WESTERN OREGON UNIVERSITY

Institutional Review Board

Please note: To avoid frustration and the unintentional loss of saved information, the best and safest approach to completing this application is to 1) download the application; 2) save it to your desktop; 3) open it with Adobe Reader; 4) fill out the form; 5) as you fill out the form, **save it with a new name to your desktop**; 6) save one final time after you have entered all the information.

☐ Faculty/ Staff Application

☐ Student Application

A. GENERAL INFORMATION

Project/Study Title:	
Principal Investigator #1 Name:	
Email:	
Phone:	
Principal Investigator #2 Name:	
Email:	
Phone:	
Principal Investigator #3 Name:	
Email:	
Phone:	
Faculty Advisor Name (if a student research project)	
Faculty Advisor Email:	
Faculty Advisor Phone:	
5ÍØîãÍ2y	DTE, SPED, HEX, or Psychology for example
5epartYŜnt	Behavioral Sciences for example
t₪23₪I·Y	
Other (e.g. other university, community organization)	

Ethics and Compliance Training: All Principal Investigators and research team members, including Faculty Advisors involved in this project/study must receive training in the ethical use of human participants in

research. WOU supports this federal training requirement and has identified an online training program offered through the Collaborative Institutional Training Initiative at the University of Miami. The CITI Social and Behavioral courses are available to the WOU community free of charge.

The CITI training is available here: https://www.citiprogram.org/

All researchers/advisors listed on IRB applications must have a CITI completion certificate. For individuals who completed the NIH training before Fall 2014, they need to include the NIH certificate. Please note that all NIH certificates are good for three years from day of completion. Once NIH certificates expire, individuals will need to take the CITI training and submit a new CITI certificate of completion with the IRB.

B. IRB APPLICATION DIRECTIONS

a. Type your responses to each question. DO NOT leave a question blank. Throughout the application, if a question does not apply to your protocol, write "n/a".

b. Review your application for grammar, spelling, thoroughness, and comprehensive information. Applications with errors such as these will be returned.

c. If you have questions regarding the IRB application process, consult with the IRB representative from your College or Department before submitting your application.

d. Student applications must be signed by a Faculty member. The faculty member's signature indicates s/he has read and approved the application.

e. Please keep one copy of the original application. If you are a student, make sure that you and your faculty member each have a copy. Be sure this copy includes a copy of the signature page.

f. Submit your application to the IRB via email to irb@wou.edu. Be sure to include a copy of the signature page. If you have questions that are not answered on the website or in this application, you may contact the IRB by phone at: 503.838.9200.

C. ANTICIPATED LEVEL OF REVIEW

Investigator Prediction of Type of Review

See Level of Review Categories to determine your research – please select one level and category number.

☐ Exempt ☐ Provide category # (1-6)____

☐ Expedited ☐ Provide category # (1-7)____

☐ Full Board

D. PURPOSE & DESIGN.

Purpose

Enter text here.

Design

Enter text here.

E. DATA COLLECTION

Estimated Completion Date: _____(mm-dd-yyyy)

IRB Approvals are good for one full year from data of approval. Renewal applications are required if data collection is to continue after one year.

1. Check (x) the methods to be used

Survey, administered by:	**Interview**
☐ Investigator ☐ Participant Self-Report ☐ Mail ☐ Phone ☐ In Person ☐ Online	☐ One-on-One ☐ Focus Group ☐ Email or Online ☐ Oral History ☐ Other

NOTE: If you are using a survey or doing interviews, you must submit a copy of the survey items or interview questions.

Observation of Public Behavior	**Examination of Archived Data or Records**
☐ In classroom ☐ At public meetings ☐ Other	☐ Academic ☐ Medical ☐ Legal ☐ Other

Taste/Sensory Evaluation	
☐ Food Tasting ☐ Olfactory ☐ Auditory	☐ Visual ☐ Examination of Tissue ☐ Specimens ☐ Other

Therapeutic	**Experimental**
☐ Biomedical ☐ Psychological ☐ Physical Therapy	☐ Biomedical ☐ Psychological ☐ Other

Other: Please describe.

n/a or enter text here.

2. Data from Participants – Select one (x)

☐ Anonymous: You will not ask for participant's name.

☐ Confidential: You will ask for participants' names, but will keep the names confidential. Readers of your research will be unable to tell the identity of the participants and there will be no way to connect particular participants with particular data.

☐ Intentionally Identified

If participants will be identified, **describe** how permission to use data in connection with participants' identities is obtained.

n/a or enter text here.

If anonymous or confidential, describe how anonymity or confidentiality will be maintained (e.g., coded to a master list and separated from data, locked cabinet, office, restricted computer, etc.) and **please indicate** who will have access to the data.

n/a or enter text here.

3. Will any of the following be recorded? Check to indicate Yes.

☐ Video recording ☐ Audio recording ☐ Photographs

If you answered YES for any of the above, where will recordings or photographs be stored? When will this material be destroyed (e.g. within 5 years of a published paper)? How will confidentiality be maintained (e.g. coded to a master list and separated from data, locked cabinet, office, restricted computer, etc.). Indicate who will have access to the data.

n/a or enter text here.

