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.
### Investigator

**PERSONNEL LOOKUP**

**INSTRUCTIONS:** Search by LastName, FirstName (e.g., Smith, John) or by SUNet ID.

<table>
<thead>
<tr>
<th>Name</th>
<th>Degree (Program/year if student)</th>
<th>Position, e.g. Assistant Professor, Resident, etc.</th>
<th>Email</th>
<th>Phone</th>
<th>Fax</th>
<th>Mail Code</th>
<th>CITI Training current</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

**Other Contact**

**PERSONNEL LOOKUP**

**INSTRUCTIONS:** Search by LastName, FirstName (e.g., Smith, John) or by SUNet ID.

<table>
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<th>Name</th>
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</tr>
</thead>
</table>

**Academic Sponsor**

**PERSONNEL LOOKUP**

**INSTRUCTIONS:** Search by LastName, FirstName (e.g., Smith, John) or by SUNet ID.

<table>
<thead>
<tr>
<th>Name</th>
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<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>
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 or (650) 724-7411 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

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) 723-7141 if you have questions.

- Regular: For greater than minimal risk studies
- Expedited: For minimal risk studies meeting specific criteria
- Exempt: Studies meeting specific criteria
- HSR Determination Form: Projects that don’t clearly qualify as human subjects research. Include the HSR Determination form in your submission
- Single IRB: Studies where Stanford IRB is being asked to rely on an external IRB.
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.
- 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 and Other Contact.
- Click the link in the Other Personnel section towards the bottom of the page to enter additional personnel.
- All users must take CITI training. If your training information is highlighted, it will be verified by IRB staff.
- You can click here to review completion records to ensure training has been completed.

Once all personnel have been entered and saved, click here to start the OPACS process.

Protocol Director

View LDAP report

PERSONNEL LOOKUP

INSTRUCTIONS: Search by LastName, FirstName (e.g., Smith, John) or by SUNet ID.

Name *
Ratan Banik

Degree (Program/year if student) *

Position, e.g., Assistant Professor, Resident, etc. *
No Title

Email *
medirbc@keyusa.com

Phone *
n/a

Fax

Department
Select Department

Mail Code

CITI Training current
Yes No

Admin Contact

PERSONNEL LOOKUP

INSTRUCTIONS: Search by LastName, FirstName (e.g., Smith, John) or by SUNet ID.

Name *
Ratan Banik

Degree (Program/year if student) *

Position, e.g., Assistant Professor, Resident, etc. *
No Title

Email *
medirbc@keyusa.com

Phone *
n/a

Fax

Department
Select Department

Mail Code

CITI Training current
Yes No
### Investigator

**PERSONNEL LOOKUP**

**INSTRUCTIONS:** Search by LastName, FirstName (e.g., Smith, John) or by SUNet ID.

<table>
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<tr>
<th>Name *</th>
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<th>Email *</th>
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</tbody>
</table>

Department

Select Department

**CITI Training current**

- [ ] Yes
- [ ] No

### Other Contact

**PERSONNEL LOOKUP**

**INSTRUCTIONS:** Search by LastName, FirstName (e.g., Smith, John) or by SUNet ID.

<table>
<thead>
<tr>
<th>Name *</th>
<th>Degree (Program/year if student) *</th>
<th>Position, e.g. Assistant Professor, Resident, etc. *</th>
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</tbody>
</table>

Department

Select Department

**CITI Training current**

- [ ] Yes
- [ ] No

### Academic Sponsor

**PERSONNEL LOOKUP**

**INSTRUCTIONS:** Search by LastName, FirstName (e.g., Smith, John) or by SUNet ID.

<table>
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<th>Name *</th>
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<th>Fax</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

Department

Select Department

**CITI Training current**

- [ ] Yes
- [ ] No

### Other Personnel

[Click here to add Other Personnel]

*Once all personnel have been entered and saved, click here to start the OPACS process.*

[Confirm Personnel]
Click the "Start" button once the Personnel section has been completed. The faculty investigators will receive an email asking them to disclose any financial interests related to this protocol. All faculty investigators must answer "Yes" or "No" before the protocol can be submitted.

**Instructions:**

Add the name and contact information of the Single IRB (siIRB) that is providing IRB review. This individual is the point of contact for communication between Stanford's IRB and the siIRB.
Complete the name and contact information for the Single IRB point of contact.

**Single IRB Information**

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single IRB Name</td>
<td></td>
</tr>
<tr>
<td>Single IRB point of contact</td>
<td></td>
</tr>
<tr>
<td>Contact Name</td>
<td></td>
</tr>
<tr>
<td>Contact Number</td>
<td></td>
</tr>
<tr>
<td>Contact Email</td>
<td></td>
</tr>
</tbody>
</table>


**Instructions:**

The study location is the location at which the Stanford research takes place. For example, a study in which data are collected at a community clinic and analyzed at Stanford would have both Stanford and Other selected.

- Whenever Other is selected, click the ADD button to enter the details for one or more other locations.
- To remove an other location, check the box next to the name, and click DELETE.
- To view/modify details of previously entered other locations, click the link of the location name.

**Study Location(s) Checklist**

- Stanford University
- Other (Click ADD to specify details)
<table>
<thead>
<tr>
<th>Location</th>
<th>US</th>
<th>International</th>
</tr>
</thead>
<tbody>
<tr>
<td>Location / Country</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contact Name</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contact Phone</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contact Email</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **Yes**  **No**  Has the location granted permission for the research to be conducted?
- **Yes**  **No**  Does the location have an IRB that will approve the research?
Instructions:
Please complete the following questions.

