthy individuals. Also, this includes the study of any illegal activities or the collection of private personal information that could put the subjects at risk through a breach of confidentiality.
3. **No deception.** The classroom project cannot include deception. Participants must be informed and given the opportunity to voluntarily consent to participation (informed consent).
4. **No publication.** Data from class projects approved under this exemption cannot be used for publication. This also includes data collection for thesis, capstone, dissertation, and practicum research.
5. **No video or audio recording.** To ensure the anonymity and confidentiality of the participating subjects no video or audio recording of the participants is allowed under this exemption.

If a class exercise, project or assignment does not fall within the above parameters, as



determined by IRB authority, the instructor will be notified and the student must complete an Application for Approval for the Use of Human Subjects in Research that will be reviewed through the normal processes of the IRB.

Classroom projects that involve human subject research as defined previously and for which the objective or design is to develop or contribute to generalizable knowledge are considered research under the purview of the IRB.

### ***Course Instructor Responsibilities in Classroom Projects Involving Human Subjects***

Course instructors have the primary responsibility for ensuring that the rights and welfare of all participants are protected. UVU Policy #138 *Institutional Review Board* (Section V, H) states, “Ethical treatment of human subjects in classroom assignments is the responsibility of the supervising faculty.”

Instructors must communicate to students about ethical principles for the protection of human subjects. This includes providing students with training about human subject research through the CITI training course or other acceptable methods (e.g., The Belmont Report, the OHRP’s “The Lab”).

Instructors should contact the IRB office by e-mail at [irb@uvu.edu](mailto:irb@uvu.edu) with any questions regarding a project.

### ***Review Categories***

There are four levels of review, primarily based on level of risk and subject characteristics. The review categories are: exempt, limited, expedited, and full review.

### ***Research That May be Considered Exempt from Full Review***

It is the position of Utah Valley University to adopt the recommendation of the Office for Protection from Research Risks (OPRR) and Department of Health and Human Services (DHHS) to review all proposed research involving human subjects being conducted by members of the University community or for studies engaging members of the UVU community as subjects. This position has been codified in UVU Policy #138 *Institutional Review Board* which states, “All research involving the use of human subjects must be submitted to the Institutional Review Board (IRB) for review prior to the initiation of the project.”

The researcher must submit the study and the appropriate documentation for exempt status to the IRB. The researcher must identify the exemption by stating which of the following apply (For items 1-6, see 45CFR46.104 (d) (1) through (6)).

(1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. This exemption is limited to normal educational practices in commonly accepted settings. For example, random assignment to different instructional methods or involving a new strategy is not exempt.

(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met: (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

(3)(i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met: (A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7). (ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else. (iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met: (i) The identifiable private information or identifiable biospecimens are publicly available; (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable

private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

(5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants.

(6) Taste and food quality evaluation and consumer acceptance studies: (i) If wholesome foods without additives are consumed, or (ii) 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 or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Determinations regarding whether research qualifies for exempt status will be made by qualified IRB staff or IRB chair/vice-chair. Some examples of exempt research may include: (1) a survey, such as a mailed or phone survey, or (2) observation techniques with no intervention, or (3) observation with no risk to subjects and no identification of the subject. Studies that use questionnaires sent to adults are usually exempt if the study is described and the reason for the study detailed. The return of the questionnaire may be evidence of the consent of the subject as long as the subject remains anonymous. Telephone surveys may also be exempt.

### ***Research Which May be Considered for Limited Review***

Several exempt categories of the previous section indicated that an increased level of review is required by the IRB; either for data security and privacy protections.

The exempt categories subject to limited IRB review are:

- Exempt (d)(2) research involving interviews, observations, surveys, interviews that are identifiable
- Exempt (d)(3) research involving benign interventions that are identifiable (directly or through links) and the responses may be damaging to the subject's reputation, financial standing, employability, educational advancement, criminal or civil liability.

Limited review 45CFR46.111(a)(7) for data security and privacy is applicable to exempt categories 2 and 3. Additional guidance is provided by The Office for Human Research Protections that is to provide more details about what is expected for this review.

- The extent to which identifiable private information is or has been de-identified and the risk that such de-identified information can be re-identified;
- The use of the information;
- The extent to which the information will be shared or transferred to a third party or otherwise disclosed or released;
- The likely retention period or life of the information;
- The security controls that are in place to protect the confidentiality and integrity of the information; and
- The potential risk of harm to individuals should the information be lost, stolen, compromised, or otherwise used in a way contrary to the contours of the research under the exemption.

In accordance with 45CFR46.111(8), for purposes of conducting the limited IRB review required by §46.104(d)(7)), the IRB need not make the determinations at paragraphs (a)(1) through (7) of this section, and shall make the following determinations if there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

When the research requires limited IRB review or a HIPAA determination (i.e., waivers or alterations of the requirement for HIPAA authorization), the review will be conducted by the IRB Chair/Vice-Chair or a Chair-designated member of the IRB and will be conducted using expedited review procedures as detailed in the subsequent section.

### ***Research Which May be Considered for Expedited Review***

An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the federal requirements. All of the authorities of the IRB may be exercised, except the reviewers may not disapprove the research. If the proposed research cannot be supported by the expedited reviewers, the review must be advanced to the full board. Expedited proposals must be disclosed at the next IRB meeting. Members of the Board may challenge expedited approvals.

Expedited review is appropriate for research that involves no more than minimal risk, or for review of minor changes to previously approved research projects and protocols. Following 45CFR46.110, the Secretary of HHS has established, and published as a Notice in the Federal Register, a list of current categories of research that may be reviewed by the IRB through an expedited review procedure. The IRB may use the expedited review procedure to review the following:

- (i) Some or all of the research appearing on the list described above, unless the reviewer determines that the study involves more than minimal risk;
- (ii) Minor changes in previously approved research during the period for which

- approval is authorized; or
- (iii) Research for which limited IRB review is a condition of exemption under 45CFR46.104(d)(2)(iii) or (d)(3)(i)(C).

The research proposal and protocols must be submitted to the University IRB to determine that all of the following requirements are satisfied:

- risks to subjects are minimal;
- risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge;
- selection of subjects is equitable and non-coercive;
- informed consent will be sought from each prospective subject or the subject's legally authorized representative;
- informed consent will be appropriately documented;
- when appropriate, the research plan makes adequate provision for monitoring data collected to ensure safety of subjects; and
- when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

Below is a list of types of research with human subjects that may be eligible for an expedited review:

- Collection of hair and nail clippings in a non-disfiguring manner.
- Collection of excreta and external secretions.
- Collection of data from subjects 18 years of age or older using non-invasive procedures routinely employed in clinical practice.
- Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.
- Anonymous voice recordings made for research purposes, such as investigations of speech defects.
- Moderate exercise by healthy volunteers.
- Study of existing data, documents, records, pathological specimens or diagnostic specimens.
- 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
- Research involving manipulation of the subject's behavior that does not involve stress or risk.

