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.

**Protocol Director**

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

**Admin Contact**

<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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</thead>
<tbody>
<tr>
<td>Email</td>
<td>Phone</td>
<td>Fax</td>
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</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

**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](mailto:IRBeducation@stanford.edu) or (650) 724-7141 if you have questions.

- [ ] Regular
- [ ] Expedited
- [ ] Exempt
- [ ] Chart Review
- [ ] HSR Determination Form
- [ ] Single IRB

- For greater than minimal risk studies
- For minimal risk studies meeting specific criteria
- Studies meeting specific criteria
- Chart review studies that only involve the use of data, documents, records
- Projects that don’t clearly qualify as human subjects research. Include the HSR Determination form in your submission.
- 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.
- Click the link in the Other Personnel section towards the bottom of the page to enter additional personnel.
- 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.

OPACS email has now been sent to PD and all faculty personnel.

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) *

n/a

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) *

n/a

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**

- **Name**: 
- **Degree (Program/year if student)**: 
- **Position, e.g. Assistant Professor, Resident, etc.**

**Other Contact**

**Personnel Lookup**

- **Name**: 
- **Degree (Program/year if student)**: 
- **Position, e.g. Assistant Professor, Resident, etc.**

**CITI Training current**: 
- Yes
- No

### Academic Sponsor

**Personnel Lookup**

- **Name**: 
- **Degree (Program/year if student)**: 
- **Position, e.g. Assistant Professor, Resident, etc.**

**CITI Training current**: 
- Yes
- No

### Other Personnel

**OPACS email has now been sent to PD and all faculty personnel.**

[Click here to add Other 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:
Please select all populations (and only those) that are specifically targeted for this study. Here are some examples:

- A researcher is conducting a study to compare two strategies designed to promote longer-term maintenance of smoking cessation. There may be students that smoke, however, the study is not designed to recruit students specifically as they are not the focus population. In this example, students would not be selected on the checklist.
- A researcher is conducting a study to test the efficacy of an after school exercise program to reduce weight gain among lower socioeconomic status pre-adolescent girls. Although some participants may be pregnant, pregnant women are not the target population and would not be selected on the checklist.

Participant Population(s) Checklist

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>☑</td>
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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 where the Stanford researcher conducts any part of the research study. For example, a study in which specimens 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)
- VAAPHCs (Specify PI at VA)
- Other (Specify other study locations)

**Other Location**

<table>
<thead>
<tr>
<th>Location</th>
<th>US</th>
<th>International</th>
</tr>
</thead>
</table>

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

**Has the location granted permission for the research to be conducted?**
- Yes
- No

**Does the location have an IRB that will approve the research?**
- Yes
- No
### Participating Site

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
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</thead>
<tbody>
<tr>
<td>Site Name *</td>
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<tr>
<td>Contact Name</td>
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<td>Contact Phone</td>
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<tr>
<td>Contact Email</td>
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</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?

### Cooperating Institution(s)

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

Yes No 1. Multi-site
- Is this a multi-site study? A multi-site study is generally a study that involves one or more medical or research institutions in which one site takes a lead role (e.g., multi-site clinical trial)
- Is Stanford the coordinating institution or are you the lead investigator for this multi-site study?

<table>
<thead>
<tr>
<th>Site Name</th>
<th>Contact Name</th>
<th>Phone</th>
<th>Email</th>
<th>Permission?</th>
<th>IRB?</th>
</tr>
</thead>
<tbody>
<tr>
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</tr>
</tbody>
</table>

Add Delete

Yes No 2. Collaborating Institution(s)
- Are there any collaborating institution(s)? A collaborating institution is generally an institution that collaborates equally on a research endeavor with one or more institutions.

Yes No 3. Cancer Institute
- Cancer-Related Studies (studies with cancer endpoints), Cancer Subjects (e.g., clinical trials, behavior/prevention) or Cancer Specimens (e.g., blood, tissue, cells, body fluids with a scientific hypothesis stated in the protocol)
- For all Cancer-related studies, see the submission instructions on the Cancer Clinical Trials website at 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://med.stanford.edu/cancer/research/trial-support/src.html for more information.

