**Purpose**: This Application is designed to help you apply for IRB approval if your human subjects research project involves the use of existing information or biospecimens and is eligible for Exempt Review under Category 4 or Expedited Review Category 8 (Continuing Review) as further described in Section X (IRB Review Categories) of the IRB Manual. If your research activities do not fall under Exempt Category 4 or Expedited Category 8, you must complete the full IRB Research Application.

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| **EXEMPT REVIEW CATEGORY 4** |
| *Note: Information should be recorded in the research records in such a way that the information or biospecimens obtained from an individual cannot be linked to the identity of that individual. If the identity of the subject can be ascertained, directly or through an identifier linked to the subject for research purposes, even temporarily, the research does not qualify as Exempt under this Category 4, unless the information/biospecimens are publicly available, falls under the HIPAA exception, or falls under the government-generated/government-collected exception.*  *Research involving protected health information (under HIPAA) cannot be reviewed as Exempt because federal regulations require IRB review and approval of the research unless the information is used for “health care operations” or “research” or for “public health activities and purposes” all as defined under HIPAA..*  *If the identifiable information or biospecimens are publicly available, or if the information or biospecimens are not identifiable, submit the Existing Information/Biospecimen Research Application with the Exempt Review Status Form.* |
| **EXPEDITED REVIEW CATEGORY 8** |
| *Continuing Review of research previously approved by the IRB during the period (of one year or less) for which IRB approval is authorized:*  *1. Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or*  *2. Where no subjects have been enrolled and no additional risks have been identified; or*  *3. Where the remaining research activities are limited to data analysis.* |

**ONLY USE THIS FORM IF YOUR RESEARCH INVOLVES THE USE OF EXISTING INFORMATION OR BIOSPECIMENS FOR RESEARCH PURPOSES.**

**Instructions**: Complete Section A to determine whether or not your research activity involves human subjects and is eligible for Exempt Review (Category 4) or Expedited Review (Category 8). If your research involves human subjects and is eligible for Exempt or Expedited Review, complete the rest of this Application to provide adequate information to the IRB so that it may evaluate your proposed use of such data or specimen. Incomplete submissions will be returned and will result in the delay of your study being reviewed.

**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. Submit form to [irb@pacific.edu](mailto:irb@pacific.edu).

If you are not sure if you should use this form or the IRB Research Application, or if you have any questions, please contact the IRB Administrator at: [irb@pacific.edu](mailto:irb@pacific.edu) or at 209.946.7716.

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| **FOR IRB OFFICE USE ONLY:** | | | |
| **IRB Protocol Review Number:** |  | **Date Received Stamp:** |  |
| Approved – Exempt Category 4  Conditionally Approved (*See Notice of Determination*)  Approved - Expedited Category 8  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.*) | | | |
| **IRB Signature:** |  | **Date Approved:** |  |
| **Signature Date:** |  |

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| **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:** |  | **Other Thesis/ Dissertation Committee Members:** |  |
| **Research/Activity Title:** |  | | |
| **Expected Start Date of Research Activities:** |  | **Expected Duration:** |  |
| **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** *(attach separate sheet/document if needed)* | (Name, Department/School, CITI Training Completion Date, Role in Research Activities) | | |

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| **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 Advisor  Typed Name:  Email: |

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| **A. Does the research involve individually identifiable information of “human subjects” (as defined by 45 C.F.R. 46.102)?** | |
| *Federal regulations regarding human subjects research apply only to research activities involving “human subjects.” Use this form only if your research does not involve direct contact with human subjects for research purposes. Attach a copy of your completed Human Subjects Research Worksheet to this Application.*  *If your research was previously approved, go directly to Question A.3.* | |
| Yes:  No: | **A.1. Are the information/biospecimens you will study publicly available?**  *Publicly available information is not considered “private.”*  *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.)* |
| **If Yes, your project involves publicly available information/biospecimens and does not meet the definition of “human subjects research.” You do not need to submit this Application for IRB Approval.**  **If No, proceed to Question A.2.** | |
| Yes:  No: | **A.2. 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 Yes, this research is not eligible for Exempt Review under Category 4 and IRB approval is needed before commencing research activities. If you believe the research is eligible for Expedited Review under Category 8, please answer question A.3. If this research is not eligible for Exempt Category 4 or Expedited Category 8 Review, please STOP using this form and submit the IRB Research Application.**  **If No, this research is eligible for Exempt Review by the IRB under Category 4. Please complete the rest of this Existing Information/Biospecimen Research Application and submit to the IRB.** | |
| Yes:  No: | **A.3. Was this research previously approved by the IRB and are you seeking one of the following situations:**   1. **Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or** 2. **Where no subjects have been enrolled and no additional risks have been identified; or** 3. **Where the remaining research activities are limited to data analysis.** |
| **If Yes, this research is eligible for Expedited Review under Category 8. Please complete the rest of this Existing Information/Biospecimen Research Application and submit it to the IRB.**  **If you answered No to A.3 *and* this research is not eligible for Exempt Review under Category 4, please STOP using this form and submit the IRB Research Application, or contact the IRB Administrator.** | |

