**Purpose**: This Application is designed to help you apply for IRB approval for research involving human subjects and to ensure that the IRB receives the appropriate information to make a determination.

|  |
| --- |
| **Before you fill out this form:** |
| * Review the IRB Manual.
* Complete the CITI training. Training is required for all individuals involved in data collection and analysis on this protocol. Training is also required for student advisors.
 |
| **YOU MAY NOT CONDUCT RESEARCH ACTIVITIES INVOLVING HUMAN SUBJECTS WITHOUT IRB APPROVAL.** |

**Instructions**: Complete the application thoroughly. All pages must be completed. Incomplete submissions will be returned and will result in the delay of your study being reviewed. Explain your research as you would to a peer who is not an expert in your field, avoid jargon and acronyms. All information pertinent to your research must be included in the Application itself and your research must be understood without the supplemental attachments. Do not rely on information presented in attachments. Submit completed application and required attachments to irb@pacific.edu.

**Submission Checklist**: The last page of this Application includes a submission checklist. Please use the checklist to confirm all required documents are submitted with this Application.

**Signatures**: Obtain all signatures prior to submitting to the IRB Administrator. A Faculty Advisor signature is required if the student is the principal investigator.

If you have any questions, please contact the IRB Administrator at: vandeola@pacific.edu or 209.946.7716.

|  |
| --- |
| **FOR IRB OFFICE USE ONLY:** |
| **IRB Protocol Review Number:** |  | **Date Received:** |  |
| [ ]  Approved [ ]  Conditionally Approved (*See IRB Approval Letter*)[ ]  Disapproved (*Activity is considered Human Subjects Research and Requires IRB Approval*)[ ]  No Determination (*Activity is not research or does not involve human subjects. IRB Approval not required.*)[ ]  Exempt Review: Category \_\_\_\_\_ [ ]  Expedited Review: Category \_\_\_\_\_ [ ]  Full Review[ ]  Limited Review Required  |
| **IRB Co-Chair Approval:** |  | **Date Approval Letter Sent:** |  |
| **Approval Date:** |  |

|  |
| --- |
| **REQUIRED RESEARCHER CONTACT INFORMATION:** |
| **Lead Researcher/** **Principal Investigator (PI):** |  | **PI University Email:** |  |
| **College/School:** |  | **PI Telephone:** |  |
| **Department:** |  |
| **PI Status:** | [ ]  Student[ ]  Faculty[ ]  Administrator[ ]  Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | **Expected Graduation Date:** (*If Student*) |  |
| **Date CITI Training was Completed by PI:** |  | **Date CITI Training was Completed by Faculty Advisor:** |  |
| **Faculty Advisor (required for Student Research):** |  | **Faculty Advisor Email:** |  |
| **Faculty Advisor Department:** |  |
| **Research/Activity Title:** |  |
| **Expected Start Date of Research Activities:** |  | **Expected Duration** *(In year format, i.e. one year, two years. etc.):* |  |
| **Has this Research Been Reviewed by Another Institutional Review Board?** | [ ]  Yes [ ]  No(if yes, Stop completing this Application and contact the IRB Administrator to determine whether a Cooperative Agreement is possible.) |
| **Project Support** | [ ]  Funded [ ]  Unfunded | **If Funded, list source:** |  |
| **Any Conflict of Interest Between Funding Source and the PI?** | [ ]  Yes [ ]  No(Refer to the University’s Conflict of Interest Policy) | **If Yes, Describe:** |  |
| **List Names of Members of the Research Team/Additional Personnel** *(only list if personnel will have interaction with subjects or access to identifiable data. - attach separate sheet/document if needed)* | (Name, Department/School, CITI Training Completion Date, Role in Research Activities) |

|  |
| --- |
| **Assurances, Signatures and Certification / Researcher Responsibilities** |
| **LEAD RESEARCHER/PRINCIPAL INVESTIGATOR**In submitting this proposed research project and signing below, I certify that:1. I have read and understand the IRB Manual regarding research involving human subjects.
2. I will conduct the research involving human subjects as presented in this Application and approved by my faculty advisor (if applicable), and the IRB.
3. I will present any proposed modifications of the research activities to the IRB for approval prior to implementation.
4. All conflicts of interest, if any, between myself and any funding agencies have been resolved to the satisfaction of the University’s Office of Sponsored Programs.
5. All data/specimens were/are collected in an appropriate and ethical manner.
6. I will report to the IRB any problems that occur to subjects related to the research activities.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature of Lead Researcher**FACULTY ADVISOR (IF LEAD RESEARCHER/PI IS A STUDENT):**My signature below verifies that:1. I will provide continued supervision and guidance to the student during the course of this student’s research project, as appropriate.
2. I confirm that I am responsible for working with the student researcher to ensure that this research is performed in an ethical manner that complies with federal regulations and University policies regarding research involving human subjects.
3. I have reviewed and concur with this research application, including the purpose, design, methodology, procedures, subjects and the provided description of risks and benefits.
4. I will assist the student and the IRB as requested if any problems develop with the research.
5. If I will be unavailable (such as during a sabbatical leave or vacation), I will arrange for an alternate faculty advisor to assume responsibility during my absence.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature of Faculty AdvisorTyped Name:Email: |

