SUBJECT: INSTITUTIONAL REVIEW BOARD FOR RESEARCH ON HUMAN PARTICIPANTS

I. INTRODUCTION:

Southern Utah University supports Institutional Review Boards (IRBs) for research on human participants. It has established policies and procedures to protect the rights, well-being, and personal privacy of individuals, and to assure a favorable climate for the conduct of scientific inquiry at SUU. Investigators who receive IRB approval for their research are protected from unwarranted legal action and are protected from personal liability.

The board is guided by the ethical principles regarding research involving humans as participants as set forth in the "Belmont Report" (Ethical Principles and Guidelines for the Protection of Human Subjects of Research, by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979). The boards acknowledge three basic principles which are particularly relevant to the ethics of research involving human participants: the principles of respect for persons, beneficence (including minimization of harms and maximization of benefits), and justice. The boards acknowledge and accept their responsibilities for protecting the rights and welfare of human research participants.

The following policies and procedures apply to all research involving human participants performed by Southern Utah University faculty, students, or staff under University auspices, whether carried out solely with University resources or with assistance of outside funds. Research is considered to be under University auspices if it involves one or more of the following:

A. The research is sponsored by the University

B. The research is conducted by, or under the direction of, any employee or agent of the University in connection with his or her employment with the institution, including the use of institutional letterhead.

C. The research is conducted by, or under the direction of, any employee or agent of the University using any property or facility of the institution.

D. The research involves the use of this institution's non-public information to identify or contact human research participants or prospective participants.

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The following activities, though research, do not require *full* submission to the IRB for approval:

1. Archival Research: Research using existing data, documents, records, or specimens as long as one of the following conditions is met:

   A. The data, documents, records, or specimens are publicly available, or

   B. The data, documents, records, or specimens cannot be linked directly or indirectly to the individual from whom they were obtained.

2. Observational Research: Observational or descriptive research of public behavior, as long as both of the following conditions are met:

   A. There are no *interventions* or *interactions* with the individuals being studied which would not have otherwise occurred.

   B. None of the information gathered will be linked directly or indirectly to any of the individuals studied.

3. Research on Normal Educational Practices Within the Investigator's own Classes: Research conducted in established or commonly accepted educational settings on such practices as

   A. Research on regular and special education instructional strategies

   B. Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods

   C. Research as required by students in a course for completion of the course requirements where only non-sensitive information is collected from participants (see IRB Approval of Student Research document on the website).

4. Research for Internal Agency Use: Research done by or at the request of an internal agency for their own use, *and* which is not intended to contribute to

generalizable knowledge (i.e. knowledge shared by professionals in a given field which is designed to contribute to that field).

No investigator may decide for him or her self whether their research needs to be submitted to the IRB. Investigators must complete the *Request for IRB Exemption* form, and submit this to the chairperson of their college's IRB. The chairperson will notify the investigator in writing of his/her decision to approve or deny the request within one week of receiving the request.

II. DEFINITIONS:

Institutional Review Board: An Institutional Review Board's (IRB's) function is to review proposed research to insure that participants' rights are protected and that the risk of harm to participants and researchers is minimized.

Research is defined as a systematic investigation, whether carried out by faculty, staff, or students, designed to develop or contribute to generalizable knowledge (i.e. knowledge shared by professionals in a given field which is designed to contribute to that field). Included in the definition are student research projects (e.g. theses, dissertations, group research projects), regardless of whether they will be submitted for presentation and/or publication in a professional venue. Activities that meet this definition constitute research for the purposes of this policy, whether or not they are supported under a program that is considered research for other purposes. In-class demonstrations of research using students enrolled in the class as participants are not considered research and as such are not regulated by policy 6.20. The course instructor is nevertheless obligated to be familiar with this policy and to adhere to its principles to respect the rights and welfare of the students involved.

A human participant is defined as a living individual about whom an investigator (professional or student) conducting research obtains 1) data through intervention or interaction with the individual, or 2) identifiable private information.

An intervention includes any manipulation of the subject, the subject's environment or stimuli to which the subject is exposed.

