

Protocol Title

Personnel Information

Protocol Director

Name:
Degree:
Title:
Email:
Phone:
Department:
Mail Code:

Yes No
 CITI Subjects tutorial completed?

Administrative Contact

Name:
Degree:
Title:
Email:
Phone:
Department:
Mail Code:

Yes No
 CITI Subjects tutorial completed?

Co-Protocol Director

Name:
Degree:
Title:
Email:
Phone:
Department:
Mail Code:

Yes No
 CITI Subjects tutorial completed?

Other Contact

Name:
Degree:
Title:
Email:
Phone:
Department:
Mail Code:

Yes No
 CITI Subjects tutorial completed?

Faculty Sponsor

Name:
Degree:
Title:
Email:
Phone:
Department:
Mail Code:

- Yes** **No**
 CITI Subjects tutorial completed?

Other Personnel:

Application Category/Type

Protocol Application Category:

Select **Medical** for investigators in:

- Lucille Packard Children’s Hospital (LPCH)
- Psychiatry & Behavioral Sciences
- School of Medicine
- Stanford Hospital and Clinics (SHC)
- Veteran’s Affairs (VA) Hospital

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

- Business
- Education
- Engineering
- Humanities
- Law
- Psychology (except MRI studies)

Protocol Application Review Type:

Learn more about [determining review type](#). If you are not certain which review type applies to your protocol, contact the IRB education specialist at (650) 724-7141 or IRBeducation@Stanford.edu. Different review types result in different application forms. Submitting an application with an incorrect review type may require you to enter and submit a new protocol application with the correct review type.

Select Protocol Category:

- Medical Non-Medical

Select Protocol Review Type:

- Regular Expedited Exempt

When Non-Medical and Exempt are selected above, then the following is displayed:

Exempt Paragraph(s)

Federal regulations state that certain research is exempt from review. However, under Stanford's Policy for the Protection of Human Subjects, a research protocol proposing the use of human subjects must be submitted to the Panel to determine if it qualifies for exempt status. EXEMPTIONS DO NOT APPLY TO RESEARCH CONDUCTED ON PRISONERS.

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

Select one or more of the following paragraphs:

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

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

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

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

Yes No Are the data and/or specimens pre-existing, i.e., "on the shelf", as of today?

Yes No Is it correct that no one (including the researcher) can identify a subject from any information recorded for this research?

Provide the dates (in format mm/dd/yyyy to mm/dd/yyyy) when these dates were collected. Provide information regarding who holds or owns the data, and who is allowed to access it.

- 5) Research conducted by or subject to the approval of Federal Department or Agency head, and designed to study or evaluate:**
 - i) public benefit or service programs;
 - ii) procedures for obtaining benefits or services under those programs;
 - iii) possible changes in or alternatives to those programs;
 - iv) or changes in methods of payment for benefits under those programs.

- 6) Taste and food quality evaluation involving wholesome/safe foods.**

Participant Population(s) Checklist

- | <u>Yes</u> | <u>No</u> | |
|-----------------------|-----------------------|--|
| <input type="radio"/> | <input type="radio"/> | Children (under 18) |
| <input type="radio"/> | <input type="radio"/> | Pregnant Women |
| <input type="radio"/> | <input type="radio"/> | Mentally Disabled |
| <input type="radio"/> | <input type="radio"/> | Decisionally Challenged |
| <input type="radio"/> | <input type="radio"/> | Cancer Subjects |
| <input type="radio"/> | <input type="radio"/> | Laboratory Personnel |
| <input type="radio"/> | <input type="radio"/> | Healthy Volunteers |
| <input type="radio"/> | <input type="radio"/> | Students |
| <input type="radio"/> | <input type="radio"/> | Employees |
| <input type="radio"/> | <input type="radio"/> | Prisoners |
| <input type="radio"/> | <input type="radio"/> | Other (i.e., any population that is not specified above) |

Study Location(s) Checklist

- Stanford University
- General Clinical Research Center (GCRC)
- Stanford Hospital and Clinics
- Lucile Packard Children's Hospital (LPCH)
- VA (Specify PI at VA) _____
- Other (Specify other study locations)

Location Name:

Contact Name:

Contact Phone:

Contact Email:

- | <u>Yes</u> | <u>No</u> | |
|-----------------------|-----------------------|---|
| <input type="radio"/> | <input type="radio"/> | Has the location granted permission for the research to be conducted? |
| <input type="radio"/> | <input type="radio"/> | Does the location have an IRB that will approve the research? |

General Checklist

- Yes** **No** **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?