Expedited review may also be appropriate for minor changes or requests for extensions in previously approved full or expedited research during the period (one year or less) for which approval is authorized.

### ***Research That Requires Full IRB Review***

Full IRB review is required for all research involving greater than minimal risk to subjects or for any research which does not fall into any of the exempt or expedited categories. This responsibility cannot be delegated. Full review is required for research involving any protected subject population. Protected groups include but are not limited to: fetuses, human in vitro fertilization, prisoners, and psychiatric patients. Depending on the type of research or target population, some groups may be vulnerable to coercion or undue influence, or have impaired capacity to make decisions and require additional safeguards. The researcher shall design subject selection and consent procedures that will protect the rights and welfare of all subjects.

## **Informed Consent and Special Considerations**

Informed consent must be sought from each prospective participant or the participant's legally authorized representative before research is begun. Consent is a continuing process and participants always retain the right to withdraw from participation in a research project. UVU policy requires that investigators inform participants of any important new information that might affect their willingness to continue participating in the research.

The IRB may approve procedures for documentation of informed consent which involves (a) a written consent form signed and dated by the participant or the participant's legally authorized representative; (b) an implied written consent form stating that the required elements of informed consent have been presented orally; or (c) in limited circumstances, waiver of documentation of consent. It is the responsibility of the IRB to determine whether the proposed method of documentation or waiver of informed consent is appropriate in protocols it reviews.

The basic elements of informed consent as stated in 45CFR46. 116 are:

- Must begin with a concise and focused presentation of the key information that is most likely to aid in understanding the reasons why one might, or might not, want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.
- Must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.
- May NOT include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.
- A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;
- A description of any reasonably foreseeable risks or discomforts to the subject;

- A description of any benefits to the subject or to others that may reasonably be expected from the research;
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and
- One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
  - A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
  - A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Additional requirements, when appropriate, may include:

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent;
- Any additional costs to the subject that may result from participation in the research;
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;
- The approximate number of subjects involved in the study;
- A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;

- A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
- For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (*i.e.*, sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

### ***Waiver of the Requirement to Obtain Written Documentation of the Consent Process***

- The UVU IRB may approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent if the IRB finds and documents that the research meets any of the following specific criteria: That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;
- That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or
- If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

### ***Informed Consent for Minors***

- *Children (minors)* are defined as persons who have not attained the legal age for consent to procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.
- *Assent* is the child's affirmative agreement to participate in research. A child's legal guardian or parent must sign an informed consent form in order for a child to participate in a research study. Where appropriate, the child should assent to participate in the research. Both consent and assent forms must be submitted to the IRB for approval. If assent will not be used, an explanation for not including this component should be included in the application.
- Children participating in research must be provided the opportunity to consent upon reaching the age of majority in order to continue their participation in the research.

### ***Informed Consent for Non-English Speaking Subjects***

DHHS regulations for the protection of human participants require that informed consent information be presented "in language understandable to the subject" and, in most situations, that informed consent be documented in writing. Consent forms should avoid jargon and should be written in the second person (e.g., If you agree to the research...) in a language and at a level that



is understandable to the participant. Informed consent will not be accomplished unless the requirement is met that the participant understands the components of the consent form.

The written consent document should embody, in language understandable to the participant, all the elements necessary for legally effective informed consent. Participants who do not speak English should be presented with a consent document written in a language they understand. The IRB must receive a copy of the document.

The PI may ask the IRB to waive the written consent process if it constitutes a culturally unacceptable or insensitive procedure.

### ***Oral Consent Using Short Form***

A short form is a written informed consent form stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject's legally authorized representative, and that the key information required by §46.116(a)(5)(i) was presented first to the subject, before other information, if any, was provided. The IRB shall approve a written summary of what is to be said to the subject or the legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Only the short form itself is to be signed by the subject or the subject's legally authorized representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the subject's legally authorized representative, in addition to a copy of the short form.

## **Confidentiality**

Every reasonable effort should be made to protect the confidentiality of subjects. Subjects should be informed about the data security measures that the researcher(s) will take to maintain confidentiality. However, absolute guarantees of confidentiality are discouraged. Such guarantees may not account for unanticipated and/or unauthorized access, particularly when conducting research involving transfer of information via internet.

It is advised that language similar to the following be included in the informed consent: “Your confidentiality will be kept to the degree permitted by the technology being used. No guarantee can be made regarding the interception of data sent via the internet by any third party.” (Penn State) or “Although every reasonable effort has been taken, confidentiality during actual internet communication procedures cannot be guaranteed.”

## **Continuing Review and Revisions**

An IRB shall conduct continuing review of research requiring review by the convened IRB at intervals appropriate to the degree of risk, not less than once per year. However, unless an IRB determines otherwise, continuing review of research is not required in the following circumstances:

- Research eligible for expedited review in accordance with §46.110;
- Research reviewed by the IRB in accordance with the limited IRB review described in §46.104(d)(2)(iii), (d)(3)(i)(C), or (d)(7) or (8);
- Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:

- Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
- Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

The PI must seek continuing review for studies that last longer than the approval period or beyond the expiration date (i.e., multiple year studies). PIs must also maintain continuous approval from each institution where the research is being conducted (multi-centered studies). Additionally, the PI must ensure that progress reports are submitted more frequently when required by the IRB. Researchers should submit an amendment if the project is to last longer than the approved period. For studies in which data collection last more than 5 years, the Chair will generally require a new submission at the 5-year mark, in addition to the continuation form.

Continuing review must take place before the expiration date of the approval period; any lapse in approval will result in suspension of subject recruitment/enrollment and, if the research is DHHS-sponsored, notification of the funding agency. Continuing review requests submitted prior to the expiration but not formally reviewed and approved by the expiration date are considered expired studies. If the request for continuation is not approved by the expiration date specified, the study automatically expires and all research must stop including recruitment, advertisement, screening, enrollment, consent, interventions, interactions, and collection of private identifiable information until approval of the continuation. There is no grace period.

The first reminder is sent approximately 60 days prior to the due date. A second reminder is sent approximately 30 days prior to the due date. The PI is responsible for responding to the IRB office in a timely manner.

If there is no response from the PI after two reminders, a termination notice is sent to the PI approximately 30 days after the expiration date. A copy of the termination notice is also sent to the Associate Vice President of Undergraduate Research, the appropriate dean, department head, and funding agency if applicable. If research approval expires and data collection continues, you will be considered in non-compliance. A new application will then be required before work can commence again.

The research protocol must satisfy the criteria set forth in 45CFR46.111, 21CFR56.111, and 38CFR16.111 for the IRB to approve the protocol for continuation. The IRB may only use expedited review procedures for continuing review under the following circumstances:

- The study was initially designated for expedited review procedures and requires continuing review
- The research involves the study of drugs and/or medical devices and either does not require an Investigational New Drug (IND) (21CFR Part 312) and/or an Investigational Device Exemption (IDE) (21CFR Part 812) and/or the device is approved for marketing and being used in accordance with labeling. The IRB must also have determined and documented at a convened meeting that the research is no greater than minimal risk and no additional risks have been identified.

