In order to ascertain whether IRB Review is required for a project, a Human Subject Research Determination (HSR) may be requested by completing this form and attaching it to the HSR application in [eProtocol](https://eprotocol.stanford.edu/):

* Create protocol
* Enter a brief title
* Enter personnel (at least the PD and Admin Contact, which can both be you if desired)
* Choose “Medical” or “Non-medical” as Category
* Choose “HSR Determination” as application type
* Click “Create”
* Upload the completed HSR Determination form under “Attachments”

For questions about this form, contact irbeducation@stanford.edu.

For additional guidance, please refer to:

* [Does my project need IRB review?](https://researchcompliance.stanford.edu/panels/hs/for-researchers/faqs#application)
* [What Qualifies as Human Subject Research?](https://stanfordmedicine.box.com/shared/static/ay0l6dewep46o49qm696g4llf3vpx0u9.pdf)
* [Use of Human Subjects in Student Projects, Pilot Studies, Oral Histories and QA/QI Projects](https://doresearch.stanford.edu/policies/research-policy-handbook/human-subjects-and-stem-cells-research/use-human-subjects-student)
* [Quality Assessment & Quality Improvement (QA/QI)](https://stanfordmedicine.box.com/shared/static/nvuzhf3pjqsrzx4890jax7uwbglbxcp4.pdf)

|  |
| --- |
| **I. Project Information - Please answer all questions.** |
| Protocol Director:      Department:      |
| Project Title:       |
| Funding:       |
| Purpose of the project:       |
| Does this project use California State Death Records/Indices? Yes [ ]  No [ ]  If Yes, **STOP**, and [submit an IRB application](https://researchcompliance.stanford.edu/panels/hs/forms/forms-templates/faqs#protocol-submission) in eProtocol. |
| Does this project utilize Radiologic or other images? Yes [ ]  No [ ]  |
| Samples or data from deceased individuals (only)? Yes [ ]  No [ ]  |
| Is the activity primarily designed to **improve** clinical care or some other program at STANFORD/LPCH/SHC or VAPAHCS? Yes [ ]  No [ ]  |
| Indicate **where** the activities/project will take place (STANFORD/LPCH/SHC, VAPHCS, or other site):       |
| Describe all project procedures. *If this project involves sites outside of STANFORD, please indicate that here, and specify exactly what Stanford’s role is in the project.*      |
| **A.) Information/Data and Specimens:** |
| MC900303657[1]a) List **all variables or data elements** that you will access or obtain for this project. Alternatively, please upload your data collection tool(s). [HIPAA & PHI](https://stanfordmedicine.box.com/shared/static/nodcdo1dq3y0gncfyv74kc3d78zi6ww6.pdf)       |
| b) Identify the source(s) of the information or specimens (i.e., from whom/where):      *If receiving data or specimens from outside of STANFORD, you may need a Data Use Agreement (DUA) or Material Transfer Agreement (MTA). See the* [*Privacy office FAQs on DUAs*](https://privacy.stanford.edu/other-resources/data-use-agreement-dua-faqs) *or the* [*Industrial Contracts Office - MTA page*](https://ico.sites.stanford.edu/mtas)*.*  |
| c) Were/are the data or specimens collected/obtained from participants specifically for this project? Yes [ ]  No [ ]  If for a different project, which one? If for clinical purposes, please explain.      d) Are the data or specimens de-identified, or will they be? Yes [ ]  No [ ]  If Yes, who did, or will, de-identify the data or specimens?     **OR**  e) Are the data or specimens coded, or will they be? Yes [ ]  No [ ]  If Yes, will you have access to the key to the code? Yes [ ]  No [ ]  |
| **B.) Drugs or Devices** |
| a) Does the project meet the FDA definition of a clinical investigation? 21 CFR 50.3(c)\*b) Does the project study the safety or efficacy of a drug (either investigational or commercially approved)?c) Does the project include testing of a [medical device](https://www.fda.gov/medical-devices/classify-your-medical-device/product-medical-device) including [*In Vitro* Diagnostic (IVD) Device](https://www.fda.gov/media/71075/download) or [software](https://www.fda.gov/medical-devices/digital-health/software-medical-device-samd) (i.e., [Mobile medical apps](https://www.fda.gov/media/80958/download), [AI/ML](https://www.fda.gov/media/109618/download))? d) Will any data resulting from this activity be submitted to the FDA?  If Yes to drug/devices questions a-d, **STOP**, and [submit an IRB application](https://researchcompliance.stanford.edu/panels/hs/forms/forms-templates/faqs#protocol-submission) in eProtocol.  | Yes [ ]  No [ ]  Yes [ ]  No [ ]  Yes [ ]  No [ ] Yes [ ]  No [ ]  |
| **C.) Results** |
| a) How will the results of this project be used?       b) Will the results be added to another ongoing research study? Yes [ ]  No [ ]  |
| c) Results are **intended** to be widely applicable to populations beyond your specific project population at STANFORD/LPCH/SHC or VAPAHCS: [ ]  True [ ]  False |
| d) Extrapolation or generalization of the project results to other settings (e.g. outside of STANFORD/LPCH/SHC or VAPAHCS) is possible, but **not** the main intent of the project. **[ ]** True [ ]  False |

