**Purpose**: This Worksheet is designed to help you determine and record whether your research project constitutes research involving human subjects pursuant to federal regulations. You may not conduct research involving human subjects without IRB approval.

**Instructions**: Complete this Worksheet to determine whether or not your research involves human subjects and therefore requires IRB review and approval. **All**  Human Subjects Research Worksheets must be submitted to [irb@pacific.edu](mailto:irb@pacific.edu).

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| **REQUIRED INFORMATION:** | | | |
| **Lead Researcher/ Principal Investigator:** |  | **PI Email:** |  |
| **Department or School:** |  | **Title (if any):** |  |
| **Faculty Advisor (required for Student Research):** |  | **Faculty Advisor Email:** |  |
| **Research/Activity Title:** |  | | |
| **Requesting IRB Formal Determination:** | **Yes**:  **No**: | | |
| **Briefly describe the project and what you expect to do with your findings:** |  | | |
| **Briefly explain the population involved or subject of the research:** |  | | |
| **Briefly explain the project’s data collection methods to be used and the location/site of data collection:** |  | | |

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| **1. Is the activity considered “Research” (as defined by 45 C.F.R 46.102(l))?** | |
| *Federal regulations regarding human subjects research apply only to activities that meet the definition of “research.” Questions in this Section 1 will help you determine whether or not your project meets the federal definition of “research.”* | |
| Check all that apply: | |
|  | **A. The activity is an *investigation*.**  *Investigation: A searching inquiry for facts, or detailed or careful examination, including research development, testing and evaluation.* |
|  | **B. The investigation is *systematic*.**  *Systematic: Having or involving a prospectively identified approach to the investigation, based on a system, methods, or plan.* |
|  | **C. The systematic investigation is designed to develop or contribute to *generalizable knowledge*.**  *Your project contributes to generalizable knowledge if you intend for findings from it to be applicable to a larger population, or otherwise intend to make the findings available for the development of knowledge beyond the individuals studied, or beyond a specific time and/or location, such as to other settings or circumstances.* |
| If you did not select boxes A, B, **and** C, your project is not considered “research” and you do not need to complete the rest of this form. Please keep a copy for your records, or submit to the IRB Administrator if you are requesting a formal determination that your project is not human subject research.  If you selected boxes A, B **and** C, your project is considered “research.” Proceed to Section 2 to determine if the research involves human subjects. | |
| **2. Does the research involve “human subjects” (as defined by 45 C.F.R. 46.102(e))?** | |
| *Federal regulations regarding human subjects research apply only to research activities involving “human subjects.” Questions in this Section 2 will help you determine whether or not your research involves individuals meeting the federal definition of “human subjects.”* | |
| Yes:  No: | **A. The research involves information or biospecimens from living individuals?**  *Information and biospecimens from living individuals includes the following:*   * *Ideas, attitudes, opinions, feelings, experiences, thoughts, beliefs, assessments, reflections, etc., reported by an individual, even when the individual provides the information while working in a professional capacity.* * *Data about living individuals that was gathered by another researcher or source.* * *Data about living individuals gathered through the use, analysis, or harvesting of cell lines, tissue, or the products of labor and delivery.* |
| If you answered “No” to Question 2.A you do not need to complete the rest of this Worksheet. Submit your Worksheet to the IRB Administrator for review.  If you answered “Yes,” continue to Questions 2.B. | |
| Yes:  No: | **B. Does the research involve *obtaining* information or biospecimens through *intervention* or *interaction* with individuals?**  *Intervention: Physical procedures, or manipulations of the individuals or the individual’s environment, that are performed for research purposes. Manipulations may be physical, social, psychological, or emotional.*  *Interaction: Communication or interpersonal contact between a member of the research team and the individual. Surveys, whether in-person, web-based, mail, email, phone, etc. – are an interaction between researchers and individuals.*  *Obtain: Record in any fashion (by writing, video, email, voice recording, etc.) for research purposes and retaining such information for any length of time.* |
| If you answered “No” to Question 2.A you do not need to complete the rest of this Worksheet. Submit your Worksheet to the IRB Administrator for review.  If you answered “Yes,” continue to Questions 2.C. | |
| Yes:  No: | **C. Will you collect or use information from subjects that is private information?**  *Publicly available information is not considered “private information.”*  *(Select NO if publicly available)*  *Private Information is defined as one or both of the following:*   1. *Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place.* 2. *Information which has been provided for specific purposes by an individual which the individual can reasonably expect will not be made public (for example, a medical record or a residual medical specimen that is “leftover” from a health care procedure.)* |
| Yes:  No: | **D. Could you, or any other researchers involved in this research, have any information which would allow you or the other researchers to readily identify an individual?**  *Information: records, specimens, x-rays, photos, recording and any other type of data.*  *Identifiable Private Information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.*  *Identifiable Biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimens.*  *Some specific circumstances in which the information would not be considered “identifiable”:*   * *The identifiers or the key to the identifier code have been destroyed.* * *The research team has entered into an agreement with the holder of the identifiers or code key that prohibits the release of the identifiers or code key to the team members.* * *Other legal requirements apply to prohibit the release of the identifiers or code key to the team members.* |
| If you answered “No” to Questions 2.C **and** 2.D your research does not appear to involve human subjects. However, if you plan to use existing information/biospecimens, you must submit the Existing Information/Biospecimen Research Application for IRB Approval prior to commencing any research activities.  If you answered “Yes” to ***either*** Question 2.C ***or*** 2.D, or both questions, your research involves human subjects. You must complete an IRB Research Application and submit the completed Application to the IRB for review and approval prior to commencing any research activities. | |

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| **What’s Next?** |
| * If your answers indicate that your project does involve human subjects research, you must complete an IRB Research Application and submit a completed Application to the IRB for review and approval prior to commencing any research activities with any required attachments. * If your answers indicate that your project is “research,” and required you to complete any question in Section 2, please submit a copy of this Worksheet to the IRB Administrator for review. * If your answers indicate that your project is not “research,” please keep a copy of this Worksheet for your records. * If you would like a formal determination letter from the IRB to document whether your project is, or is not, human subjects research, please ensure this form is complete and note your request on page 1 of the Worksheet. * If you are not sure if your project is research involving human subjects, or if you have any questions, please contact the IRB Administrator. |