Institutional Review Board
Review Determination Form

This form is to be used by WPU researchers and students who are uncertain about whether IRB review and approval is required for their proposed research and activities. Please complete this form and return via email to irb@warnerpacific.edu. Submit attachments where needed. Response time is typically between 2-3 weeks.

SECTION 1: CONTACT INFORMATION
Principal Investigator (PI)/Faculty Advisor Name:
Co-PI/Other Personnel:
Will this project be utilized by a graduate student for fulfillment of degree requirements? Student name: Student ID #:
Division/Department/Program:
Email Address(es):
Phone:
Project Title:

SECTION 2: DETERMINATION OF "RESEARCH"

Federal Definition of Research (45.102(d)):

Research – a *systematic investigation*, including research development, testing and evaluation, *designed to develop or contribute to generalizable knowledge*.

- If all response below are YES the activities meet the definition of "Research"
- If ANY checked NO, the activity may not meet the definition of "Research"

Note: The IRB makes the final determination as to whether the activities meet definition of Research based on the information provided on this form.

1. Do the proposed activities constitute an *investigation:* a searching inquiry for ascertaining facts, detailed or careful examination?
   ☐ **Yes** ☐ **No, please why not:**

2. Do the proposed activities involve a *systematic approach*? "Systematic" means having or involving a system, method, or plan.
   ☐ **Yes** ☐ **No, please why not:**

3. Are the proposed activities designed to *develop* or *contribute to knowledge*? (*Designed*: done with purpose and intent. *Develop*: to elaborate or expand in detail. *Contribute*: to be an important factor in; help to cause. *Knowledge*: truth, facts, information).
   ☐ **Yes** ☐ **No, please why not:**

4. Is the information obtained *generalizable (scholarly)*? This includes activities designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations beyond the specific study population), inform policy, or generalize feelings.
   ☐ **Yes** ☐ **No, please why not:**

SECTION 3: DETERMINATION OF HUMAN SUBJECT

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

Human subject - a *living individual about whom* an investigator (whether professional or student) conducting research obtains: (1) data through *intervention or interaction* with the individual or (2) *identifiable private information.*

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for the research purposes.

Interaction includes communication or interpersonal contact between researcher and subject.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record information). Private information must be individually identifiable. *Individually identifiable* includes where the identity of the subject is or may be ascertained by the researcher or associated with the information.

About (*whom*) includes questions about the living individual. These would not include questions about processes. For example, anonymous survey asking questions about how a training program is organized would not meet this definition.

Use the definitions to answer the following questions

1. Do the activities include obtaining information *about (whom) living individuals?*

   ☐ **Yes, the activities involve human subjects.**

   ☐ **No,** please attach a copy of the proposed questions that are considered to not meet the definition of "about whom" or describe why the research if not on living individual or does not meet the definition of "interaction" or "intervention":

2. Do the activities involve obtaining individually identifiable and *private* information about living individuals?

   ☐ **Yes, the activities involve human subjects.**

   ☐ **No,** please explain the type of information that will be obtained and the reasons why it is not considered individually identifiable private information.

3. Do the activities involve analysis of existing *data/specimens* (i.e., data/specimens have already been collected and are available for analysis, i.e. there will be no ongoing collection of specimens)?

☐ **Yes** ☐ **No**

3a. If "yes" to #3, will the *data/specimen be coded* such that a link exists that could allow the source of the data/specimens to be re-identified (i.e., key available to decipher the code)?

☐ **Yes** ☐ **No**

3b. If "yes" to #3a, then one of the following must be true in order to not meet the definition of human subjects:

☐ The provider pf the data/specimens will remove the code before sending the data/specimens to the researcher.

☐ The holder of the key and investigator enter into an agreement prohibiting the release of the key to the investigator under any circumstances, until the individuals are deceased. Provide copy of this agreement (informal email exchange is sufficient. Provide a copy in this document submission).

☐ The investigator has documentation of written policies and operating procedures from a repository or data management center that prohibits the release of the key to the investigators under any circumstances, until the individuals are deceased (provide this documentation).

☐ There are other legal requirements prohibiting the release of the key to the investigator, until the individuals are deceased. (Provide copy of these legal requirements).

4. Human subjects are defined by FDA regulations as "an individual who is or becomes a participant in research, either as a recipient of the test article or as a control."

