



IRB PROPOSAL FORM FOR USE OF HUMAN SUBJECTS IN RESEARCH

SOUTHERN UTAH UNIVERSITY IRB PROPOSAL FORM FOR USE OF HUMAN SUBJECTS IN RESEARCH

Information entered into this form may be lost if this file is not first downloaded (i.e., saved to a local device) and then opened with Adobe Reader or Adobe Acrobat prior to the entry of any information.

1. Title of Research Proposal:

2. Principal Investigator (PI):

Title of PI (e.g. Faculty Staff, Student):

College, Organization, or Office

Department:

Address:

Phone Number or Extension:

E-mail:

Fax

3. Is the PI is a Student? If YES Complete this Section.

YES NO

Faculty Supervisor

Title of Faculty Supervisor:

Faculty Supervisor's College, Organization, or Office

Faculty Supervisor's Address:

Faculty Supervisor's Phone (xxx.xxx.xxxx):

Faculty Supervisor's Department:

Faculty Supervisor's E-mail:

4. Other Investigators: (may be named individually or collectively if a whole class is involved)

5. IRB Training Certificates

The principal investigator and supervisor, if applicable, has submitted an NIH Ethics in Research Training Completion Certificate to The SUU IRB or SUU's SPARC Office. Please note: It is the PI's responsibility to make certain that all individuals involved with the project receive appropriate and adequate training in the protection of human research participants. If the PI is a student, this responsibility rests with the supervisor:

YES

NO

Will be Attached to Signed Paper Copy

6. Start Date of Proposed Research

End Date of Proposed Research

(Please note that IRB approval may only be granted for one year at a time.)

7. The Proposed Research is for (Check All that Apply)

Faculty Research

Student Research Project

Class Project

SUU Administration

SUUSA

Grant Proposal

Other

Specific Course for Class Project (If Applicable)

8. Intended Dissemination of Results

Off Campus Presentation and/or Publication

Class Presentation

SUU Campus Community

Other

9. Describe Your Research Question(s) And Justify Why This Research Needs To Be Conducted.

10. Describe How Research Subjects Will Be Recruited And Any Proposed Compensation Or Incentives There Are To Participate.

Which Method(s) Of Recruitment Will Be Used:

Flyer

Newspaper Ad

Online Recruitment

Class Presentation

Other

Paste Here Or Attach A Script, Flyer, Or Recruitment Text To The Printed Copy Of This Document.

11. Describe All Materials And/Or Apparatuses To Which The Participants Will Be Exposed. Include A Copy Of The Materials Here Or As An Attachment To The Printed Document.

12. Describe The Research Methodology In Common, Non-technical Language. Describe Your Research Design. The SUU IRB Needs To Know Exact Procedures And Exactly What Will Be Done With Your Research Participants. If Any Form Of Deception Is Used, It Must Be Described And Justified.

**RISK/BENEFITS & PARTICIPANT INFORMATION
ASSESSMENT OF RISK AND VULNERABLE POPULATION STATUS**

Part A: Assessment of Vulnerability

13. Indicate which of the following describes the research participants (the individuals from or about whom you will be obtaining information).

Active Independent Adults (Non-SUU) SUU Faculty, Staff or Students

Estimated Number of Participants

Inclusion of Potentially Vulnerable Participants (Check all that apply):

- Pregnant Women or Fetuses
- Cognitively Challenged Individuals
- Physically Challenged Individuals
- Individuals 65 Years of Age or Older
- Hospital Patients
- Individuals with Learning Disabilities
- Prisoners
- Children (Minors, Less than 18 Years of Age)
- Economically Disadvantaged Individuals
- Faculty's Own Students
- Others Who Might Be Subject to Risk

Estimated Number of Potentially Vulnerable Participants. List Category and Estimated Number

Part B: Privacy & Confidentiality

Will the **Data Collected** Be Anonymous: No Names or Other Identifiers (e.g. SSN's, Student ID's) Will be Attached to Any of the Data OR Will the Data Be Confidential: Names or Other identifiers (e.g. SSN's, Student ID's) will be Associated with At Least Some of the Data Collected?

Anonymous Confidential

If You Selected Confidential. Please Answer Each of the Following Three Questions. Your Answers Should be Complete and as Concise as Possible.

- I. Who specifically will have access to the confidential data?
- II. What steps will be taken to ensure that the data remains confidential?
- III. For all confidential data (visual, auditory, or printed), when and how will this data be destroyed or de-identified?

Will **Participation in this Research** Be Anonymous: participants' identity will not be known, directly or indirectly, to the researchers OR Confidential: At least some of the participants' identity will be known?

Anonymous Confidential

If You Selected Confidential. Please Answer Each of the Following Two Questions. Your Answers Should be Complete and as Concise as Possible.

- I. Who specifically will have access to the participants' identity?
- II. What steps will be taken to ensure that participation in the study remains confidential?

Part C: Risks & Benefits

Total Time Commitment
Requested from Participants

If Total Time Commitment Varies According to Each Type
of Participant, Please Describe Below.

Indicate Which Of The Following Types Of Information Will Be Solicited From or About The Participants.