|  |
| --- |
| **II. Project Documents**  |
| **Please upload to the Attachments section any of the following that pertain to your project:*** Surveys/questionnaires/instruments
* Interview or focus group questions
* Data collection tools
* Data Use Agreements (DUA) or Material Transfer Agreements (MTA)
 |

|  |
| --- |
| MC900303657[1]**III. Quality Assessment and/or Quality Improvement:** An activity conducted to assess, analyze, critique, and improve current processes in an institutional setting, involving data-guided, systematic activities designed to bring about prompt improvements. [**Note**](http://stanfordmedicine.box.com/shared/static/nvuzhf3pjqsrzx4890jax7uwbglbxcp4.pdf) **– projects can be published as QA/QI.** |
| Do you consider this project to meet the definition of **QA/QI** as noted above? | Yes No**[ ]  [ ]**  |

|  |
| --- |
| **IV. Program evaluation:** A systematic method for collecting and analyzing information with the intention to answer questions about the effectiveness and efficiency of specific projects or programs.  |
| Do you consider this project to meet the definition of **PROGRAM EVALUATION** as noted above? | Yes No**[ ]  [ ]**  |

|  |
| --- |
| **V. case report/case series:** A summary of clinical data, including medical history and other relevant information, that was collected for the purposes of analyzing and diagnosing the individual’s condition and/or for instructional purposes.  |
| Do you consider this project to meet the definition of **CASE REPORT/CASE SERIES** as noted above? | Yes No**[ ]  [ ]**  |
| If Yes, how many cases do you intend to collect for this project?       |

|  |
| --- |
| MC900303657[1]**VI. Research**: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. [*Mor**e info*](https://stanfordmedicine.box.com/shared/static/ay0l6dewep46o49qm696g4llf3vpx0u9.pdf) |
| Do you consider this project to meet the definition of **RESEARCH**?  | Yes No**[ ]  [ ]**  |

|  |  |
| --- | --- |
| **VII. Stem cells or Fetal tissue**  |  Yes No |
| Does your project involve the use of human fetal tissue, embryos or gametes?  If Yes, **STOP**, and consult with IRB/SCRO staff.  | **[ ]  [ ]**  |
| Does your project involve human embryonic stem cells (hESC), adult human stem cells, induced pluripotent stem cells (iPSC), cancer stem cells, progenitor cells, or somatic nuclear transplantation?  If Yes, **STOP**, consult with IRB/SCRO staff.  | **[ ]  [ ]**  |

|  |  |
| --- | --- |
| **VIII. Other** | Yes No  |
| Is your project being conducted all or in part at the VA, or with VA resources or personnel?  | **[ ]  [ ]**  |

\**Clinical investigation* means any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.