System Requirements:

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

Before you begin:

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

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

What to expect:

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

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

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

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

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

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

**Application Category/Type**

<table>
<thead>
<tr>
<th>Select Application Category</th>
<th>Medical</th>
<th>Non-Medical</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></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@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

Form Type:
Select a Form Type below to create the eProtocol application for IRB review. Learn more about different review types or contact IRB@education@stanford.edu or (650) 723-7141 if you have questions.

- Regular
- Expedited
- Exempt
- HSR Determination Form

For greater than minimal risk studies
For minimal risk studies meeting specific criteria
Studies meeting specific criteria
Projects that don’t clearly qualify as human subjects research. Include the HSR Determination form in your submission.
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 IRB to determine if it qualifies for exempt status. All protocols must meet Stanford IRPP ethical standards governing the conduct of research.

Exempt status WILL NOT be granted when research:

- involves prisoners as participants
- involves children in category 2 below EXCEPT for the observation of public behavior when the researcher does not participate in the activity being observed
- involves significant physical invasions or intrusions upon the privacy of the participants

Review your exempt category selection(s) below. Make changes as applicable.

☐ 1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
   i) research on regular and special education instructional strategies; or
   ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

☐ 2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior UNLESS:
   i) information obtained is recorded, such that human subjects can be identified directly or through identifiers linked to the subjects;
   AND
   ii) any disclosure of the human subjects’ responses outside the research could reasonably place subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation.

☐ 3. Research involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is NOT exempt under 2 above, if:
   i) the human subjects are elected or appointed public officials or candidates for public office; or
   ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

☐ 4. Research, involving the collection or study of existing data, documents, or records, if these sources are publicly available OR if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

YES NO

☐ Are the data, documents, or records pre-existing (on the shelf as of today)? If no, you do NOT qualify for Exempt Category 4.

Note: Information must be recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.

Provide the dates these data were collected (use mm/dd/yyyy to mm/dd/yyyy). Indicate where the data came from (e.g., public records, data collected for a non-research purpose, previous study records, teacher’s personal records, registrar’s office).
5. Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:
   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 procedures; or
   iv) possible changes in methods or levels of payment for benefits or services 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.

7. Benign Behavioral Interventions (Stanford Exempt Category 7): Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection.
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.
### 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>Mail Code</td>
<td></td>
</tr>
<tr>
<td>Select Department</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**CITI Training current**

- Yes
- No

### Other Contact

**PERSONNEL LOOKUP**

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

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

**CITI Training current**

- Yes
- No

### Academic Sponsor

**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>
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<td>Fax</td>
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<td>Department</td>
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<tr>
<td>Select Department</td>
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</tr>
</tbody>
</table>

### Other Personnel

- Click here to add Other Personnel

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

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

**Instructions:**

Select all populations (and only those) that are specifically targeted for this study. You must select at least one category.

For example:

- A researcher is conducting an internet survey asking about emotional responses to certain scenarios. Students may respond, but the study is not designed to recruit students specifically, so students would not be selected on the checklist.

**Participant Population(s) Checklist**

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
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<tr>
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<td>☑</td>
</tr>
</tbody>
</table>
| ☐   | ☑  | Students /
| ☑   | ☐  | Stanford students  ☐ Other students |
| ☐   | ☑  | Employees |
| ☐   | ☑  | Other (i.e., any population that is not specified above) |
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 that takes place in a high school where surveys are collected and then analyzed at Stanford would require both Stanford and Other to be selected.

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

**Study Location(s) Checklist**

- Stanford University
- Other (Click ADD to specify details)
Choose one. For multiple sites, add each individually.

**Other Location**

- **Within the US**
  - Location Name:

- **Outside the US/International**
  - Country:

**Note:** You are responsible for ascertaining if local permission is needed for doing research in the proposed site (e.g., in the case of schools, workplaces, tribal settings). If permission is required, you must obtain it before beginning the research.

**Instructions:**

- If you answer YES to *Collaborating Institution*, click the ADD button to enter the name of each institution.
- To remove an institution, check the box next to the name, and click DELETE.
- To view/modify previously entered institutions, click the institution name.

**General Checklist**

1. **Collaborating Institution(s)**
   - **Yes No**
     - Generally, when one or more institutions work together equally on a research endeavor, it is a collaboration.
     - Are there any collaborating institutions?