An interaction includes any communication with a subject, whether orally or in writing, whether in person (e.g. face-to-face) or not (e.g. via mail, email, telephone)

Identifiable private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation is taking

place. Also included is information provided for specific purposes by an individual, which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e. the identity of the participant is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human participants.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Harm may take any of the following forms: physical, psychological, social, legal, and economical. The investment of time required from the participant is also considered a harm, though it may be minimal if the time requirement is negligible.

Vulnerable Populations include but are not limited to individuals who cannot give legal consent (e.g. minors), physically handicapped individuals, prisoners, pregnant women, non-English speakers, students (if the investigator is also someone who is responsible for assigning grades to the participants), and individuals with impaired cognitive functions.

Signed Informed Consent must be sought under circumstances where there is more than minimal risk and/or vulnerable populations are tested. For research which poses no more than minimal risk and which does not test a vulnerable population, unsigned informed consent is generally required. Informed consent is used to minimize risks and the possibility of coercion or undue influence. Information must be presented in language understandable to the participant or the participant's legally authorized representative. Signed informed consent must be documented with a written form approved by the IRB and signed by the participant or the participant's legally authorized representative.

Legally Authorized Representative means an individual, judicial or other body authorized under applicable law to consent on behalf of the prospective participant to the participant's participation in the procedures(s) involved in the research.

Exempt Status is given to proposals which pose no more than minimal risk, test only participants who belong to the SUU campus community and who are not considered vulnerable, and where there is no intent to publish/present the results off campus. Only an IRB can assign a protocol exempt status. Protocols with this status are not

subject to continuing reviews, audits, or project closure requirements, as long as no material changes are made to the protocol. Initial review and status determination of these proposals are made by a college IRB.

Expedited Status is given to proposals which pose no more than minimal risk, test participants who do not belong to the SUU campus community and who do not constitute a vulnerable population. Whether the results of these studies are published/presented off campus is not a consideration. Protocols which pose no more than minimal risk, test only participants who belong to the SUU campus community and who are not considered vulnerable, and where there is an intent to publish/present the results off campus are given expedited status as well. Only an IRB can assign a protocol expedited status. Proposals assigned this status are reviewed by a college IRB.

Full Board Review Status is given to a proposal if more than minimal risk is involved or a vulnerable population(s) is tested. Only an IRB can assign a protocol full board review status. Proposals assigned this status are initially assessed by a college IRB but are reviewed by the University IRB.

Office of Sponsored Projects (OSP) is charged with assisting faculty and other university personnel to achieve funding for research and other scholarly activity and to provide oversight on issues of federal, state and university compliance, laws and regulations.

Office for Human Research Protections (OHRP) is a federal office charged with ensuring compliance with the Code of Federal Regulations, 45 CFR 46, for federally funded research.

Human Research Protections Program (HRPP) is an SUU sponsored program charged with protecting the rights and welfare of human research participants, as well as training, administering, and overseeing SUU's institutional review boards.

III. POLICIES AND PROCEDURES:

A. The boards use as their guide the Code of Federal Regulations, 45 CFR 46, Protection of Human Subjects, (Revised November 13, 2001). The following policies and procedures serve to operationalize and summarize relevant aspects of the Code.

B. IRB Membership:

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1. The IRB will consist of five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by SUU. Each IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of 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 participants. In addition to possessing the professional competence necessary to review specific research activities, each IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. Each IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of participants, such as children, prisoners, pregnant women, handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these participants.

2. Every nondiscriminatory effort should be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession or academic discipline.

3. 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.

4. Each IRB shall include at least one member who is not otherwise affiliated with SUU and who is not part of the immediate family of a person who is affiliated with the institution.

5. No IRB may have a member participate in an 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.

6. IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

C. IRB Training

1. With the exception of members from the community, each member of an IRB will complete the computer based training program sponsored by NIH currently located at http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp prior to conducting any IRB business. In addition, the chair of each IRB will complete the computer based training program sponsored by OHRP currently located at http://137.187.172.152/cbttng_ohrp/cbts/assurance/login.asp , prior to conduction business related to the chair position. Proof of completion certificates will be kept on file with SUU's OSP.