Yes No 4. Tissues and Specimens
- Human blood, cells, tissues, or body fluids (tissues)?
- Tissues to be stored for future research projects?
- Tissues to be sent out of this institution as part of a research agreement? For guidelines, please see https://sites.stanford.edu/ico/mtas
- Human Embryos or Gametates?

SCRO #

Yes No 5. Veterans Affairs (VA)
- The research recruits participants at the Veterans Affairs Palo Alto Health Care System (VAPAHCS).
- The research involves the use of VAPAHCS non-public information to identify or contact human research participants or prospective subjects or to use such data for research purposes.
- The research is sponsored (i.e., funded) by VAPAHCS.
- The research is conducted by or under the direction of a VA employee (VA-paid or VA Without Compensation (VOWC) appointment) while on their VA time.
- The research is conducted using any property or facility of VAPAHCS.
- Research done at or involving the VA must be reviewed and approved by the Research and Development Committee before any research is started. Please contact the Research Administration office at the Palo Alto VA at 650-495-5000 ext. 65416

Yes No 6. Payment
- Subjects will be paid/reimbursed for participation? See payment considerations.

Yes No 7. Funding
- Training Grant?
- Program Project Grant?
- Federally Sponsored Project?
**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>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Funding Administered By</td>
<td>STANFORD</td>
</tr>
</tbody>
</table>

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

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

**Grant # (if available)**

**Funded By (include pending) **

**Grant/Contract Title**

* if different from Protocol Title

<table>
<thead>
<tr>
<th>Yes/No</th>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>For Federal projects, are contents of this protocol the same as described in Federal proposal application?</td>
</tr>
<tr>
<td>Yes</td>
<td>Is this a Multiple Project Protocol (MPP)?</td>
</tr>
<tr>
<td>Yes</td>
<td>Is this protocol under a MPP?</td>
</tr>
</tbody>
</table>
Resources

Please demonstrate that you have adequate resources to conduct the project.

a. Qualified staff.

Please state and justify the number and qualifications of your study staff.

b. Training.

Describe the training you will provide to ensure that all persons assisting with the research are informed about the protocol and their research-related duties and functions.

c. Facilities.

Please describe and justify.

d. Sufficient time.

Explain whether you will have sufficient time to conduct and complete the research. Include how much time is required.

e. Access to target population.

Explain and justify whether you will have access to a population that will allow recruitment of the required number of participants.

f. Access to resources if needed as a consequence of the research.

State whether you have medical or psychological resources available that participants might require as a consequence of the research when applicable. Please describe these resources.

g. Lead Investigator or Coordinating Institution in Multi-site Study.

Please explain (i) your role in coordinating the study, (ii) procedures for routine communication with other sites, (iii) documentation of routine communications with other sites, (iv) planned management of communication of adverse outcomes, unexpected problems involving risk to participants or others, protocol modifications or interim findings.
Federal regulations state that certain research is exempt from review. However, under Stanford’s Policy for the Protection of Human Subjects, a research protocol proposing the use of human subjects must be submitted to the Panel to determine if it qualifies for exempt status. EXEMPTIONS DO NOT APPLY TO RESEARCH CONDUCTED ON PRISONERS.

In order to qualify as Exempt, a protocol must be no more than minimal risk AND must only involve human subjects in one or more of the following paragraphs.

Select one or more of the following paragraphs:

1. Research conducted in established educational settings, involving normal educational practices, such as:
   i. research on education instructional strategies, or
   ii. research on the effectiveness or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), surveys, interviews, or observation of public behavior * UNLESS
   i. information is recorded with identifiers linked to the subjects AND
   ii. subjects’ responses could place subjects at risk (e.g., criminal or civil liability, financial standing, employability or reputation).

3. Research involving educational tests, surveys, interviews, or observation of public behavior is exempt if:
   i. the subjects are elected or appointed public officials or candidates for public office; or
   ii. federal statute requires confidentiality of identifiable information to be maintained permanently

4. Research involving the collection or study of existing data, documents, or records. Sources must either be publicly available or information must be recorded without identifiers linked to the subjects.

YES NO

- Are the data and/or specimens pre-existing, i.e., “on the shelf”, as of today?
- Is it correct that no one (including the researcher) can identify a subject from any information recorded for this research?

