



Institutional Review Board Application for Exempt Review

This form is to be used by WPU faculty, staff, researchers, and students who plan on research involving Human Subjects. This form is to request Exempt Review approval. Please complete this form and return via email to irb@warnerpacific.edu. Response time is typically between 2-3 weeks.

SECTION 1. PRINCIPLE INVESTIGATOR INFORMATION

Principle Investigator (PI)/ Faculty Advisor Name:

Department:

Position:

Address:

Email:

Phone Number:

CO-PI/Other Personnel:

Position:

Address:

Email:

Phone Number:

Title of Proposal:

Proposed Duration of Project (months/years):

Anticipated Start Date:

Is there funding? ☐ Yes ☐ Not yet ☐ No

Type of Funding: ☐ Federal ☐ Federal pass-through ☐ State ☐ Foundation ☐ Other

SECTION 2: HUMAN SUBJECTS RESEARCH DETERMINATION

*Federal regulations specify that certain types of research pose low risk to participants, and therefore **MAY** qualify for **EXEMPTION** under federal regulations. To determine if your study is exempt, answer the following screening questions. **Please include attachments where needed.***

1. ☐ **Yes** ☐ **No** Does the Project involve prisoners, or participants confined in a correctional facility?
2. ☐ **Yes** ☐ **No** Do survey or interview techniques involve minors as subjects?
3. ☐ **Yes** ☐ **No** Does the project include Food and Drug Administration (FDA) regulated research?
4. ☐ **Yes** ☐ **No** Will you be recording the subjects participation by videos or audio for reasons **other** than transcription?
5. ☐ **Yes** ☐ **No** Will blood or bodily fluids be drawn?
6. ☐ **Yes** ☐ **No** Will you be using pregnant women?
7. ☐ **Yes** ☐ **No** Are live fetuses subjects in the research?
8. ☐ **Yes** ☐ **No** Will alcohol/drugs be administered to or from participants?
9. ☐ **Yes** ☐ **No** Are personal records (medical, academic, etc.) used with identifiers **and** without written consent?
10. ☐ **Yes** ☐ **No** Are there any participants who may not be legally/mentally/cognitively competent?
11. ☐ **Yes** ☐ **No** Will participants be asked to report their own or others' sexual experiences, alcohol, or drug use, **and** will their identities be known to you?

IF you answer “**YES**” to **any** of the above questions, then your research is **NOT** exempt and you need to fill out the non-exempt application.

IF you answer “**NO**” to **all** of the above questions, your research **MAY** be exempt. Complete the remaining sections.

SECTION 3: EXEMPTION DETERMINATION

Your project may qualify for an exemption if the ONLY involvement of human subjects falls within these categories below. Check the appropriate categories that apply to your research project.

1. ☐ Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
 - i. research on regular and special educational instructional strategies, OR
 - ii. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. ☐ Research involving the use of educational tests (cognitive, diagnostic, aptitude, and/or the achievement), survey procedures, interview procedures or observations of public behavior unless:
 - i. information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; and
 - ii. any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability; or
 - iii. be damaging to the participants' financial standing, employability, or reputation.

PLEASE NOTE: According to 45 CFR 46.401(b), this exemption does NOT apply to survey or interview procedures when the participants are children.

3. ☐ Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under category (2) of this section, if:
 - i. the human participants are elected or appointed public officials or candidates for public office;
 - ii. federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. ☐ Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the participants. PLEASE NOTE: According to the Office for Human Research Protections (OHRP), "to qualify for this exemption the data, documents, records, or specimens must be in existence before the project begins. The principle behind this policy is that the rights of individuals should be respected; participants must consent to participation in research."
5. ☐ Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
 - i. public benefit or service programs;
 - ii. procedures for obtaining benefits or services under those programs;
 - iii. possible changes in or alternatives to those programs or procedures;
 - iv. possible changes in methods or levels of payment for benefits or services under those programs.
6. ☐ Taste and food quality evaluation and consumer acceptance studies:
 - i. if wholesome foods without additives are consumed or
 - ii. if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

SECTION 4: JUSTIFICATION OF EXEMPTION CATEGORY

Complete the explanation under the category selected in Section 3 above. If you need more room, please attach additional papers to this document.

Category 1: Specify whether 1(i) or 1(ii) applies and briefly explain.

Category 2: Assure that condition 2(i) will be met and briefly explain how; and assure that condition 2(ii) applies; and attach a copy of test/survey/interview questions or items.

Category 3: Explain why conditions 2(i) and 2(ii) cannot be met; and attach a copy of test/survey/interview questions or items; and either assure and briefly explain that condition 3(ii) applies, or explain subject's public office and how it precludes anonymity (i.e., 3(i)).

Category 4: Briefly explain the nature of the existing data/documents and briefly explain either their public availability or the procedures to ensure anonymity and confidentiality.

Category 5: Briefly explain method by which the project is reviewed and approved by a federal department/agency head; and identify and describe which of the 5(i) – 5(iv) categories apply.

Category 6: Assure that condition 6(i) will be met; and assure via documentation regarding approved safety levels that condition 6(ii) will be met.

SECTION 5: STUDY SPECIFIC QUESTIONS

Provide below brief details of the proposed research. Use lay language and avoid technical terms.

1. **Specific Aims/Research Question/Study Goals:**
2. **Participants (describe your inclusion criteria and methods of recruiting):**
3. **Procedures (describe your data collection methods, etc.):**
4. **Data confidentiality and security during collection, analysis, and storage:**
5. **Risks (describe any potential risks to participants-physical, psychological, social, legal, other):**
6. **Benefits (describe any benefits to the participants and society):**

SECTION 6: ATTACHMENTS

Please include the application and supporting materials (recruiting materials, survey questions, interview guide, etc.) in your submission to the WPU Institutional Review Board.

1. Consent forms / consent process descriptions
2. Recruiting materials
3. Surveys / interview questions

Completed applications must be submitted by email to irb@warnerpacific.edu

DATA COLLECTION CANNOT BEGIN UNTIL APPROVAL IS GRANTED BY IRB

SECTION 7: INVESTIGATOR'S RESPONSIBILITIES AND ASSURANCES

☐ I certify that the information provided in this application, and in all attachments, is complete and correct

WPU DETERMINATION OF EXEMPT REVIEW

Researchers do not complete this section. For IRB staff only.

☐ The activities, as described are **APPROVED**. You may now begin collecting data.

☐ The activities as described are **NOT APPROVED**. Revision and resubmission required. You **MAY NOT** begin collecting data.

IRB Chair:

Date: