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 the 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.

### Protocol Director *

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name *</td>
<td></td>
</tr>
<tr>
<td>Email *</td>
<td></td>
</tr>
<tr>
<td>Department</td>
<td>Select Department</td>
</tr>
<tr>
<td>CITI Training current</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes</td>
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</table>

### Admin Contact *

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name *</td>
<td></td>
</tr>
<tr>
<td>Email *</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes</td>
</tr>
</tbody>
</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

Form Type:
Select a Form Type below to create the eProtocol application for IRB review. Learn more about different review types or contact IRBeducation@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@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 in your submission.
- Single IRB
  - Studies where Stanford IRB is being asked to rely on an external IRB.
This form type may only be used for studies involving materials (data, documents, or records) that have been collected for research or non-research purposes, or materials that will be collected for non-research purposes.

Do not use this form if you plan on interaction or intervention with participants, if the chart review involves evaluating the safety and effectiveness of a drug or device, or if you are obtaining or analyzing specimens or you are creating a data repository. Instead, submit an expedited or regular form.
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.
- Click the link in the Other Personnel section towards the bottom of the page to enter additional personnel (including persons without SUNetIDs).
- You can click here to review completion records to ensure training has been completed.
- Only those entered in the following roles will have edit access to the Protocol application: PD, Admin Contact, Co-PD and Other Contact.

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

Protocol Director

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

CITI Training current

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
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.

For all Cancer-related studies, see the submission instructions on the Cancer Clinical Trials website at [http://med.stanford.edu/ccto.html](http://med.stanford.edu/ccto.html)

**IMPORTANT**: Your study involves cancer, therefore review and approval by the Stanford Cancer Institute Scientific Review Committee (SRC) is required before accrual can begin. See [http://cancer.stanford.edu/trials/srctop.html](http://cancer.stanford.edu/trials/srctop.html) for more information.
**Instructions:**
The **study location** is the location at which the 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
- Clinical & Translational Research Unit (CTRU)
- Stanford Hospital and Clinics
- Lucile Packard Children’s Hospital (LPCH)
- VAPAHCS (Specify PI at VA)
- Other (Click ADD to specify details)

### Other Location
<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:**
- If you answer YES to **Collaborating Institution**, click the ADD button to enter the details for one or more institutions.
- To remove an institution, check the box next to the name, and click DELETE.
- To view/modify details of previously entered institutions, click the link of the institution name.

**Reminder:**
If this study is a clinical trial that must be registered on ClinicalTrials.gov and Stanford is responsible for the registration, contact clinicaltrials-gov@stanford.edu or ccto-website@stanford.edu (for cancer trials) to register the study.

### General Checklist

<table>
<thead>
<tr>
<th>Yes No</th>
<th>1. Collaborating Institution(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Are there any collaborating institution(s)?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Yes No</th>
<th>2. Funding</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Training Grant?</td>
</tr>
<tr>
<td></td>
<td>Federally Sponsored Project?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Yes No</th>
<th>3. Veterans Affairs (VA)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>The research involves the use of VAPAHCS non-public information.</td>
</tr>
<tr>
<td></td>
<td>The research is sponsored (e.g. funded) by VAPAHCS.</td>
</tr>
<tr>
<td></td>
<td>The research is conducted by or under the direction of any employee or agent of VAPAHCS in connection with his VAPAHCS responsibilities.</td>
</tr>
<tr>
<td></td>
<td>The research is conducted using any property or facility of VAPAHCS.</td>
</tr>
</tbody>
</table>

Research done at or involving the VA must be reviewed and approved by the Research and Development Committee before any research is started. Contact the Research Administration Office at the VA at 650-492-5000 ext 65418.

### Cooperating Institution(s)

<table>
<thead>
<tr>
<th>Institution Name *</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact Name</td>
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</tr>
<tr>
<td>Contact Phone</td>
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<tr>
<td>Contact Email</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>Has the location granted permission for the research to be conducted?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
<td>Does the location have an IRB that will approve the research?</td>
</tr>
</tbody>
</table>
### Funding

**Funding - Grants/Contracts**

Please click on 'Add' to add Grants/Contracts

**Funding - Fellowships**

Please click on 'Add' to add Fellowships

**Funding - Other**

**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**

<table>
<thead>
<tr>
<th>Funding Administered By</th>
<th>STANFORD</th>
</tr>
</thead>
</table>

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

- Principal Investigator
- SPO # (if available)
- SPO # Pending
  
  (e.g. 123456)

**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)** (e.g. 123456)
- **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**
Title
Chart Review

Confirm that this project constitutes research under:

Expedited Category 5:
1. Yes ☐ No ☐ Research involving materials (data, documents, records) that 1) have been collected, or 2) will be collected solely for non-research purposes (such as medical treatment or diagnosis).