The continuing review is done in accordance with Federal regulations. If the study was originally approved by the full board and the study is open to enrollment of new subjects, the request for continuation of the research must be reviewed by the full board, which will continue to assess the risk and determine the appropriate level of review. Continuing review of such a research project must occur at a convened meeting at which a quorum of the IRB members (50% + 1) are present, including at least one member whose primary concern is in a nonscientific area. In order for the research undergoing continuing review to be approved, it must receive the approval of a majority of the members present at the meeting (45CFR46.108 (b)).

### ***Continuing Review Risk Assessment and Monitoring***

The IRB should assess whether there is any new information that would necessitate revision of the protocols and/or informed consent document. IRBs have the authority to disapprove or require modifications in (to secure re-approval of) a research activity (45CFR46.109 (a)). When conducting continuing review and evaluation whether the research continues to satisfy the criteria for IRB approval, IRBs should pay particular attention to the following four aspects of the research:

- Risk assessment and monitoring;
- Adequacy of the process for obtaining informed consent;
- Investigator and institutional issues; and
- Research progress.

The IRB has the authority to observe the conduct of research or to appoint an independent party to act on its behalf. Patterns of non-compliance by the PI can trigger formal inquiries by the IRB. The IRB may require verification of the study procedures during continuing review when materials submitted for continuing review are inconsistent with those previously submitted, when inconsistencies cannot be resolved by communication, or when it is determined that additional protections are necessary as part of a corrective action plan when unanticipated problems or adverse events have occurred.

When findings of observational investigations warrant corrective actions, the IRB may terminate or suspend the study (45CFR46.113). An investigator may appeal the suspension by submitting a written request to the IRB Chair.

No IRB may have a member participate in the IRB's continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB (45CFR46.107 (d)).

### ***Amendments or Revisions to Approved Research***

Federal regulations require that any proposed change or revision to a currently approved research which affects human participants must be reviewed and approved by the IRB prior to the implementation of that change.

A minor change 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 of research that would allow review using the expedited procedure.

Some examples of minor revisions are: changes in telephone numbers; addition/deletion of associates or staff; the deletion of questions in a survey; changes in funding; addition or deletion of PIs; alteration of the project title; advertisement changes; the number of participants enrolled in the research; qualifications of the research team; the facilities available to support safe conduct of the research; or similar factors which would not warrant review of the proposed changes by the convened IRB.

Non-minor revisions are those that may involve increased risk to participants or that substantially change the nature of the research. Examples may be: revisions to the recruitment plan, study design, or methodology; changes to any instruments including surveys and questionnaires; adding/revising eligibility criteria or changes to the study population; adding a research site; and changing the informed consent to include a newly identified risk related to the study (this may require that participants sign a new consent form).

#### ***Process for Making Minor Modification to Approved Protocols***

Minor modifications may be made to protocols upon submission of an Amendment Request form, and may be reviewed on an expedited basis. Minor modifications are reviewed and approved by the IRB Chair as they are received by the IRB office. When determining what constitutes a non- minor change that will require resubmission of a new application, the following criteria shall be followed:

- 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.
- Research design or methodology: Research methods shall be considered discreet. Surveys, focus groups, interviews, observations, and other accepted research designs shall not be considered interchangeable. Likewise, methods of delivery shall 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.

To apply for approval of a revision, submit an Amendment Request form to the IRB office.

Prepare any new and/or revised documents and submit copies to the IRB office attached to the Amendment Request form. Revision approvals do not necessarily change the approval or expiration date of the protocol. It merely approves the modification to the study and allows the PI to begin using the modified or new procedures/documents. The PI must receive an approval e-mail from the IRB office prior to implementing the approved changes.

#### ***Unanticipated Problems Involving Risks to Participants or Others***

An unanticipated problem involving risks to participants or others is any incident, experience, or outcome that meets **both** of the following criteria:

- 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;
- 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.

## **Documentation and Records Retention Procedures**

The IRB Administrator, or his/her designee, will prepare and maintain adequate documentation of its activities, including:

Copies of all original research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved consent documents, applications for study re-approval, study progress reports and interim reports, modifications, adverse event report forms submitted by investigators, and other reports submitted to the studies.

Minutes of IRB meetings in sufficient detail to show the following:

- The presence of a quorum throughout the meeting including the presence of one member whose primary concern is in a non-scientific area;
- Attendance at the meetings including those members who are participating through video or teleconference;
- Alternate members attending the meeting and members participating by video or teleconference have received and reviewed all required information;
- The approval of previous meeting minutes;
- Discussion of expedited reviews and determinations;
- Actions taken by the IRB;
- The vote on actions including the number of members voting for, against, and abstaining;
- That the informed consent document was reviewed in accordance with applicable criteria and contains all of the required elements;
- The justification for waiving any or all of the required elements of informed consent
- A determination of risk level of investigational devices;
- That any IRB member who has a real or potential conflict of interest relative to the proposal under consideration abstained from voting on the proposal (and that the quorum was maintained);
- The basis for requiring changes in or disapproving research;
- A written summary of the discussion of controverted issues and their resolution;
- Review of additional safeguards to protect vulnerable populations if entered as study subjects; and:
  - The frequency of continuing review of each proposal;
  - IRB Standard Operating Policies and Procedures determined by the IRB;
  - Copies of all logs, audit reports and continuing review activities, as appropriate.
  - Copies of all correspondence between the IRB and the investigators;
  - A roster of regular and alternate IRB members identified by name; earned degrees; representative capacity; indications of experience such as board

certifications, licenses, etc., sufficient to describe each regular and alternate member's chief anticipated contribution to the IRB's deliberations; and any employment or other relationship between each member and the IRB and/or institution (e.g., full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant);

- Copies of the IRB Standard Operating Procedures Manual;
- Statements of significant new findings provided to subjects;
- Reports of any complaints received by subjects;
- Access to current conflict of interest statements from IRB members.

### ***Maintenance of IRB Records***

Consistent with resources available, UVU's IRB will attempt to maintain records indefinitely wherever possible. At a minimum, IRB records will be retained for three years after completion of the research at the site or sites over which the IRB has jurisdiction for the study. Records will be retained longer if required by applicable FDA or DHHS regulations or by the sponsor. These records will be accessible for inspection and copying by authorized representatives of the FDA, VA, OHRP, or other appropriate federal departments or agencies at reasonable times and in a reasonable manner.

The IRB Administrator and the administrative staff will securely store and maintain these documents as required to protect the privacy and confidentiality of subjects and sponsor data. All electronic access to these files will be limited to authorized individuals, and access by persons other than IRB, IRB staff, and IRB officials will be documented, along with the purpose for which the files were accessed, and an audit trail kept of specific projects viewed or copied.

