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

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.

- **Regular**
  - For greater than minimal risk studies
- **Expedited**
  - For minimal risk studies meeting specific criteria
  - Studies meeting specific criteria
- **Exempt**
  - Projects that don't clearly qualify as human subjects research. Include the HSR Determination form in your submission.
- **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.
Federal regulations state that certain research is exempt from IRB review. However, under Stanford's Human Research Protection Program (HRPP), 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, EXCEPT for research aimed at involving a broader subject population that only incidentally includes prisoners
- involves children in category 1, EXCEPT for educational tests or the observation of behavior when the investigator does not participate in the activities being observed
- involves children in category 2, EXCEPT for educational tests or the observation of public behavior when the investigator does not participate in the activities being observed under paragraphs (2)(i) and (ii); paragraph (2)(iii) may not be applied to children
- involves children in category 3

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:

Select one or more of the following paragraphs.

1. Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods

2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:
   - i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
   - ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
   - iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § .111(a)(7)

3(i). 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 and at least one of the following criteria is met: See §3(iii) below for more on the definition of a benign behavioral intervention.
   - A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
   - B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
   - C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § .111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

YES NO

- Is deception involved?

4. Secondary research for which consent is not required: Secondary research uses of identifiable private
information or identifiable biospecimens, if at least one of the following criteria is met:

- i) The identifiable private information or identifiable biospecimens are publicly available;
- ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
- iii) Reserved for future use;
- iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

   - (i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.
   - (ii) [Reserved]

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. Reserved for future use.

8. Reserved for future use.
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.

Start  Cancel

For all Cancer-related studies, see the submission instructions on the Cancer Clinical Trials website at [http://med.stanford.edu/ccco.html](http://med.stanford.edu/ccco.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/srcotop.html](http://cancer.stanford.edu/trials/srcotop.html) for more information.

Ok
Other Location

Note: * denotes mandatory field.

Location

Location / Country *

Contact Name

Contact Phone

Contact Email

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

Is the site engaged in human subjects research? If yes, attach the site’s IRB approval letter in Attachments Section  
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?

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.

3. Cancer Institute

Cancer-Related Studies (studies with cancer endpoints). Cancer Subjects (e.g., clinical trials, prevention/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 checklist on the Cancer Clinical Trials website at http://med.stanford.edu/cancer_clinical_trials 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/clinical_trials/approval.htm for more information.

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://vcais.stanford.edu/vcais)

Human Embryos or Gametes?

5. Veteran Affairs (VA)

The research involves 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 a VA employee (VA-paid or VA-funded) in a VA facility or on 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 initiated. Please contact the Research Development office at the Palo Alto VA at 650-495-5000 ext. 59118.

6. Payment

Subjects will be paid or reimbursed for participation (See payment considerations).

7. Funding

Training Grant?

Program Project Grant?

Federally Sponsored Project?

Lead Site

Note: • denotes mandatory field.

Site Name *

Contact Name

Contact Phone

Contact Email

Has the location granted permission for the research to be conducted? •

Is the site engaged in human subjects research? If yes, attach the site’s IRB approval letter in Attachments Section

Save Cancel
Funding - Grants/Contracts

Note: * denotes mandatory field.

Instructions:

If this is a Multiple Project Protocol (MPP), attach a listing of all protocols funded under this MPP in the Attachments section. Include the eProtocol number, PD, and initial approval date.

Funding Administered By
Stanford

Search SPO Information by Principal Investigator or SPO Number

Principal Investigator

- SPO # (if available)
- SPO # Pending

(e.g. 123456)

Grant # (if available)

Funded By (include pending)

Grant/Contract Title if different from Protocol Title

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

**Note:** * denotes mandatory field.

Funding administered by
STANFORD

Search SPO Information by Principal Investigator or SPO Number

Name of Fellow *

- SPO # (if available)
- SPO # Pending
- N/A

(e.g. 123456)

Fellowship Reference # (if available)

Funded By

Fellowship Title if different from Protocol Title

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

Gift Funding

**Note:** * denotes mandatory field.

Name of Donor *

Dept. Funding

**Note:** * denotes mandatory field.

Department Name *

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

**Note:** * denotes mandatory field.

Other Fund Name *
Please demonstrate that you have adequate resources to conduct the project.

