- 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. To submit a 'Determination of Human Subject Research form in eProtocol, select 'Create a Protocol' on the 'My Dashboard' webpage. After completing the requested information, select 'Human Subject Research (HSR)' as your type of review. Complete the application and attach this form for review (there is also a link to this form in the attachments section of the protocol application).
- 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