2. **Payment or Reimbursement**
   - **Yes No**
     - Subjects will be paid/reimbursed for participation? See payment considerations.

3. **Funding**
   - **Yes No**
     - Training 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.

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., Undergraduate Funding)
Please click on 'Add' to add Other Funding
Instructions:
Remember to attach a copy of each applicable federal grant application, including competing renewals, in the Attachments section of this protocol application form.

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

**Funding - Grants/Contracts**

Funding Administered By: STANFORD

Search SPO Information by Principal Investigator or SPO Number

- Principal Investigator: [Field]
- SPO # (if available): [Field]
  (e.g. 123456)
- SPO # Pending

Grant # (if available): [Field]
Funded By (include pending) *
Grant/Contract Title if different from Protocol Title: [Field]

- Yes
- No
For Federal projects, are contents of this protocol consistent with the Federal proposal application?
### 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 consistent with the Federal proposal application?

### Gift Funding

- **Name of Donor**: 

### Dept. Funding

- **Department Name**: 

### Other Funding (e.g., Undergraduate funding)

- **Other Fund Name**: 

Resources

a. Qualified staff
   State your and/or your study staff's qualifications to conduct this study.

b. Training
   Describe the training you have received regarding the research-related duties and functions of this protocol. Also, describe the training received by study staff assisting you with the research.

c. Facilities
   Describe where the study will take place, including where data will be collected and where it will be analyzed.

d. Time
   How much time will be needed to conduct and complete the research?

e. Participant access
   Will you have access to a population that will allow recruitment of the required number of participants?

f. Access to resources
   Will you have access to psychological resources that participants might need as a consequence of participating in the research? If yes, describe these resources. Enter N/A if the need for psychological resources is not anticipated.
Title
Non Med Exempt

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 IRB to determine if it qualifies for exempt status. All protocols must meet Stanford HRPP ethical standards governing the conduct of research.

Exempt status WILL NOT be granted when research:
- involves prisoners as participants
- involves children in category 2 below EXCEPT for the observation of public behavior when the researcher does not participate in the activity being observed
- involves significant physical invasions or intrusions upon the privacy of the participants

Review your exempt category selection(s) below. Make changes as applicable.

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   - research on regular and special education instructional strategies; or
   - research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior UNLESS:
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   - any disclosure of the human subjects' responses outside the research could reasonably place subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

3. Research involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is NOT exempt under 2 above, if:
   - the human subjects are elected or appointed public officials or candidates for public office; or
   - federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. Research, involving the collection or study of existing data, documents, or records, if these sources are publicly available OR if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

YES NO
- Are the data, documents, or records pre-existing (on the shelf as of today)? If no, you do NOT qualify for Exempt Category 4.

Note: Information must be recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.

Provide the dates these data were collected (use mm/dd/yyyy to mm/dd/yyyy). Indicate where the data came from (e.g., public records, data collected for a non-research purpose, previous study records, teacher's personal records, registrar's office).
5. Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:
   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 procedures; or
   iv) possible changes in methods or levels of payment for benefits or services 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.

7. Benign Behavioral Interventions (Stanford Exempt Category 7): Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection.
Complete Sections 1-11. Specify N/A or 'none' as appropriate. Do not leave any required sections blank.

1. Purpose

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

   b) State what you hope to learn from the study and assess the importance of this new knowledge. 

2. Study Procedures

   a) Describe ALL the procedures human participants will undergo. Are the research procedures the least risky that can be performed consistent with sound research design? 

   b) State if audio or video recording will occur. Describe how the recordings will be used, e.g., shown at scientific meetings, used for transcription. Describe the final disposition of the recordings, e.g., erased, stored. 

   c) DECEPTION: Will participants be fully informed about the purpose of the study? If no: provide a rationale for deception. 

