Complete this form if you are unsure whether your proposed research constitutes as human subjects research or to request documentation that your research does not constitute as human subjects research. The information provided on this form will be reviewed and evaluated by the Human Subjects staff to determine whether the proposed research qualifies as human subjects’ research.

Email the completed form to [hsc@research.ucsb.edu](mailto:hsc@research.ucsb.edu) for review and determination.

For additional information on what constitutes as human subjects’ research, see the guidance [Does Your Project Require IRB Review](https://www.research.ucsb.edu/human-subjects/for-researchers)?

**UCSB Study Personnel:**

|  |  |
| --- | --- |
| Principal Investigator: | Date: |
| Email: | Department: |
| Name of Person Completing Form: | |
| Title of Project: | |
| Provide a brief description of the proposed activities: | |

**Determining if the project/activity meets the definition of Research:**

|  |
| --- |
| Q1: Is this project/activity an investigation (e.g., conducting an inquiry or detailed or careful examination for facts?  Yes  No |
| Q2: Is the investigation systematic (e.g., having or involving a system method or plan)? Do you have a hypothesis and study design?  Yes  No |
| Q3: Is the systematic investigation designed to develop or contribute to generalizable knowledge (universally or widely applicable?)  Yes  No |

**Determining if the project/activity meets the definition of Human Subjects’ Research:**

|  |
| --- |
| Q4: Will the research team gather private or personal information *about* potentially living individuals[[1]](#footnote-1)? (This may include, but is not limited to, questions about an individual’s opinion, characteristics, or individual behavior.)  Yes  No |
| Q5: Will the research team gather data through any of the following mechanisms[[2]](#footnote-2)? (check all that apply):  Physical procedures by which data are gathered (i.e., venipuncture) and/or manipulations of the subject or the subject’s environment that are performed for research purposes (“intervention”)  Communication or interpersonal contact between the researchers and subject(s) (“interaction”)  Not Applicable |
| Q6: Will the research team gather data that is about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place (“private information”)?  Yes  No |
| Q7: Will the research team gather data that individuals have provided for specific purposes in which the individuals can reasonably expect that it WILL NOT be made public, such as a medical record (“private information”)?  Yes  No |
| Q8: Can the individuals’ identities be readily ascertained or associated with the information by the research team (“identifiable information”)?  Yes  No |

**Determining if the project/activity is Quality Assessment/Improvement/Program Evaluation:**  Not Applicable

|  |
| --- |
| Q9: Is the activity designed to assess, analyze, critique, and improve current processes in an institutional setting, involving data-guided, systematic activities to improve a program?  Yes  No |
| Q10: Will the activity involve randomization into different intervention groups?  Yes  No |
| Q11: Is the activity primarily designed to (check all that apply):  Improve a practice or process to ensure it confirms with expected norms?  Evaluate a specific program only to provide information for and about that program?  Be applied to populations beyond the specific study population? |

**Determining if the project/activity uses existing specimens or data:**  Not Applicable

|  |
| --- |
| Q12: Describe the source of the data or specimens (i.e., from whom/where): |
| Q13: Are the data or specimens publicly available?  Yes  No |
| Q14: Can the research team identify the individual(s) associated with the data or specimens?  Yes  No |
| Q15: Will the data or specimens be de-identified prior to acquisition?  Yes  No |
| Q16: Are the data or specimens coded?  Yes  No  If “yes”, will the research team have access to the key to the code?  Yes  No |
| Q17: Were the data or specimens collected specifically for this project?  Yes  No |
| Q18: Were the data or specimens originally collected for research purposes under an IRB-approved protocol?  Yes  No |

1. CA state decedent medical records and death data files are protected under CA law and may require IRB review. [↑](#footnote-ref-1)
2. Examples of interactions, interventions, or physical procedures may include, audio recording, video-taping, photography, surveys, interviews, focus groups, educational tests, collection of biological specimens, ingestions of liquids, solids, topical applications, etc. [↑](#footnote-ref-2)