System Requirements:

- If using Windows, use Internet Explorer (IE) or Firefox as your browser.
- If using Macintosh, use Safari or Firefox as your browser.
- Your browser must be configured to Allow Pop-ups while using eProtocol. See instructions for allowing pop-ups.

Before you begin:

If this is your first time submitting a protocol for review, see FAQs for information to consider beforehand.

The answers to many of your questions may be found on the IRB (Human Subjects) website.

What to expect:

- Your eProtocol application form will be created and an eProtocol number will be generated after you enter basic information (Protocol Title, Personnel Information, Form and Review Type) on the following screens.
- Once you have an eProtocol number, you may continue to complete the application, or you may exit the system and return at a later time to complete it. You must click the Save (Diskette) icon to save your work before exiting.
**Instructions:**

- At minimum, a Protocol Director (PD) and Administrative Contact must be entered; the same person may be entered for both roles.
- If the PD is a student (e.g., Undergraduate, Graduate, or Post-Doc) you must also enter an Academic Sponsor. Those entered as Academic Sponsors should be listed in categories 1 and 2 of Administrative Guide 23.
- Only those entered in the following roles will have **edit access** to the Protocol application: PD, Admin Contact, Co-PD, Other Contact and Academic Sponsor.
- You will be prompted to add **Other Personnel** after you have selected the form type.
- All researchers must complete required human subjects training (CITI - Collaborative Institutional Training Initiative) prior to protocol approval.
Application Category:

Select Medical for investigators performing research in:

- School of Medicine (SoM)
- Lucile Packard Children’s Hospital (LPCH)
- Stanford Hospital and Clinics (SHC)
- Veteran’s Affairs (VA) Hospital
- Psychology fMRI studies

Select Non-Medical for investigators in:

- Business
- Education
- Engineering
- Humanities & Sciences
- Law

Form Type:
Select a Form Type below to create the eProtocol application for IRB review. Learn more about different review types or contact IRBeducation@lists.stanford.edu or (650) 724-7141 if you have questions.
Application Category:

Select **Medical** for investigators performing research in:

- School of Medicine (SoM)
- Lucile Packard Children’s Hospital (LPCH)
- Stanford Hospital and Clinics (SHC)
- Veteran’s Affairs (VA) Hospital
- Psychology fMRI studies

Select **Non-Medical** for investigators in:

- Business
- Education
- Engineering
- Humanities & Sciences
- Law

---

**Application Category/Type**

Select Application Category:

- **Medical**
- **Non-Medical**

**Form Type:**

Select a Form Type below to create the eProtocol application for IRB review. Learn more about different review types or contact [IRBeducation@lists.stanford.edu](mailto:IRBeducation@lists.stanford.edu) or **(650) 724-7141** if you have questions.

- Regular: For greater than minimal risk studies
- Expedited: For minimal risk studies meeting specific criteria
- Exempt: Studies meeting specific criteria
- Chart Review: Chart review studies that only involve the use of data, documents, records
- HSR Determination Form: Projects that don’t clearly qualify as human subjects research. Include the [HSR Determination form](https://example.com) in your submission
- Single IRB: Studies where Stanford IRB is being asked to rely on an external IRB
- Single Patient IND: Single patient treatment where the PD must obtain an IND from the FDA. Include FDA Form 3926 in your submission.
- Humanitarian Use Device (HUD): Treatment using a device with a Humanitarian Device Exemption (HDE) issued by FDA.
Instructions:
- You MUST select an entry from the Personnel Lookup field to properly populate personnel information. Do NOT manually enter your name in the 'Name' field.
- At minimum, a Protocol Director (PD) and Administrative Contact must be entered; the same person may be entered for both roles if needed.
- Only those entered in the following roles will have edit access to the Protocol application: PD, Admin Contact, Co-PD and Other Contact.
- Click the link in the Other Personnel section towards the bottom of the page to enter additional personnel.
Funding

- Grants/Contracts
  - Please click on 'Add' to add Grants/Contracts

- Fellowships
  - Please click on 'Add' to add Fellowships

- Other Funding
  - Gift Funding
    - Please click on 'Add' to add Gift Funding
  - Dept. Funding
    - Please click on 'Add' to add Dept Funding
  - Other Funding (e.g., Med. Scholars)
    - Please click on 'Add' to add Other Funding
Instructions:
Remember to attach a copy of each applicable federal grant application, including competing renewals, in the Attachments section of this protocol application form.

If this is an umbrella protocol, attach in the Attachments section of this protocol application form, a listing of all protocols funded under this umbrella. Include protocol ID number, PI, and approval date.

Funding - Grants/Contracts

Funding Administered By
STANFORD

Search SPO Information by Principal Investigator or SPO Number

Principal Investigator

- SPO # (if available)
- SPO # Pending

Grant # (if available)

Funded By (include pending) *

Grant/Contract Title
if different from Protocol Title

- Yes
- No
For Federal projects, are contents of this protocol the same as described in Federal proposal application?

- Yes
- No
Is this a Multiple Project Protocol (MPP)?

- Yes
- No
Is this protocol under a MPP?
### Funding - Fellowships

**Funding administered by:** STANFORD

**Search SPO Information by Principal Investigator or SPO Number**

- **Name of Fellow:** 
  - [ ] SPO # (if available) [ ] SPO # Pending [ ] N/A

**Fellowship Reference # (if available):**

**Funded By:**

**Fellowship Title if different from Protocol Title:**

**Yes**  **No** For Federal projects, are contents of this protocol the same as described in Federal proposal application?

### Gift Funding

**Name of Donor:**

### Dept. Funding

**Department Name:**

### Other Funding (e.g., Med. Scholars)

**Other Fund Name:**
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 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:

<table>
<thead>
<tr>
<th>I. QA/QI?</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Do you consider this project to meet the definition of QA/QI as noted above?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Will the activity involve randomization into different intervention groups?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Is the activity primarily designed to:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. Improve clinical care at Stanford/LPCH/SHC or VAPAHCS, or to improve some other program?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. Be applied to populations beyond your specific study population?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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]

**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?

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).

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]

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>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?</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>Does your project include a non-FDA-approved assay or In Vitro Diagnostic Device?</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>Will any data resulting from this activity be submitted to the FDA?</td>
<td></td>
</tr>
</tbody>
</table>

### VI. Other Considerations

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Does your project involve the use of fetal tissue? If yes, name the source in procedures on p.1</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>Does your project involve human embryonic stem cells (hESC), adult human stem cells, pluripotent cells or somatic nuclear transplantation?</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>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</td>
<td></td>
</tr>
</tbody>
</table>
Title

[ Insert Project Title ]

2. Attachments

Instructions

- Complete the Human Subject Research Determination Form and attach it below. This attachment is required for this submission.
- Click ADD to add documents.
- To view an attached document, click on the link for that attachment in the Title column.
- To remove an attachment, check the box next to the Title and DELETE.

Add

Please click on 'Add' to attach documents
<table>
<thead>
<tr>
<th>Type:</th>
<th>--------Please Select--------</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title: *</td>
<td></td>
</tr>
<tr>
<td>Attachment(File Name):</td>
<td>Choose File   No file chosen</td>
</tr>
</tbody>
</table>