Institutional Review Board
Warner Pacific University
2219 SE 68th Avenue
Portland, Oregon 97215
503-517-1050

IRB Application for EXPEDITED /FULL REVIEW

This form is to be used by WPU faculty and students who plan on research involving Human Subjects. This form is to request Expedited or Full Review human subjects' research approval. If you believe the activities are Exempt, you may use the IRB Exemption Application. If you believe the activities do not meet the definition of "human subjects research" complete the Review Not Required Form. Submit electronically to irb@warnerpacific.edu. Response time is typically between 2-3 weeks.

SECTION 1: INVESTIGATOR'S ASSURANCE

☐ This is a new protocol submission
☐ This is a revised initial review protocol submission with requested modifications
☐ This is an amendment submission

Indicate which sections are revised: (Check each applicable section and include all protocol revisions in red.

- ☐ Section 1
- ☐ Section 2 (indicate which parts):
- ☐ Section 3 (indicate which parts):

Principal Investigator:
Department:
Address:
Email:
Phone Number:
Co-Principal Investigator/Other Personnel:
Position:
Address:
Phone Number:
Title of Protocol:
Is there funding?: ☐ Yes ☐ Not yet ☐ No

Notice: If this is a funded project, a copy of the research proposal must be submitted.

SECTION 2: INVESIGATOR S RFESPONSIBILITIES

Mark each box when understood / agreed / certified

I understand WPU's policies concerning research involving human subjects and:

1. ☐ I understand that I have ultimate responsibility for the protection of the rights and welfare of human participants, the conduct of this study, and the ethical performance of this research.
2. ☐ I will maintain the IRB related documents (including the signed consent forms, as applicable) for a minimum of three years after the completion of the study.
3. ☐ I understand that it is my responsibility to ensure that all study personnel receive the mandatory human subjects' research protection education (either CITI or NIH) and to maintain a training documentation file (training must be renewed every three years.

I agree to:

1. ☐ Comply with all WPU/IRB policies, decisions, conditions, and requirements.
2. ☐ Obtain prior approval from the IRB before amending or altering the research protocol or changing the approved consent/assent form.
3. ☐ Notify the Institutional Review Board of the development of any financial interest not already disclosed.
4. ☐ Notify the Institutional Review Board for all adverse events and unanticipated problems as soon as possible. In case of DHHS supported activities, I will also report these problems to the Department of Health and Human Services (through the respective granting office).

I certify that:

1. ☐ The time and resources are available to complete this project
2. ☐ The equipment, facilities, and procedures to be used in this research meet recognized standards for safety.
3. ☐ New information that may affect the risk-benefit assessment for this research will be reported to the Institutional Review Board.
4. ☐ I agree to ensure adequate supervision of all research study personnel and to meet with the investigators(s), if different than myself, on a regular basis to monitor progress.
5. ☐ The information provided in this application and all attachments is complete and correct.

Signature of the Principal Investigator: **Date:**

SECTION 3: INSTRUCTIONS IRB APPLICATION FOR EXPEDITED/FULL REVIEW

Application Requirements:

1. The IRB application for Expedited/Full Review has three parts:
    A. Investigator's Assurance cover sheet (Section I)
    B. Project Narrative (Section IV)
    C. Appendices (Section V)

2. All questions must be answered. Please enter N/A for questions that do not apply.

3. Consent documents must be written in at least 12 pt. font.

4. Applications must be page numbered, including Appendices.

5. Submit complete applications and accompanying materials in separate documents by email, to **irb@warnerpacific.edu**.

6. The Investigators Assurance serves as the researcher's contact information page and signature of assurance. This form must be filled out completely and accompanied by proper signatures.

7. Information for student research only:
    A. Graduate/undergraduate students cannot function as Principal Investigators (PIs).

    B. Application must be signed and submitted by the advisor/PI (i.e., the faculty advisor must complete and sign the Investigator's Assurance as PI).

    C. The student must sign the "Students Only" box on the bottom portion of the Investigator Agreement and provide their WPU ID number.

    D. Graduate Studies requires PhD students to have committee approval of their dissertation prior to IRB submission (contact GSE for more details).

    E. Student investigators may not include themselves as a human participant in their research. Also, recruitment of human participants from their immediate family, friends and associates should be avoided.

Federal Definition of Human Subject (46.102(f)):

Human subject - a *living individual about whom* an investigator conducting research obtains:

(1) data through *intervention or interaction* with the individual OR
(2) *identifiable private information*.

SECTION 4: PROJECT NARRATIVE

Research Description:

In an attached document, explain the following.

1. Why: (i.e., describe specific study aims, research questions to be studied, study goals and a brief description of the scientific background.)

