EXEMPT DETERMINATION APPLICATION

IRB Review Request for Projects Using Human Subjects

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

Purpose: Some categories of minimal risk research qualify for exemption from the federal regulations and do not require additional oversight by the IRB; however, these studies do require review by SOU's IRB to determine their eligibility for exemption. An exempt determination from SOU's IRB is required in order to conduct exempt human subject research at Southern Oregon University. Use this form to request an exempt determination from the IRB.

Instructions:

Initial requests: Complete this form after you have reviewed the "Exempt Categories" flow chart and have determined your study may qualify for exemption under one of the exemption categories. If you determine your study qualifies for exemption, complete this application and submit the items noted in the Submission Checklist at the end of the form.

Amendment requests: To amend research previously determined exempt, complete this form only after you have reviewed the "Exempt Categories" flow chart and have determined your study may still qualify for exemption. Provide responses according to the amended research plans. If your study is no longer eligible for exemption, stop and prepare a Non-Exempt Research Application.

SOU's IRB will review and verify the exempt determination. If the IRB determines the study does not qualify for exemption, you will need to prepare and submit a protocol using the Non-Exempt Research Application.

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

1. Exemption Verification Request (select one of the following):

☐ **INITIAL REVIEW REQUEST** *(proceed to question 2)*

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

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

☐ **AMEDMENT REVIEW REQUEST**

Describe the changes:

Provide a rational for the changes:

Is the project end date changing?

☐ Yes ☐ No Revised End Date (month and Year):

For amendment requests, provide responses in the remainder of this form according to the amended research plans.

2. Institutional Review Board Review Request Form: All research personnel, including the Principal Investigator, Faculty Advisors, Co-Investigators, and Research Assistants, must be listed on the IRB Review Request Form.

☐ Institutional Review Board Review Request Form is attached.

3. Funding Source:

☐ Yes
☐ No

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

If "yes", list the funding agency:

List the PI(s) of the funded grant:

II. SCREENING

Complete this section to identify study characteristics that do not qualify for exemption.

1. Below are specific characteristics that disqualify a research study from exemption with the exception of item v. Answer the following: Note If you answer "Yes" to any of the following with the exception of item v., stop filling out this form and fill out the Non-Exempt Research Application.

☐ Yes ☐ No	**i.** Does this research involve the use of any drug, substances, or biologics?
☐ Yes ☐ No	**ii**. Does this research involve the use of an investigational 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 genetic information and/or tests?
☐ Yes ☐ No	**v.** Does this research propose to study prisoners as a targeted population? ☐ Yes ☐ No Is this original research, i.e. not secondary? ☐ Yes ☐ No Is this research being conducted on behalf of a federal agency? *If yes, list federal agency(ies) and continue to question 2 below.*

2. In some circumstances, studies that otherwise qualify for exemption must undergo expedited or full board review by the IRB. These are typically due to additional, study specific circumstances. Answer the following to determine if your study is otherwise ineligible for exemption: Note if you answer "Yes" to any of the following, stop filling out this form and fill out the Non-Exempt Research Application.

☐ Yes ☐ No	**i.** Is there a state, federal, or other applicable law (e.g. tribal or other international law) that prohibits an exemption determination?
☐ Yes ☐ No	**ii.** Does the agency funding your research or an agency with whom you are working prohibit an exemption determination and require that you have IRB approval?
☐ Yes ☐ No	**iii.** Are there any other study specific requirements that prohibit exemption?

If you answered YES to any of the above questions with the exception of question 1, item v. above, STOP filling out this form and fill out the Non-Exempt Research Application.

III. EXEMPT CATEGORY(IES) 45 CFR 46.104(d)

Based on your review of the "Exempt Categories" flow chart, select one or more of the categories below that appear to be applicable to your research. Then complete the Exempt Category Worksheet(s) as directed.

☐ **Category #1: Education Research Conducted in Educational Settings**

Fill out Category 1 Worksheet - Education Research Conducted in Educational Settings

☐ **Category #2: Interactions Involving Educational Tests, Surveys, Interviews, or Observations**

Fill out Category 2 Worksheet - Interactions Involving Educational Tests, Surveys, Interviews, or Observations

☐ **Category #3: Research Involving Benign Behavior Interventions**

Fill out Category 3 Worksheet - Research Involving Benign Behavior Interventions

☐ **Category #4: Secondary Research - data originally collected for a <u>different</u> primary purpose**

Fill out Category 4 Worksheet - Secondary Research - data originally collected for a different primary purpose

☐ **Category #5: Research and Demonstration Projects that are Conducted or Supported by a Federal Department or Agency**

Fill out Category 5 Worksheet - Research and Demonstration Projects that are Conducted or Supported by a Federal Department or Agency

☐ **Category #6: Taste and Food Quality Evaluation and Consumer Acceptance Studies**

Fill out Category 6 Worksheet - Taste and Food Quality Evaluation

☐ **Category #7: Storage and Maintenance for Secondary Research**

Fill out Category 7 Worksheet - Storage and Maintenance for Secondary Research

☐ **Category #8: Research Involving the Use of Identifiable Private Information or Identifiable Biospecimens for Secondary Research**

Fill out Category 8 Worksheet - Research Involving the Use of Identifiable Private Information or Identifiable Biospecimens for Secondary Research

If your research does not fit any of the above categories,
stop filling out this form and fill out <u>Non-Exempt Research Application</u>.

