INSTITUTIONAL REVIEW BOARD
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Request for Determination of IRB Jurisdiction

This worksheet is intended to assist investigators in determining if their activity meets the regulatory definitions of human subject research and, therefore, requires IRB review. **Use this form only if you are uncertain as to whether your study requires IRB review or if your study involves humans (or data previously collected from humans) and you believe that IRB review is not required.** If you have any questions while completing this worksheet, please contact the IRB at 503-352-1478 or irb@pacificu.edu.

- Please read all information and follow the instructions as precisely as possible. All text in **red** is explanatory. Please delete it after filling out this template.
- Do not remove or change the heading. Leave the version date as it is. This corresponds to the date the template was last updated by the IRB.
- Do not change the margins of this template. All margins are set to 0.75 inches.
- Do not change the font (12 point, Times New Roman) used in this template.
- Do not remove any section or question from this template. If something does not apply, please state so.

Title of Proposed Activity

Enter information here.

Brief Description of Proposed Activity (250 words or less)

Enter description here. Remember to include as much relevant and detailed information as possible so that the IRB can make an accurate determination. Be sure to include:

- who will participate in the activity (briefly describe the characteristics of the population you will be recruiting and/or what organizations with which you will be working),
- what the activity will entail,
- where the activity will take place,
- when the activity will take place (be sure to include the anticipated month and year the activity will end),
- why you are pursuing this activity (as a capstone that will not be disseminated and/or applied outside of the local context, etc.),
- and how you will structure the activity (briefly describe the procedures you will use).

Section A: Is your activity considered research?

Research generally means a **systematic investigation** – including research development, testing, and evaluation – designed to develop or contribute to **generalizable knowledge** (45 CFR 46.102(d)).

Systematic Investigation: A predetermined method for answering a certain question or studying a specific topic. The term **systematic** implies that there is a clear methodology that is followed in the collection and analysis of data.

Generalizable Knowledge: Investigations designed to develop or contribute to generalizable knowledge are those designed to draw general conclusions (i.e., gather information that could be

applied to populations and/or locations outside of the specific study population and/or location), or to inform policy. If an investigator intends to conduct a study solely for the purpose of informing improvements to a local program, service, or practice, or for quality assurance purposes, the investigation **would not** be considered a contribution to generalizable knowledge. However, if the study is conducted with the intent of (a) the results being used to inform others' programs, services, or practices, (b) the results being used to draw general conclusions about a question or topic, (c) the results being used to inform policymakers, or (d) the study potentially being replicated by other investigators, then the investigation **would** be considered a contribution to generalizable knowledge.

One common indicator of a study that is intended to contribute to generalizable knowledge is if the results of that study are disseminated outside of the local context. Examples of dissemination include publication in a scholarly journal, presentation at a professional conference, or placement of a paper in a library. However, it is important to note that plans to publish or present an account of a study does not necessarily mean that the investigation fits the definition of generalizable knowledge; the **primary intent** and **design** of the investigation must be to create knowledge that may be applied by others outside of the local setting.

A **clinical investigation** also is considered to be research by the FDA (21 CFR 56.102(c)).

Clinical Investigation: An experiment involving human subjects that tests the safety or efficacy of any drug, biological product, or medical device for human use, or any human food additive, color additive, electronic product, or any other article subject to regulation by the FDA where the results are intended (or required) to be submitted to the FDA in support of a research or marketing permit or if they will be used to inform a future marketing permit application.

		YES	NO
1.	**Is your activity (a) a systematic investigation designed to develop or contribute to generalizable knowledge or (b) a clinical investigation?**	_____	_____

If you answered **YES**, your activity is considered research. **Continue to Section B below.**

If you answered **NO**, **explain your answer below and submit this form to the IRB. Do not continue to Section B.**

Explanation of NO answer (if applicable):
Enter explanation here. Remember to include as much relevant and detailed information as possible so that the IRB can make an accurate determination.

Section B: Does your research involve human subjects?

		YES	NO
1.	**Is the data being collected through interaction or intervention (see definitions below) with living individuals?**	_____	_____

Interaction includes any communication or interpersonal contact between the investigator and the subject (45 CFR 46.102(f)). Examples of interactions include **surveys**, **focus groups**, and **interviews**.

Intervention includes both physical procedures to gather data and manipulations

of the subject or the subject's environment that are performed for research purposes.

Furthermore, any experimental activity in which some or all subjects receive a **test article** is considered to be an intervention. A test article is any **drug** for human use, **biological product** for human use, **medical device** for human use, **human food additive**, **color additive**, **electronic product**, or any other article subject to regulation under the Food, Drugs and Cosmetics Act or under Sections 351 or 354-360F of the Public Health Service Act. (21 CFR 56.102(e)).

If you answered **YES**, your research is considered human subjects research. **Submit a complete proposal to the IRB (do not submit this form).**

If you answered **NO**, your research involves existing data and may be human subjects research. **Continue to Question 2 below.**

		YES	NO
2.	**Does the data contain individually identifiable information about living individuals?**		

In other words, the identity of the subject (a) is or may be readily determined by the investigator, or (b) is associated with the subject's information (45 CFR 46.102(f)).

Examples of individually identifiable information include (but are not limited to): names, birth dates, identification numbers (e.g., Social Security cards, driver's licenses, etc.), full-face photographs, street addresses, phone numbers, email addresses, etc.

		YES	NO
3.	**Is the information private?**		

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 (e.g., a medical record or an education record).

If you answered **YES** to **both** Question 2 and Question 3, your research is human subjects research. **Submit a complete proposal to the IRB (do not submit this form).**

If you answered **NO** to either Question 2 or Question 3, **explain your NO answer(s) below and submit this form to the IRB.**

Explanation of NO answer(s) (if applicable):
Enter explanation here. Remember to include as much relevant and detailed information as possible so that the IRB can make an accurate determination.

Section C: Principal Investigator Information

In completing and submitting this form, I certify that this activity is not currently underway and will not begin until either (a) a determination has been obtained from the IRB that this activity does not constitute human subjects research or (b) a research proposal for this activity has been approved by the IRB.

Name	
Program	
Email	
Telephone	
Fax	
Date	
Signature	