2. IRB members will receive continued training at the beginning of their meetings on an as needed basis. This training will be provided by SUU's Director of the HRPP.

D. Types of IRBs at Southern Utah University

1. The University will establish and maintain one University IRB and at least one IRB for each individual college that conducts research using human participants. The number of committee members per college IRB will be justified by the volume of proposals that each receives.

2. Membership for the University and college IRBs will adhere to the requirements described in Section III.B of this document. In addition, the following will apply:

i. One member of each college IRB will be affiliated with a different college.
ii. The University IRB will consist of one member from each college IRB, two at-large positions (one of which will be filled by a non-scientist), and one member of the community who is not affiliated with SUU.

3. College IRBs will review protocols for all research activities which involve human research participants submitted by faculty, staff, or students from their own college. In the event that a college IRB determines that a protocol involves more than minimal risk and/or involves one or more vulnerable populations, the protocol will be sent to the University IRB for review. In addition to these reviews, the University IRB will review protocols submitted by an investigator not affiliated with Southern Utah University (SUU) who wishes to conduct research on the campus of SUU.

E. Appointment of Members to the University and College IRBs

1. The Institutional Official appoints members to each college IRB and University IRB at the beginning of each academic year. Members of a college IRB serve a four-year term. Members of the University IRB serve a two-year term. Exceptions to the length of service may be made only to prevent a complete turnover in membership in any given year. Each IRB should have at least two members with one or more years of service to a college IRB. At the final IRB meeting of the spring semester, the members of each IRB will elect a chairperson for their committee by a majority vote of its members.

2. Faculty who serve on the IRB at the University level shall not be required to serve on any other University level committee.

F. College IRB Review of Research

1. Researchers seeking IRB approval must complete and submit an initial *Proposal Submission* form to their college's IRB. Within one week of its receipt, the chairperson of the college IRB will disseminate the form to one of the members of that college's IRB for an initial assessment of minimal risk and vulnerable population status. The member who conducts this initial review must not be a community or non-scientist member of the IRB. The member assigned to the initial review will complete the *Initial Assessment of Minimal Risk and Vulnerable Population Status* form. This form must be submitted to the chairperson within one week of receipt of proposal from the college IRB chairperson.

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2. Proposals determined to involve more than minimal risk and/or use of vulnerable population(s) will be forwarded by the college IRB chairperson to the University IRB chairperson for review.

3. Proposals determined to pose no more than minimal risk AND which do not involve a vulnerable population(s) will be assigned either *Exempt* or *Expedited* status by the initial reviewer. The initial reviewer will complete either the *Documentation of Exempt Review* or *Documentation of Expedited Review* form. The completed form must be returned to the college IRB chairperson along with and at the same time as the *Initial Assessment of Minimal Risk and Vulnerable Population Status* form.

   i. The initial reviewer will consult the OHRP website for a current list of research categories permissible for expedited review.

   ii. The initial reviewer will document which category(ies) permissible for expedited review apply.

4. IRB members who review protocols which receive exempt or expedited status will duly consider each of the following in their assessment of the protocol:

   i. Minimization of risks and maximization of benefits

   ii. Required elements for informed consent

   iii. Method for obtaining informed consent

   iv. Method of subject selection and recruitment

   v. Privacy and confidentiality

5. In the event a protocol is approved by the initial reviewer, the IRB chairperson will notify the primary investigator (PI) or faculty/staff supervisor (if PI is a student) of this decision in writing. Notification will occur within 2 business days of the chairperson's receipt of the initial reviewer's decision to approve the protocol.

6. In the event the protocol is NOT approved by the initial reviewer, the IRB chairperson will notify the primary investigator (PI) or faculty/staff supervisor (if PI is a student) of this decision in writing. Included in the documentation will be a description /explanation of the reason(s) for its non-approval. Notification will occur within 2 business days of the chairperson's receipt of the initial reviewer's decision to not approve the protocol. The PI will be given an opportunity to resubmit the protocol after making any and all revisions requested by the initial reviewer, or request a university IRB full board review of the protocol as is. Revised protocols are to be submitted to the college IRB chairperson, who will forward them on to the initial reviewer for reconsideration. The reviewer will notify the chairperson of his/her decision (in writing and with adequate explanation if again the proposal is not accepted) within one week of receiving the resubmission.