|  |
| --- |
| **A.1. PURPOSE AND OBJECTIVES OF THE RESEARCH.** Please explain the purpose and objectives of the research. Attach additional pages as needed. |
|  |
| **A.2. CONTRIBUTION TO, OR DEVELOPMENT OF, GENERALIZABLE KNOWLEDGE.**Please explain how the research will contribute to, or help develop, generalizable knowledge. |
|  |

|  |
| --- |
| **B. DESCRIPTION OF SUBJECT POPULATION(S)** |
| B.1. Who are the subject groups and how will they be recruited? |  |
| B.2. What is the maximum number of subjects you will enroll? |  |
| B.3. Are you recruiting for subjects?  | [ ]  Yes (*If yes, include a copy of any recruitment materials (e.g., flyer, email, text, verbal recruitment script.*)[ ]  No |
| B.4. Indicate how the participants will be recruited (select all that apply): [ ]  Email [ ]  Online [ ]  Flyer [ ]  Telephone [ ]  In Person [ ]  Mail [ ]  Database or record review [ ]  Marketing Pool [ ]  Other: [ ]  N/A Existing Data/Specimen (*no contact with subjects*) |
| B.5. What are the criteria for selection and/or exclusion of subjects?  |  |
| B.6. Does this study include minors? | [ ]  Yes - *If Yes, state minimum and maximum ages:* [ ]  No |
| B.7. Does this study include adults? | [ ]  Yes - *If Yes, state minimum and maximum ages:* [ ]  No |
| B.8. Will all research be conducted in English? | [ ]  Yes [ ]  No – *If No, what language(s) will be used:*(*Note: All applicable research materials need to be submitted in the language being used with the participants (unless no written version exists), along with English translations/script. The name of the translator and a statement about the translator’s qualifications must be provided with this IRB Research Application*.) |
| B.9. Where will research activities involving subjects occur? (e*.g., Stockton campus, specific address, [City, Country], etc*.) |  |
| B.10. If any vulnerable populations are being used, please justify. (See page 68, XV. in IRB Manual for description of vulnerable populations.) |  |

|  |
| --- |
| **C. RESEARCH ACTIVITIES INVOLVING HUMAN SUBJECTS** |
| C.1. Describe the research activities involving each subject group described in Section B. Include the expected amount of time subjects will be involved in each activity. *Attach the methodology section of your grant proposal, dissertation or thesis if applicable*. |
|  |
| C.2. How will the information/biospecimen be collected from subjects? Check all that apply. [ ]  Questionnaires (attach a copy) [ ]  Interviews (attach a list of questions) [ ]  Observances (briefly describe below

|  |
| --- |
|  |

 [ ]  Standardized tests (list names of tests ***and*** attach copy of each test)

|  |
| --- |
|  |

 [ ]  Other: |

| **D. INFORMATION/BIOSPECIMENS** |
| --- |
| **D.1. How will the information/biospecimens be recorded (e.g., notes, tapes, computer files, completed questionnaires, tests, etc.)?** |
| D.1 | [insert answer here] |
| **D.2. Will medical records or other patient data be accessed? Refer to the IRB Manual (page 62, Section XIII) for more information on HIPAA regulations and a sample HIPAA authorization.** |
| Yes: [ ] No: [ ]  | *If Yes, complete the HIPAA Questionnaire and provide a copy of the HIPAA Authorization Form that will be used to obtain subjects’ authorization.* |
| **D.3. Who will have access to the gathered data/specimens, and how will confidentiality be maintained *during* the study, *after* the study, and *in reporting* the results?** |
| D.3 | [insert answer here] |
| **D.4. What are the plans for the information/biospecimens after the completion of this study (publication/presentation) and how and when will the information/biospecimens be maintained during the retention period (see page 77, Section XVII of the IRB Manual for more information). Describe method(s) of destroying the data, including any audio/visual recordings.** |
| D.4. | [insert answer here] |

