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>
</tr>
</thead>
<tbody>
<tr>
<td>Email *</td>
<td>Phone *</td>
<td>Fax</td>
</tr>
<tr>
<td>Department</td>
<td>Select Department</td>
<td>Mail Code</td>
</tr>
<tr>
<td><strong>CITI Training current</strong></td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

### Other Contact

**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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</tr>
<tr>
<td><strong>CITI Training current</strong></td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</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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<td>Select Department</td>
<td>Mail Code</td>
</tr>
<tr>
<td><strong>CITI Training current</strong></td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>
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 / MRI 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) 724-7141 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

<table>
<thead>
<tr>
<th>Application Category/Type</th>
<th>Create</th>
</tr>
</thead>
<tbody>
<tr>
<td>Select Application Category:</td>
<td>Medical</td>
</tr>
</tbody>
</table>

**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) 724-7841 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.
- **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.
- 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.

Confirm Personnel
### Investigator

**PERSONNEL LOOKUP**

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

<table>
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<tr>
<th>Department</th>
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<tbody>
<tr>
<td>Select Department</td>
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</tbody>
</table>

**CITI Training current**

Yes [ ] No [ ]

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### Other Contact

**PERSONNEL LOOKUP**

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</thead>
<tbody>
<tr>
<td>Select Department</td>
</tr>
</tbody>
</table>

**CITI Training current**

Yes [ ] No [ ]

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### Academic Sponsor

**PERSONNEL LOOKUP**

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

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<tr>
<th>Department</th>
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</thead>
<tbody>
<tr>
<td>Select Department</td>
</tr>
</tbody>
</table>

**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.*

Click here to start OPACS
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 (sIRB) that is providing IRB review. This individual is the point of contact for communication between Stanford's IRB and the sIRB.

**Single IRB Information**
Please click on 'Add' to add Single IRB Information
Complete the name and contact information for the Single IRB point of contact.

**Single IRB Information**

- **Single IRB Name**: 
- **Single IRB point of contact**
  - **Contact Name**: 
  - **Contact Number**: 
  - **Contact Email**: 


---

**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
- Clinical & Translational Research Unit (CTRU)
- Stanford Hospital and Clinics
- Lucile Packard Children's Hospital (LPCH)
- Other (Click ADD to specify details)
<table>
<thead>
<tr>
<th>Location</th>
<th>☑ US ☑ International</th>
</tr>
</thead>
<tbody>
<tr>
<td>Location / Country *</td>
<td></td>
</tr>
<tr>
<td>Contact Name</td>
<td></td>
</tr>
<tr>
<td>Contact Phone</td>
<td></td>
</tr>
<tr>
<td>Contact Email</td>
<td></td>
</tr>
<tr>
<td>☑ Yes ☑ No</td>
<td>Has the location granted permission for the research to be conducted?</td>
</tr>
<tr>
<td>☑ Yes ☑ No</td>
<td>Does the location have an IRB that will approve the research?</td>
</tr>
</tbody>
</table>
Please complete the following questions.

**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?

**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.

Please click on 'Add' to add Cooperating Institution(s).

**Yes** No 3. Tissues and Specimens

Human Embryos or Gametes?

SCRO #

Human Stem Cells (including hESC, iPSC, cancer stem cells, progenitor cells)

SCRO #

If "Yes" to any of the SCRO questions, STOP Contact the IRB to determine the eligibility for sIRB review.

**Yes** No 4. 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 (e.g., funded) by VAPAHCS.

The research is conducted by or under the direction of any employee or agent of VAPAHCS in connection with his/her VAPAHCS responsibilities.

The research is conducted using any property or facility of VAPAHCS.

If "Yes" to any of the VA questions, STOP Contact the IRB to determine the eligibility for sIRB review.

**Yes** No 5. 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/cctr.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 6. Clinical Trials

Investigational drugs, biologics, reagents, or chemicals?

Commercially available drugs, reagents, or other chemicals administered to subjects (even if they are not being studied)?

Investigational Device / Commercial Device used off-label?