IV. Project Details

1. State the purpose of this research and your research question(s):

2. Provide an overview of your design and methods.

IV. Continued - Project Details

3. Will your research only involve the analysis of existing data?

☐ Yes

☐ No (proceed to question 4)

a) Briefly describe the type(s) of existing data that will be analyzed (i.e. documents/records, specimens, survey or clinical data).

If specific forms or survey data will be analyzed, please submit a copy of the survey instrument or forms with this application.

b) Where is the data currently held, or who is the custodian of the data?

c) Were the data collected under an IRB-reviewed/approved protocol? ☐ Yes ☐ No

If yes, please submit a copy of the IRB approval or determination of exempt status with this application.

d) How many records will be included in the analysis, or what is the sample size of the data set?

4. Describe your research population (e.g., children ages 9-12 from Walker Elementary School, adult hysterectomy patients at Rogue Valley Medical Center, etc.) and include any inclusion/exclusion criteria for participants with justification (e.g. gender exclusion, or ethnicity exclusion, minor inclusion, etc.):

IV. Continued - Project Details

5. Number of anticipated participants by gender. **Male:** **Female:** **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).

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. Select the methods to be used during data collection. (Attach a copy of survey items or instruments used during the data collection process - See Checklist)

Survey

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

Interview

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

Other

- ☐ Public Observation
- ☐ Ethnography
- ☐ 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

IV. Continued - Project Details

8. Select one of the options for the type of data that will be collected and describe how your 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.*

9. Explain how anonymity, privacy and/or confidentiality will be maintained. If you are only using existing data, explain how the pre-existing records will be safeguarded.

10. 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 3 years.*

11. Describe how you will dispose of the data.

12. 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.

V. 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)

VI. Study Site Location

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 any required approvals (attach documentation of permission).

VI. Continued - Study Site Location

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

☐ Yes ☐ No *(proceed to section VII. Vulnerable Populations)*

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.

VII. Vulnerable Populations

1. Are any participants from population considered vulnerable, special, or not legally competent to give consent? (Check all that apply). ☐ Yes ☐ No *(proceed to question 3)*

- ☐ Pregnant women, fetuses, or neonates
- ☐ Prisoners
- ☐ Children
- ☐ Other (describe below)
- ☐ Veterans
- ☐ Cognitively Impaired Persons
- ☐ Minorities
- ☐ Economically or Educationally Disadvantaged Persons

2. If any of the above are checked, describe how consent without coercion will be obtained. Please note: a parent or guardian must sign and return a parental permission form for participants who are under the age of 18 prior to obtaining assent from minors. In addition, you must obtain assent from minors if they are old enough to read and write.

VII. Continued - Vulnerable Populations

3. Is this study by design likely to involve any participants who are not fluent in English?

☐ Yes ☐ No

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. Give an explanation of your procedures in this section 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.

VIII. Investigator and Faculty Advisor Agreements 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. Investigator's Assurances

This investigation involves the use of human participants. I understand SOU's policy concerning research involving human participants, and I agree:

1. To obtain voluntary and informed consent, or permission and assent, of persons who will participate in this study, as required by the IRB.

2. To report to the IRB any adverse effects on participants which become apparent during the course of, or as a result of, the activities of the investigation.

3. To cooperate with members of the IRB charged with review of this project, and to give progress reports as required by the IRB.

4. To adhere to the protocol as written and approved by the IRB.

5. To obtain prior approval from the IRB before amending or altering the project or before implementing changes in the approved consent form (i.e., changes that would alter what is required of the participant).

6. To not collect any data until Exemption or full Approval by the IRB has been acknowledged.

7. To maintain documentation of IRB approval, consent forms and/or procedures together with the data for at least three years after the project has been completed or paper has been published—whichever is later.

8. To treat participants in the humane manner specified on this form.

IRB Protocol No. _____

To be assigned by IRB Administrator

VIII. Investigator and Faculty Advisor Agreements and Responsibilities

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

By signing below, 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 acknowledgement of Exemption, or full Approval has been granted by the IRB, and that the project will be conducted in accordance with the above stated assurances.

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