2. What & How: (i.e., describe what the researchers and the participants will be doing and how these activities will be accomplished.)

3. Who: (i.e., describe who the participants are and how they will be identified.)

4. When: (i.e., describe the order of research activities in a timeline.)

Study Design & Setting:

In an attached document, explain the following:

1. Describe the study design:

2. Identify the sites or locations where the research/data analysis will be conducted:

3. Describe the Principal Investigator's experience conducting research at study site(s) (or similar sites) and familiarity with populations and communities:

4. Is the research conducted outside the United States?

   ☐ Yes ☐ No

   If yes, describe site-specific regulations or customs affecting the research, local scientific and ethical review structure.

5. Are there any permissions that have been, or will be, obtained from cooperating institutions, community leaders, or individuals, including approval of an IRB or research ethics committee?

   ☐ Yes ☐ No

   If yes, provide a list of the permissions (also include copies with the application, if available).

6. Does the research require approval from other WPU compliance committees?
   (e.g., Radiation Safety Committee (RSC), Institutional Animal Care and Use Committee (IACUC), and Institutional Biosafety Committee (IBC), etc.)

   ☐ Yes ☐ No

   If yes, the PI is responsible for seeking approval from the other committees required for this research. Work cannot start until final approval is received from all appropriate committees. List each compliance committee review required.

7. Provide an approximate number of subjects to be enrolled <u>and</u> justify the sample size:
   (Provide information for each subject group, as defined in the sections 8A and 8B below. For example, minors' #, crime victims' #s, etc.)

8. Approximate total number of subjects to be recruited:
Please identify subjects that will be recruited by checking all that apply in 8A and 8B. Submit additional materials as required.

8A. Children or Adult: *Check all that apply*

Age	Consent/Permission /Assent Required
☐ Birth to 3 years	Parental Permission Form
☐ 4-7 years	Parental Permission Form and Verbal Child's Assent
☐ 8-17 years	Parental Permission Form and Child's Written Assent
☐ 18 & over	Written Consent

8B. Potentially Vulnerable Populations: *If potentially vulnerable populations will be recruited, identify these groups by checking below.*

☐ Neonates/Fetuses
☐ Children include in application.)
☐ Prisoners
☐ Decisionally impaired (for groups not already identified on this list)
☐ HIV/AIDS patients
☐ Native American Tribes
☐ Crime victims
☐ Substance abusers
☐Persons living outside the U.S.
☐ Non-English speaking
☐ Terminally ill
☐ Institutionalized individuals
☐ College Students
☐ Pregnant women

9. Are there groups of people purposefully being excluded? ☐ Yes ☐ No
If yes, identify the groups that are being excluded [Check all that apply and explain the reasons for exclusion below:

☐ Ethnic/racial groups	☐ Pregnant women	☐ Non-English speaking
☐ Adults 65 or older	☐ Males	☐ Sexual orientation
☐ Children (under 18)	☐ Females	☐ Marital status
☐ Religion	☐ Other	

Explain the reasons for the exclusion criteria identified above.

10. Describe safeguards to protect the rights and welfare of vulnerable populations.

Refer to the Institutional Review Board Handbook for further instructions regarding children, prisoners, and participants who become incarcerated after enrolling as well as instructions regarding human fetuses and neonates.

Data Collection Methods

Check all method(s) to be used (Include copies of all the data collection methods checked in Survey, Questionnaire or Interview sections below, including translations, if applicable.)

1. ☐ **Survey/Questionnaire – Identify modality(ies)**
   ☐ In person ☐ Web-based ☐ E-mail ☐ Postal mail ☐ Telephone ☐ Other:

2. ☐ **Interview – Identify modality(ies)**
   ☐ One-on-one ☐ Focus group ☐Oral history ☐ Other:

3. ☐ **Observation of Public Behavior – Identify modality(ies)**
   ☐ Classroom ☐ Public meetings ☐ Other:

4. ☐ **Examination of Archived Data/Secondary or Records**
   Briefly describe the records to be examined:

5. ☐ **Taste Evaluation**
   ☐ Wine/alcohol ☐ *Non-wholesome food ☐ Genetically altered food

6. ☐ **Examination of Human Pathological or Diagnostic Tissue Specimens (e.g.,bodily fluids)**

7. ☐ **Unproven or Untested Procedures**
   ☐ Biomedical ☐ Psychological ☐Other:
   If any checked, describe:

8. ☐ **Recordings – Identify type(s)**
   ☐Voice ☐Video ☐Photograph/Image

   Check Method of recording: ☐ Analog ☐ Digital
   Check the purpose of the recordings: ☐ For transcription ☐ Other
   If checked 'Other' explain: (For example, recorded for speech pattern analysis, archiving purposes, presentation at the meetings, etc.)