Access to electronic records in computer systems will be limited by appropriate access control measures, and at a minimum will require individual user ID and password for system access. Electronic systems will be backed up and have a data recovery and disaster management plan compliant with the DHHS/NIH Automated Systems Security Handbook. User actions with respect to creating, modifying, and deleting data from automated systems will be logged for audit purposes.

#### Applicable Regulations

21CFR56.103(a)  
21CFR56.108(a-b)  
21CFR56.115  
38CFR16.108 (a)  
38CFR16.103 (b)(4-5)  
38CFR16.115  
45CFR46.108 (a)  
45CFR46.103 (b)(4-5)  
45CFR46.115  
ICH 3.2.2

Reference: DHHS/NIH Automated Information Systems Security Program Handbook (Release 2.0, dated May 1994).

## Research Closure, Suspension and Termination

### *Close Out of Research*

At the conclusion of any study, the PI must notify the IRB office. Research studies that are not closed properly by the PI may be terminated. A non-exempt study is considered complete when data collection and data analysis are done and when all participants have completed participation and the participant's records will no longer be needed. The PI may close approved protocols under certain other circumstances. The PI is responsible for promptly closing out an IRB approved study if the following conditions exist:

- All research/clinical investigation activities including data analysis and reporting are complete;
- The PI never initiated the study;
- Subject accrual is finished, the data are de-identified, and there are no identifying links or codes to the de-identified data;
- The PI plans to leave the University and intends to continue the research activities at another institution;
- The study has been open for a period of three or more years and the PI has enrolled no subjects in the study.

The PI request to close out an IRB approved study is done by submitting a Human Subjects Research Close Out form to the IRB office. The Close Out form is available online at [www.uvu.edu/irb](http://www.uvu.edu/irb). Close out documentation is retained by the IRB office for a period of 3 years from closure or 3 years from resolution of any complaint pertaining to the research project.

When closing out a study, the PI completes a final review report unless: 1) he/she never initiated the study or; 2) the study received initial/continuation review within the last six months and the PI has enrolled no subjects in the last six months.

The PI cannot close out an active IRB approval if:

- He/she is still following subjects or;
- He/she is analyzing identifiable data (including data with codes or links to identifiers).
- The IRB notifies a PI that IRB approval or active IRB status has expired or that the IRB has inactivated IRB approval due to non-response from the PI to IRB requests. The IRB may suspend or terminate IRB approval.

If the study has been open for a period of three or more years and the PI has not enrolled subjects in the study, the IRB requires study closure unless there are extenuating circumstances for keeping the project open (e.g., the study is about a rarely seen condition).

Procedures for closing a study fall into five categories:

- Final review
- Non-response from PI to IRB request for revisions
- Closure due to non-enrollment
- Lapse of approval due to non-response to request for continuation or final review
- PI initiated withdrawal.

Regardless of the category for study closure, the expiration date for IRB approval falls on the

first day after the approval period end date.

Once the PI has closed the research and so notified the IRB, he or she may not recruit or enroll human subject participants. There can be no intervention, interaction, nor follow-up with enrolled human research participants, nor any continued collection of data or analysis of data previously collected as part of the research protocol. Studies are not to be closed until the PI has determined that the study is ready to be closed and when all personal identifiable information of the participants has been destroyed. Data analysis must be completed in order to close a study. A PI may not re-open a study once it has been reported to the IRB that it is closed. A new application including supporting documentation is required.

### ***Suspension and Termination***

#### ***Suspension***

Suspension is a postponement or temporary interruption of research activities. Suspension may occur for the following reasons:

- Unexpected problem or serious adverse effects that significantly increase risks relative to benefits;
- Evidence that a PI failed to adequately protect participants in a research study;
- Willful or repeated failure to comply with federal regulations, state laws, or institutional rules that govern human research activities;
- Proven research fraud or scientific misconduct;
- At the request of the institutional official who is responsible for oversight of research involving human subjects;
- At the request of the research sponsor, OHRP, or other duly authorized regulatory or governmental department or agency head;
- Any other reason deemed necessary by a simple majority vote of the convened IRB (a quorum must be present);
- The IRB or the PI decides that new enrollment and risk-bearing activities should be interrupted pending an investigation into any problem, or alleged problem, with a particular study;
- The Close Out form has not been received and given final approval within 12 months after the last review (or less than 12 months if the study was designated for review at more frequent intervals). This suspension occurs automatically if more than 12 months have passed since the last approval was granted. This is the only situation for which suspension is automatic (i.e., without any action on the part of the board). It is the responsibility of the PI to monitor approval dates to ensure that IRB approval for each study is up to date.

In contrast to a study that has been terminated, a study that is suspended may be reopened without resubmission as a new protocol.

At the time the study is suspended, the IRB will establish a unique and specific plan that, if completed by the PI, will lead to re-review of the study resulting in a decision as to whether to continue or end the suspension or to terminate the research. An audit of the PI's research may be required. At a minimum, the unique and specific plan will include a set of questions or conditions that must be addressed by the PI with a specified time period in which the investigator



provides a written response. The IRB may not end the suspension for continuing review delinquency until the requested information is provided by the PI and is reviewed and approved by the board.

### ***Termination***

Termination is a non-voluntary action resulting in permanent discontinuation of all study-related activities. In contrast to a study that has been voluntarily closed, a study that has been terminated may not be reopened without submission and approval of a new protocol. Termination may occur for the following reasons:

- Unexpected and serious adverse effects that significantly increase risks relative to benefits;
- Evidence that a PI failed to adequately protect participants in a research study;
- Willful or repeated failure to comply with federal regulations, state laws, or institutional rules that govern human research activities;
- Proven research fraud or scientific misconduct;
- At the request of the institutional official who is charged with responsibility for oversight of research involving human subjects;
- At the request of the study sponsor, OHRP, or other duly authorized regulatory or governmental department or agency head;
- The PI leaves the institution and fails to request closure of the study or fails to reassign the PI's responsibilities and duties to another qualified PI;
- Any other reason deemed necessary by a simple majority vote of the convened IRB (a quorum must be present).

A research project that is terminated by the IRB will be reported to the institutional official, the Sponsored Programs office and/or research sponsor or agency head (if applicable), and to the appropriate department head. Disciplinary action or sanctions may be appropriate and decisions will be made on a case-by-case basis. At the IRB level, appropriate sanctions might include a request for further information, an audit of ongoing research activities, or suspension of all ongoing research conducted by the same PI or group of PIs until all research activities are shown to be free of similar problems. The PI will be reminded that if a study is terminated, no further enrollment or data collection is permitted.

## **Investigation of Complaints, Allegations of Non-Compliance and Unanticipated Problems**

### **Background**

The right of research subjects to lodge a concern (e.g., allegation), complaint, or question and to be assured that the concern, complaint, or question is taken seriously and resolved in a timely manner is of prime importance. The IRB is responsible for investigating concerns, complaints, and questions from subjects and any improprieties involving investigators or their staff. The IRB Chair or designee handles these issues in a timely manner, assuring protection of human subjects, and the IRB holds any violators accountable to the applicable regulation. It should be noted that investigations themselves are ethical actions; both complainants and investigators must be protected from the risks associated with loss of confidentiality.