Provide the dates (in format mm/dd/yyyy to mm/dd/yyyy) when this data was collected.
Provide information regarding who holds or owns the data, and who is allowed to access it.
5. Research conducted by or subject to the approval of Federal Department or Agency head, and designed to study or evaluate:
   i) public benefit or service programs;
   ii) procedures for obtaining benefits or services under those programs;
   iii) possible changes in or alternatives to those programs; or
   iv) changes in methods of payment for benefits under those programs.

6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.
Complete Sections 1 - 11. Specify N/A as appropriate. Do not leave any required sections blank.

1. Purpose

a) In layperson's language state the purpose of the study in 3-5 sentences.

b) State what the investigator(s) hope to learn from the study. Include an assessment of the importance of this new knowledge.

c) Explain why human subjects must be used for this project. (i.e. purpose of study is to test efficacy of investigational device in individuals with specific condition; purpose of study is to examine specific behavioral traits in humans in classroom or other environment)

2. Study Procedures

a) Describe all the research procedures, from screening through closeout, which the human subject must undergo in the research project, including study visits, drug treatments, randomization and the procedures that are part of standard of care.

b) Explain how the above research procedures are the least risky that can be performed consistent with sound research design.

c) State if deception will be used. If so, provide the rationale and describe debriefing procedures. Since you will not be fully informing the participant in your consent process and form, complete an alteration of consent (in section 9). Submit a debriefing script (in section 11).

d) State if audio or video recording will occur. Describe what will become of the recording after use, e.g., shown at scientific meetings, erased. Describe the final disposition of the recordings.
3. Background
   
a) Describe past findings leading to the formulation of the study.

4. Participant Population
   
a) State the following: (i) the number of participants expected to be enrolled at Stanford-affiliated site(s); (ii) the total number of participants expected to enroll at all sites; (iii) the type of participants (i.e., students, patients with certain cancer, patients with certain cardiac condition) and the reasons for using such participants.

b) State the age range, gender, and ethnic background of the participant population being recruited.

c) State the number and rationale for involvement of potentially vulnerable subjects in the study (including children, pregnant women, economically and educationally disadvantaged, decisionally impaired, homeless people, employees and students). Specify the measures being taken to minimize the risks and the chance of harm to the potentially vulnerable subjects and the additional safeguards that have been included in the protocol to protect their rights and welfare.

d) Describe how potential participants will be identified for recruitment (e.g., chart review, referral from individual's treating physician, those individuals answering an ad). Describe how participants will be recruited and how they will initially learn about the research (e.g., clinics, advertising). Attach recruitment materials in Section #11 (Attachments). You may not contact potential participants prior to IRB approval. See guidance Advertisements: Appropriate Language for Recruitment Material.

e) Inclusion and Exclusion Criteria.
   
   Identify inclusion criteria.

   Identify exclusion criteria.
4. Participant Population

f) Describe your screening procedures, including how qualifying laboratory values will be obtained. If you are collecting personal health information prior to enrollment (e.g., telephone screening), please request a limited waiver of authorization in section #10.

__________

Payment. Explain the amount and schedule of payment, if any, that will be paid for participation in the study. Substantiate that proposed payments are reasonable and commensurate with the expected contributions of participants and that they do not constitute undue pressure on participants to volunteer for the research study. Include provisions for prorating payment. See payment considerations

__________

h) Costs. Please explain any costs that will be charged to the participant.

__________

i) Estimate the probable duration of the entire study. Also estimate the total time per participant for: (i) screening of participant; (ii) active participation in study; (iii) analysis of participant data.
5. Risks

a) Describe risks. Include risks to privacy, confidentiality, etc..

b) If you are conducting international research, describe the qualifications/preparations that enable you to both estimate and minimize risks to participants. Also complete the International Research Form and attach it in the Attachments section. If not applicable, enter N/A.

c) Could any disclosure of the participant's response outside the research reasonably place them at risk of loss of insurability, criminal or civil liability, or be damaging to the participant's financial standing, employability, or reputation?
6. Benefits
   a) Describe the potential benefit(s) to be gained by the participants or by the acquisition of important knowledge which may benefit future participants, etc.