9. ☐ **Other:**
   A. ☐ Social Media:
   B. ☐ Internet:

Recruitment Methods
In an attached document, explain the following:

Does the study involve the recruitment of participants? ☐ Yes ☐ No
Describe recruitment/advertising methods:

Check all that apply and attach all recruitment materials that will be used:

☐ Person to person ☐ Media (TV, newspaper, radio, Web site)
☐ Phone ☐ Social Media
☐ Postal mail ☐ Other:
☐ E-mail

1. How will potential subjects be identified and how will potential subjects be approached to participate? (Explain in detail and answer for each subject group).

2. Who will obtain consent/assent and when will that be done? (Explain in detail and answer for each subject group).

3. What screening procedures or tools will be used? (Explain in detail and answer for each subject group).

Consent Process

*Choose all that apply and **attach appropriate forms** to this application*

☐ Adult(s) ☐ Children ☐ Parent(s) ☐ Guardian(s)/legally authorized representatives

☐ Written	*A consent, assent, or permission form that contains all of the required elements of informed consent.* ***If checked, submit with application.***
☐ Alteration of informed consent/assent process	*Requesting IRB approval for waiver of some or all of the element of informed consent, assent, or permission (i.e. medical record review, deception research, or collection of biological specimens).* ***If checked, submit with application.***
☐ Waiver Documentation of Informed consent/assent	*Requesting IRB approval for waiver of the requirement for documentation of informed consent, assent, or permission (i.e. telephone survey or mailed survey, internet research, or certain international research).* ***If checked, submit with application.***
☐ Waiver of Informed consent/assent	*Requesting IRB approval for waiver of the requirement for the informed consent, assent, or permission process (i.e. medical record review, deception research, or collection of biological specimens).* ***If checked, submit with application.***

What steps have been taken to prevent potential coercion or undue influence in recruiting subjects and obtaining consent or assent? (For example, if the project involves students of the PI or a product developer who will be testing the product, a neutral third party must be engaged in these processes.)
Explain in detail.

Study Procedures

In an attached document, explain the following:

1. Describe any study procedures that have not been described elsewhere:

2. Does the study involve the collection of data/specimens (including the use of existing data/specimens)? ☐ Yes ☐ No
   If yes, indicate how, when, where and from whom specimens or data will be obtained and what data or specimens will be collected.

3. Is there a data and safety monitoring plan (required for greater than minimal risk studies)?
   ☐ Yes ☐ No
   If yes, describe the plan.

4. Are there any anticipated circumstances under which participants will be withdrawn from the research without their consent? ☐ Yes ☐ No
   If yes, describe the circumstances, as well as any associated procedures to ensure orderly termination:

Risks/Benefits

In an attached document, explain the following:

1. Potential risks to participants **(check all that apply):**
   - ☐ Invasion of privacy to the subject or family
   - ☐ Breach of confidentiality
   - ☐ Physical harm or discomfort
   - ☐ Psychological/emotional discomfort or distress
   - ☐ Psychological effect that is more than discomfort or distress
   - ☐ Social stigmatization
   - ☐ Economic (e.g., employment, insurability)
   - ☐ Legal
   - ☐ Any study related activity which subjects might consider sensitive, offensive, threatening, or degrading?
   - ☐ Withholding standard care and procedures
   - ☐ Significant time or inconvenience
   - ☐ Other:

2. Does the study pose risk to individuals other than the participants?
   Explain in detail:

3. Indicate the risk category that most accurately describes the risk level for the risks identified in questions 1 & 2 above:
   - ☐ Not greater than minimal risk[1]
   - ☐ Greater than minimal risk, but presenting the prospect of direct benefit to individual subjects
   - ☐ Greater than minimal risk, no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition
   - ☐ Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of subjects

4. How will these potential risks be minimized in order to protect subjects' rights and welfare? **Explain in detail.**

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

6. Is it probable that a subject's previously unknown physical or psychological condition will be discovered (e.g. disease, depression, genetic predisposition, illegal activity etc.) as a result of the study activities? ☐ Yes ☐ No
   If yes, explain in detail what are the types of conditions that could be discovered and how will these situations be handled?

7. Describe, in detail, the expected benefits of this project *(NOTE: **compensation is not considered a benefit**)*:
   A. To the individual subjects:

   B. To society:

8. Explain how, in your assessment, benefits of this study outweigh the risks. (e.g. risk/benefit ratio):

Available Resources

In an attached document, explain the following:

1. Are there research staff members, in addition to the Principal Investigator/Student Investigator?
   - ☐ No ***(If no, skip to 3)***
   - ☐ If yes, please outline training plans to ensure that research staff members are adequately informed about the protocol and study-related duties.