References [45CFR46.116(a) and 21CFR50.25(a)][45CFR46.103(b)(4)(iii) and 21CFR56.108(a)(4)]

Definitions:

Concerns and/or complaints: These could include a study that threatens to be offensive, that threatens to cause physical, psychological and/or emotional injury; and that break or threaten confidentiality. These concerns/complaints can be voiced or raised with the IRB by a research subject or other concerned individuals.

Non-compliance: This can include: conducting research without IRB review, not obtaining consent, using the wrong consent form, failing to report adverse events or serious adverse events or other problems, failure to maintain adequate records, failure to follow the IRB approved protocol, modifying an approved protocol without IRB approval, inadequate supervision, or inadequate training.

On-going non-compliance: This includes risks or harm that is intrinsic, either structurally or functionally, to the continuing operation of the project.

Serious non-compliance: This includes risks or harm to a subject that is significant and has the potential for lasting physical or emotional harm.

Protocol Violation: This is IRB approved human subject research that is modified or altered in a manner that results in significant deviation from the approved protocol.

Unanticipated Problems and/or Adverse Events: These risks to participants or others are events or problems that are undesirable, unintended, and harmful or detrimental to the welfare of study participants or other individuals involved with a research study. Reportable events are not limited to physical injury, but include psychological, social, and emotional harm or injury. Reporting of unanticipated problems is the responsibility of the investigator.

Unapproved Research: This is human subject research that is initiated, conducted, and analyzed without applying for, or seeking, IRB approval.

### ***Investigation of Complaints or Allegations of Non-Compliance***

The IRB shall be responsible for reviewing and determining all issues of serious or continuing noncompliance with 45CFR46, or University policy. Any serious and/or continuing noncompliance will be reported to the IRB Chair.

A research subject (past, current, or prospective), a designated spokesperson, family member, or anyone with a concern about a human research study may raise concerns, complaints, or questions about a research project by telephone, in writing, or in person to any member of the IRB.

All credible reports of alleged noncompliance and inappropriate involvement of human participants in research will be investigated.

All allegations and reports of noncompliance shall be documented, provided with a case number, and a report made of actions taken to investigate, conclusions reached and recommendations

completed.

Upon receipt of a concern (e.g., allegation), complaint, or questions, the IRB Chair or designee shall attempt to gather the following information from the complainant as appropriate:

- subject's (or complainant's) name,
- address, and phone number;
- study protocol title (or acronym)
- the name of the PI;
- date(s) of the incident, and;
- an explanation of the concern, complaint, or question.

This information is not mandatory, and an individual may report an incident anonymously; however, the IRB Chair or designee advises the individual that a thorough review may not be possible, without this information, and that follow-up responses to the individual are not feasible.

The IRB Chair, or designee, shall handle the concern, complaint, or question in a confidential manner to the extent allowed by law. They shall carefully explain the risks associated with expressing a concern, making a complaint or allegation, and limits of confidentiality that can be expected given the nature of the issue raised.

Minor, non-serious, non-ongoing allegations will be investigated by the IRB Chair and a report provided to the PI and their department chair. The IRB Chair may also place the matter on the agenda of the next convened IRB meeting.

Allegations considered by the IRB Chair to be serious and/or ongoing will be submitted to an ad hoc investigative committee comprised of the IRB Chair (or designee), at least one IRB member, a tenured faculty member who is not on the IRB, and the IRB Administrator (ex-officio).

The investigative committee should work as expeditiously as possible and, depending on the context of the investigation, consult with the investigator, subjects of the study, other faculty, and if necessary legal counsel.

If the conclusion of the investigative committee is that the allegations were correct and serious and ongoing, then the IRB Administrator shall also notify the Office of Human Research Protection (OHRP).

Depending upon the nature of the complaint or concern raised, and on the findings of the investigative committee, a final report shall be submitted to the IRB Chair, the full IRB, the Institutional Official, the investigator(s), and the respective department chair and dean.

If the nature of the serious and ongoing allegation is acute, then the IRB Chair shall immediately suspend IRB authorization, pending the outcome of the investigation by the ad hoc investigative committee.

### ***Investigation of Unanticipated Problems or Adverse Events***

IRB approved research may still result in physical or psychological harm to human subjects. Not all contingencies may be addressed or anticipated in the preparation, review, and approval of

IRB projects. Mechanisms are therefore required to address unanticipated problems or adverse events. Because the investigator is participating in good faith with the IRB, every effort should be made to handle each incident with sensitivity and in a timely manner.

***It is the responsibility of the investigator to report unanticipated problems or adverse events in an expeditious manner.***

In the event of a serious event or problem, the IRB Chair is authorized to immediately suspend research by the investigator. This should be done in coordination with the investigator as much as possible. If the investigator fails to suspend research after a serious event or unanticipated problem, the IRB Chair, or designee, will withdraw IRB approval and appoint an ad hoc investigative committee. The investigator has the right of appeal to the full IRB.

In the case of a serious event or problem, the investigator has the option of placing a voluntary hold on the IRB approval of their study.

If subjects are not at immediate risk of harm, a convened board will review serious and non-serious unanticipated problems occurring on studies under the direct oversight of the IRB. The IRB may endorse interim action by the Chair, if any, or may take a different action of additional actions.

If a majority of IRB members vote that a submitted report is an unanticipated problem, the following steps will be taken:

The Chair or the Chair's designee will notify the Institutional Official or designee.

The Board will vote on additional actions. Possible actions to be considered include:

- Suspension of the research
- Termination of the research
- Notification of current participants when such information may relate to participants' willingness to continue to take part in the research
- Modifications of the protocol
- Modification of the information disclosed during the consent process
- Providing additional information to past participants
- Requiring current participants to re-consent to participation
- Modification of the continuing review schedule
- Monitoring of the research
- Monitoring of the consent process
- Referral to other organizational entities
- The investigator will be notified
- The investigator has the right of appeal to the full IRB
- The study records and IRB minutes will document the findings and actions of the Board.

The Institutional Official or designee shall receive notification of any research suspended or terminated for cause and shall make or direct any necessary reports to the Institutional Official or designee, who will make outside reports as needed.

Non-serious events or unanticipated problems do not require a suspension of IRB approval. In consultation with the IRB Chair, or their designee, the investigator may submit an Action

Request form to the IRB, which should be handled as expeditiously as possible.

If the non-serious adverse event or problem is not suitably handled by a change of protocol, then the IRB Chair may take the following actions:

- Place the matter on the agenda of the next full IRB meeting for review. The IRB is free to change and alter the actions of the Chair in a majority vote.
- Conduct additional inquiries including possible consultation with respective department chairs, other IRB members, the Institutional Official, and other UVU officials.

### ***Investigation of Protocol Violations***

Protocol violations occur when an investigator does not follow the approved parameters of a study. Serious violations result from an intentional disregard of the study procedures and parameters and can result in real harm to human subjects. Non-serious violations, by far the most common, reflect inadvertent, incidental and non-intentional breaches of the approved study parameters. The seriousness of the violation is also affected by the ongoing or sporadic nature of the violation.