Physical health disorders, past or present

Mental health disorders, past or present

Sexual attitudes or behaviors

Alcohol or tobacco use

Illegal activities

Feelings/thoughts/attitudes about colleagues or co-workers

Feelings/thoughts/attitudes about employers

Feelings/thoughts/attitudes about significant others

Financial status or activity

Behaviors considered undesirable in the present local culture

Any other information which might reasonably cause embarrassment and/or other emotional distress to participants

Any other information which most people generally keep private and/or confidential

If any of the above information is solicited, then this is an indication that a risk (physical, psychological, social, economical, or legal) **could** present itself. To minimize these risks, participants must be informed of the nature of the risks and how they will be minimized. Describe how risk will be explained to participants and minimized.

Will Participants be Subjected to the Following Procedures? Check All that Apply

Blood sampling

Other invasive biomedical procedures

Moderate or strenuous exercise

Procedures which could cause physical pain/discomfort

Procedures which could cause psychological pain/discomfort

Procedures designed to increase stress levels

Consumption of food or beverage other than water

Administration of a non-food related drug or chemical

Physical therapy

Psychological intervention/treatment

X-ray or similar imaging techniques

Use of radiation or lasers

Use of potentially hazardous materials

Exposure to stimuli of a mature nature (language, violence, nudity, sexual content)

Any other procedure capable of causing harm. Please describe:

If You Indicated A Procedure Above, This Indicates That A Risk (Physical, Psychological, Social, Economical, or Legal) Could Present Itself. For Each Procedure Indicated Above:

- A. Explain the procedure, relevant apparatus and/or stimuli involved;
- B. Explain the nature of the risk, its consequences, and how it will be minimized;
- C. Explain what will be done in the event the risk does become a reality.

Please Describe all Probable Benefits to Participants, Others, and the Discipline/Organization Affected by this Research

14. Indicate All Locations of Data Collection

On Campus

Off Campus

Online (Internet, Web-Based)

Off Campus Locations (If Applicable)

Private residence

Commercial establishment (e.g., restaurant, store, gym clubs)

State or federal office (e.g., Dept. of transport, Workforce services)

Other university/college campus

School (public or private)

National or state parks

Other. Please Describe

NOTE: Except for participants tested/interviewed on campus, in their private residence, or via the internet, it is likely that on site testing/interviewing will require permission from the site manager/director. A copy of the request must be attached. Documented approval from the site manager/director MUST be obtained prior to initiating on site research activities. Failure to obtain such documentation will void any IRB approval for the research project and could result in disciplinary action.

15. An Informed Consent Statement/Document:

will not be presented verbally or in writing

will only be read to all participants

will only be read by all participants

will be presented to be read and signed by all participants

If the proposed research involves more than minimal risk and/or tests one or more vulnerable populations, the SUU INFORMED CONSENT TEMPLATE should be used to construct the informed consent document. In almost all of these cases, this document will need to be signed by the participant and/or his/her legal guardian, and the primary investigator.

Explain why Informed Consent Will not be Sought (If Applicable)

Include the Script to be Read to Participants (If Applicable) in the Section Below. If the Script Cannot be Included on this Form, then Attach it with the Submitted Application.

Include the Informed Consent Document (If Applicable) in the Section Below. If the Informed Consent Document cannot be included on this Form, then Attach it with the Submitted Application.

Be Sure All Required, and Applicable Elements are Included in Your Informed Consent Document:

Your name and position at SUU

An explanation of the purposes of the research

The expected duration of the subject's participation

A description of the procedures to be followed

If a survey or interview is involved, include the following statement: You may skip any question you do not wish to answer.

If surveying/interviewing participants, a description of the type/nature of the questions

Include the statement: Participation is voluntary. You may discontinue the study at any time for any reason without penalty. You may ask questions at any time (via e-mail if internet-based).

A description of any reasonable, foreseeable risks or discomforts to the participant

A description of any benefits to the participant which may reasonably be expected from the research

A statement explaining whether participation and the data collected is anonymous or confidential

Who to contact for information or concerns regarding the study (both PI and SUU IRB contact information should be provided)

A statement whether or not compensation will be awarded and the details thereof

The following statement: The Institutional Review Board (IRB) of Southern Utah University has reviewed this study for the protection of the rights of human subjects in research studies, in accordance with federal and state regulations.

Is this Research being Funded (or Intended to be Funded) by a Grant?

NO

YES (Please Describe)

I approve this protocol for submission to the SUU IRB:

Principal Investigator's Signature (Typed Signature is Acceptable)

Date

Faculty Supervisor's Signature (If Applicable; Typed Signature is Acceptable)

Date

The PI or Faculty Supervisor (if PI is a student) will be informed in writing of the IRB's decision. The proposed research may not be initiated prior to receipt of IRB approval.

Should you wish to modify this proposal prior to its approval, please contact the SUU IRB Chairperson immediately with intended modifications, and submit the revised proposal as soon as possible.

Modifications to an approved IRB proposal MUST be requested by completing the Proposed Changes to a Previously Approved Protocol Form. No changes may be initiated until such approval is granted, unless they are to eliminate or reduce immediate harm to participants.

Everyone named (individually or collectively) in this proposal is required to be familiar and comply with SUU policy 6.20.

Please Submit this Proposal via E-mail to Garrett Strosser (garrettstrosser(at)suu.edu) along with all applicable attachments and supplemental materials.