- See *Does My Project Need IRB Review?*
- If there is ***any question*** whether your project involves ***human subjects*** you must submit this form to the IRB. Complete all sections then attach to the HSR determination form application in eProtocol.
- The IRB will send you a ***Human Subject Research (HSR) Determination,*** or will contact you if needed.

Activities that are ***clinical investigations*** covered under FDA regulations [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

Purpose of the project: *Describe what you hope to learn from this project in 3-5 sentences. If this is a QA/QI project, identify the specific process or procedure that this project aims to improve or evaluate.*

Describe all project procedures:

I. QA/QI?	Yes	No
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.		
1. Do you consider this project to meet the definition of QA/QI as noted above?	○	○
2. Will the activity involve randomization into different intervention groups?	○	○
3. Is the activity primarily designed to: a. Improve clinical care at Stanford/LPCH/SHC or VAPAHCS, or to improve some other program? b. Be applied to populations beyond your specific study population?	○ ○	○ ○
NOTE: For a proposed project to be conducted at the hospital as Quality Assurance/Quality Improvement (QA/QI) it must be reviewed by the Chief Quality Officer at the hospital in order to proceed.		

II. RESEARCH? [OHRP & FDA]	More info	Yes	No
Research: A systematic investigation designed to develop or contribute to generalizable knowledge **FDA: Clinical investigations involving human subjects: *Must*** submit eProtocol application to IRB			
1. Do you consider this project to meet the definition of ***research***?		○	○
2. Is the activity a systematic investigation, including (but not limited to) a hypothesis, research development, testing, and evaluation?		○	○
3. Is the activity primarily designed to develop ***generalizable*** knowledge?		○	○
4. Is the activity for thesis or dissertation research?		○	○

III. ACTIVITY INVOLVES HUMAN SUBJECTS?	More info	Yes	No
Does your project involve:			
1. Living individuals?		○	○
2. Intervention, including manipulation of a person, or a person's environment?		○	○
3. Interaction (through surveys, interviews, tests, or observations)? ➔ *If "yes", attach the survey, interview, or test questions*		○	○
4. Obtaining identifiable private information ***about*** living individuals?		○	○

IV. DOES THIS PROJECT USE EXISTING DATA OR SPECIMENS? (IF NO, SKIP QUESTIONS 1-8 BELOW).	Yes	No
1. Source of the data or specimens:		
2. Are the data or specimens publicly available?	○	○
3. Can the researcher identify the individual associated with the data or specimens?	○	○
4. Are the data or specimens de-identified? ➔ *If "yes", who did, or will, de-identify the data or specimens?*	○	○
5. Are the data or specimens coded? ➔ *If "yes", will you have access to the key to the code?*	○ ○	○ ○
6. Were the data or specimens originally collected for this project?	○	○
7. Were the data or specimens originally collected as part of clinical care?	○	○
8. 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.*	○	○
NOTE: For activities that involve obtaining, using, or disclosing protected health information (PHI) you must contact the Privacy Office at 650-725-1828 or email.		

V. CLINICAL INVESTIGATION? [FDA]	Yes	No
1. 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?	○	○
2. Does your project include a non-FDA-approved assay or In *Vitro* Diagnostic Device?	○	○
3. Will any data resulting from this activity be submitted to the FDA?	○	○

VI. OTHER CONSIDERATIONS	Yes	No
1. Does your project involve the use of fetal tissue? If yes, name the source in procedures on p.1	○	○
2. Does your project involve human embryonic stem cells (hESC), adult human stem cells, pluripotent cells or somatic nuclear transplantation?	○	○
3. 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*	○	○

Clear Form