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| **B. How are the information/biospecimens identified when they are made available to the Lead Researcher/Research Team? (Select as appropriate.)** | |
|  | **Direct Identifiers** (including research subject name, address, social security number, entire medical record, etc.)  **Coded** (a key or code exists that can link individuals to the data/specimen)  **No Identifier** (The researcher is unable to individually identify a subject based upon information provided/collected with the data/specimens.) |

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| **C. How are informaton/biospecimens maintained by the Lead Researcher/Research Team? (Select as appropriate.)** | |
|  | **Direct Identifiers** (Subjects will be identifiable throughout the study and analysis but not in the reporting of results.)  **Coded** (The information will be recorded by the Lead Researcher in such a manner that subjects cannot be identified, directly, or through identifiers linked to the subjects other than by a code or key, which code or key may be accessed by researchers.)  **No Identifier** (The researcher is unable to individually identify a subject based upon information provided/collected with the data/specimens. If a code or key exists which links individuals to data/specimens, the researchers are restricted from obtaining this key.) |

| **D. General Questions Regarding Your Research.** | |
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| **RESEARCH PURPOSE** | |
| **D.1. Briefly describe the specific purpose and objective of the project.** *One paragraph is generally sufficient.* | |
| D.1 | [insert answer here] |
| **DESCRIPTION OF DATA/SPECIMEN** | |
| Yes:  No: | **D.2. Will any information/biospecimens be collected directly from subjects after submission of this Application?** ***If Yes, STOP completing this form, you need to submit the IRB Research Application.*** |
| Yes:  No: | **D.3. Are the data, documents, records and/or biospecimens pre-existing?** |
| Yes:  No: | **D.4. If pre-existing, were the information/biospecimens originally collected solely for research purposes?**  *Explain if collected for other purposes:* |
| **D.5. What are the types of information/biospecimens to be used in this study?** | |
| D.5 | [insert answer here] |
| **D.6. What is the source of the information/biospecimens? Who is providing you with the information/biospecimens?** *Include the name and location of the individual, entity, repository (e.g., tissue bank), or institution for each source. If from a University study, please specify the IRB Protocol Number and PI name.* | |
| D.6 | [insert answer here] |
| **D.7. Explain how identifiable private information will be recorded so that it is not identifiable?** (*Check the following as applicable*.) | |
| D.7 | The key to decipher the code (the identifying link between specimen/data and individuals) has been/will be destroyed.  You and your research team have entered into an agreement with the holder of the key to the code (i.e., source of specimens/data) prohibiting the release of the key to you and your research team under any circumstances.  There are other legal requirements prohibiting the release of the key to you and your research team. Identify the legal requirements:  Other (*Please explain*): |
| **D.8. Please list all demographic data variables, and any other variables that you will acquire: *If necessary, please use a separate sheet/document to provide this detail.*** | |
| D.8 | [insert answer here] |
| **D.9. Will you be accessing academic records? If so, please describe the records you will be accessing as well as the source of these records.** | |
| D.9 | [insert answer here] |
| **D.10. From what populations(s) are/will the information/biospecimens come from (e.g., healthy adults, patients with tuberculosis, children in [foreign country], etc.)** | |
| D.10 | [insert answer here] |
| **D.11. How many subjects are included in the information/biospecimens that you will receive (e.g., about a dozen, 100-200, more than a thousand)?** | |
| D.11 | [insert answer here] |
| Yes:  No:  N/A: | **D.12. Will the subjects who provide the coded information/specimen collaborate/be contacted on other activities related to the conduct of this research?** (*Examples of such activities include, but are not limited to: (1) the study, interpretation, or analysis of the data resulting from the coded information or specimens; and (2) authorship of presentations or manuscripts related to the research*.) |
| **RESEARCH PROCEDURES** | |
| **D.12. Provide a brief description of how you will use the information/biospecimens and attach a copy of the research protocol. Please limit your response to provide only a basic understanding of the procedures you will use.** *One paragraph is generally sufficient.* | |
| D.12 | [insert answer here] |
| **D.13. Describe the potential for harm, if any, that could result from this research. Include: the type of harm, the circumstances in which it could occur, the individuals or groups who could experience it, and the likelihood, magnitude and duration of harm.** (*Example: Harm may occur due to accidental disclosure or harm may result to individuals, or to the groups or communities to which they belong, even when data/specimens are anonymous*.) | |
| D.13 | [insert answer here] |
| **D.14. Describe the steps you have taken or will take to minimize any risk of harm to individuals or groups that could result from this research.** | |
| D.14 | [insert answer here] |