2. If necessary to the research, describe the minimum qualifications for each research role (e.g., RN, social worker), their experience in conducting research, and their knowledge of study sites and culture(s).

3. Briefly describe how the research facilities and equipment at the research site(s) support the protocol's aims (e.g., private rooms available for interview, etc.).

4. Are there provisions for medical and/or psychological support resources (e.g., in the event of incidental findings, research-related stress)? ☐ Yes ☐ No ☐ N/A (not needed)
   If yes, describe the provisions and their availability:

Reportable Events

In an attached document, explain the following:

Outline plans for communicating reportable events (e.g. adverse events or unanticipated problems involving risks to participants or others, breach of confidentiality, child abuse, and suicidal ideation).

Research Related Injuries

1. Does this research involve greater than minimal risk to participants? ☐ Yes ☐ No
   If yes, are there provisions for medical care and compensation for research-related injuries? ☐Yes ☐ No

   If yes, outline these provisions (*Medical treatment should be available including first aid, emergency treatment and follow-up care as needed. If the research plan deviates from this policy, provide appropriate justification. Compensation for physical injuries that result from study participation is not generally required)*.

Participant Privacy

In an attached document, explain the following:

Describe provisions to protect participants' privacy (their desire to control access of others to themselves, e.g., the use of a private interview room) and to minimize any sense of intrusiveness that may be caused by study questions or procedures.

Data Confidentiality

In an attached document, explain the following:

1. Will the information obtained be recorded in such a manner that participants can be identified, either directly or through identifiers linked to the participants? ☐ Yes ☐ No

2. Will identifiable data (data including identifiers) be made public? ☐ Yes ☐ No

   If no, describe provisions to maintain confidentiality at each phase of the data in the research. If engaging in internet or social media research, provide copies of the sites privacy policy and include an explanation of how approval.

3. Will the information obtained be recorded in such a manner that participants can be identified, either directly or through identifiers linked to the participants? ☐ Yes ☐ No

4. Will identifiable data (data including identifiers) be made public? ☐ Yes ☐ No

   If yes**,** verify by checking "yes" that participants will be informed of what identifiable data will be public and this information is included in the consent/assent form/processes.
   ☐ **Yes**

   If no, describe provisions to maintain confidentiality at each phase of the data in the research. If engaging in internet or social media research, provide copies of the sites privacy policy and include an explanation of how approval is obtained for performing research activities that include these sites or explain why approval is not required:

5. Method(s) of protection and location of data storage (Check all that apply):
   ☐ Locked office ☐ Coded to a master list
   ☐ Locked cabinet ☐ Other:

   When coded to a masters list, check the appropriate description of how the master list will be kept separate from data:
   ☐ Restricted computer ☐ Encrypted Data
   ☐ Password protected ☐ Fire Wall system
   ☐ Locked in private office ☐ Other:

6. How long will research materials be stored, and when will they be destroyed, including voice/video/digital/images? (*WPU guidelines require the data to be kept for a minimum of three years after the completion of the research*).

7. Will the data be transmitted from one location to another? ☐ Yes ☐ No
   If yes:
   i. How long will data be transmitted and stored?
   ii. What are the plans for the data at the end of the storage period?

8. How will research team members and/or other collaborators have access to information about study participants?

Cost and Payments

In an attached document, explain the following:

1. Identify any costs that participants may incur during the study, including transportation costs, childcare, or other out-of-pocket expenses:

2. Will subjects be compensated for these costs? ☐ Yes ☐ No

3. Are there any OTHER payments compensations or reimbursements that participants may receive during the study that re not related to participant incurred costs? ☐ Yes ☐ No
   If yes, specify the amount, method and timing of disbursements:

4. Will compensation be extra credit? ☐ Yes ☐ NO
   If yes, students must be able to complete an alternative assignment for extra credit should they choose not to participate in the research. This assignment must be comparable, with respect to time and effort, as the participation in research. **Describe the alternative assignment.**

5. When will the participants be compensated?
   ☐ Before the study ☐ Installments during the study ☐ Withdrawal/complete the study

Multi-site Study Management

In an attached document, explain the following:

1. Does the study involve multiple sites? ☐ Yes ☐ No
   If yes, describe the plans for communication among sites regarding adverse events, interim results, protocol modifications, monitoring of data, etc.