(if NO checked above)

Lead Site Name:
Contact Name:
Contact Phone:
Contact Email:

Yes **No**

- Has the location granted permission for the research to be conducted?
- Does the location have an IRB that will approve the research?

(if YES checked above)

Participating Site Name:
Contact Name:
Contact Phone:
Contact Email:

Yes **No**

- Has the location granted permission for the research to be conducted?
- Does the location have an IRB that will approve the research?

- Yes** **No** **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.

Institution Name:
Contact Name:
Contact Phone:
Contact Email:

Yes **No**

- Has the location granted permission for the research to be conducted?
- Does the location have an IRB that will approve the research?

- Yes** **No** **Payment**
- Subjects will be paid for participation? See [payment considerations](#).

- Yes** **No** **Funding**
- Training Grant?
- Program Project Grant?
- Federally Sponsored Grant?
- Industry Sponsored Clinical Trial?

Funding Checklist

None

Grants/Contracts

Funding Administered by:

- STANFORD
- PAIRE
- VA
- Other

SPO# (if available): _____

Grant# (if available): _____

Funded by (include pending): _____

Principal Investigator: _____

Grant/Contract Title if different
from Protocol Title _____

Yes

No

For Federal project, are contents of this protocol the same as described in Federal proposal application?

Is this a Multiple Project Protocol (MPP)?

Is this protocol under an MPP?

Fellowships

Funding Administered by:

- STANFORD
- PAIRE
- VA
- Other

SPO# (if available): _____

Fellowship Reference#
(if available): _____

Funded by: _____

Name of Fellow: _____

Fellowship Title if different
from Protocol Title _____

Yes

No

For Federal projects, are contents of this protocol the same as described in Federal proposal application?

Other

Gifts

Name of Donor: _____

Account#: _____

Department

Department Name: _____

Account#: _____

Other (e.g. OTL, URO)

Other Fund Name: _____

Account#: _____

Resources

a. Qualified staff.

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

b. Training.

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

c. Facilities.

Please describe and justify.

d. Sufficient time.

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

e. Access to target population

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

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

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

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

Please explain (i) your role in coordinating the studies, (ii) procedures for routine communication with other sites, (iii) documentation of routine communications with other sites, (iv) planned management of communication of adverse outcomes, unexpected problems involving risk to participants or others, protocol modifications or interim findings.

Protocol Information

1. Purpose

- a) In layperson's language state the purpose of the study in 3-5 sentences.
- b) State what the Investigator(s) hope to learn from the study. Include an assessment of the importance of this new knowledge.

2. Study Procedures

- a) Describe all the procedures. 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 what will become of the recording after use, e.g., shown at scientific meetings, erased. Describe the final disposition of the recordings.
- c) State if deception will be used. If so, provide the rationale and describe debriefing procedures. Since you will not be fully informing the participant in your consent process and form, complete an alteration of consent (in section 9). Submit a debriefing script (in section 11).

3. Background

- a) Describe past experimental and/or clinical findings leading to the formulation of the study.

4. Subject Population

- a) State the following: (i) the number of participants expected to be enrolled at Stanford-affiliated site(s); (ii) the total number of participants expected to enroll at all sites; (iii) the type of participants (i.e. students, teachers, government officials) and the reasons for using such participants.
- b) State the age range, gender, and ethnic background of the participant population being recruited.
- c) State the number and rationale for involvement of potentially vulnerable subjects in the study (including children, pregnant women, economically and educationally disadvantaged, decisionally impaired, homeless people, employees and students). Specify the measures being taken to minimize the risks and the chance of harm to the potentially vulnerable subjects and the additional safeguards that have been included in the protocol to protect their rights and welfare.
- d) If women, minorities, or children are not included, a clear compelling rationale must be provided (e.g., disease does not occur in children, drug or device would interfere with normal growth and development, etc.).
- e) State the number, if any, of participants who are laboratory personnel, employees, and/or students. They should render the same written informed consent. If payment is allowed, they should also receive it. Please see Stanford University policy at <http://www.stanford.edu/dept/DoR/rph/7-5.html>.
- f) Describe how potential participants will be identified for recruitment (e.g., response to an ad, classroom recruitment, word of mouth, letters mailed home). Describe recruitment procedures. Attach recruitment materials in Section #11 (Attachments). You may not contact potential participants prior to IRB approval.
- g) Payment. Explain the amount and schedule of payment, if any, that will be paid for participation in the study. Substantiate that proposed payments are reasonable and commensurate with the expected contributions of participants and that they do not constitute undue pressure on participants to volunteer for the research study. Include provisions for prorating payment. See [payment considerations](#).
- h) Costs. Please explain any costs that will be charged to the participant.
- i) Estimate the probable duration of the entire study. Also estimate the total time per participant for: (i) screening of participant; (ii) active participation in study; (iii) analysis of participant data.