General Checklist
Yes No 1. Funding
   Yes  Federal Sponsored Project?

Yes No 2. Collaborating Institution(s)/sites
   Are there any collaborating institutions/sites?

Yes No 3. Enrolling Students?
   Students

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

- Fellowships
  Please click on 'Add' to add Fellowships

- Other
  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

<table>
<thead>
<tr>
<th>Field</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Funding Administered By</td>
<td>STANFORD</td>
</tr>
<tr>
<td>Search SPO Information by Principal Investigator or SPO Number</td>
<td></td>
</tr>
<tr>
<td>Principal Investigator</td>
<td></td>
</tr>
<tr>
<td>SPO # (if available)</td>
<td></td>
</tr>
<tr>
<td>SPO # Pending</td>
<td>(e.g. 123456)</td>
</tr>
<tr>
<td>Grant # (if available)</td>
<td></td>
</tr>
<tr>
<td>Funded By (include pending)</td>
<td></td>
</tr>
<tr>
<td>Grant/Contract Title if different from Protocol Title</td>
<td></td>
</tr>
</tbody>
</table>

- 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?

- **STANFORD**
  - PAVIR
  - VA
  - OTHER

### Gift Funding

**Name of Donor** *

### Dept. Funding

**Department Name** *

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

**Other Fund Name** *
1. Title

sIRB

a) In 3-5 sentences, state the purpose of the study in lay language.

b) Describe the procedures and research activities that will be conducted by the Stanford researcher(s).

c) Will you be working with any Political Action Committees or other political organizations that are involved in partisan activities? If yes, describe below. See Admin Guide 1.5.1 for restrictions on doing research involving partisan organizations.
2. Potential Conflict of Interest

**STANFORD UNIVERSITY OUTSIDE PROFESSIONAL ACTIVITIES CERTIFICATION SYSTEM (OPACS)**

Investigators are required to disclose any financial interests that reasonably appear to be related to this protocol.

You will be unable to submit this protocol until all financial interest tasks are completed. Click here to send reminder emails.

<table>
<thead>
<tr>
<th>Financial Interest Tasks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigators</td>
</tr>
<tr>
<td>PD</td>
</tr>
</tbody>
</table>

INSTRUCTIONS FOR ADMIN CONTACT

- Please reload this page to see updated financial interest information.
- Issues submitting protocol? Hover over information icons.
- Incomplete tasks must be completed by the investigator. Forward instructions below.

To Disclose Financial Interests for this protocol:

1. Log on to your dashboard at https://OPACSprod.stanford.edu
2. Click the red "enter response" button for this protocol
3. If you enter "yes", you will need to disclose related financial interests

Issues? Please submit an [OPACS HelpSU](#) ticket.
3. Attachments

**NOTE:** Upload the following (as applicable): * IRB Reliance Agreement, IRB Authorization Agreement (IAA), or Memorandum of Understanding (MOU)
- Single IRB's most current approval letter and approved documents
- Federal grant (if Stanford is the prime awardee)
- Study protocol
- Stanford consent document(s) with the Stanford required language
- Local Context Document

**Instructions**
- Click **ADD** to attach 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 click **DELETE**.

<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</td>
</tr>
</tbody>
</table>
IRB Reliance Agreement (e.g., IAA, MOU)
Single IRB Approval Letter
Single IRB Approved Documents
Federal Grants
Stanford consent document(s)
Study protocol
Local Context Document
FDA Documents
Other

Obligations

The Protocol Director agrees to:

- Adhere to principles of sound scientific research designed to yield valid results
- Conduct the study according to the protocol approved by the single IRB
- Be appropriately qualified to conduct the research and be trained in Human Research protection, ethical principles, regulations, policies and procedures
- Ensure all Stanford research personnel are adequately trained and supervised
- Ensure that the rights and welfare of participants are protected including privacy and confidentiality of data
- Ensure that, when de-identified materials are obtained for research purposes, no attempt will be made to re-identify them.
- Disclose to the appropriate entities any potential conflict of interest
- Submit ongoing activities to the sIRB, i.e. modifications, continuing reviews, adverse events, protocol deviations, other reportable events, and any other information as required by the sIRB
- Report promptly any determinations of serious or continuing noncompliance, unanticipated problems, unanticipated deaths, and issues related to breach of confidentiality to the Stanford IRB.
- The Stanford IRB needs to be notified of any unresolved complaints, Protocol Director Changes, changes in Conflict of Interest, or when the study is closed, suspended or terminated.
- Apply relevant professional standards.

Any change in the research protocol must be submitted to the sIRB for review prior to the implementation of such change. Any complications in participants or evidence of increase in the original estimate of risk should be reported at once to the sIRB before continuing with the project. The investigators must inform the participants of any significant new knowledge obtained during the course of the research.

All data including signed consent form documents must be retained for a minimum of three years past the completion of the research. Additional requirements may be imposed by your funding agency, your department, or other entities. (Policy on Retention of and Access to Research Data, Research Policy Handbook, http://dorresearch.stanford.edu/policies/research-policy-handbook/conduct-research/retention-and-access-research-data)

☐ By checking this box, I verify that I, as the Protocol Director (PD) responsible for this research protocol, have read and agree to abide by the above obligations, or that I have been delegated authority by the PD to certify that the PD has read and agrees to abide by the above obligations.