Does the activity involve human subjects as defined by the FDA regulation? The activity involves human subjects if EITHER of the following is checked:

☐ An individual will be a recipient of any test article (i.e., drug, medical device) or as a control

☐ An individual on whose specimen a medical device will be used

SECTION 4: STUDY INFORMATION

1. Purpose, specific aims, and/or objectives:

2. Target population:

3. Procedures used to gather information (e.g. communication or interpersonal contact with individuals, manipulation of individuals, manipulation of individual's environments, or physical procedures). Indicate if these procedures would be conducted as part of standard care, regardless of research.

4. Description of data/samples gathered about individuals without using interaction or intervention including names of datasets, URLs, etc.
   a. What data will be collected, and describe how and by whom the data will be analyzed

   b. How were the data/samples originally gathered form individuals (e.g., obtained as part of another IRB approved protocol at this institution/ another institution or as part of routine clinical practice or Performance Improvement projects)?

      Can the collected information be directly or indirectly associated .linked with individual identities?

   c. Can others directly or indirectly associate/link the collected information with individual identities?

   d. List and attach with submission a copy of any applicable agreements (e.g., Data Use Agreement-DUA, an attestation from the data provider) that indicate that under no circumstances will you have access to the identities (or links to identities) of individuals form whom the data was collected.

5. NIH Genome-Wide Association Study (GWAS)
   Do you plan to submit data to the NIH Genome-Wide Association Study data repository (*Check with NIH)*.
   ☐ **Yes** ☐ **No**

If you checked "yes" above,

a. Discuss the risks to individuals, their families, and groups of populations associated with the data to be submitted.

b. Submit the following supporting documents:
   - A copy of any relevant data sharing plans, for examples, the data sharing plan that was part of your grant application
   - A copy of the informed consent of study participants form whom the data was obtained
   - Documentation of IRB approval of the data collection.

SECTION 5: PRINCIPAL INVESTIGATIOR/FACULTY ADVISOR

Principal Investigator's or Faculty advisor Signature:

Date:

WPU DETERMINATION OF HUMAN SUBJECTS RESEARCH

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

☐ The activities as described **DO NOT** constitute Human Subjects Research. IRB Application not required.

☐ The activities as described **DO** constitute Human Subjects Research. An IRB Application **IS REQUIRED.** Please see Page 8 for types of IRB application. If you are a student, please speak with faculty or advisor before moving ahead with this process.

IRB Chair: Date:

Please note that the Warner Pacific IRB is responsible for approving the research processes set forth in the application. However, the Warner Pacific IRB is not responsible for giving permission to collect data from WPU staff, faculty, and/or students. For questions of accessibility, please contact the appropriate Department/Division Chair or Dean, Vice President, or Executive Cabinet.

REVIEW CATEGORIES

Research involving human participants or data derived from human participants falls into one of three categories:

EXEMPT (requires one reviewer → an IRB co-chair)

- Approval for 4 years
- Reviews typically take 2 to 3 weeks (reviews may take longer if researchers do not respond rapidly to any concerns raised by the co-chair)
- Generally, research that does not propose to disrupt or manipulate participants' normal life experiences, or incorporate any form of intrusive procedures, may be classified as exempt.
- Please see Page 10 of Warner Pacific's *Procedures for Research Involving Human Participants*

EXPEDITED (requires two reviewers → an IRB member + an IRB co-chair)

- Approval for 1 year (continuation request required for longer duration)
- Reviews typically take 3 to 4 weeks (reviews may take longer if researchers do not respond rapidly to any concerns raised by the IRB member or co-chair)
- Research that is judged to involve no more than minimal risk to participants and includes appropriate informed consent procedures can be classified as expedited.
- Please see Page 11 of Warner Pacific's *Procedures for Research Involving Human Participants*

FULL BOARD (requires all IRB members to review and a meeting to be convened)

- Approval for 1 year (continuation request required for longer duration)
- Reviews typically take 4 to 6 weeks during the academic year and are not conducted during the summer
- Research that is judged to involve **more than minimal risk**, as defined earlier in this document, must be submitted for full-board review. Full-board review is necessary when researchers plan to use procedures that are personally intrusive and/or have the potential to produce stress or trauma beyond what is likely to be encountered by the participants in their everyday lives.
- Please see Page 15 of Warner Pacific's *Procedures for Research Involving Human Participants*