NON-EXEMPT RESEARCH APPLICATION

IRB Review Request for Projects Using Human Subjects

Non-Exempt Research Application reflects changes to the Federal Regulations 45 CFR part 46 effective January 21, 2019.

Purpose: This application is designed to facilitate the Institutional Review Board (IRB) review of proposed human subjects research. The IRB serves to protect the rights and welfare of human subjects in research in accordance with federal, state, and institutional regulations and policies. Use this form to request review of non-exempt research from the IRB.

Instructions:

Complete this application as part of the initial protocol submission. A complete protocol submission initiates IRB review of research involving human subjects. Incomplete or unreadable applications will extend the IRB review process. Submit this application and all applicable research materials (research plan, attachments, consent form templates, surveys, interview guides, recruitment materials, etc. to the IRB administrator at trammellj@sou.edu.

Direct any questions regarding this form or human subjects research to the IRB Administrator Marie Trammell by email at trammellj@sou.edu or phone at (541) 552-8662.

SOU's IRB will review and make a determination on the proposed human subjects research. You may not begin research, including recruitment of participants, until you have received full Approval by the IRB. The IRB cannot retroactively approve human subjects research.

I. STUDY AND INVESTIGATOR INFOMRATION	
Study Title:	
Principal Investigator Name:	
Co-Investigator/ Student Name:	
Co-Investigator/ Student Name:	
List Additional Co-Investigators:	

I. CONTINUED - STUDY AND INVESTIGATOR INFOMRATION

1. What are the anticipated project dates for beginning and ending human subjects research?

Start (month and year): End (month and year):

2. Funding source:

Is this research funded or sponsored from an internal SOU Department or external source?

☐ Yes ☐ No

If "yes", list the funding agency & grant code index:

List the PI(s) of the funded grant:

II. RISK ASSESSMENT

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.

In the Principal Investigator's opinion, this research presents (select one of the following):

☐ No greater than minimal risk; **briefly explain in the text box below.**

☐ Greater than minimal risk; **briefly explain in the text box below.**

III. RESEARCH PLAN

1. Answer "Yes" or "No" to the questions.
If the answer to any of the following questions is "yes," incorporate relevant information into the Research Plan Narrative.

☐ Yes	☐ No	i. Does this research involve the use of any drug, substance, or biologics?
☐ Yes	☐ No	ii. Does this research involve the use of a medical device?
☐ Yes	☐ No	iii. Does this research involve the use of any ionizing radiation (X-ray, DEXA scan, etc.?)
☐ Yes	☐ No	iv. Does this research involve the use of Protected Health Information (PHI)?
☐ Yes	☐ No	v. Does this research involve coded or identifiable DNA samples or genetic information?

2. Research plan for proposed research activities.

For the following sections, provide information about the proposed research activities as an attachment to this application and title it "Appendix A - Research Plan Narrative." Use the bolded words for each section below as section headings to ensure all parts are addressed.

For each section below, rationale from the IRB is listed in italics followed by instructions . You must address each section in the research plan. Incomplete information will result in delay of review by the IRB.

I. **Introduction and Background** - *In reviewing the protocol, the IRB must consider the rational for the study and the importance of the knowledge that may reasonably be expected to result.*

Briefly summarize the nature, scientific rationale and significance of the proposed study and any relevant background information on the topic. Explain the relevance of the study to previous and/or continuing work in the field. Discuss why novel inquiry is necessary. If there is a gap in knowledge, explain how it is anticipated that this research will address the gap. If this research is intended to replicate previous research, provide rationale.

II. **Specific Aims/Study Objectives** - *The IRB must evaluate the objectives of the research in order to determine whether the risks to participants are reasonable in relation to the importance of the knowledge that may be gained.*

Clearly outline the specific research question(s). Include the study objective(s) and/or hypothesis.

III. CONTINUED - RESEARCH PLAN

III. **Methods, Material, and Analysis** - *The study design, methods and procedures must be adequately described in order for the IRB to understand all activities in which human subjects will participate. The IRB must also be able to differentiate those procedures that are performed for research purposes from those that are performed for routine care and evaluation.*

Note: The focus of this section is on methods and procedures. If sub-item is not applicable to your research skip to the next.

A. Describe the study design and research methods used to meet the study aims and objectives (e.g. on-line survey, open ended interview, participant observation, etc.).

B. If there are will be multiple groups of participants completing different sets of activities or tasks, clearly delineate the activities to occur for each group.

C. Describe in chronological order all research activities or procedures involving participants. This should walk the reader/reviewer step-by-step through the research activities and include a description of the research procedures and instruments.

D. Include an estimate of the time each participant will spend completing the activities, the number of sessions the participant will engage in, and the total length of participation from beginning to end of the study.

E. If follow-up with participants is planned, discuss the procedures and under what circumstances follow up will occur.

F. Describe the methods of data collection and recording that will be utilized in the study (e.g., hand-written notes, survey platform, computer programs, videotapes, audiotapes, photographs, etc.).

G. Describe the specific locations where the activities will be conducted.

H. Explain how the data will be analyzed/studied (i.e., quantitatively or qualitatively and what statistical tests are planned), how the interpretation will address the research questions, and how the research will be disseminated.

1. Describe how the data will be reported (e.g., aggregated, anonymously, pseudonyms for participants, etc.)

IV. **Potential Benefits of the Research** - *In order to approve this research, the IRB must determine that the anticipated benefits to research participants and the knowledge researchers expect to gain are reasonable in relation to the potential risks.*

A. Describe any anticipated benefits that may result from the research. Consider the following:

1. Direct benefits that may result from participation (e.g., psychological or emotional benefits, learning benefits, physical benefits, etc.). If there are no direct benefits to participants, clearly state this

2. Benefits to the general participant population.

3. General benefits of the research for society, science, humanity; potential generalizable knowledge. If there are knowledge gaps, state how this research will address those gaps.

IV. PROJECT DETAILS

1. Describe your research population (e.g., students from Walker Elementary School, adult hysterectomy patients at Rogue Valley Medical Center, etc.) and provide the rationale for including the participant population.

2. List the inclusion criteria such as age range, race or ethnicity, gender, language and literacy, etc.

3. List the exclusion criteria and rationale. If there is no exclusion criteria state "n/a."

4. Does this study include minors?

☐ Yes ☐ No If "yes," state ages of minors: minimum: maximum:

5. Number of anticipated participants. **Total:**

a) Provide justification for your sample size:

Number of participants must be sufficient to appropriately answer the research questions(s). Small scale designs are acceptable if such designs adequately answer the research question(s).

IV. CONTINUED - PROJECT DETAILS

6. How will subjects be recruited? (Attach a copy of any recruitment materials to be used - See Checklist)

- ☐ Email (indicate source of emails below)
- ☐ Flyer (Provide a copy with the protocol)
- ☐ In Person
- ☐ Other (Describe below)
- ☐ Online Recruitment (SONA, MTURK, etc.)
- ☐ Social Media (indicate where/how below)
- ☐ Telephone
- ☐ Mail (indicate source of addresses below)

7. Describe how the participant population is accessed or obtained (e.g., access to listservs, online databases, etc.). Discuss relevant permissions. **Attach notice of permission**.

8. Describe any screening tests and/or procedures that will be used to ensure that potential participants are eligible to participate.

9. If any part of the recruitment procedures involves a language other than English, describe any differences in the recruitment procedures for non-English speaking participants. If all participants are English speakers write "n/a."

10. For research involving treatment (e.g. behavioral intervention, device studies, etc.), describe how research treatment will be distinguished from regular treatment. If research does not involve treatment write "n/a."

IV. CONTINUED - PROJECT DETAILS

11. Select the methods to be used during data collection. **Attach a copy of survey items or instruments used during the data collection process.**

Survey

- ☐ Mail
- ☐ Phone
- ☐ In Person/Paper
- ☐ Online (Qualtrics, MechanicalTurk, etc.)

Interview

- ☐ One-on-One
- ☐ Phone
- ☐ Email or Online
- ☐ Focus Group

Other

- ☐ Public Observation
- ☐ Oral History
- ☐ Educational Intervention/Evaluation
- ☐ Behavioral Intervention
- ☐ Other (describe below)
- ☐ Participant Observation
- ☐ Food Taste/Quality Evaluation
- ☐ Secondary Research on previously collected data or biospecimens
- ☐ Secondary Research on data or biospecimens where subjects give or waive broad consent

12. Indicate the **total amount of time** that will be requested from each person who participates in this research study. Include a detailed description of time required by the participant in Appendix A - Research Plan section III part D.

V. PARTICIPANT PRIVACY, DATA DISPOSITION, AND DATA CONFIDENTIALITY

1 . Select one of the options for the type of data that will be collected and describe how the data will be handled and protected below.