1. Purpose
a) In layperson's language, state the purpose of the study and what you hope to learn in 3-5 sentences.

b) Estimate the approximate number of medical charts you expect to review for this study.

c) Describe the source of the data that you will be studying, e.g., STRIDE, CERNER, EPIC, etc. (NOTE: Use STRIDE whenever possible for medical records research at Stanford.)
2. Participant Population

a) Indicate if you will target the medical records data or documents of any vulnerable populations not already listed in the Participant Population section, e.g., economically or educationally disadvantaged, or homeless people. Enter N/A if these populations are not targeted.

b) Identify the inclusion criteria for the medical records you will study. Provide the age range of the persons whose charts you will be reviewing.

c) If you intend to exclude a particular age group, ethnic group, or gender, provide a rationale for doing so, e.g., the disease does not occur in children.

d) If children are involved in your research, confirm that the following regulation applies:

☐ Yes  ☐ No  45 CFR 46.404: The research must present no greater than minimal risk to children and adequate provisions must be made for soliciting the assent of the children and the permission of their parents or guardians. [Note: IRB Waivers of Assent and Consent are considered adequate provisions. See Section 5]
3. Confidentiality Protections

Before answering the following questions, [click here](#) to learn about HIPAA and the authorized use of identifiable protected health information (PHI).

a) Specify PHI (Protected Health Information). PHI is health information linked to HIPAA identifiers (see link above). List BOTH health information AND HIPAA identifiers. If you are using STRIDE, use the [Clinical Data Work Sheet](#) to ensure that your request will match your IRB-approved protocol. Be consistent with information entered in section 5a.

b) Describe how the data will be maintained (e.g., paper or electronic spreadsheet, desktop computer, laptop or other portable device).

c) You are required to comply with University Policy that states that ALL electronic devices: computers (laptops and desktops; OFFICE or HOME); smart phones; tablets; external hard disks, USB drives, etc. that may hold identifiable participant data will be password protected, backed up, and encrypted. See [http://med.stanford.edu/datasecurity/](http://med.stanford.edu/datasecurity/) for more information on the Data Security Policy and links to encrypt your devices.

Provide any additional information on ALL data security measures you are taking. You must use a secure database such as STRIDE, RedCap, or Medrio. If you are unsure of the security of the system, check with your Department IT representative.

Please see [this link](#) for more information on IRT Information Security Services and [this link](#) for more information for securing mobile computing devices. Additionally, any PHI data on paper must be secured in a locked environment.

- By checking this button, you affirm that you will comply with the aforementioned.

d) Indicate who will have access to the data (e.g., research team, sponsors, consultants).

e) If data will be de-identified after it is collected, describe who will be responsible for the de-identification, and confirm that none of the HIPAA identifiers listed in this hyperlink will be linked to the data.
4. Potential Conflict of Interest

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.

Financial Interest Tasks

<table>
<thead>
<tr>
<th>Investigators</th>
<th>Role</th>
<th>Email</th>
<th>Has Financial Interest?</th>
<th>Date Financial Interest Answered</th>
<th>Date OPACS Disclosure Submitted</th>
<th>Date OPACS Review Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ratan Banik</td>
<td>PD</td>
<td><a href="mailto:mediirbc@keyusa.com">mediirbc@keyusa.com</a></td>
<td>Incomplete</td>
<td>Incomplete</td>
<td>Incomplete</td>
<td>Pending</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://OPACSprd.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.
5. Waivers of Consent, Assent, HIPAA Authorization

Instructions

- A waiver of consent AND a waiver of HIPAA authorization is required for all medical chart reviews. Both should be added below. Add a waiver of assent if you are accessing the information of children (<18 years old).
- Click ADD to enter detailed information on each of the above waivers. Once entered and saved, a row will be displayed in tabular form for each item (Waiver of Consent, Waiver of HIPAA Authorization, etc.) entered.
- To view/modify the details of previously entered information, click the link in the Waivers Type column for the desired item.
- To remove an item, check the box next to the Waivers and click DELETE.

**Waivers**

Please click on ‘Add’ to add Waivers
6. Attachments

**NOTE:** For research done at or involving the VA, the **VA required questions** document must be saved to your computer, completed and attached. When attaching, set the attachment type to **VA required questions**.

**Instructions**
- Click **ADD** to attach documents (e.g., federal grant/sub-contract).
- 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**.

**Please click on 'Add' to attach documents**
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 IRB.
- Ensure adequate resources are available to conduct the study.
- 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.
- Report promptly any new information, modification, or unanticipated problems that involve risks to participants or others.
- Apply relevant professional standards.

Any change in the research protocol must be submitted to the IRB 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 IRB before continuing with the project. Inasmuch as the Institutional Review Board (IRB) includes faculty, staff, legal counsel, public members, and students, protocols should be written in language that can be understood by all Panel members. The investigators must inform the participants of any significant new knowledge obtained during the course of the research.

IRB approval of any project is for a period of one to three years. For continuing projects and activities, it is the responsibility of the investigator(s) to resubmit the project to the IRB for review and re-approval prior to the end of the approval period. A Notice to Renew Protocol is sent to the Protocol Director 7 weeks prior to the expiration date of the protocol.

All data 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://doresearch.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.