IDE Exempt Device (Commercial Device used according to label, Investigational In Vitro Device or Assay, or Consumer Preference/Modifications/Combinations of Approved Devices)

Will this study be registered on clinicaltrials.gov? (See Stanford decision tree)

Is Stanford responsible for ClinicalTrials.gov registration? (See Stanford decision tree)

NCT# (e.g. 000001234)

(Only required if Stanford is responsible for registration)
<table>
<thead>
<tr>
<th>Yes/No</th>
<th>7. Tissues and Specimens</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Tissues to be sent out of this institution as part of a research agreement? For guidelines, please see <a href="https://sites.stanford.edu/ico/mtas">https://sites.stanford.edu/ico/mtas</a></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Yes/No</th>
<th>8. Biosafety (APB)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Are you submitting a Human Gene Transfer investigation using a biological agent or recombinant DNA vector? APB #</td>
</tr>
<tr>
<td></td>
<td>Are you submitting a Human study using biohazardous/infectious agents? If yes, refer to the <a href="https://biosecurity.stanford.edu">Administrative Panel on BioSafety website</a> prior to performing studies. APB #</td>
</tr>
<tr>
<td></td>
<td>Are you submitting a Human study using samples from subjects that are known or likely to contain biohazardous/infectious agents? If yes, refer to the <a href="https://biosecurity.stanford.edu">Administrative Panel on BioSafety website</a> prior to performing studies. APB #</td>
</tr>
<tr>
<td></td>
<td><em>IRB approval does not negate the need for APB approval, including the following issues: use of rDNA, use of Biological/Infectious Agent, use of samples from patients/participants that are known or likely to be infected with a Biological/Infectious Agent in a research lab.</em></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Yes/No</th>
<th>9. Equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Use of Patient related equipment? If Yes, equipment must meet the standards established by Hospital Instrumentation and Electrical Safety Committee (650-725-5000)</td>
</tr>
<tr>
<td></td>
<td>Medical equipment used for human patients/subjects also used on animals?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Yes/No</th>
<th>10. Funding</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Federally Sponsored Project?</td>
</tr>
<tr>
<td></td>
<td>Industry Sponsored Clinical Trial?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>11. Overall study risk level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimal/low risk (e.g., innocuous procedures)</td>
</tr>
<tr>
<td>Medium risk (e.g., invasive procedures, therapy with chemotherapy, antibodies, or a non-FDA approved potentially toxic drug)</td>
</tr>
<tr>
<td>High risk (e.g., first-time-in-humans drug or device study, novel therapeutic procedure, some biological agents or Recombinant DNA Vector studies)</td>
</tr>
</tbody>
</table>
**Funding**

- **NONE**

**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.

<table>
<thead>
<tr>
<th>Funding - Grants/Contracts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Funding Administered By</td>
</tr>
<tr>
<td>Search SPO Information by Principal Investigator or SPO Number</td>
</tr>
<tr>
<td>Principal Investigator</td>
</tr>
<tr>
<td>SPO # (if available)</td>
</tr>
<tr>
<td>SPO # Pending</td>
</tr>
<tr>
<td>Grant # (if available)</td>
</tr>
<tr>
<td>Funded By (include pending)</td>
</tr>
<tr>
<td>Grant/Contract Title</td>
</tr>
<tr>
<td>if different from Protocol Title</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>
Title

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

b) 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 STARR, use the Data Privacy Attestation to ensure that your request will match your IRB-approved protocol.
2. Radiotopes or Radiation Machines

a) List all standard of care procedures using ionizing radiation (radiation dose received by a subject that is considered part of their normal medical care). List all research procedures using ionizing radiation (procedures performed due to participation in this study that is not considered part of their normal medical care). List each potential procedure in the sequence that it would normally occur during the entire study.

b) For research radiotopes projects, provide the following radiation-related information:

Identify the radionuclide(s) and chemical form(s).

For the typical subject, provide the total number of times the radioisotope and activity will be administered (mCi) and the route of administration.

If not FDA approved provide dosimetry information and reference the source documents (package insert, MIRD calculation, peer reviewed literature).

c) For research radiation machine projects, provide the following diagnostic procedures:

For well-established radiographic procedures describe the exam.

For the typical subject, identify the total number of times each will be performed on a single research subject.

For each radiographic procedure, provide the setup and technique sufficient to permit research subject dose modeling. The chief technologist can usually provide this information.

For radiographic procedures not well-established, provide FDA status of the machine, and information sufficient to permit research subject dose modeling.
d) For research radiation machine projects, provide the following diagnostic procedures:

For a well-established therapeutic procedure, identify the area treated, dose per fraction and number of fractions. State whether the therapeutic procedure is being performed as a normal part of clinical management for the research participant's medical condition or whether it is being performed because the research participant is participating in this project.