7. College IRBs will NOT conduct *ex post facto* reviews of protocols.

G. University IRB Review of Research

1. The chairperson from a college IRB will forward proposals which have been assessed as more than minimal risk or which involve the use of one or more vulnerable populations to the University IRB. The college IRB chairperson will also forward a copy of the completed *Initial Assessment of Minimal Risk and Vulnerable Population Status* form for said proposal.

2. Within one week of its receipt, the University IRB chairperson will disseminate copies of these materials to each member of the University IRB. The University IRB will meet between one and three weeks following the dissemination of all materials to its members.

3. University IRB meetings require that a majority of its members be present including at least one non-scientist member (i.e. a quorum). University IRB full board reviews require that all members of the committee receive a copy of the proposal no less than one week prior to a scheduled meeting. Approval of the protocol is by a majority vote of this quorum. Should the quorum fail during a meeting, the IRB may not take further actions or votes unless the quorum can be restored.

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4. All IRB meetings will be open to the PI and the general public in accordance with Utah state law. The PI and any other individual affiliated with a proposal being reviewed may not be present during voting on said proposal.

5. University IRB members will duly consider each of the following in their assessment of a protocol:

   i. Risk/benefit analysis

   ii. Informed consent

   iii. Selection of subjects

   iv. Privacy and confidentiality

   v. Monitoring and observation

   vi. Additional safeguards

   vii. Incentives for participation

6. In the event a proposal is NOT approved through the University IRB review, the PI or faculty/staff supervisor (if PI is a student) must be notified in writing of this decision within two business days. Included in the documentation will be a description/explanation of the reason(s) for its non-approval. The PI will be given an opportunity to respond in person or in writing at the next IRB meeting.

7. University IRB members will document their reviews by completing the *Documentation of Full Board Review* form. This form will solicit protocol specific information in each of the categories listed in section III.G.5.

8. In the event that investigators not affiliated with Southern Utah University wish to conduct research on the SUU campus, those investigators must submit a copy of a) the IRB proposal they submitted to their own institution, and b) a copy of their IRB's approval letter. The chairperson of the University IRB will forward

these materials to each of the University IRB members. Concerns will be reviewed at the next meeting, with the minutes of the meeting serving as the review. A letter of acknowledgement will then be sent to the PI and any SUU affiliates.

9. The University IRB will NOT conduct *ex post facto* reviews of protocols.

H. Continuing Reviews of Approved Research

1. Proposals assigned expedited or full board review status and approved by a college or the University IRB will be subject to continuing review by the IRB that initially approved the research.

2. The IRB responsible for approving the initial research protocol will establish how often the research will be reviewed. All research which requires continuing review must be reviewed no less than once annually. The frequency with which a protocol will undergo continuing review will be proportionate to the level of risk involved in the research and the extent to which a PI or faculty/staff supervisor (if PI is a student) has a history of infractions to policy 6.20.

3. Continuing reviews must be substantive and meaningful. Within two weeks prior to the established deadline for a continuing review, the PI must complete and submit the *Continuing Review of Approved Research* form to the chairperson of the IRB which approved the research initially.

4. The *Continuing Review of Approved Research* form will consist of a protocol summary and a status report on the progress of the research. The form will solicit information on the following:

i. the number of subjects accrued;

ii. a summary of adverse events and any unanticipated problems involving risks to subjects or others and any withdrawal of subjects from the research or complaints about the research since the last IRB review;

iii. a summary of any relevant recent literature, interim findings, and amendments or modifications to the research since the last review;

iv. any relevant multi-center trial reports;

v. any other relevant information, especially information about risks associated with the research; and

vi. a copy of the current informed consent document and any newly proposed consent document.

5. If the research was approved through a college IRB, the IRB member who originally approved the protocol or the college IRB chairperson will conduct the continuing review within two weeks of receiving the *Continuing Review of Approved Research* form. In the event the reviewer determines that the research should be discontinued or revised, the *Continuing Review of Approved Research* form will be disseminated to all members of the college IRB and discussed at the next convened meeting, one to three weeks after receiving the review form.