5. Risks

- a) For the following categories, describe the potential risk(s) and estimate their frequency, severity, and reversibility.
 - Physical well-being.
 - Psychological well-being.
 - Political.
 - Economic well-being.
 - Social well-being.
- b) In case of overseas research, describe qualifications/preparations that enable you to estimate and minimize risks to subjects.
- c) Describe the planned procedures for protecting against and minimizing all potential risks. Include the means for monitoring to detect hazards to the participant (and/or to a potential fetus if applicable). Include steps to minimize risks to the confidentiality of identifiable information.
- d) Discuss plans for ensuring necessary medical or professional intervention in the event of a distressed participant.

6. Benefits

Describe the potential benefit(s) to be gained by the subjects or by the acquisition of important knowledge which may benefit future subjects, etc.

7. Privacy and Confidentiality

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 individually identifiable data you will obtain, use or disclose to others.
- c) Describe: (i) how data will be maintained (e.g., paper or electronic spreadsheet, desktop computer, laptop or other portable device); (ii) how you will maintain the confidentiality and data security, (e.g., password protected computer, encrypted files, locked cabinet and office); and (iii) who will have access to the data (e.g., research team, sponsors, consultants)
- d) If you will be sharing data with others, describe how data will be transferred (e.g., courier, mail) or transmitted (e.g., file transfer software, file sharing, email). If transmitted via electronic networks, describe how you will secure the data while in transit. See <http://www.stanford.edu/group/security/securecomputing/iso-guidelines.html>.
- e) If you plan to code the data, describe the method in which it will be coded and indicate who will have access to the key to the code.
- f) How will you educate research staff to ensure they take appropriate measures to protect the privacy of participants and the confidentiality of data collected (e.g. conscious of oral and written communications, maintaining paper and electronic data)?

8. Potential Conflict of Interest

- a) Does anyone who:
- recruits, selects, consents, or treats participants
 - plans to analyze data
 - plans to serve as an author on any papers originating from this research
 - is an immediate family member (spouse, dependent child as defined by IRS, domestic partner) of any of the above
- Yes No have consulting arrangements, responsibilities or equity holdings in the Sponsoring company, vendor(s), provider(s) of goods, or subcontractor(s)?
- Yes No have a financial relationship with the Sponsoring company, vendor(s), provider(s) of goods, or subcontractor(s) including the receipt of honoraria, income, or stock/stock options as payment?
- Yes No serve as a member of an advisory board with the Sponsoring company, vendor(s), provider(s) of goods, or subcontractor(s)?
- Yes No receive any gift funds from the Sponsoring company, vendor(s), provider(s) of goods, or subcontractor(s)?
- Yes No have an ownership or royalty interest in any intellectual property utilized in this protocol?
- b) Yes No To your knowledge, does any one in a supervisory role to you have a conflict of interest related to this study?

If one or more of the above relationships exist, please include a statement in the consent form to disclose this relationship, i.e., a paid consultant, a paid member of the Scientific Advisory Board, has stock or stock options, or receives payment for lectures given on behalf of the sponsor (see sample consent form). The consent form should disclose what institution(s) or companies are involved in the study through funding, cooperative research, or by providing study drugs or equipment (see sample consent form).

If you answer yes to any of the questions above, you must file a Conflict of Interest (Col) disclosure. [See http://www.stanford.edu/dept/DoR/ad_hoc.html](http://www.stanford.edu/dept/DoR/ad_hoc.html) for more information. Contact Barbara Flynn at (650) 723-7226, or bflynn@stanford.edu.

- c) Yes No To your knowledge, does Stanford University have an ownership or royalty interest in any intellectual property utilized in this protocol?

9. Consent Background

See more information on [Informed Consent](#).