For a therapeutic procedure that is not well-established, provide FDA status of the machine, basis for dosimetry, area treated, dose per fraction and number of fractions.

### Radiation Procedures

<table>
<thead>
<tr>
<th>Identify Week/Month of study</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of Exam *</td>
<td></td>
</tr>
<tr>
<td>Identify if SOC or Research *</td>
<td></td>
</tr>
</tbody>
</table>

- [ ] Standard of Care
- [ ] Research

[Save]
### Investigational Devices and Uses

#### Device Information

Describe the device to be used.

- **Device Name**: 
- **Manufacturer**: 
- **Risk**:  
  - Significant
  - Non-significant

See Significant and Non-Significant Risk Medical Devices guidance.
**Device Information**

**Describe the device to be used.** *

<table>
<thead>
<tr>
<th>Device Name *</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer</td>
<td></td>
</tr>
</tbody>
</table>

**IDE Exemption**

Select one of the following the IDE exemption categories: *

- This is a legally marketed device being used in accordance with its labeling.

- This is an *in vitro* diagnostic device that complies with the labeling requirements in 21 CFR 809.10(c), [http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?n=809.10](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?n=809.10), and for the testing of the device all of the following statements are true:
  - It is non-invasive.
  - It does not require an invasive sampling procedure that presents significant risk.
  - It does not by design or intention introduce energy into a subject.
  - It is not used as a diagnostic procedure without confirmation by another medically established diagnostic product or procedure.

- The study includes consumer preference testing, testing of a modification, or testing of a combination of devices that are legally marketed devices [that is, the device(s) have an approved PMA, cleared Premarket Notification (510k), or are exempt from 510k] AND the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk.
**Investigational Drugs, Reagents, Chemicals**

**Drug, Reagent, Chemical Information**

<table>
<thead>
<tr>
<th>Drug Name *</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Source (i.e. Pharmacy, Sponsor, etc..)</th>
</tr>
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<tr>
<td></td>
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</table>

If not pre-mixed, where will the material be mixed and by whom:

<p>| |</p>
<table>
<thead>
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<table>
<thead>
<tr>
<th>Manufacturer</th>
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<table>
<thead>
<tr>
<th>IND # (if available)</th>
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<table>
<thead>
<tr>
<th>Dosage</th>
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<tr>
<td></td>
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</table>

**Administration Route:**

<p>| |</p>
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</table>

**Holder of IND**

* Indicate who holds the IND:

- The IND is held by the sponsor.
  Provide a copy of the investigator's brochure, the sponsor's protocol and the FDA letter issuing the IND number (attach in section #16). The FDA letter does not have to be provided if the IND number is on the sponsor's protocol.

- The IND is held by the STANFORD (SHC, LPCH, VA) investigator.
  Provide a copy of the investigator's brochure (if available), the clinical protocol and a copy of the FDA letter issuing the IND number and all correspondence with the FDA on the IND (attach in section #16).

- The IND is held by a non-STANFORD investigator.
  Provide a copy of the investigator's brochure (if available), the clinical protocol and a copy of the FDA letter issuing the IND number (attach in section #16).

**Pharmacy Dispensing or Security and Controlled Access Plan.**

- Yes
- No

Will the investigational drug/biologic be maintained and dispensed by a pharmacy or through an outpatient clinic monitored by a pharmacy?

**Pharmacy Name**

<p>| |</p>
<table>
<thead>
<tr>
<th></th>
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<tr>
<td></td>
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</tbody>
</table>

Describe below (or attach in section 16) the procedures to be followed to prevent the investigational drug from being used by a person other than the investigator, and to prevent it from being used in someone other than a research participant.

<p>| |</p>
<table>
<thead>
<tr>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>
**Commercial Drugs, Reagents, Chemicals**

**Drug, Reagent, Chemical Information**

**Drug Name** *

Source (i.e. Pharmacy, Sponsor, etc.)

If not pre-mixed, where will the material be mixed and by whom:

Manufacturer

IND# (if available)

Dosage

Administration Route:

**IND Exemption**

* Yes  No  Is this new and different uses of this commercially available drug, reagent or chemical?

* Yes  No  Are all of the IND statements shown below true?