The IRB Chair, or their designee, shall be responsible for determining the degree of seriousness and urgency of each complaint and/or violation and determine the appropriate mechanism for addressing the violation.

Non-serious incidents shall be handled informally by the IRB Chair, or their designee, and the investigator or their representative, such as their department chair or other representative. If the investigation is not suited to an informal process, and if it is not urgent, then the incident will be placed on the agenda of the next IRB meeting. The investigator, and/or their representative, will be invited to attend.

Serious incidents, when they occur, shall be investigated by an ad hoc investigative committee as previously outlined. A report of the outcome shall be made to the investigator, the department chair, dean, and the full IRB and the Institutional Official.

### ***Investigation of Unapproved Research***

Any research at UVU that involves human subjects that is not approved by the IRB contravenes federal statute (45CFR46), is against UVU policy (UVU policy #138) and is in violation of the obligations assumed to obtain the Federal-Wide Assurance number. Unapproved research can take many forms and be conducted by UVU-affiliated faculty, students, staff, and administrators or by researchers unaffiliated with UVU. It can be conducted on human subjects who are affiliated with UVU, such as students, staff, faculty, or trustee, or on UVU property.

Unapproved research, particularly by students, may be conducted because investigators are unaware of the role and purview of the IRB. Alternatively, investigators may knowingly choose to design, conduct and analyze unapproved research for philosophical or other reasons. Given that no attempt is made to comply with federal regulations and UVU policy, investigation and enforcement of UVU policy should be more expeditious. In the case of investigators who knowingly choose to not comply with federal statute, enforcement penalties will be more

stringent. In addition, to abrogating the shared responsibility necessary for the ethical conduct of research, unapproved research has the potential to result in loss of federal funding for UVU. A research subject (past, current, or prospective), a designated spokesperson, family member, or anyone with a concern about a human subject study may raise concerns, complaints, or questions about an unapproved research project by telephone, in writing, or in person to any member of the IRB.

Given that the IRB may not be made aware of the unapproved research in a timely manner, the IRB Chair or designee shall immediately contact the chair of the respective department and/or the investigator to ascertain the specifics of the incident. The IRB Chair or designee shall also maintain a case file outlining the specifics of the incident. The report shall be submitted, as appropriate to the convened Board, the department chair, dean, the Institutional Official, the Vice President of Academic Affairs, and if necessary, legal counsel.

Depending on the context and severity of the unapproved research, the IRB Chair may take the following actions:

- Training the investigator in the process of preparing an IRB proposal and facilitate the IRB review
- Further communication with the investigator
- Further education of the investigator
- Formation of an ad hoc investigative committee
- Administrative action, such as suspension of recruitment, enrollment, and analysis
- Suspension of the project (to be immediately reported to the Institutional Official)
- Reduction of approval time to 3 or 6 months
- Institution of a data management plan
- Referral to other institutional bodies and individuals, possibly including but not limited to: the department chair, dean, the Institutional Official, the Vice President of Academic Affairs, and if necessary legal counsel
- In the event that involvement with the human subjects is ongoing, subjects will be contacted and notified of the study suspension.

### ***Board Considerations and Determinations Regarding Noncompliance and Unanticipated Problems***

Investigation of each incident is contingent on the establishment of the facts that resulted in the incident being reported. As describe above the following considerations should take place:

All incidents, reports and/or complaints shall receive a case number and the current status of the investigation will be monitored and reported.

The fact of each incident should be clearly established.

Investigations shall not depend on hearsay.

Determination of the degree of seriousness of each reported violation and the appropriate response shall be the responsibility of the IRB Chair or designee.

Non-serious Violation: Depending on the nature of the reported incident the IRB Chair may:

- Informally meet with the investigator and/or their representative to establish or confirm the facts of the incident and create an appropriate response. The matter should be reported to the investigator, department chair, and dean if necessary, and included in the report summary provided to the full Board and the Institutional Official.
- Place the matter on the agenda of the full Board. It is expected that the facts of the case be established before the meeting and presented to the IRB. The full Board shall make a determination on the nature of the violation and the appropriate response.

The results of the report shall be presented to the investigator, who shall have the option of appealing the determination, or making another response, to the full Board in person.

Serious Violation: Depending on the nature of the reported incident the IRB Chair may:

- Place the matter on the agenda of the full Board. It is expected that the facts of the case be established before the meeting and presented to the IRB. The full Board shall make a determination on the nature of the violation and the appropriate response. Appropriate responses include but are not limited to those listed above (VII, c).
- Form an *ad hoc* investigative committee, comprised of the IRB Chair (or designee), at least one IRB member, a tenured faculty member who is not on the IRB, and the IRB Administrator (ex-officio).

The investigative committee should work as expeditiously as possible and depending on the context of the investigation, consult with the investigator, subjects of the study, other faculty, and if necessary legal counsel.

If the nature of the serious and ongoing allegation is acute, then the IRB Chair shall immediately suspend IRB authorization, pending the outcome of the investigation by the ad hoc investigative committee.

### ***Reporting Requirements***

IRB Reporting: If the incident is adjudged to be a serious violation then the IRB Administrator shall submit a report to the Office of Human Research Protections, as obligated under the Code of Federal Regulations (45CFR46).

Institutional Reports: When the IRB Chair, the full Board or the ad hoc investigative committee reaches a finding it shall be reported to the investigator and department chair. A summary of the finding shall be maintained in the IRB office.

If the conclusion to an ad hoc investigative committee is that a serious violation has taken place, then reports shall be sent to the investigator, the department chair, dean, the full Board, and the Institutional Official. If the investigator disagrees with the finding, they shall have the option of presenting an appeal to the IRB which shall vote on the appeal. The IRB, as an independent body, and as stipulated under 45CFR46, is the final avenue of appeal.

## **External Reporting**

Utah Valley University (UVU) requires compliance with all applicable accreditation, local, state, and federal reporting requirements in the conduct of research involving human subjects. The IRB notifies appropriate university officials when research falls under the purview of a federal regulatory agency and one or more of the following occurs:

- Unanticipated problems involving risks to subjects or others; and/or
- Serious or continuing noncompliance with the regulations or requirements of the IRB; and/or
- Suspension or termination of IRB approval for research due to noncompliance; and/or
- Department of Health and Human Services (DHHS) submitted or funded studies that are not otherwise approvable under 45CFR46 Subpart B, which include pregnant women, fetuses, and neonates; and/or
- DHHS submitted or funded studies which include prisoners; and/or
- Food and Drug Administration (FDA) regulated or DHHS or U.S. Department of Education submitted or funded studies which include children and are not otherwise approvable under applicable subparts; and/or
- Changes in IRB membership; and/or
- Certification of IRB approval; and/or
- Exceptions to informed consent in emergency medical research; and/or
- Regulatory agency requests for a report;
- Inquiries or sanctions from government oversight agencies.