- ☐ a) Anonymous - *You will not ask for participant's name and participant's identity cannot be deduced from answers to questions asked.*
- ☐ b) Confidential - *Researchers will know participants' names or identities, but will keep them confidential. Readers of the research results will be unable to tell the identity of the participants and there will be no way to connect participants with the data.*
- ☐ c) Unnamed but potentially identifiable - *The population you are studying is very small and/or the questions asked will make participants readily identifiable.*
- ☐ d) Intentionally Identified - *Participants will agree to be identified and be associated with the research.*

V. CONTINUED - PARTICIPANT PRIVACY, DATA DISPOSITION, AND DATA CONFIDENTIALITY

2. Explain how anonymity, privacy and/or confidentiality will be maintained. Consider the following: The methods used to identify and contact potential participants, the settings in which an individual will be interacting with an investigator, the appropriateness of others in attendance during research activities, and the sensitivity of the requested information. If you are only using existing data, explain how the pre-existing records will be safeguarded.

3. Describe what personal or identifiable information will be obtained to facilitate the research and as part of the data collection. If participant data will be collected without identifiers, please state this.

4. Will any of the following media be part of the data collection process?

- ☐ Audio Recordings
- ☐ Photographs
- ☐ Video Recordings
- ☐ Other - Describe Below
- ☐ Digital Recordings
- ☐ Media **will not** be collected as part of this research project

5. Describe the steps that will be taken to secure data and/or specimens for the research.

V. CONTINUED - PARTICIPANT PRIVACY, DATA DISPOSITION, AND DATA CONFIDENTIALITY

6. Will participants' private information be coded (i.e., identifying information has been replaced with a number, pseudonym, etc.)? Describe how the information will be coded. Include the following information: how the key to decipher the code will be stored, who will have access to the code key, if the code key will be retained, how long it will be retained, and justification for retaining the code key.

☐ Participants' private information **will not** be coded.

7. Will participants' identities be disclosed as a result of this research (e.g., attributing a direct quote, etc.)? Provide justification for appropriateness of direct identification, the parameters for disclosure (e.g., will participants be allowed to review and withdraw information prior to dissemination), how will permission from participants be solicited including any restrictions?

☐ Participants' identities **will not** be disclosed.

8. Indicate where and how you will store the data, and how long you plan to retain it. *Research involving any type of use of human subjects must be retained for at least 3 years.*

9. Describe the security of the area where the data will be stored (e.g., locked file cabinet, password protected computer, encryption, firewalls, etc.).

10. Who will have access to the data?

V. CONTINUED - PARTICIPANT PRIVACY, DATA DISPOSITION, AND DATA CONFIDENTIALITY

11. Describe how you maintain security of the data during transmission and/or sharing.

12. Describe how you will dispose of the data.

13. Describe any intent for future use of data beyond this research project including: if other researchers will be permitted to access/use the data, how data will be maintained and stored, how participant permissions for future use will be obtained and tracked.

14. Will participants be compensated or provided with incentives (including extra credit)?

☐ Yes ☐ No

If yes, what will the incentive/compensation be, when will it be given, how will it be provided, and what is the source of funding? Please indicate if compensation will be self-funded.

Explain how the incentive or the method and amount of compensation is appropriate for the participant population and study activities (e.g., based on time commitment, number of study visits, age of participant population, etc.).

VI. INFORMED CONSENT

1. What form of consent will be obtained? (Attach Letter of Informed Consent, or Consent Script)

- ☐ Written - adult participants (attach adult consent form)
- ☐ Written - minor participates (attach youth assent form and parental consent form)
- ☐ Implied (attach cover letter or describe terms)
- ☐ Verbal (attach consent script)
- ☐ Seeking Waiver of Consent (fill out and attach Request for Wavier or Alteration of Informed Consent Form)

2. Where and when will the informed consent process take place (i.e., in-person in private room, over the phone, etc.)?

3. Are there any cultural considerations for the consent process (e.g., tribal or group permission requirements, technological limitations, etc.)?

4. What steps will be taken to ensure voluntary participation and to minimize the possibility of coercion or undue influence?

5. Describe how the investigator will ensure that the participants understand all aspects of their involvement in the research (i.e., will participants be asked questions about the procedures, or will they be encouraged to ask questions?)?

VI. INFORMED CONSENT

6. Describe any special provisions for individuals who might have trouble comprehending the consent information.

7. If any participants do not speak English:

If research participants do not speak or read English well enough to understand information about the research study/project and the Informed Consent and/or Youth Assent forms, these documents must be provided in the language of the participants(s) and submitted with the protocol.