F. DESCRIPTION OF PARTICIPANTS

1. Approximate number: _____ Age Range (e.g. 18 to 24): _____

2. How will participants be selected? Please describe in the box below.

n/a or enter text here.

3. Will participants be compensated? (Include extra credit.) ☐ YES ☐ NO

If yes, how much, when, and how? Must they complete the project to be paid? Please describe below.

n/a or enter text here.

4. What form of consent will be obtained? In most situations a written informed consent is required.

☐ Implied (attach cover letter or describe terms)

☐ Verbal (attach consent script)

☐ Written – adult participant(s) (attach consent form)

☐ Written – minor participant(s) (attach consent form)

☐ Seeking Waiver of Consent (Contact the IRB for further information)

☐ Consent not applicable (e.g. archival data)

Explain why consent is not applicable or necessary in the box below:

5. Are any participants not legally able to give consent (e.g. those who are minors and/or under the care of a guardian)? ☐ YES ☐ NO

If yes, please describe how consent will be obtained. *Please note:* a parent or guardian **must sign** and return an informed consent form for participants who are under 18 years of age or if over 18 and under the guardianship of an adult or agency. In addition, it is recommended that you also obtain assent from minors if they able to read and write .

If yes, please describe how consent will be obtained. Please note: a parent or

6. Will any ethnic group or gender be excluded from the study pool? ☐ YES ☐ NO

If yes, justify the exclusion.

n/a or enter text here.

7. Is this study by design likely to involve any participants who are not fluent in English? ☐ YES ☐ NO

If yes, submit both the English and the translated version of consent forms and surveys, if applicable. 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 Student Assent forms, these documents must be provided in the primary language of the participant(s). Qualified translators should be used and translated documents should be included with this application. You should give a full explanation of your procedures in this section.

n/a or enter text here.

8. Does this study involve participants located outside of the United States? ☐ YES ☐ NO

If yes, explain exactly "who the participants are," and the identities (if possible) and responsibilities of any additional investigators.

n/a or enter text here.

G. Deception

If the research protocol is designed to withhold complete information when consent is obtained, then some level of deception is involved. If deception is required for the validity of the research, explain why this is necessary. Include a description of when and how participants will be debriefed regarding the deception. If a participant objects to the deception and does not want his/her data included in the study, explain what you will do.

n/a or enter text here.

H. Risks and Benefits

1. Describe any potential risks to the participants, and describe how you will minimize these risks. These include stress, discomfort, social risks (e.g. embarrassment), legal risks, invasion of privacy, and side effects.

n/a or enter text here.

2. In the event that any of these potential risks occur, how will they be handled (e.g. compensation, counseling, etc.)?

n/a or enter text here

3. Will this study interfere with participants' normal routines (e.g. prevent them from going to class and/or work)? ☐ YES ☐ NO

If yes, the participant needs to agree that the researcher is not liable for the disruptions.

4. Describe the expected benefits to the individual participants and to members of society.

n/a or enter text here.

5. If blood or other biological specimens will be taken, please address the following:

a. Brief description of sampled tissue
b. Describe the personnel involved and procedure(s) for obtaining the specimen(s). Note that the IRB requires that only trained, certified, or licensed persons may draw blood. Contact the IRB for more details on this topic.

n/a or enter text here.

I. Drugs and Alcohol

1. Will any investigational new drug (IND) be used? ☐ YES ☐ NO

2. Will any other drugs be used? ☐ YES ☐ NO

3. Will alcohol be ingested by the participants? ☐ YES ☐ NO

J. Research/Project Funding

1. Is there, or will there be, extramural funding that directly supports the research? ☐ YES ☐ NO

If yes, list the funding agency: _____

List the PI(s) of the funded grant: _____

K. Investigator's Assurances

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

1. To obtain voluntary and informed assent/consent 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 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).
5. To not collect any data until full approval by the IRB has been acknowledged.
6. 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.
7. To treat participants in the humane manner specified on this form.

PRINCIPAL INVESTIGATORS

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 of participants, may not begin until full approval has been granted by the IRB, and that the project will be conducted in accordance with the above assurances.

_____	_____	_____
Signature	Print Name	Date
_____	_____	_____
Signature	Print Name	Date
_____	_____	_____
Signature	Print Name	Date

Faculty Sponsor (if PI is a student)

The information provided in this form is accurate and the project will be conducted in accordance with the above assurances.

_____	_____	_____
Signature	Print Name	Date
_____	_____	_____
Email Address	Phone	Date

##########

INSTITUTIONAL REVIEW BOARD: These assurances are acceptable and this project has adequate protections for participants. This project has been properly reviewed and filed, and is in compliance with federal, state, and university regulations.

_____	_____	_____
Signature	Print Name	Date

IRB ONLY: This protocol has been reviewed and approved as:

☐ Exempt ☐ Expedited ☐ Full Board