Reporting to regulatory federal agencies is not required if the principal investigator (PI) voluntarily closes down a study due to new subject accrual or temporarily halts the research procedures. The IRB, IRB Chair, or administrative officials may recommend voluntary closure to the PI, but the PI makes the decision whether closure is appropriate. However, if the IRB or IRB Chair requires suspension or termination, then the incident may be reportable.

### ***Unanticipated Problems Involving Risks to Subjects***

When the IRB finds that UVU research has experienced unanticipated problems involving risk to the subject or others, the IRB Chair or designee prepares a report within fifteen days from the date the IRB conducts final review of the unanticipated problem. The report includes the title of the research protocol and/or grant proposal; name of the PI on the protocol; IRB number assigned to the research protocol; the number (project identifier) of any applicable federal award(s) (grant, contract, or cooperative agreement); the nature of the event; the findings of UVU or the IRB; and actions taken by the PI, UVU, and/or the IRB to address the issue. The Associate Vice President of Academic Affairs (AVPAA), in consultation with the IRB Chair, approves the report, which the IRB Administrator sends to the federal agency with a copy to the IRB, PI, and other university administrators as determined by the IRB.

When research is regulated by the FDA, the IRB requires the PI to report to the sponsor, who must report to the FDA with a copy to the IRB. If the PI is also the sponsor, then the IRB requires that the PI report to the FDA. The IRB may choose to prepare and send the report directly to the FDA.

If the DHHS conducts or funds the research, the IRB Administrator sends the report to the OHRP.



If an agency that is subject to the “Common Rule,” other than the DHHS, conducts or funds the research, the IRB Administrator sends the report to the agency as required by the agency and OHRP.

The IRB Administrator is responsible for placing the report(s) in the IRB study file.

### ***Serious or Continuing Noncompliance***

When the IRB finds that research involves serious or continuing noncompliance, the IRB Chair or designee prepares a report within fifteen days from the date the IRB conducts final review of the serious and/or continuing noncompliance. The report includes the title of the research protocol and/or grant proposal; name of the PI on the protocol; IRB number assigned to the research protocol; the number (project identifier) of any applicable federal award(s) (grant, contract, or cooperative agreement); the nature of the event; the findings of UVU or the IRB; and actions taken by the PI, UVU, and/or the IRB to address the issue. The AVPAA, in consultation with the IRB Chair, approves the report. The IRB Administrator sends the report to the federal agency with a copy to the IRB, PI, and other university administrators as determined by the IRB.

When research is FDA regulated, the IRB requires the PI to report to the sponsor, who must report to the FDA with a copy to the IRB. If the PI is also the sponsor, then the IRB requires the PI to report to the FDA. The IRB may choose to prepare and send the report directly to the FDA.

If the DHHS conducts or funds the research, the IRB Administrator sends the report to OHRP.

If an agency that is subject to the “Common Rule,” other than the DHHS, conducts or funds the research, the IRB Administrator sends the report to the agency as required by the agency and OHRP.

The IRB Administrator maintains all correspondence relating to the serious or continuing noncompliance. The IRB Administrator provides a copy of the federal report(s) and any final IRB actions to the AVPAA, the IRB, the PI and any other university administrators as determined by the IRB. The IRB Administrator is responsible for placing the report(s) in the IRB study file.

### ***Suspension or Termination of Research***

When the IRB suspends or terminates approval of a research protocol, the IRB Chair or designee prepares a report to the applicable federal agency within fifteen days from the date the IRB conducts final review of the suspension or termination. The report includes the title of the research protocol and/or grant proposal; name of the PI on the protocol; IRB number assigned to the research protocol; the number (project identifier) of any applicable federal award(s) (grant, contract, or cooperative agreement); the nature of the event; the findings of UVU or the IRB; and

actions taken by the PI, UVU, and/or the IRB to address the issue. The AVPAA, who may consult with the IRB Chair, approves the report, which the AVPAA sends through the IRB Chair to the federal agency with a copy to the IRB, PI, and other university administrators as determined by the IRB.

IRB Administrator sends a copy of the report to the PI and other University administrators as determined by the IRB.

If the DHHS conducts or funds the research, the IRB Chair sends the report to the OHRP.

If an agency that is subject to the “Common Rule,” other than the DHHS, conducts or funds the research, the IRB Chair sends the report to the agency as required by the agency and OHRP.

When research is FDA regulated, the IRB requires the PI to report to the sponsor, who must report to the FDA with a copy to the IRB. If the PI is also the sponsor, then the IRB requires the PI to report to the FDA. The IRB may choose to prepare and send the report directly to the FDA.

The IRB Chair maintains all correspondence relating to the suspension or termination. The IRB Chair provides a copy of the federal report(s) and any final IRB actions to IRB Administrator, who is responsible for placing the report(s) in the IRB study file.

### ***Pregnant Women, Fetuses, and Neonates***

Upon receipt of an IRB application or request, IRB Chair screens protocols for any inclusion of pregnant women, fetuses, or neonates in research submitted to or funded by the DHHS.

If the IRB finds that the research is not otherwise approvable for pregnant women, nonviable neonates, or neonates of uncertain viability under 45CFR46 Subpart B and the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates, IRB Chair, with input from the IRB and the PI, prepares a report to the DHHS based on the current guidance from OHRP. The AVPAA, in consultation with the IRB Chair, approves the report, which IRB Administrator sends a copy to the PI and to OHRP per OHRP guidance within fifteen days of IRB approval of the report.

The IRB Administrator places a copy of all correspondence in the IRB protocol file and database.

If the OHRP disagrees with the IRB findings on the research involving pregnant women, fetuses, nonviable neonates, or neonates of uncertain viability, IRB Chair shares the information from OHRP with the IRB and the PI.

### ***Prisoners***

Upon receipt of an IRB application or request, the IRB Chair screens protocols for any inclusion of prisoners in research submitted to or funded by DHHS.

The IRB Chair notifies the PI of the DHHS reporting requirement if it finds that the PI has submitted the protocol to DHHS or that the research is DHHS funded and includes prisoners.

With input from the IRB Chair and/or the PI, the IRB Administrator prepares a report to the DHHS based on the current guidance from OHRP on research which includes prisoners. The AVPAA and IRB Chair approve the report and send it to OHRP within fifteen days of IRB approval of the report. The IRB Administrator places a copy of all correspondence in the IRB protocol file.

If the OHRP disagrees with the UVU IRB classification of the research involving prisoner(s), the IRB Chair shares the information from OHRP with the IRB and the PI.

### ***Children***

Upon receipt of an IRB application or request, the IRB Chair screens protocols for any inclusion of children in research submitted to or funded by DHHS or the U.S. Department of Education or regulated by FDA.