Investigational Drug, Biologic, or Device

In an attached document, explain the following:

1. Does the study involve an investigational Drug, Biologic, or Device? ☐ Yes ☐ No

2. Identify and describe the drug/biologic/device (e.g., marketing status):

3. Is there an IND/IDE, classification of a device as significant vs. non-significant risk?
   ☐ Yes ☐ No

4. Describe its administration use:

5. Compare the research drug/biologic/device to the local standard of care”

6. Describe plans for receiving, storage, dispensing and return (to ensure that they will be used only for participants and only by authorized investigators):

7. If proven beneficial, describe anticipated availability and cost to participants post-study, and plans (if applicable) to make available:

HIPAA Privacy Protections

1. Are HIPPA privacy protections required? ☐ Yes ☐ No

   If unsure, refer to the HIPPA Application Supplemental Form for guidance or call ORI for assistance.

Please note: Protected Health Information obtained from a Covered Entity [e.g. a hospital or community health center] requires these protections. WPU is NOT a Covered Entity)

Human Data and Human Specimen Banking
(These are the repositories established by WPU investigators for the purpose of storing data and/or specimens for future research purposes. Data banking included electronic data files and databases.)

In an attached document, explain the following:

1. Does the study include Specimen Banking?
2. Does the study include Data Banking?
3. Identify what will be collected and stored and what information will be associated with specimens:
4. Describe where and how long the data/specimens will be stored and whether participants'' permission will be obtained to use the data/specimens in other future research projects:
5. Identify how and who may access data/specimens:
6. Will specimens and/or data be sent to OR from research collaborators outside of WPU?

Sharing Study Results

In an attached document, explain the following:

1. Is there a plan to share study results with individual participants? ☐ Yes ☐ No
   If yes, describe the plan:

2. Is there a plan to disseminate aggregate results to the community where the research is conducted? ☐ Yes ☐ No
   If yes, describe the plan:

Disclosure of Financial Interests

1. Does the PI, Co-PI, or any other person responsible for the design, conduct, or reporting of this research have an economic interest in, or act as an officer, or director of, any outside entity whose financial interest would reasonable appear to be affected by the results if the study?
   ☐ Yes ☐ No

   If yes, complete below:
   i. Name of the person with a potential financial conflict of interest (COI)

   ii. Explain the potential financial conflict of interest

   iii. Explain how the potential financial conflict of interest will be managed.

Regulatory Compliance
This section is for documenting compliance with other regulatory requirements

In an attached document, explain the following:

1. Are student records being used?
   If yes, describe how compliance will be maintained with the Family Educational rights and Privacy Act (FERPA):

2. Does this project have funding from any of the following federal agencies? (check all that apply):
   ☐ Department of Defense (DOD) ☐ Department of Navy
   ☐ Department of Education ☐ Environmental Protection Agency (EPA)
   ☐ Department of Energy ☐ Department of Defense (DOD)
   ☐ Department of Justice ☐ Department of Defense (DOD)

If any of the above are checked, describe the plans to comply with the regulations required by that agency: (See Regulatory Compliance required by Federal Funding Agencies for a list of these regulations).

SECTION 5: APPENDICES

1. **Informed Consent/Assent/Permission forms**
   (See Informed Consent or Waiver of Consent Checklist for guidance.)

2. **Training and Experience**
   All staff engaged in human subjects' interaction and intervention, or working with identifiable human data or private information about live human subjects activities are required to complete training. The submission packet must include documentation of training for all personnel listed in the protocol, including student investigators and PI's. It is the PI's responsibility to ensure that all other staff (not listed on the protocol) complete this training and keep documentation. The IRB may request documentation of training at any time as part of a post approval monitoring activities.

   IRB applications received without current training certificates are considered incomplete. The effective application receipt date will be when the complete application (including training) is received.

   Training is available online through the National Institute of Health: https://phrp.nihtraining.com. Submit completion documentation directly to the IRB at irb@warnerpacific.edu.

   In addition to the NIH training, please describe any specialized training, education, or experience that would help to minimize the risks, particularly if working with vulnerable populations and/or sensitive topics. If the researcher will be advised by an expert or on-site mentor, note this information in the application.

3. **Recruitment Materials (Posters, Flyers, Scripts)**

4. **Data Collection Instruments (Interviews, Surveys, Focus Group Questions)**

5. **Expedited Checklist (optional)**
   The IRB makes the final determination of whether a non-exempt project is eligible for review under expedited or full board review. If you believe that the research is non-exempt and eligible for expedited review, you may fill out the expedited checklist and attach to this application.

6. **Addendums as appropriate**

Note: Please submit completed applications by email to **irb@warnerpacific.edu.**

DATA COLLECTION CANNOT BEGIN UNTIL IRB APPROVAL IS GRANTED