| **E. BENEFITS, RISKS, and COSTS** |
| --- |
| **E.1. *Minimal risk*** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. See IRB Manual for more information on assessing the risk to subjects.**In the Principal Investigator’s opinion, this research presents:**[ ]  **No greater than minimal risk, or** [ ]  **Greater than minimal risk.** Please select all that apply and explain below:[ ]  **Physical**[ ]  **Psychological** (*emotional, behavioral, including anxiety, etc*.) [ ]  **Sociological** (*embarrassment, loss of respect of others, labeling a subject in a way that will have negative consequences*)[ ]  **Loss of Confidentiality** (*All research will have at least “minimal” risk of loss of confidentiality where research data is recorded. The risk is only not applicable when you send anonymous surveys in a non-public setting with non-sensitive subjects that cannot be identified with the subjects; or when using existing de-identified data/specimens*.)[ ]  **Criminal or Civil Liability**[ ]  **Deception**[ ]  **Economic**[ ]  **Other - Please explain**. |
| E.1.1 | [insert explanation here of each risk selected above.] |
| **E.2. What safeguards will you use to eliminate or minimize each of the risks described in E.1 above? If subjects experience adverse reactions, how will they be managed?** |
| E.2. | [insert answer here] |
| **E.3. If applicable, what are the costs to the subjects (monetary, time, etc.)?** |
| E.3. | [insert answer here] |
| **E.4. What are the potential benefits to the subjects?** |
| E.4. | [insert answer here] |
| **E.5. What compensation or reimbursement, if any, will be offered to subjects (e.g., time, travel, meals, expenses, general incentive to participate, etc.), how will payment be scheduled throughout the study and what is the method of payment (e.g., cash, check, gift certificate, gift item, academic/extra credit, drawing)?** |
| E.5. | [insert answer here] |

| **F. INFORMED CONSENT, ASSENT, and PERMISSIONS** |
| --- |
| *Copies of all informed consent materials must be submitted with this Application. In general, an informed consent procedure that includes all of the elements of informed consent and written documentation is required. The IRB may waive all or portions of these requirements as further explained in the IRB Manual Section XII. Justification for any waiver or alteration of requirements must be provided below.* |
| **F.1. Considering all participant groups, indicate the consent/assent process(es) involved in the research (select all that apply).**[ ]  In person[ ]  Remote (e.g., online, phone, Skype, etc.) [ ]  Other: |
| **F.2. Will the consent process include all of the elements of the informed consent procedure (including all required elements in the informed consent form and the required documentation)? See IRB Manual Section XII.E-F for a description of the informed consent form requirements and Section XII.H for a description of the documentation requirements.** |
| Yes: [ ] No: [ ]  | *If No, please explain below the justification to waive or alter the elements of informed consent which must be approved by the IRB (e.g., why oral consent should be approved, etc.).* |
| *Expl. of Waiver or Alteration* | [insert explanation here] |
| **F.3. Will the consent and/or assent process be documented by the use of a written consent form that will be signed by the subject or the subject’s legally authorized representative? See IRB Manual Section XII for a description of the documentation requirements.** |
| Yes: [ ] No: [ ]  | *If No, please explain below the justification to waive or alter the documentation requirements of informed consent which must be approved by the IRB.* |
| *Expl. of Waiver or Alteration* | [insert explanation here] |
| **F.4. If the research activities involve only the storage, maintenance, or secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or nonresearch purposes), will the broad consent procedure be used? See IRB Manual Section XII.G for a description of the “broad consent” requirements.** |
| Yes: [ ] No: [ ]  | *If No, please explain if informed consent will be obtained pursuant to the full informed consent requirements (See IRB Manual Section XII.E-F) or provide the justification to waive or alter the documentation requirements of informed consent which must be approved by the IRB. The “broad consent” requirements may not be altered or omitted.* |
| *Expl. of Waiver or Alteration* | [insert explanation here] |
| **F.5. Will the informed consent procedure include an oral presentation to the subject/legally authorized representative? See IRB Manual Section XII.J for a description of the “oral consent” requirements.** |
| Yes: [ ] No: [ ]  | *If Yes, a copy of the short form informed consent document and summary of the oral presentation must be approved by the IRB.* |

| **G. OTHER COMPLIANCE ISSUES** |
| --- |
| **G.1. If this project may be subject to other regulations, such as state or local laws protecting special populations, please identify and explain:** |
|  |
| **G.2. If this project involves any of the following activities, requiring consideration by another committee, please check:** (*It is the Principal Investigator’s responsibility to submit the research project for the approval of the other committee*.)[ ]  **Animal Use and Care**[ ]  **Radiation Safety** (including the use of x-rays, microwaves, etc.) [ ]  **Biological Safety** (including recombinant DNA, biohazards, etc.)[ ]  **Chemical Safety** (including hazardous waste materials, chemical carcinogens, flammable materials, lab safety, etc.) |

|  |
| --- |
| **Submission Checklist** |
| **Incl.** | **N/A** | **Items** |
|[ ]   | IRB Research Application, completed and signed by the PI and Faculty Advisor (if applicable) |
|[ ]   | CITI Completion Report for the Protection of Human Subject Research Training. Training is required of all personnel on the research team involved in data collection/analysis and is valid for 3 years. |
|[ ] [ ]  Research Investigator Financial Interest Disclosure Statement (regarding Conflicts of Interest) |
|[ ] [ ]  Recruitment Materials (Emails, letters, scripts, flyers, posters, brochures, etc.) |
|[ ]   | Informed Consent/Assent Materials |
|[ ] [ ]  Translator/Transcriber Qualifications |
|[ ]   | Data Collection Materials (Questionnaires, surveys, data collection forms, focus group/ interview scripts, etc.) |
|[ ] [ ]  For funded and/or sponsored research: the human subjects portion of the grant proposal. |