POLICY #6.20
SUBJECT: Institutional Review Board for Research on Human Participants

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I. PURPOSE

N/A

II. REFERENCES

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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.

H. Institutional Review Board (IRB): IRB means an Institutional Review Board established in accord with, and for the purposes expressed in this policy. 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.

I. Interaction: 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).

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

K. Legally Authorized Representative: Legally Authorized Representative means an individual, jud tc se ! = , , sub ˇ t ion . oo L s

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.

P. Sponsored Programs, Agreements, Research, and Contracts (SPARC): SPARC 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.

Q. Vulnerable Populations: 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.

IV. POLICY

A. Introduction

Southern Utah University (SUU) 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.

Policies, definitions, and guidelines, where applicable, are taken or modified from The Code of Federal Regulations (CFR) Title 45 (Public Welfare), Part 46 (Protection of Human Subjects Subparts A,B,C,D,E) and are referred to throughout this Policy. Some policies related to human subjects Research are included in the above cited sources, but do not appear in this policy, for the sake of parsimony. If not included in this policy, the SUU IRB adheres to Health and Human Services written policies for decisions and guidance, if warranted.

The IRB 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 IRB 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 IRB acknowledges and accepts responsibilities for protecting the rights and welfare of human Research participants.

The following policies and procedures apply to all Research involving Human Participants,

ii. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the Research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

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

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

v. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

vi. 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.

vii. Research required by students in a course, for completion of the course requirements, where only non-sensitive information is collected from participants, or all foreseeable risk are minimized or eliminated.

viii. 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).

The IRB retains final judgment as to whether a particular activity is exempt or whether it requires another category status (i.e., Expedited Review or Full-Board Review).

ascertain the acceptability of proposed Research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If the 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.

ii. Every nondiscriminatory e f ort should be made to ensure that the IRB does not consist entirely of men or entirely of women, and that no selection is made to the IRB on the basis of gender. The IRB shall not consist entirely of members of one profession or academic discipline.

iii. The IRB shall include at least one member whose primary concerns are in scienti f c areas and at least one member whose primary concerns are in nonscienti f c areas.

iv. The IRB shall include at least one member who is not otherwise a f iliated with SUU and who is not part of the immediate family of a person who is a f iliated with the institution.

v. No IRB member shall participate in the IRB's initial or continuing review of

b. Membership for the University IRB will adhere to the requirements described in Section IV.B. of this document

c. Typically, IRB members will review protocols for all Research activities which involve human Research participants submitted by faculty, staff, or students from their own college after being assigned to a review by the IRB chairperson. In the event that the IRB member determines that a protocol involves more than Minimal Risk the protocol will be sent to the IRB chairperson for a Full-Board review. In addition to these reviews, the 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.

5. Appointment of Members to the University IRB

   a. The Institutional Official appoints members to the IRB at the beginning of each academic year. Members of the University IRB serve up to a three-year term. IRB members can serve additional three-year terms, if warranted.

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

6. Review of Research Proposals

   a. Researchers seeking IRB approval must complete and submit an *IRB Proposal Submission* form to the IRB. All proposals must be received by the IRB chairperson electronically by the 7th day of the month during the fall and spring semesters to be considered for review in the same month. Proposals received after the 7th day of the month will be considered in the subsequent month. Within one week of its receipt, the chairperson of the IRB will disseminate the proposal submission form to one of the members of the IRB for an initial assessment of Minimal Risk and vulnerable population status. The member who conducts this initial review will typically be the board member associated with the college from whence the proposal originated. The IRB 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 IRB chairperson within one week of receipt of proposal.

   b. Proposals determined to involve more than Minimal Risk will be forwarded to the IRB chairperson and will be distributed to members of the IRB for a Full-Board Review.

   c. Proposals determined to pose no more than Minimal Risk 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 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.

d. 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

e. 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.

f. In the event the protocol is NOT approved by the initial reviewer, the IRB chairperson, solely or along with other members of the IRB, will review the protocol. In the event that the protocol is rejected, 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. The PI will be given an opportunity to resubmit the protocol after making any and all revisions requested by the initial reviewer, or request an IRB Full-Board review of the protocol as is. Revised protocols are to be submitted to the IRB chairperson, who will forward them on to the initial reviewer for reconsideration. Submission of revised protocols can occur on a rolling basis during the Fall and Spring semesters. The reviewer will notify the chairperson of their decision (in writing and with adequate explanation if again the proposal is not accepted) within one week of receiving the resubmission.

g. IRBs will NOT conduct ex post facto reviews of protocols. Conducting human subjects Research without prior IRB approval is in violation of Policy 6.14, and infractions will result in written notification to the SUU Research Integrity Officer.

7. IRB Full-Board Review of Research

a. For proposals which have been assessed as more than Minimal Risk a Full-Board review will occur. The IRB member assigned to review the initial protocol submission will forward a copy of the completed *Initial Assessment of Minimal Risk and Vulnerable Population Status* form for said proposal.

b. Within one week of its receipt, the IRB chairperson will disseminate copies of these materials to each member of the IRB. The IRB will meet between the 15th and end of each month as needed during the fall and spring semesters to conduct Full-Board review(s).

c. IRB meetings require that a majority of its members be present including at least one non-scientist member (i.e., a quorum). 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.

d. All IRB meetings will be open Ů ota mf a ŧ mei Ɣ Ոd. i † h l ώ

Approved Research

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e. 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.

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

    a. The investigator will notify the chairperson 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 the IRB chairperson within two (2) days of the incident.

    b. The IRB chairperson, will report the incident immediately to SPARC, the director of HRPP, the Institutional Official, and the Provost. In cases where the Research is supported by a Federal grant, SPARC 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.

    c. The 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 SPARC, 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.

14. Notification of IRB Decisions and Actions

    a. All IRB decisions pertaining to a protocol will be conveyed in writing (electronically) to the PI or faculty/staff supervisor (if PI is a student)

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

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.

viii. A formal report to be sent to the Research Integrity Officer with a

compliance with Federal regulations and institutional policies relevant to the protection of Human Participants.

B. Record-Keeping & Reporting

1. Ensuring that IRB records are being maintained appropriately and that the records are accessible, upon request, to authorized Federal o f icials.

2. Ensuring that the certi f cation of IRB approval of proposed Research to the appropriate Federal department or agency for Federally supported Research.

C. Monitoring & Oversight

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V. RELEVANT FORMS/LINKS

- Protecting Human Research Participants Online Training

VI. QUESTIONS/RESPONSIBLE OFFICE

The responsible office for this Policy is the Provost/Vice President for Academic Affairs. For questions about this Policy, contact the current Institutional Review Board Director.

VII. POLICY ADOPTION AND AMENDMENT DATES

Date Approved: December 5, 1994

Amended: January 28, 2005; November 29, 2007; May 3, 2013; December 1, 2016

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