* See [*Does My Project Need IRB Review?*](http://humansubjects.stanford.edu/research/documents/HSresearch_if_IRB_review_neededFLW03H04.pdf)
* If there is ***any question*** whether your project is***human subject research*** you must submit this form to the IRB. Complete all sections then email toIRBCoordinator@lists.stanford.edu.
* The IRB will send you a ***Notice of Determination of Human Subject Research,*** or will contact you if needed.

Activities that are ***clinical investigations*** covered [under FDA regulations](http://humansubjects.stanford.edu/research/documents/HSresearch_reg_definitionsAID03H13.pdf) [FDA 21 CFR 50.3(c); 21 CFR 50.3(e); 21 CFR 56.102(g)] *require IRB review*. 🡺 Submit an eProtocol application to the IRB at <https://eprotocol.stanford.edu/irb>

|  |  |  |
| --- | --- | --- |
| **Protocol Director:**       | Degree:       | Title:       |
| Dept/Div:       | Mail Code      | Phone:      Email:       |
| **Alt. Contact:**       | Degree:       | Title:       |
| Phone:       | Email:      |
| **Project Title:** |
| **Date Submitted:** |
| **Project supported by funding?** [ ]  No [ ]  Yes \* Please name your funding source in the text box provided. If pending, please state as such.\* If Federal funding, provide copy of grant proposal with this form. | **This activity involves Conflict of Interest?**[ ]  No [ ]  Yes – *Contact OPACS/CoI Review Program:**See* [*https://opacs.stanford.edu/*](https://opacs.stanford.edu/) *for information.*  |
| **Purpose of the project:** *Provide a**3-5 sentence lay description, and what you hope to learn from this project.*      |
| **Describe all project procedures:**      |

|  |
| --- |
| **QA/QI?**  |
| **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. | **Yes No** |
| Do you consider this project to meet the definition of QA/QI as noted above? | **[ ]  [ ]**  |
| Will the activity involve randomization into different intervention groups? | **[ ]  [ ]**  |
| Is the activity primarily designed to:* Improve clinical care at Stanford/LPCH/SHC or VAPAHCS, or to improve some other program?
* Be applied to populations beyond your specific study population?
 | **[ ]  [ ]** **[ ]  [ ]**  |

|  |
| --- |
| **MC900303657[1]Research? [OHRP & FDA]** [***More info***](http://researchcompliance.stanford.edu/hs/research/documents/HSresearch_what_qualifiesGUI03H12.pdf) |
| **Research**: A systematic investigation designed to develop or contribute to generalizable knowledge **FDA**: Clinical investigations involving human subjects: ***Must*** submit eProtocol application to IRB | **Yes No** |
| Do you consider this project to meet the definition of ***research***?  | **[ ]  [ ]**  |
| Is the activity a systematic investigation, including (but not limited to) a hypothesis, research development, testing, and evaluation?  | **[ ]  [ ]**  |
| Is the activity primarily designed to develop ***new*** knowledge?  | **[ ]  [ ]**  |
| Is the activity for thesis or dissertation research? | **[ ]  [ ]**  |

|  |  |
| --- | --- |
| MC900303657[1]**Activity involves Human Subjects?** [***More info***](http://humansubjects.stanford.edu/research/documents/HSresearch_definitionsAID03H11.pdf) | **Yes No** |
| **Does your project involve:** |  |
| * Living individuals?
 | **[ ]  [ ]**  |
| * Intervention, including manipulation of a person, or a person’s environment
 | **[ ]  [ ]**  |
| * Interaction (through surveys, interviews, tests, or observations)?

*🡺 If “yes”, attach the survey, interview, or test questions*  | **[ ]  [ ]**  |
| * Obtaining identifiable private information ***about*** living individuals
 | **[ ]  [ ]**  |
| I**f this project uses existing data or specimens, answer the following:** |  |
| * Describe the source of the data or specimens (i.e., from whom/where):
 |  |
| * Are the data or specimens publicly available?
 | **[ ]  [ ]**  |
| * Can the researcher identify the individual associated with the data or specimens?
 | **[ ]  [ ]**  |
| * Are the data or specimens de-identified?

*🡺 If “yes”, who did, or will, de-identify the data or specimens?*       | **[ ]  [ ]**  |
| * Are the data or specimens coded?

*🡺 If “yes”, will you have access to the key to the code?* [ ]  No [ ]  Yes | **[ ]  [ ]**  |
| * Were the data or specimens originally collected for this project?
 | **[ ]  [ ]**  |
| * Were the data or specimens originally collected as part of clinical care?
 | **[ ]  [ ]**  |
| * Were the data or specimens originally collected for research purposes under a Stanford IRB approved protocol?

*🡺 If “yes”, provide the IRB (eProtocol) number:*      .  *If not obtained at Stanford, attach the consent form under which the data or specimens were obtained.* | **[ ]  [ ]**  |

|  |  |
| --- | --- |
| **Clinical Investigation? [FDA]** | **Yes No** |
| Does your project include testing the safety and efficacy of a drug or device in a human subject, including analysis or comparison of outcome data about a drug or device?  | **[ ]  [ ]**  |
| Does your project include a non-FDA-approved assay or In *Vitro* Diagnostic Device? | **[ ]  [ ]**  |
| Will any data resulting from this activity be submitted to the FDA? | **[ ]  [ ]**  |

|  |  |
| --- | --- |
| **Other Considerations** | **Yes No** |
| Does your project involve the use of fetal tissue? If yes, name the source in the procedures box | **[ ]  [ ]**  |
| Does your project involve human embryonic stem cells (hESC), adult human stem cells, pluripotent cells or somatic nuclear transplantation? | **[ ]  [ ]**  |
| Is your project being conducted all or in part at the VA, or with VA resources or personnel?*🡺 If “yes”, contact the VAPAHCS IRB Coordinator prior to performing this activity* | **[ ]  [ ]**  |

|  |
| --- |
| ***For IRB Use Only - IRB Determination*** |
| **Date Reviewed:**      **Reviewed by:**            |