Study Title

System Requirements:

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

Before you begin:

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

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

What to expect:

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

Instructions:

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

Protocol Director *

PERSONNEL LOOKUP

Name *
Email *
Department
Select Department

Degree (Program/Year if student) *
Position, e.g. Assistant Professor, Resident, etc. *

Fax

Mail Code

CITI Training current: Yes No

Admin Contact *

PERSONNEL LOOKUP

Name *
Email *
Department
Select Department

Degree (Program/Year if student) *
Position, e.g. Assistant Professor, Resident, etc. *

Fax

Mail Code

CITI Training current: Yes No

Investigator

PERSONNEL LOOKUP

Name *
Email *
Department
Select Department

Degree (Program/Year if student) *
Position, e.g. Assistant Professor, Resident, etc. *

Fax

Mail Code

CITI Training current: Yes No

Other Contact

PERSONNEL LOOKUP

Name *
Email *
Department
Select Department

Degree (Program/Year if student) *
Position, e.g. Assistant Professor, Resident, etc. *

Fax

Mail Code

CITI Training current: Yes No
Once all personnel have been entered and saved, click here to start the DMAPS process.

Protocol Director

Search

INSTRUCTIONS: Search by Last Name, First Name (e.g., Smith, John) or by ID/ID.

Name

Rank

Phone

Fax

Department

Mail Code

CIT Training status

Admin Contact

Search

INSTRUCTIONS: Search by Last Name, First Name (e.g., Smith, John) or by ID/ID.

Name

Rank

Phone

Fax

Department

Mail Code

CIT Training status

Investigator

Search

INSTRUCTIONS: Search by Last Name, First Name (e.g., Smith, John) or by ID/ID.

Name

Position, e.g. Assistant Professor, Resident, etc.

Phone

Fax

Department

Mail Code

CIT Training status

Other Contact

Search

INSTRUCTIONS: Search by Last Name, First Name (e.g., Smith, John) or by ID/ID.

Name

Position, e.g. Assistant Professor, Resident, etc.

Phone

Fax

Department

Mail Code

CIT Training status

Academic Sponsor

Search

INSTRUCTIONS: Search by Last Name, First Name (e.g., Smith, John) or by ID/ID.

Name

Position, e.g. Assistant Professor, Resident, etc.

Phone

Fax

Department

Mail Code

CIT Training status

Other Personnel (Click here to add Other Personnel)

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

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 a 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, Post-Doc), you must also enter an Administrative Sponsor. Students entered as an Administrative Sponsor will be listed in categories 1 and 2 of Administrative Guide 23.
- Only those entered in the following roles will have access to the Protocol application: PD, Admin Contact, Investigator, and Other Contact.
- Click the link in the Other Personnel section towards the bottom of the page to enter additional personnel (including personnel without Subjects). All users must take CIT Training. If your training information is highlighted, it will be verified by ISD staff.
- You can check here to review completion records to ensure training has been completed.
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/cccto.html](http://med.stanford.edu/cccto.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.

Ok
Choose one. For multiple sites, add each individually.

Within the US

Location Name •

OR

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.
**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, PO, 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 *

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

Note: * denotes mandatory field.

Other Fund Name *

Stanford University | eProtocol

Non-Medical Exempt  Protocol ID: 30123  (Vahan Bakh)  Protocol Title: Exempt Non-Medical

Resources

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

2. 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.

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

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

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

6. 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.
Protocol Information: Exempt Non-Medical

In order for a proposal to be considered exempt, a protocol must not be 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 normal educational practices that are not likely to adversely impact students’ opportunity to learn required educational content or the assessment of educational programs who provide education. This includes research on regular and special educational instructional strategies, and research on the effectiveness of the programs among instructional techniques, curricula, or classroom management methods.

