IRB MED
EXEMPT
FORM

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 guidance for submitting a medical protocol application.

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.

Personnel Info:

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 and Other Contact .

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

Name	Degree (program/year if student)	Title
E-mail	Phone	Fax
Dept		Mail Code
[Drop Down Menu]		
CITI Training current (within last 2 years) ○Yes ○No		

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

Name	Degree (Program/year if student)	Title
E-mail	Phone	Fax
Dept		Mail Code
[Drop Down Menu]		
CITI Training current (within last 2 years) ○Yes ○No		

Co-Protocol Director [Clear]
PERSONNEL LOOKUP
INSTRUCTIONS: Search by LastName, FirstName *(e.g., Smith, John)* or by SUNet ID.

Name	Degree (Program/year if student)	Title
E-mail	Phone	Fax
Dept		Mail Code
[Drop Down Menu]		
CITI Training current (within last 2 years) ○Yes ○No		

Other Contact [Clear]
PERSONNEL LOOKUP
INSTRUCTIONS: Search by LastName, FirstName *(e.g., Smith, John)* or by SUNet ID.

Name	Degree (Program/year if student)	Title
E-mail	Phone	Fax
Dept		Mail Code
[Drop Down Menu]		
CITI Training current (within last 2 years) ○Yes ○No		

Academic Sponsor [Clear]
PERSONNEL LOOKUP

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

Name	Degree (Program/year if student)	Title
E-mail	Phone	Fax
Dept		Mail Code
[Drop Down Menu]		
CITI Training current (within last 2 years) ○Yes ○No		

Other Personnel Click here to add Other Personnel

If the popup is clicked, then:

Find User [Find]

SUNet ID:	
First Name:	
Last Name:	

Training Details [Close]

Protocol ID: User:		
Module Name	Module Date Completion	Expiry Date

Find User [Find]

SUNet ID:	
First Name:	
Last Name:	

Click here to add Other Personnel, if you are sure the SUNet ID does not exist for the person

"Click here to add Other *Personnel*, if you are sure the SUNet ID does not exist for the person"

Other Personnel [Save]

First Name:		Last Name:	
Degree:		Role:	
Email:		Phone:	
Fax:		Department:	
Mail Code:			

Application Category:

Select Medical for investigators in:

1. Lucile Packard Children's Hospital (LPCH)
2. Psychiatry & Behavioral Sciences
3. School of Medicine (SoM)
4. Stanford Hospital and Clinics (SHC)
5. Veteran's Affairs (VA) Hospital

Select Non-Medical for investigators in:

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

Application Category/Type -

Create

Select Application Category:	○ Medical	○ Non-Medical
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"at"stanford.edu. Note that different review types result in different application forms.		
Select Review Type:	○ Regular	○ Expedited ○ Exempt

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

Exempt Review

Create

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 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?
○	○	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 this data was 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; or
   iv) changes in methods of payment for benefits 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.

Instructions:

Please select all populations (and only those) that are specifically targeted for this study. Here are some examples:

- A researcher is conducting a study to compare two strategies designed to promote longer-term maintenance of smoking cessation. There may be students that smoke; however, the study is not designed to recruit students specifically as they are not the focus population. In this example, students would not be selected on the checklist.
- A researcher is conducting a study to test the efficacy of an after school exercise program to reduce weight gain among lower socioeconomic status pre-adolescent girls. Although some participants may be pregnant, pregnant women are not the target population and would not be selected on the checklist.

Participant Population(s) Checklist

Yes	No	
○	○	Children (under 18)
○	○	Pregnant Women and Fetuses
○	○	Neonates (0 - 28 days)
○	○	Abortuses
○	○	Mentally Disabled
○	○	Decisionally Challenged
○	○	Cancer Subjects
○	○	Laboratory Personnel
○	○	Healthy Volunteers
○	○	Students
○	○	Employees
○	○	Prisoners
○	○	Other (i.e., any population that is not specified above)

Study Location

Instructions:

The study location is the location at which the research takes place. For example, a study in which specimens are collected at a community clinic and analyzed at Stanford would have both Stanford and Other selected.

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

Study Location(s) Checklist

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

Location Name	Contact Name	Contact Phone	Contact Email	Permission?	IRB?

If "Other" was selected, then:

	[Add]
	Click on 'Add' to add Other Locations

Location Name *	
Contact Name	
Contact Phone	
Contact Email	

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

○Yes ○No Does the location have an IRB that will approve the research?

Other Location

General Checklist

Instructions:

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

Reminder: If your study meets the ICMJE definition of a clinical trial, regardless of the funding source, you must register your study at http //clinicaltrials.stanford.edu prior to enrolling any research participants.

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?
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.
Yes	No	Cancer Institute
○	○	Cancer-Related Studies (studies with cancer endpoints), Cancer Subjects (e.g., clinical trials, behavior/prevention) or Cancer Specimens (e.g., blood, tissue, cells, body fluids with a scientific hypothesis stated in the protocol).
For all Cancer-related studies, see the submission instructions on the Cancer Clinical Trials website *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 Cancer Clinical Trials - SRC for more information.*		
Yes	No	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 http //stanford.edu/group/ICO/researcher/reMTA.html
○	○	Human Embryos or gametes? SCRO#
Yes	No	Veterans Affairs (VA)
○	○	The research recruits participants at the Veterans Affairs Palo Alto Health Care System (VAPAHCS).
○	○	The research involves the use of VAPAHCS non-public information to identify or contact human research participants or prospective subjects or to use such data for research purposes.
○	○	The research is sponsored (i.e., funded) by VAPAHCS.
○	○	The research is conducted by or under the direction of any employee or agent of VAPAHCS (full- time, part-time, intermittent, consultant, without compensation (WOC), on-station fee-basis, on- station contract, or on-station sharing agreement basis) in connection with her/his VAPAHCS responsibilities.
○	○	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 started Please contact the Research Administration office at the Palo Alto VA at 650-493-5000 ext. 65418		
Yes	No	Payment
○	○	Subjects will be paid for participation? See payment considerations
Yes	No	Funding
○	○	Training Grant?
○	○	Program Project Grant?
○	○	Federally Sponsored Project?