☐ Yes	☐ No	Is this study likely to involve any participants who are not fluent in English? If "no" skip to the next question.
☐ Yes	☐ No	Is the researcher/investigator fluent in the language?
☐ Yes	☐ No	Will a translator be used?
☐ Yes	☐ No	Will translated consent materials be used?
☐ Yes	☐ No	Are there any differences in the consent process for different populations based on the language they speak? Describe any differences below.

Give an explanation of your procedures below of how your non-English speaking participants will be fully informed. Note - If conducting interviews, focus groups, or surveys in person, a qualified translator must be present.

8. Describe how the researcher plans to document that each participant has provided informed consent or permission and assent.

☐ Researcher(s) are seeking Waiver or Alternation of Informed Consent and application is attached to the protocol.

☐ Documentation is described as follows:

VI. INFORMED CONSENT

9. Vulnerable populations and additional considerations for obtaining consent. Check all that apply to the proposed research activities:

a) Vulnerable Populations:

- ☐ None of these apply to the proposed research activities.
- ☐ Pregnant women, fetuses, or neonates
- ☐ Prisoners
- ☐ Minors (those under the age of 18 for the majority), or individuals of diminished capacity
- ☐ Other (describe below)
- ☐ Seeking Waiver or Alteration of Informed Consent
- ☐ Veterans
- ☐ Minorities
- ☐ Economically or Educationally Disadvantaged Persons

Describe the capacity of the participant and their ability to provide consent or assent, and describe how consent or assent to participate will be obtained and documented. *Note: If working with neonates or fetuses, consent <u>may</u> be required by both the mother and father.*

Describe how the investigator will assess the participants' ability to provide consent or assent.

b) Deception:

- ☐ Proposed research activities **do not** involve deception.
- ☐ Proposed research activities involve deception
- ☐ Seeking Waiver or Alteration of Informed Consent

Explain how participants will be deceived and why it is necessary for the study. Describe the debriefing process and provide a script.

VII. RISKS AND HARM

1. Describe any reasonably foreseeable risks or harm or discomforts for individuals and/or groups that may result from participation in the research. While risks associated with participation may not be expected, most protocols carry some risk. Consider the following risks and check all that apply:

- ☐ Information risks (e.g., loss of privacy and/or breach of confidentiality).
- ☐ Psychological or emotional risks (e.g., fear, stress, confusion, guilt, loss of self-esteem, depression, triggering of past emotional experiences).

  Attach a list of community agencies or counseling services so that participants can be directed to assistance as needed.
- ☐ Social risks (e.g., social stigma, chance of being ostracized or shunned), economic risks (e.g., change in employment or insurability).
- ☐ Physical risks or harms (e.g., fatigue, pain and discomfort, potential for injury, illness or disease, or death, side effects and contraindications of drugs or substances used in the research).
- ☐ Legal risks (e.g., risk of prosecution, mandatory reporting).
- ☐ Genetic privacy risk (e.g., stigmatization, self-stigmatization, limits to insurance coverage or employability, misattributed paternity, etc.
- ☐ Other. Describe below.

For <u>each</u> identified risk, explain the following: likelihood of the risk occurring, the magnitude of the effects the risks would have should they occur, how the risks will be minimized, and how the risks will be disclosed in the informed consent process.

VIII. STUDY LOCATIONS AND ENGAGED INSTITUTIONS

1. Will research activities occur at other site(s) or organizations other than SOU (e.g. public schools, companies, tribes, non-profit organizations, etc.)?

☐ Yes ☐ No

If yes, list all sites and describe the status of approvals. **Attach documentation of permission**.

VIII. CONTINUED - STUDY LOCATIONS AND ENGAGED INSTITUTIONS

2. Will individuals from other universities/organizations with an IRB be engaged in this research?

☐ Yes ☐ No List the engaged sites below and state the approval status (approved, approval pending, not approved). **Attach documentation of approval.**

3. Will individuals from other sites/organizations without an IRB be engaged in this research?

☐ Yes ☐ No If "yes" contact the IRB Administrator at (541) 552-8662 for additional information.

4. Does this research involve activities outside of the United States?

☐ Yes ☐ No If "yes" list the country(ies) below and indicate the status of permissions.

a) Are there additional requirements that apply to research conducted in the listed countries (e.g., European Union and the General Data Protection Regulations)?