2. Research that only includes intrusions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behaviors (including visual or auditory recording) if at least one of the following criteria is met:
   - 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 a risk of criminal or civil liability or be damaging to the subjects financial standing, employability, educational advancement, or reputation;
   - c. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can be readily ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determinations required by § 511(f)(7)

3. Research involving behavioral interventions in connection with the collection of information from an adult subject through verbal or written responses (including data entry) or audio/visual recording if the subject prospectively agrees to the assessment and information collection and at least one of the following criteria is met:
   - 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 a risk of criminal or civil liability or be damaging to the subjects financial standing, employability, educational advancement, or reputation;
   - c. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can be readily ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determinations required by § 511(f)(7)

4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biopspecimens, if at least one of the following criteria is met:
   - a. The identifiable private information or identifiable biopspecimens are publicly available;
   - b. The information, which may include information about biopspecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
   - c. Reserved for future use
   - d. 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 to be maintained in an information technology system that is subject to and in compliance with section 200(a) of the E-Government Act of 2002, 44 U.S.C. 3504, or, 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 under 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 the department or agency head (or the approval of the head of a subunit subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise enhance 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 consultant arrangements, cooperative agreements, or grants. Exempt projects also include evidence of alternative regulatory requirements using authorities such as section 111(d) and 475A of the Food and Drug

6. Taste and food quality evaluation and consumer acceptance studies:
   - If wholesome foods without additives are consumed, or
   - If a food is consumed that contains a food ingredient at or below the level for use as a fabric, 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
Purpose

d) 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.

Study/Procedures

a) Describe ALL the procedures that 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) Uses of the study involve deception? Exemplify: Occurs when information about the study is oversimplified without consent, or when subjects are intentionally misled about the study. If this study involves deception:

(d) Explain and justify the deception
(e) Explain the debriefing procedure (ensure a debriefing document is attached to the protocol) OR explain why debriefing would not be appropriate

Reserved for future use
Protocol Information / Participant Population(s)

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 capacities)

d) Reserved for future use

e) Are any participants for your students, laboratory personnel and/or employees? See Stanford University policy at http://ohsresearch.ohsresearchpolicy.ohsresearchpolicy, subjects and human subjects research, employees, or laboratory.

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 THE NOTICE OF LIMITATION. ALL FINAL OR REVISED RECRUITMENT MATERIALS, FLYERS, ETC. MUST BE SUBMITTED TO THE IRB FOR REVIEW AND APPROVAL BEFORE USE.

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 processed, 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)?
Risks

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

2) If you are conducting research outside the US (international research), describe qualifications/preparations that enable you to both estimate and minimize risks to participants. Please review the Listing of Social-Behavioral Research Standards, to ensure that your research complies with all applicable standards. Then complete the 'International Research Form' and attach it in the Attachments section. If not applicable, enter 'NA'.

3) Will you be working with any Political Action Committees or other political organizations that are involved in partisan activities? If yes, describe below. See Annex Guide 1.5.1 for restrictions on doing research involving partisan organizations.

Children's Informed Consent (EHW)

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

- 46.456 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 consent of the child or permission of their parents or guardians.
- 46.459 Research involving greater than minimal risk but presenting the prospect of direct benefit: (regular review only)
- 46.460 Research involving greater than minimal risk and no prospect of direct benefit: (regular review only)
- 46.457 Research not otherwise approvable: (regular review only)

Reason:

Benefits

- 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'.

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 inquiries will not be overheard).

- 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.

- 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.
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 email.]

**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 OFACCS Disclosure Submitted?</th>
<th>Date OFACCS Review Completed?</th>
</tr>
</thead>
<tbody>
<tr>
<td>[Name]</td>
<td>[Role]</td>
<td>[Email]</td>
<td>[Yes/No]</td>
<td>[Date]</td>
<td>[Date]</td>
<td>[Date]</td>
</tr>
</tbody>
</table>

**INSTRUCTIONS FOR ADMIN CONTACT**

1. Present interest in a page or non-understood financial interest information.
3. Use completed tasks that must be completed by the investigator. Forward instructions below.

To disclose financial interest for this protocol:

1. Log on to your dashboard at [Dashboard Link].
2. Click the red "enter expression" button for this protocol.
3. If you enter "yes," you will need to disclose related financial interests.

Instructions? Please submit an OFACCS module ticket.

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**Participant Information**

If you are using a document (e.g., information sheet, oral script, consent, assent, or other document) that discusses a participant's role 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.

- **Describe the process you will use to inform participants about your study:** Include the following: Who will obtain consent? When and how will it be done?

**Please click on "Add" to add Participant Information**

---

**Participant Information**

**Note:** • denotes mandatory field.

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

- Data, audio recordings, images, computerized systems, questionnaires, informed consent, investigator's brochure, etc.
- To view an attachment, 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.
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 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, modifications, or unexpected 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 increased 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://research.stanford.edu/policies/research-policy-handbook/ethical-research/protection-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.