1. **Qualified staff.**
   - Please state and justify the number and qualifications of your study staff.

2. **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.

3. **Facilities.**
   - Please describe and justify.

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

5. **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.

6. **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.

7. **Lead Investigator or Coordinating Institution in Multi-site Study.**
   - Please explain (a) your role in coordinating the studies, (b) procedures for routine communication with other sites, (c) documentation of routine communications with other sites, (d) planned management of communication of adverse outcomes, and unexpected problems involving risk to participants or others, (e) protocol modifications or interim findings.
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:

1. Research conducted in established or commonly accepted educational settings, that specifically involves minimal educational practices that are not likely to adversely impact students to adequately learn required educational content or the assessment of educational performance of students through educational assessments and does not use research methods that are inconsistent with psychological principles, informed consent, or norms of ethical practice.

2. Research that only involves educational testing (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording).

3. Research involving the use of existing educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) as long as:
   a) The information obtained is to be used in a non-identifying manner.
   b) The information obtained is recorded by the investigator in such a manner that the identity of the subjects cannot be readily ascertained, directly or through identifiers linked to the subjects.
   c) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot be readily ascertained, directly or through identifiers linked to the subjects, and the IRB has determined that the method of collecting data does not pose significant risk of harm to the subjects.

4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:
   a) The information, which includes information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot be readily ascertained, directly or through identifiers linked to the subjects, and the investigator does not contact the subjects, and the investigator will not re-identify subjects.
   b) The research is conducted by or on behalf of a Federal department or agency, or on the approval of or on other subordinate agencies that have been delegated authority to conduct the research and demonstration projects, and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or services, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or subcontracts, cooperative agreements, or grants. Exemption projects also include agencies that are covered by the Federal Data Collection and Reporting Act, 44 U.S.C. 3501 et seq.
   c) The research is conducted by or on behalf of a Federal department or agency, or on the approval of or on other subordinate agencies that have been delegated authority to conduct the research and demonstration projects, and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or services, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or subcontracts, cooperative agreements, or grants. Exemption projects also include agencies that are covered by the Federal Data Collection and Reporting Act, 44 U.S.C. 3501 et seq.

5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of the department or agency head or the approval of an other subordinate agencies that have been delegated authority to conduct the research and demonstration projects, and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or services, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or subcontracts, cooperative agreements, or grants. Exemption projects also include agencies that are covered by the Federal Data Collection and Reporting Act, 44 U.S.C. 3501 et seq.

6. Taste and food quality evaluation and consumer acceptance studies:
   a) If food or food products without additives are consumed, or
   b) If a food or food product contains a label ingredient or below the level and if it is not found to be toxic, carcinogenic, or otherwise harmful or detrimental to health, and if the label contains a statement that it is safe to eat, 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. Reserved for future use.

8. Reserved for future use.
Purpose:

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

- b) State what the investigators 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)

Study Procedures:

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

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

- c) State the description will be used. If no, provide the rationale and describe if defining procedures. These will require not 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). If data of 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.

Background:

- a) Describe past findings leading to the formulation of the study.

Participant Population:

- a) State the following: (i) the number of participants expected to be recruited 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 enrolling 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, dually diagnosed, homeless, people, and students). Specify the measures being taken to minimize the risks and the chance of harm to the potentially vulnerable subject 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 actually learn about the research. E.g., clinic advertising. Attach recruitment materials to Section 11 (Attachments). You must contact potential participants prior to IRB approval. See guidance Advertisements, Appropriate Language for Recruitment Material.
Participant Population:

- 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/reimbursement. Explain the amount and schedule of payment or reimbursement, 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 under pressure on participants to volunteer for the research study. Include provisions for providing payment. See payment considerations.

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

- Estimate the probable duration of the entire study. Also estimate the total time per participant for: (a) screening of participant; (b) active participation in study; (c) analysis of participant data.

Risks:

- Describe risks. Include risks to privacy, confidentiality, etc.