☐ Yes ☐ No

If yes, describe and discuss how these are addressed for the proposed research and **include any approval documentation.**

IX. Human Subjects Conflict of Interest

1. It is the responsibility of the Principal Investigator (PI) to ensure that any research personnel, including the PI, complete the Human Subjects Conflict of Interest form for those individuals who have identified a real, perceived, or potential conflict of interest.

2. The PI must keep completed copies of all Human Subject Conflict of Interest forms for their records.

3. The PI must submit with this application Human Subject Conflict of Interest forms for those individuals who have identified a real, perceived, or potential conflict of interest on their form.

☐ No conflicts are identified.

☐ Yes, conflicts are identified and Human Subject Conflict of Interest forms are attached for the following individuals:

X. INVESTIGATOR AGREEMENT AND RESPONSIBILITIES

A. Conduct of the Research

1. I accept responsibility for the ethical conduct of this research and protection of participants as set forth in the Belmont Report, Declaration of Helsinki, the Nuremberg Code, the Common Rule, and the ethical principles of my discipline.

2. I accept responsibility for ensuring this research is conducted according to:

   a) sound research design and methods;

   b) the parameters of the research plan and activities described in these application materials;

   c) the applicable terms of the grant, contract and/or signed funding agreements; and

   d) applicable laws and regulations, including those for protecting the rights, safety, and welfare of human subjects.

3. I certify that I am or my faculty advisor is sufficiently qualified by education, training, and/or experience to assume responsibility for the proper conduct of this research. I accept responsibility for ensuring that members of this research team, including study staff and trainees, are appropriately qualified, trained and supervised.

4. I accept responsibility to personally conduct and/or directly supervise this research. I certify that I have sufficient time and resources to properly conduct and/or supervise this research.

B. Ensuring and Maintaining Compliance

1. I will comply with relevant regulatory and institutional requirements, including those relating to conflicts of interest, responsible conduct of research and research misconduct.

2. I understand it is my responsibility to ensure that any research personnel, including myself, responsible for the design, conduct, and reporting of research declare any potential conflicts of interests related to the research and to maintain current records. I will ensure changes in conflicts of interest are promptly disclosed to the IRB.

3. I will ensure that informed consent is obtained as approved by the IRB and a copy is provided to participants, unless the IRB waives these requirements.

4. I will obtain initial IRB approval prior to implementing human subject research activities as well as prior approval for any amendments to this research.

5. I will conduct this research within the approval period issued by the IRB. I agree to submit a request for continuing review of this research at least 45 days in advance of the expiration date.

6. I will submit a closure report form prior to protocol expiration or within 45 days of completion of all activities involving human subjects or identifiable participant data.

7. I will maintain approval, as applicable, will collaborative entities including approvals from other countries or jurisdictions.

8. I will promptly report to the IRB (no later than seven days of discovery) any instances of noncompliance with the approved protocol or requirements of the IRB and any unanticipated problems.

9. I will assist in the facilitation of any monitoring and/or auditing of study activities and/or records as required by the IRB, funding entities, sponsors, and any federal and state regulatory agencies.

C. Investigator Records, Reports and Documentation

1. I will maintain research records, all protocol materials, and any other documents associated with this research (e.g., research plan, signed consent forms, and IRB correspondence).

2. I will maintain records for at least three years after this research ends, or for the length of time specified in applicable regulations or institutional or sponsor requirements, whichever is longer. I will take measures to prevent accidental or premature destruction of these documents.

3. I will ensure the safe and secure storage of this research data (whether in paper or electronic formats) and for protecting the confidentiality of the data in accordance with the approved protocol.

4. I will submit written reports to the IRB and permit inspection of the research records as required by the IRB.

IRB Protocol No. _____

To be assigned by IRB Administrator

XI. Investigator Assurance of Agreements and Responsibilities

Original signatures must be submitted to the IRB office CS East #236

By signing below, I attest to having read and agree to uphold the responsibilities and duties outlined above. In addition, I certify that the information provided in this application is accurate and complete. I understand that research involving human participants, including the recruitment, may not begin until full Approval has been granted by the IRB.

Principal Investigator

_____ _____

PI Signature *Date*

_____

PI Print Name

Co-Investigators

_____ _____

Co-Investigator Signature *Date*

_____

Co-Investigator Print Name

_____ _____

Co-Investigator Signature *Date*

_____

Co-Investigator Print Name

_____ _____

Co-Investigator Signature *Date*

_____

Co-Investigator Print Name

Attach additional Investigator Signature Pages as needed