7. Privacy and Confidentiality

Most medical research must comply with the Health Insurance Portability and Accountability Act (HIPAA) regulations if it uses protected health information (PHI). See more information on HIPAA. PHI is health information with one or more of the following identifiers:

1. Names
2. Social Security numbers
3. Telephone numbers
4. All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if, according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combing all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000
5. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death, and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older
6. Fax numbers
7. Electronic mail addresses
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers, including license plate numbers
13. Device identifiers and serial numbers
15. Internet Protocol (IP) address numbers
16. Biometric identifiers, including finger and voice prints
17. Full face photographic images and any comparable images; and
18. Any other unique identifying number, characteristic, or code (except the unique code assigned by the Investigator(s) to code the research data, unless the code was derived from other identifiable information, such as the SSN).

Privacy Protections

a) Describe how the conditions under which interactions will occur are adequate to protect the privacy interests of participants (e.g., privacy of physical setting for interviews or data collection, protections for follow-up interactions such as telephone, email and mail communications).
Confidentiality Protections

b) Specify the PHI (protected health information) or other individually identifiable data or specimens you will obtain, use or disclose to others. PHI is health information linked to one or more of the HIPAA identifiers listed above. List BOTH health information AND identifiers.

c) Describe: (i) how data will be maintained (e.g., paper or electronic spreadsheet, desktop computer, laptop or other portable device); (ii) how you will maintain the confidentiality and data security, (e.g., password protected computer, encrypted files, locked cabinet and office); and (iii) who will have access to the data (e.g., research team, sponsors, consultants).

d) If you will be sharing data with others, describe how data will be transferred (e.g., courier, mail) or transmitted (e.g., file transfer software, file sharing, email). If transmitted via electronic networks, describe how you will secure the data while in transit. See http://www.stanford.edu/group/security/securecomputing/.

e) If you plan to code the data, describe the method in which it will be coded and indicate who will have access to the key to the code.

f) How will you educate research staff to ensure they take appropriate measures to protect the privacy of participants and the confidentiality of data collected (e.g. conscious of oral and written communications, maintaining paper and electronic data)?
8. 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:medirbc@keyusa.com">medirbc@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://OPACSpd.stanford.edu](https://OPACSpd.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.
9. Consent Background

Consent Background
Please click on 'Add' to add Consent Background
a) Describe the informed consent process. Include the following.
   (i) Who is obtaining consent? (The person obtaining consent must be knowledgeable about the study.)
   (ii) When and where will consent be obtained?
   (iii) How much time will be devoted to consent discussion?
   (iv) Will these periods provide sufficient opportunity for the participant to consider whether or not to participate and sign the written consent?
   (v) What steps are you taking to minimize the possibility of coercion and undue influence?
   (vi) If consent relates to children and if you have a reason for only one parent signing, provide that rationale for IRB consideration.
10. Assent Background (less than 18 years of age)

**Assent Background**

Please click on 'Add' to add Assent Background
Assent

Assent Information Type: * Assent
Title: *
Sponsors Assent Version Nbr: (if any)
Assent Form (file name): * Choose File No file chosen

a) Describe the assent process. Include the following:
   (i) Who is obtaining child assent? (The person must be knowledgeable about the study.)
   (ii) When and where will assent be obtained?
   (iii) Will a parent or guardian be present when assent is obtained?
   (iv) How much time will be devoted to the assent discussion?
   (v) Will these periods provide sufficient opportunity for the child to consider whether to assent?
   (vi) What steps are you taking to minimize the possibility of coercion and undue influence?

b) What is the procedure to assess the child's understanding of the information contained in the assent? How will the information be provided to the child if he/she does not understand English or has a hearing impairment? How will affirmative assent be obtained (e.g., oral response, signature on form, combination of methods, other)?

c) What steps are you taking to determine that the child has the capacity to participate in the decision-making process?
11. 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, advertisements, questionnaires, sponsor’s protocol, investigator’s brochure, etc.).
- 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
- 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 raise risks to participants or others to
- 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 maximum period of one year. 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.

Department Chair must approve faculty and staff research that is not part of a sponsored project. VA applicants must have Division Chief or Ward Supervisor approval. E-mail the Department Chair approval to IRBCoordinator@lists.stanford.edu.

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://doresearch.stanford.edu/policies/research-policy-handbook/conduct-research-retention-and-access-research-data)

PLEASE NOTE: List all items (verbatim) that you want to be reflected in your approval letter (e.g., Amendment, Investigator’s Brochure, consent form(s), advertisement, etc.) in the box below. Include number and date when appropriate.

☐ 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