**Investigational New Drug (IND) Regulations**

The IND Regulations [21 CFR 312.2(b)] state that clinical investigation of a drug product is exempt from the requirements for an IND if all of the following apply:

- The Drug used in the investigation is lawfully marketed in the United States.
- The investigation is not intended to be reported to FDA in support of new indication for use or to support any other significant change in the labeling for the drug.
- The investigation is not intended to support a significant change in the advertising of the product.
- The investigation does not involve a route of administration or dosage level, use in a participant population, or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product.
- The investigation is conducted in compliance with the requirements for IRB review and informed consent [21 CFR parts 56 and 50].
- The investigation is conducted in compliance with the requirements concerning the promotion and sale of drugs [21 CFR part 312.7], e.g., the drug may not be represented as safe or effective for the purposes for which it is under investigation, nor may it be commercially distributed or sold.
5. 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>PD</td>
<td><a href="mailto:medirbc@koyusa.com">medirbc@koyusa.com</a></td>
<td>Incomplete</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](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](#).
6. HIPAA Background

If the central IRB is responsible for HIPAA review requirements, skip this section.

If your protocol involves Protected Health Information (PHI) you must include one or more of the following unless your consent form(s) contain embedded HIPAA language. In cases where HIPAA language is included in the consent(s), you may still need to include a Limited Waiver of Authorization.

- **HIPAA Authorization** (Click HERE for HIPAA Authorization template)
- **Waiver of Authorization (e.g., retrospective chart reviews)**
- **Waiver of Authorization for Recruitment (e.g., telephone screens that include questions eliciting PHI, chart reviews to determine eligibility)**
- **Alteration of Authorization allow for a waiver of the signature requirement for HIPAA authorization (e.g. for studies conducted over the telephone or by mail)**

**Instructions**
- Click ADD to enter detailed information on one of the above categories, and attach relevant documents. Once entered and saved, a row will be displayed in tabular form for each item (HIPAA Authorization, Waiver of Authorization, etc.) entered.
- To view/modify the details of previously entered information or to replace a document with an updated version, click the link in the HIPAA Information Type column for the desired item.
- To view the current authorization document, click the link in the Title column for the desired item.
- To remove an item, check the box next to the Title and click DELETE.

**HIPAA Background**

Please click on 'Add' to add HIPAA Background

**Authorization**

**HIPAA Information Type:**

**Title:**

**Authorization (file name):**

Choose File

No file chosen

Save
a) Describe the protected health information (PHI) needed to conduct screening or recruitment. PHI is health information linked to one or more of the HIPAA identifiers. 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.

b) Please Answer:
- Yes  No  Do you certify that the use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals?
- Yes  No  Do you certify that the research could not practically be conducted with out the waiver?
- Yes  No  Do you certify that you have adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted?
- Yes  No  Do you certify that the research could not practically be conducted with out access to and use of the protected health information?

c) Please describe an adequate plan to protect any identifiers from improper use and disclosure.

d) Please describe an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.
Waiver of Authorization for Recruitment

HIPAA Information Type: * Waiver of Authorization for Recruitment
Title: *

a) Describe the Protected Health Information (PHI) needed to conduct the research. PHI is health information linked to HIPAA identifiers. 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.

b) Please Answer:
   - Yes  No  Do you certify that the use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals?
   - Yes  No  Do you certify that the research could not practically be conducted with out the waiver?
   - Yes  No  Do you certify that you have adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted?
   - Yes  No  Do you certify that the research could not practically be conducted without access to and use of the protected health information?

c) Please describe an adequate plan to protect any identifiers from improper use and disclosure.

d) Please describe an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.
HIPAA Background

Alteration of Authorization

HIPAA Information Type:* Alteration of Authorization
Title:*

Attachment (optional) 

Choose File  No file chosen

a) Describe the protected health information (PHI) needed to conduct screening or recruitment. PHI is health information linked to one or more of the HIPAA identifiers. 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.

b) Please Answer:

- Yes  No  Do you certify that the use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals?
- Yes  No  Do you certify that the research could not practically be conducted with out the waiver?
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d) Please describe an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.
7. Attachments

NOTE: Upload the following (as applicable):

- 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

Attachments

Type: Please Select
Title: *
Attachment (File Name): Choose File

Please click on ‘Add’ to attach documents
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 single IRB, i.e. modifications, continuing reviews, adverse events, protocol deviations, other reportable events, and any other information as required by the single IRB.
- 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 single 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 single IRB 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://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.