6. If the research was initially approved through the University IRB, the chairperson will submit the review form to all members of the University IRB. Assessment of the continuing review information will be conducted at the next University IRB meeting, one to three weeks after receiving the review form.

7. IRB members/chairpersons who conduct continuing reviews will receive a copy of the initial protocol including any modification previously approved by the IRB. Upon request, members will have access to the complete IRB protocol file and relevant IRB minutes.

8. Decisions based on assessment of the *Continuing Review of Approved Research* form will be conveyed in writing to the PI or faculty/staff supervisor (if PI is a student) within two business days of reaching a decision.

I. Request for an Extension of an Approved Protocol

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1. IRB approval for a specific protocol (expedited or full board review status only) will in most cases terminate within one year of its approval date.

2. It is at the discretion of the IRB member who reviewed the protocol to establish the expiration date for the protocol's approval. Consideration will be given to the nature of the risks and benefits associated with the research.

3. Requests for an extension of the project's approval expiration date will require the PI to submit a completed *Approved Protocol Extension* form to the chairperson of the IRB that initially approved the protocol. This form just is submitted no later than four weeks prior to the project's expiration date to avoid any disruption in research activities.

4. If an extension is requested for a protocol initially approved by a college IRB, the chairperson of the IRB or the member who reviewed protocol initially, will review the application and decide whether to grant the extension.

5. If an extension is requested for a protocol initially approved by the University IRB, the chairperson of that IRB will forward the request to all members of the committee, who will review and decide on the request at a meeting to be convened one to three weeks after all members have received the request.

6. Final decisions to grant or refuse a request for extension will be conveyed to the PI or faculty/staff supervisor (if PI is a student) in writing within 2 business days of arriving at the decision. If the decision is made to not grant an extension, the reason(s) why will be detailed in writing.

J. Project Closure

1. All approved protocols with expedited or full board review status require the PI or faculty/staff supervisor, if the PI is a student, to complete and submit a *Project Closure* form within 30 days of the project's completion. This form is to be submitted to the chairperson of the IRB that initially approved the protocol.

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K. Random and Selected Audits of Approved Research

1. Once in the fall and once in the spring semester, one previously approved and on-going research protocol in each college will be randomly selected by the college IRB chairperson for a random audit. The University IRB chairperson will similarly select an on-going research protocol that had been previously approved, for a random audit.

2. Investigators with a history of infractions to policy 6.20 may be targeted for selected audits of approved and on-going research activities. The chairperson of the IRB that initially approved the protocol will decide whether to require an audit, which he/she will conduct. Investigators with several infractions or severe infractions are more likely to be subjected to a selected audit.

3. An audit's purpose is to ensure that no material changes to the protocol have been made since the previous IRB review. The auditor will examine the PI's materials and apparatus, speak to one or more research assistants (if applicable), and review raw data records. Where participants' contact information is known, and the PI has a history of infractions to policy 6.20, the auditor will contact 1-5 participants to verify the PI's adherence to the approved research protocol. The auditor may also contact participants in the event that inconsistencies/infractions appear in the course of the audit.

L. Amendments to Previously Approved Protocols

1. Primary investigators who wish to amend and/or revise a previously approved protocol must complete and submit the *Proposed Changes to a Previously Approved Protocol* form to the chairperson of the IRB that approved the research initially.

2. *Proposed Changes to a Previously Approved Protocol* form submitted to a college IRB chairperson will be reviewed by him/her or forwarded to the IRB member who approved the research initially. The IRB member will be required to review and decide whether to approve the changes within one week of receiving the form. The reviewer will complete his/her section of the form and return it to the IRB

chairperson (if not self), who will notify the PI in writing within 2 business days.

3. In the event an IRB member has concerns with regards to the proposed changes, the original *Proposal Submission* form and the *Proposed Changes to a Previously Approved Protocol* form will be disseminated to all members of the college IRB. Concerns will be addressed at the next college IRB meeting, one to three weeks after the chairperson receives the reviewer's decision.

