INSTITUTIONAL REVIEW BOARD
SOUTHERN OREGON UNIVERSITY

Request for Wavier or Alteration of the Informed Consent Process

This form must be included with all project applications when requesting a waiver or alteration of the informed consent process. This form cannot be used in research involving an FDA-regulated product or in research involving prisoners.

I. PROJECT IDENTIFICATION	
Title of Project:	
Principal Investigator:	

II. TYPE OF REQUEST	
☐	Waiver of informed consent requirement for recruitment purposes only. Informed consent will be sought from participants prior to enrollment
☐	Waiver of requirement to obtain informed consent
☐	Waiver or Alteration of one or more specific elements of the informed consent process

III. CRITERIA TO BE ELIGIBLE TO SUBMIT A WAIVER OR ALTERATION REQUEST

The principal investigator must check that the proposed research meets one of the following criteria in order to be eligible to submit a waiver or alteration request.

☐ The research could not be practicably carried out without the waiver or alteration

and

The research is to be conducted by or subject to approval of state and local officials and is designed to study, evaluate, or otherwise examine procedures for obtaining benefits under public service programs; possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs.

☐ The research meets all of the following criteria for requesting a waiver or alteration of the informed consent process:

i. The research involves no more than minimal risk to the participants
ii. The waiver or alteration will not adversely affect the rights and welfare of the participants.
iii. The research could not practicably be carried out without the waiver or alteration.
iv. Whenever appropriate, the participants will be provided with additional pertinent information after participation.

IV. JUSTIFICATION FOR WAIVER OR ALTERATION

The principal investigator must provided a response for each of the items listed below if applicable.

Blank page provided if response requires additional space.

1. Describe why the research would not be possible without the waiver or alteration. If requesting an alteration in the informed consent process, describe how it will be altered.

2. If applicable, indicate the specific public benefit or service program, and the procedures or alternatives involved. Check if not applicable to your research. ☐

3. Explain why the research for which the waiver or alteration is requested will involve no more than tangible or intangible risk.

4. Explain why the waiver or alteration will not adversely affect the rights and welfare of the participants.

IV. CONTINUED - JUSTIFICATION FOR WAIVER OR ALTERATION

5. If the participants will be provided additional pertinent information after their participation, describe the additional information and how it will be provided.

V. INVESTIGATOR CERTIFICATION

By providing your signature below, you the principal investigator acknowledges the following:

1. This project involves no more than minimal risk to the participant. Minimal risk is defined as 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.

2. Even if the waiver or alteration is granted, the SOU IRB may require other conditions, such as providing subjects with an information sheet about the research.

3. Even though a waiver or alteration may be granted, I acknowledge that it is still my responsibility to ensure that the rights and welfare of the participants are protected in accordance with SOU and other federal requirements.

Signature _____ Date _____

VI. ADDITIONAL SPACE FOR RESPONSES OR COMMENTS

VII. REVIEW BY SOU IRB

This section is to be completed by the SOU IRB Chair based upon the actions taken during the expedited review process, or at a convened meeting of the SOU IRB.

This waiver request meets one of the criteria for approval:

☐	The research could not be practicably carried out without the waiver or alteration **and** The research is to be conducted by or subject to approval of state and local officials and is designed to study, evaluate, or otherwise examine procedures for obtaining benefits under public service programs; possible changes in or alterations to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs.
☐	The research meets all of the following criteria for requesting a waiver or alteration of the informed consent process: i. The research involves no more than minimal risk to the participants ii. The waiver or alteration will not adversely affect the rights and welfare of the participants. iii. The research could not practicably be carried out without the waiver or alteration. iv. Whenever appropriate, the participants will be provided with additional pertinent information after participation.

The action taken regarding this waiver request is indicated by the box checked below:

☐	The request for waiver of informed consent is approved for recruitment only.
☐	The request for waiver or alteration of the informed consent requirement is approved for the study as requested.
☐	The request for waiver of the informed consent requirement is approved only as indicated in the below remarks.
☐	The request for waiver or alteration of the informed consent requirement is not approved. The reasons for the disapproval are indicated in the remarks below.

Remarks:

_____ _____

Signature of SOU's IRB Chair Date