9.1 Consent

Consent Information Type: *Consent*

Title:

Sponsor's Consent Version Number:

Consent Form (file name):

- a) Describe the informed consent process. Include the following:
 - Who is obtaining consent and from whom will consent be obtained, e.g., participant, parent, legally authorized representative (LAR), conservator? (The person obtaining consent must be knowledgeable about the study).
 - When and where will consent be obtained?
 - How much time will be devoted to consent discussion?
 - Will these periods provide sufficient opportunity for the participant to consider whether or not to participate and sign the written consent?
 - What steps are you taking to minimize the possibility of coercion and undue influence?
 - If consent relates to children and if you have a reason for obtaining only one parent signature, provide that rationale for IRB consideration.
 - Confirm that the information being communicated during the consent process will not include exculpatory language through which the participant or his LAR is made to waive or appear to waive any of the participant's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.
- b) What is the procedure to assess understanding of the information contained in the consent? How will the information be provided to participants if they do not understand English or if they have a hearing impairment? See [HRPP Chapter 14.5](#) for guidance.
- c) What steps are you taking to determine that potential subjects are competent to participate in the decision-making process? If your study may enroll adults who are unable to consent, describe (i) how you will assess the capacity to consent, (ii) what provisions will be taken if the participant regains the capacity to consent, (iii) who will be used as a legally authorized representative, and (iv) what provisions will be made for the assent of the participant.

10. Assent Background (Less than 18 years of age)

See more information on [Assent](#).

10.1 Assent

Assent Information Type: *Assent*

Title:

Sponsor's Assent Version Number:

Assent Form (file name):

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

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

- c) What steps are you taking to determine that the child has the capacity to participate in the decision-making process? Will consent be obtained from both parents (unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child), or from just one parent? Provide a rationale if only one parent will consent.

11. Attachments

11.1 Advertisements

Attachment Name:
Attached Date:
Attached By:
Submitted Date:

11.2 Cooperating Institution(s) Approval

Attachment Name:
Attached Date:
Attached By:
Submitted Date:

11.3 Federal Grant/Sub-contract

Attachment Name:
Attached Date:
Attached By:
Submitted Date:

11.4 Information Sheets/Brochures

Attachment Name:
Attached Date:
Attached By:
Submitted Date:

11.5 Package Inserts

Attachment Name:
Attached Date:
Attached By:
Submitted Date:

11.6 Phone Scripts

Attachment Name:
Attached Date:
Attached By:
Submitted Date:

11.7 Program Project Grant/List

Attachment Name:
Attached Date:
Attached By:
Submitted Date:

11.8 Questionnaires

Attachment Name:
Attached Date:
Attached By:
Submitted Date:

11.9 Sponsor's Protocol

Attachment Name:
Attached Date:
Attached By:
Submitted Date:

11.10 Sponsor's Protocol Amendments

Attachment Name:
Attached Date:

Attached By:
Submitted Date:

11.11 Training Grant/List

Attachment Name:
Attached Date:
Attached By:
Submitted Date:

11.12 Un-sponsored Research Approval

Attachment Name:
Attached Date:
Attached By:
Submitted Date:

11.13 VA Required Questions

Attachment Name:
Attached Date:
Attached By:
Submitted Date:

11.14 Other

Attachment Name:
Attached Date:
Attached By:
Submitted Date:

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
- Disclose to the appropriate departments 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 submitted to the IRB for review prior to the implementation of such change. Any complications in subjects or evidence of increase in the original estimate of risk should be reported at once to the IRB before continuing with the project. Inasmuch as the Institutional Review Board (IRB) include faculty, staff, legal counsel, public members, and students, protocols should be written in language that can be understood by all Panel members. The investigators must inform the participants of any significant new knowledge obtained during the course of the research.

IRB approval of any project is for a maximum period of one year. For continuing projects and activities, it is the responsibility of the investigator(s) to resubmit the project to the IRB for review and re-approval prior to the end of the approval period. A Notice to Renew Protocol is sent to the Protocol Director 7 weeks prior to the expiration date of the protocol.

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

All data including signed consent form documents must be retained for a minimum of three years past the completion of the research. Additional requirements may be imposed by your funding agency, your department, or other entities. (Policy on Retention of and Access to Research Data, Research Policy Handbook, <http://www.stanford.edu/dept/DoR/rph/2-10.html>)

List all items (verbatim) you want to be reflected in your approval letter, i.e. Amendment, Investigator's Brochure, consent form(s), advertisement, telephone script, diary card, etc. Include number and date when appropriate.

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

The Protocol Director has read and agrees to abide by the above obligations.