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

- 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?
Protocol Information / Privacy and Confidentiality

1. Benefits
   a. Describe the potential benefits to be gained by the participants or by the acquisition of important knowledge which may benefit future participants, etc.

Privacy and Confidentiality

All medical research must comply with the Health Insurance Portability and Accountability Act (HIPAA) regulations if it involves 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 subunits 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, according to the current publicly available data from the Bureau of the Census.
5. All geographic units at the same level as the initial three digits of a zip code.
6. 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 18 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 80 or older
7. Driver’s license or other similar identification numbers
8. Medical device identifiers
9. Medical record numbers
10. Access accounts
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers, including license plate numbers
13. Device identifiers and serial numbers
14. Health care claims numbers
15. Internet Protocol (IP) address numbers
16. Internet identifiers, including IP and domain names
17. Voice numbers
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 USN)

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 listed in 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 cabinets and offices), and (iii) who will have access to the data (e.g., research team, sponsors, consultants)

If you will be sharing data with others, describe how data will be transferred (e.g., courier, mail or transmitted (e.g., via 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/personal_computing/].

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.

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., unconscious of oral and written communications, maintaining paper and electronic data)?
Potential Conflict of Interest

In accordance with the institutional requirements, all investigators are expected to disclose any financial interests that reasonably appear to be related to this protocol.

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

<table>
<thead>
<tr>
<th>Investigators</th>
<th>Role</th>
<th>Email</th>
<th>Has Financial Interest?</th>
<th>Date Financial Interest Answered</th>
<th>Date OFACS Disclosure Submitted?</th>
<th>Date OFACS Review Complete?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ratey Beck</td>
<td>PI</td>
<td><a href="mailto:ratey@stanford.com">ratey@stanford.com</a></td>
<td>incomplete</td>
<td>incomplete</td>
<td>incomplete</td>
<td>Pending</td>
</tr>
</tbody>
</table>

INSTRUCTIONS FOR ADMIN CONTACT

- Please review the page to view and accept financial interest information.
- Users submitting protocols should review the information section.
- Incomplete tasks must be completed by the investigators. Forward instructions below.

To disclose financial interests for this protocol:

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

Issues? Please submit an OPACS Helpdesk ticket.
Consent

Consent Information Type: *

Consent

Title: *

Sponsor's Consent Version Number: (if any)

Consent Form (file name): * Browse... No file selected.

☐ Check if VA related

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.
Assent Background

**Note**: • denotes mandatory field.

**Assent Information Type**: • Assent

**Title**: *

**Sponsors Assent Version Nbr**: (if any)

**Assent Form (file name)**: • Browse... No file selected.

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
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.

- "Select..." to select documents (e.g., research protocol contract, amendments, 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.

**Note:** * denotes mandatory field.

- **Document Type**
  --Please Select--

- **Title**

- **Attachment (File Name)**
  [Browse...]
  No file selected.
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 Protections, ethical principles, regulations, policies, and procedures.
- Ensure all Stanford research personnel are adequately trained and supervised.
- Ensure that the rights and welfare of all 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 pose risks to participants or others.
- Apply relevant professional standards.

Any change in the research protocol must be submitted to the IRB for review prior to the implementation of such change. Any complications in participants or evidence of increase in the original estimate of risk should be reported at once to the IRB before continuing with the project.Researcher's checklist: 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 or event 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 to restructure the project to the IRB for review and re-approval prior to the end of the approval period. A Notice to Amend Protocol(s) sent to the Protocol Director 2 weeks prior to the expiration date of the protocol.

Department Chair must approve funding and all research that is not part of a sponsored project. All applicants must have IRB Reviewer/Staff Assistant approval.

E-mail the Department Chair approval to IRB Coordinator, irb@stanford.edu.

All data including signed consent forms must be retained for a minimum of three years post the completion of the research. Additional requirements may be imposed by your funding agency, your department, or other entities. Please refer to the Research Data, Research Policy Handbook, http://research.stanford.edu/policies/research-policy-handbook.

Please note: List all items (revised) that you want to be reflected in your approval letter (e.g., Amendment, Investigator’s Brochure, consent forms, advertisement, etc.) in the box below. Include number and date when applicable.

☐ 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.