4. *Proposed Changes to a Previously Approved Protocol* form submitted to the University IRB chairperson will be forwarded by him/her to all the members of the IRB. The IRB members will be required to review and decide whether to approve the changes within one week of receiving the form. The reviewer will complete his/her section of the form and return it to the IRB chairperson. Should one or more IRB members have any concerns with respect to the proposed changes, these will be discussed at the next University IRB meeting, one to three weeks after the chairperson receives the *Proposed Changes to a Previously Approved Protocol* forms from the IRB members.

5. Proposed changes to a previously approved protocol may not be initiated prior to receiving IRB approval, except when necessary to eliminate apparent immediate hazards to the participant. Instructions to this effect will be clearly printed on the *Proposed Changes to a Previously Approved Protocol* form and the initial *Proposal Submission* form.

M. Reports of Unanticipated Problems, Risks, and Hazards to Participants

1. The investigator will notify the chairperson of his/her college's IRB as well as the chairperson of the University IRB of any unforeseeable risks or hazards to participants, as soon as they become evident. Initial contact will be made wither in person or by phone. The investigator must complete and submit the *Incident Report* form to both chairpersons within two days of the incident.

2. The University IRB Chairperson, or the college IRB chairperson if the former is unavailable, will report the incident immediately to the OSP, the director of HRPP, the Institutional Official, and the Provost. In

cases where the research is supported by a federal grant, OSP will immediately notify OHRP and the Federal agency that awarded the grant. Initial contact will be made either in person or by phone. Copies of the *Incident Report* form filed by the investigator will be sent to the above mentioned people and offices immediately upon receipt of the form.

3. The University IRB and the chairperson of the college IRB will meet as soon as possible to discuss the implications of the incident and what, if any, action(s) need to be taken. A representative from OSP, HRPP, the University Official, the Provost, and the University's legal consultant will be invited or requested to attend. Proposed actions from this meeting will not supersede those required by OHRP and/or the federal granting agency, to the extent required by law.

N. Notification of IRB Decisions and Actions

1. All IRB decisions pertaining to a protocol will be conveyed in writing to the PI or faculty/staff supervisor (if PI is a student), within two business days of arriving at the decision.

2. All IRB decisions and actions will be documented at their respective meetings. The minutes of these meetings will be e-mailed to each IRB's members, OSP, the Director of the HRPP, and the Provost, as soon as they become available.

O. Nature and Retention of IRB Records

1. The chairperson of each IRB is responsible for keeping adequate records of its members, the minutes of IRB meetings, correspondence with researchers, and all completed IRB forms.

2. IRB records must be retained for at least 3 years, and records relating to research that is conducted must be retained for at least 3 years after completion of the research.

3. All records will be kept by the SUU Director of the OSP. Files must be accessible for inspection and copying by authorized representatives of the University and of the DHHS, and by the public in accordance with Utah state law, at reasonable times and in a reasonable manner.

4. The minutes of IRB meetings will record the members who attended the meeting, actions taken at the meeting, the outcome of the vote on research protocols including the number of members voting for or against approval and abstaining, the basis for requiring any modifications or revisions in research procedures or the informed consent process or forms, documentation of any specific findings required by the federal regulations, and a written summary of the discussion of issues and their resolution.

P. Noncompliance with Policy 6.20

1. All faculty, students, and staff named individually or collectively (e.g. "students enrolled in PSY 3410 research design") in an approved research protocol must adhere strictly to policy 6.20.

2. All reports of non-adherence to the policy will be investigated by the chairperson of the IRB that initially approved the protocol.