| **E. Complete this Section E if research involves genetic information/tests.** | |
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| **E.1. Indicate the genetic information collected and/or genetic tests conducted (select all that apply):** | |
| E.1 | **Genetic Tests**. The term genetic test includes an analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detects genotypes, mutations, or chromosomal changes in an individual or the individual’s blood relatives in order to diagnose or determine a genetic characteristic.  **Genetic Information**: The term genetic information means information about a genetic characteristic of an individual or an individual’s blood relative derived from a genetic test.  **Genetic Counseling**: including obtaining, interpreting, or assessing genetic information.  **Other** (*Please explain*): |
| **E.2. Will the genetic testing or information collected include any of the following (select all that apply):** | |
|  | Genetic Information that may be linked to a participant’s health status, such as genetic markers for cancer, heart disease, etc.  Information normally recorded in a participant’s medical record, the disclosure of which could reasonably lead to stigmatization or discrimination.  Information that, if released, could reasonably damage an individual’s financial standing, employability, or reputation within the community.  None of the above applies. |
| Yes:  No: | **E.3. Will the collection or testing of the genetic information take place outside of California or the United States?** If Yes, specify the location(s) where the collection and/or testing will occur: |
| Yes:  No: | **E.4. Does the research include “anonymous genetic research”?**  If Yes, please specify the repository in Question D.6 above.  *Please note that under current law, genetic research may only be considered “anonymous” if it meets all of the following requirements: (1) there is no possibility that the individuals providing the samples could be identified or located;* ***and*** *(2) the investigator may not hold a code to the samples that could allow a sample to be linked to the individual who provided it.* |
| Yes:  No: | **Does the research included “coded genetic research”?**  If Yes, please specify the repository in Question D.6 above.  *Please note that under current law, genetic research may only be considered “coded” if it meets all of the following requirements: (1) the code is not derived from individual identifiers; (2) the code key is kept securely and separately from the specimens and information;* ***and*** *(3) the code keep is not accessible to the PI (unless specifically approved by the IRB (please contact the IRB Administrator if this is the case).* |

| **F. Complete this Section F if research involves genetic information/tests.** | |
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| **F.1. Will the research be conducted by, or on behalf of a federal department/agency using government-generated or government-collected information, obtained for nonresearch activities? If any information is identifiable, it must be maintained in accordance with section 208(b) of the E-Government Act of 2002 and the Privacy Act of 1974.** | |
| F.1 | [insert answer here] |
| **F.2. Will the research involve only information collection and analysis involving the investigator’s use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E (the HIPAA Privacy Rule) for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR § 164.501 or for “public health activities and purposes” as described under 45 CFR § 164.512(b)?** | |
| F.2 | [insert answer here] |

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| **Submission Checklist** | | |
| **Incl.** | **N/A** | **Items** |
|  |  | Human Subjects Research Worksheet |
|  |  | Existing Information/Biospecimen 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) |
|  |  | Research Protocol |
|  |  | Data Use Agreement with entity providing existing data/specimen |
|  |  | For funded/sponsored research: The human subjects portion of the grant proposal. |