3. Reserved for future use
4. Participant Population

a) How many participants do you expect to enroll? What type of participants will you enroll (e.g., high school students, teachers, government officials)?

b) What are the age range, gender, and racial or ethnic background of the participant population being targeted?

c) If applicable, explain why potentially vulnerable participants are needed (e.g., children, pregnant women, students, economically or educationally disadvantaged, homeless, people with impaired decision making capacity).

d) Reserved for future use


f) How will you recruit participants (e.g., ads, classroom recruitment, word of mouth, letters mailed home, email)? Attach recruitment materials in the Attachments section. YOU MAY NOT CONTACT POTENTIAL PARTICIPANTS PRIOR TO IRB NOTICE OF EXEMPTION. ALL FINAL OR REVISED RECRUITMENT MATERIALS, FLYERS, ETC. MUST BE SUBMITTED TO THE IRB FOR REVIEW AND APPROVAL BEFORE USE.
4. Participant Population

   g) PAYMENT or REIMBURSEMENT. Will participants be paid or reimbursed for participation? If yes, how much, and explain why proposed payments/reimbursements are reasonable. Explain how payment will be prorated, if there is more than one study session. See payment considerations.

   h) Explain what costs will be incurred by the participant. If none, enter 'none'.

   i) What is the total time that each participant will spend in the entire study (e.g., 20 minutes, 2 hours, 3 days)?
5. Risks

a) Describe any reasonably anticipated potential risks(s), including risk(s) to physical, psychological, political, economic or social well-being. If risks are not reasonably anticipated, enter ‘none’.

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

c) Reserved for future use

""

d) Children's Findings (OHRP)

Select the category below that best describes your research, if children are involved.

- 46.404 Research not involving greater than minimal risk. 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 permission of their parents or guardians.

- 46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit... (regular review only)

- 46.406 Research involving greater than minimal risk and no prospect of direct benefit...(regular review only)

- 46.407 Research not otherwise approvable...(regular review only)

Rationale:
6. Benefits

a) Describe the potential benefit(s) to be gained by the participants and/or by society as a result of this study. If none, enter 'none.'

7. Privacy and Confidentiality

Privacy

Privacy refers to the environment in which data are collected from participants (e.g., interviewing participants individually in a place where personal responses will not be seen or overheard).

a) Explain where the research takes place (e.g., in a lab, online, at school). Describe how you will maintain privacy in this setting.

Confidentiality

Confidentiality refers to your agreement with the participant about how the participant's identifiable personal information (i.e., identifiable data) will be handled, managed, stored, and disseminated.

b) What identifiable data will you obtain from participants? Enter 'none' if identifiable data will not be obtained. Discuss how you will protect the participants' identity, if applicable.
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://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.
9. Participant Information

If you are using a document (e.g., information sheet, oral script, consent, assent, or other document) that discusses the participant’s involvement in your research, attach under “Participant Information” by clicking on the ADD button below and then selecting the appropriate option in the drop-down menu.

a) Describe the process you will use to inform participants about your study. Include the following:
Who will obtain consent? When and how will this be done?

Instructions:

- Click ADD to enter relevant document(s). Once entered and saved, a row will be displayed in tabular form for each item entered.
- To view/modify the details of previously entered information or to replace a document with an updated version, click the link in the Document Type column for the desired item.
- To view the current document, click the link in the Title column for the desired item.
- To remove an item, click the box next to the Title and DELETE.

Participant Information

Please click on 'Add' to add Participant Information

---

Document Type *

- Information Sheet
- Oral Script
- Other Document
Protocol Application Form

Protocol ID: 41679 (Ratan Banik)
Title: Exempt Nonmedical

Non-Medical

10. Reserved for future use

11. Attachments

Click ADD to attach relevant study documents to this section (e.g., surveys, questionnaires, federal grants). All final or revised recruitment materials, flyers, questionnaires, surveys, etc. must be submitted to the IRB for review and approval before use.

Add

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

- Advertisements
- Cooperating Institution(s) Approval
- Federal Grant(s)
- Questionnaires
- Training Grant/List
- Academic Sponsor Oversight/Scientific Review
- Scientific and Scholarly Review
- 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 IRB
- Be appropriately qualified to conduct the research and be trained in Human Research protection ethical principles, regulations, policies and procedures
- Ensure all 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
- Apply relevant professional standards.

Any change in the research protocol must be re-submitted to the iRB for review to re-certify exemption. Any complications in subjects or evidence of increase in the original estimate of risk should be reported to the 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 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](http://doresearch.stanford.edu/policies/research-policy-handbook/conduct-research/retention-and-access-research-data))

☐ By checking this box, 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.