3. The IRB chairperson will present the evidence to his/her IRB members. Should the IRB decide that a preponderance of the evidence support one or more infractions to policy 6.20, the IRB chairperson is authorized to take one or more of the following actions voted on by the IRB members (which one will depend on the severity and frequency of the infraction):

   i. A letter describing the infraction(s) and cautionary statements may be sent to the PI or faculty/staff supervisor (if PI is a student).

   ii. A letter describing the infraction(s) and IRB actions in response to the infractions(s) may be sent to the chairperson of the PI's or faculty/staff supervisor's (if PI is a student) department.

   iii. A letter describing the infraction(s) and IRB actions in response to the infraction(s) may be sent to the OSP, director of HRPP, and the Provost.

iv. A letter describing the infraction(s) and IRB actions in response to the infraction(s) may be sent to OHRP and/or the federal Agency which funded the project.

v. The PI or faculty/staff supervisor (if PI is a student) may be required to suspend or discontinue the research project for which IRB approval was granted.

vi. The PI or faculty/staff supervisor (if PI is a student) may be required to suspend or discontinue all research activities for which IRB approval has been granted.

vii. The PI or faculty/staff supervisor (if PI is a student) may be prohibited from participating in any research activity while remaining at SUU.

Q. Responsibilities and Rights of the Institution

1. The institution will encourage and promote constructive communication among the institutional officials, research administrators, department heads, research investigators, clinical care staff, human participants, and all other relevant parties as a means of maintaining a high level of awareness regarding the safeguarding of the rights and welfare of the participants, recognizing the ethical codes of behavior operating within the various academic disciplines.

2. The institution will support the principle of free inquiry, and provide an atmosphere favorable for research and supportive of academic freedom.

3. The institution will exercise appropriate administrative overview carried out at least annually to assure that its practices and procedures designed for the protection of the rights and welfare of human subjects are being effectively applied.

i. The University will staff, maintain, and support the HRPP.

ii. HRPP is responsible for:

Communication & Education

a. Promoting communication among the research administrators, department heads, investigators, clinical care staff, human subjects, and institutional officials, as a means of maintaining a high level of awareness regarding the ethical conduct of research, and safeguarding the rights and welfare of subjects.

b. Maintaining access to the institution's Assurance, copies of pertinent Federal regulations, policies and guidelines related to the involvement of human participants in research, as well as institutional policies and procedures.

c. Educating the members of its research community in order to establish and maintain a culture of compliance with Federal regulations and institutional policies relevant to the protection of human participants.

Record-keeping & Reporting

a. Ensuring that IRB records are being maintained appropriately and that the records are accessible, upon request, to authorized Federal officials.

b. Ensuring that the certification of IRB approval of proposed research to the appropriate Federal department or agency for federally supported research.

Monitoring & Oversight

a. Ensuring that appropriate oversight mechanisms to ensure compliance with the determinations of the IRB have been implemented.

b. Ensuring that all cooperating performance sites in Federally supported research have appropriate OHRP-approved assurances and provide Certifications of IRB review to the appropriate Federal authorities.

c. Ensuring that performance sites cooperating in non-Federally supported research have, and can document, appropriate mechanisms to protect human participants.

d. Ensuring that cooperative IRB review arrangements are documented in writing in accordance with OHRP guidance.

e. Ensuring that all independent investigators, who rely on the institution's IRB, have documented, in accordance with OHRP guidance, their commitment to the institution's human participants protection requirements and to the IRB's determinations.

4. The institution will provide for meeting space and sufficient staff to support the IRBs' review and record-keeping duties.

5. Research covered by this policy may be subject to further appropriate review by officials of the institution. However, those officials may not approve research if it has not been approved by an IRB.

R. Responsibilities and Rights of the Investigator

1. The primary investigator (and supervisor if applicable) must complete the NIH sponsored training course, currently located at: http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp . The primary investigator or supervisor (if PI is a student) is responsible for ensuring that all other investigators involved with the project are appropriately and adequately trained in the protection of human research participants.

2. Proof of completion certificates will be kept on file with SUU's OSP. No protocol will be approved by an IRB until all required certificates are on file with OSP.

3. The PI and faculty/staff supervisor (if PI is a student) must read and understand SUU Policy 6.20, and all instructions provided by the IRBs for securing and maintaining IRB approval.

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4. Should investigators wish to appeal an IRB decision, they must first do so internally. That is, the appeal must be presented initially to the chairperson of the IRB that approved the protocol initially. If the investigator feels his/her appeal was not resolved, the investigator may then appeal to the director of HRPP. Not that no individual or office at the University may approve a protocol which was not approved by one of the IRBs.