If the IRB Chair finds that the research is not otherwise approvable but presents an opportunity to understand, prevent, or alleviate serious problems affecting the health or welfare of children under the applicable FDA, DHHS, or U.S. Department of Education subpart, the IRB Administrator, with input from the IRB Chair and the PI, prepares a report to the DHHS based on the current guidance from the applicable agency. The AVPAA, in consultation with the IRB Chair, approves the report and sends a copy to the PI within fifteen days of IRB approval of the report. The IRB Administrator submits a copy to the institutional official of the applicable federal agency (e.g., Secretary of DHHS through OHRP, Secretary of U.S. Department of Education, or Commissioner of FDA) based on current guidance from the agency. The IRB Administrator places a copy of all correspondence in the IRB protocol file and database.

If the applicable federal agency disagrees with the IRB findings on the research involving children, the IRB Chair shares the information from the agency with the IRB and the PI.

### ***Changes in IRB Membership/Registration***

When a change in IRB membership occurs, the IRB Administrator notifies OHRP/FDA via their online registration system. The IRB Administrator or designee enters the required information regarding the changes in membership and submits the data to OHRP/FDA within fifteen days of receipt of the AVPAA's approval of the membership.

The IRB Administrator is responsible for revising registration information such as changes in IRB member contact or Chair contact information within 90 days of the change, changes in the IRB's decision to review or discontinue review of types of FDA products or FDA clinical investigations within 30 days, or the University's decision to disband an IRB within 30 days of permanent cessation of the IRB's review of research.

### ***Certification of IRB Approval***

When a funding agency requires certification of IRB approval, the PI contacts the IRB to request that the IRB Administrator prepare the certification document or indicates in the IRB application

that the sponsor requires certification of IRB approval. The PI is responsible for requesting IRB documentation of IRB approval in accordance with the funding agency requirements.

The PI may provide the IRB Administrator with a copy of the agency certification form. The IRB Administrator prepares the required agency form(s) and obtain the signature of the UVU authorized organizational representative for sponsored research or of an authorized IRB member.

The IRB Administrator retains a copy of the certification form in the IRB protocol file and forwards the original certification form to the investigator.

The PI transmits the certification of IRB approval to the funding agency within the time period specified by the agency and provides the Office of Sponsored Programs (OSP) a copy.

To prepare a certification form for grants/contracts that fund more than one IRB protocol, the PI provides the IRB Administrator with a list of pertinent IRB protocol numbers. The IRB Administrator verifies the IRB numbers and IRB approval prior to preparing and issuing the certification document. The PI transmits the certification to the agency and provides OSP with a copy.

#### ***Exception to Informed Consent in Emergency Medical Research***

When the IRB approves an exception from the general informed consent requirements for emergency research under FDA and DHHS regulations, the PI provides the sponsor with a copy of the information publicly disclosed prior to the initiation and at the completion of the study. The PI is responsible for maintaining a copy of the report.

When the IRB does not approve an exception from the general informed consent requirements for emergency research under FDA and DHHS requirements, the IRB Administrator, with input from the IRB and the IRB Chair, prepares a report of the reasons why the IRB did not approve the exception. The AVPAA, in consultation with the IRB Chair, approves the report. The IRB Administrator submits the report to the sponsor and the PI within fifteen days of approval.

The IRB Administrator places a copy of the report in the IRB files.

#### ***Agency-Requested Reports***

A federal agency may periodically ask the IRB or UVU for a specific report on a variety of issues (e.g., alleged noncompliance submitted to a federal agency). The IRB Administrator is responsible for informing the IRB Chair of any inquiries from a government oversight office, such as OHRP or FDA or any other agencies. The IRB Chair reviews the request and designates an IRB member to assist the IRB Administrator with preparation of the report (e.g., the IRB Chair oversees noncompliance report preparation.)

The designated IRB member, in consultation with the IRB Administrator, prepares the report in accordance with the agency's request relative to content and timing.

The AVPAA, in consultation with the IRB Chair, approves the report. The IRB Administrator, IRB Chair, or AVPAA determines who receives a copy of the report depending on the nature of the request.

#### Reports: IRB Determination of UVU Officials to Receive Copy of Reports

The IRB Chair or the AVPAA determine appropriate institutional officials within UVU who will receive a copy of a report on a case-by-case basis when the IRB sends any of the federally mandated reports discussed in this SOP to a federal agency. These determinations are in accordance with applicable federal requirements and in accordance with applicable university policies

Examples of institutional officials who may receive copies of a report include, but are not limited to, the following:

- Vice Presidents;
- Dean of the College/Schools;
- Associate Dean of the College/Schools;
- Department Chairs;
- Legal Counsel;
- Director of the Office of Sponsored Program Administration;
- University Compliance Officer;
- Other University administrators as determined by the AVPAA and/or IRB Chair.

#### REFERENCES

45CFR46 Subpart B

45CFR46 Subpart C

45CFR46 Subpart D

21CFR50 Subpart D

May 2003 OHRP Guidance on the Involvement of Prisoners in Research

May 2005 OHRP Guidance on the HHS 45CFR46.407 Review Process for Children Involved as Subjects in Research

## **Review and Maintenance of the IRB Standard Operating Procedures**

The IRB's Standard Operating Procedures must be regularly reviewed and maintained so as to reflect consistency with all current federal regulations, state and local laws, University policy, and determined practices of the IRB. To ensure that the SOP's are maintained properly, at least once per year, a subcommittee of the full board will be appointed by the IRB Chair, under the direction of the Institutional Official, to review the procedures and to make recommendation to the full board of needed changes. A change to the IRB's Standard Operating Procedures will require the sustaining vote of a quorum of the full board before a change may be implemented.

## **Appendices**

45CFR46: <http://www.hhs.gov/ohrp/humansubjects/guidance/>

**OHRP Decision Charts:** <http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html>

**Belmont Report:** <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html>

**Declaration of Helsinki:** [http://www.hhs.gov/ohrp/archive/irb/irb\\_appendices.htm#i6](http://www.hhs.gov/ohrp/archive/irb/irb_appendices.htm#i6)

**Utah Governmental Immunities Act:**

**List of Acronyms:**

- IRB: Institutional Review Board
- 45CFR46: Common Rule
- CFR: Code of Federal Regulations
- UVU: Utah Valley University
- FDA: Federal Drug Administration
- OHRP: Office for Human Research Protections
- GRAMA: Governmental Records Access and Management Act
- FERPA: Family Education Records Protection Act
- HIPPA: Health Insurance Portability and Accountability Act
- OI: Institutional Official
- AAHRPP: Association for the Accreditation of Human Research Protection Programs
- PRIM&R: Public Responsibility in Medicine and Research
- DHHS: Department of Health and Human Services
- FWA: Federal Wide Assurance
- SOP: Standard Operating Procedures
- CITI: Collaborative Institutional Training Initiative
- SRA: Society of Research Administrators
- IA: IRB Administrator
- NIH: National Institutes of Health
- PI: Principal Investigator
- IND: Investigational New Drug
- IDE: Investigational Device Exemption
- ID: Identification
- AVPAA: Associate Vice President of Academic Affairs
- OSP: Office of Sponsored Programs