Funding Checklist

☐ NONE

Funding – Grants/Contracts [Add] [Delete]

	SPO#	Grant#	Administered By	Funded By
☐				

Please click on 'Add' to add Grants/Contracts

Funding – Fellowships [Add] [Delete]

	Fellow	Title	Administered By	Funded By

☐				

Funding – Other

Gift Funding [Add] [Delete]

	Gift Name	Account Number
☐		

Dept. Funding [Add] [Delete]

	Department	Account Number
☐		

Other Funding (e.g., OTL, URO) [Add] [Delete]

	Other Funding	Account Number
☐		

Funding – Grants/Contracts

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 Administered By	
SPO # (if available)	
Grant # (if available)	
Funded By (include pending)	
Principal Investigator	
Grant/Contract Title if different from Protocol Title	
○Yes ○No For Federal projects, are contents of this protocol consistent with the Federal proposal application?	
○Yes ○No Is this a Multiple Project Protocol (MPP)?	
○Yes ○No Is this protocol under a MPP?	

Funding - Fellowships

Funding administered by	
SPO # (if available)	

Fellowship Reference # (if available)	
Funded By	
Name of Fellow *	
Fellowship Titleif different from Protocol Title	
○ Yes ○ No For Federal projects, are contents of this protocol the same as described in Federal proposal application?	

Gift Funding

Name of Donor *
Account Number *

Dept Funding

Department Name *
Account Number *

Other Funding (e.g., OTL, URO)

Other Fund Name*
Account Number *

Resources

Please demonstrate that you have adequate resources to conduct the project.

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.

Exempt Paragraphs(s)
Title

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Select one or more of the following paragraphs:

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   (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?
○	○	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 this data was 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; or
   iv) changes in methods of payment for benefits 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.

Protocol Information

Sections 1-3

Complete Sections 1 - 11. Specify N/A as appropriate. Do not leave any required sections blank.

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.

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)

2. Study Procedures

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

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

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).

d) 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.

3. Background

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

4. (a-e) Participant 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, patients with certain cancer, patients with certain cardiac condition) and the reasons for using such participants.

b) State the age range, gender, and ethnic background of the participant population being recruited

c) S
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) 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 initially learn about the research (e.g., clinics, advertising). Attach recruitment materials in Section #11 (Attachments). You may not contact potential participants prior to IRB approval. See guidance Advertisements: Appropriate Language for Recruitment Material

e) Inclusion and Exclusion Criteria.
Identify inclusion criteria.

Identify exclusion criteria.

4. (f-i) Participant Population

f) 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

g) Payment. Explain the amount and schedule of payment, if any, which will be paid for participation in the study. Substantiate that proposed payments are reasonable and commensurate with the expected contributions of participant and that they do not constitute undue pressure on the participant 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) Describe risks. Include risks to privacy, confidentiality, etc.

b) In case of overseas research, describe qualifications/preparations that enable you to both estimate and minimize risks to participants.

c) Could any disclosure of the participant's response outside the research reasonably place them at risk of loss of insurability?

6. Benefits

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

7. Privacy and Confidentiality

Most medical research must comply with the Health Insurance Portability and Accountability Act (HIPAA) regulations if it uses 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 subdivisions 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, if, according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combing all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000s
5. 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 89 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 90 or older
6. Fax numbers
7. Electronic mail addresses
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers, including license plate numbers
13. Device identifiers and serial numbers
14. Web Universal Resource Locations (URLs).
15. Internet Protocol (IP) address numbers
16. Biometric identifiers, including finger and voice prints
17. Full face photographic images and any comparable images; and
18. Any other unique identifying number, charactristic, 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 SSN).

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 linked to 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 cabinet, locked 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 ISO website .

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

New PHS regulations require that financial interests must be disclosed by investigators, and those that are identified as financial conflicts of interest must be eliminated or managed prior to final approval of this protocol.

When the Personnel section of this protocol is completed, the investigators will receive an email with a link to their OPACS dashboard. In OPACS, the investigator must click on the link for this protocol and answer the Financial Interest questions.

Investigators who have not received an email form OPACS can still complete their disclosures by going to their OPACS dashboard directly at opacsprd.stanford.edu. They should contact their school's COI Manager with any issues with OPACS.

The table below displays the names of investigators, and whether they have entered their financial interest disclosure, if any, in OPACS and the status of review of conflicts of interest.

You will not be able to submit this protocol until the "Financial Interest" question has been answered in OPACS for all investigators listed in the table.

Review of this protocol by IRB will occur when all investigators listed have answered the Financial Interest question in OPACS, either Yes or No.

Approval of this protocol will only occur when all investigators who have Financial Interests have submitted their OPACS disclosure and review of the information has been completed by their COI Manager.

Note: If any changes to disclosures are made while this page is open, simply reload the page to see current information.

9. Consent Background

Consent Background

Title	Consent Type	Created Date

Clicking Add Button

Consent Background
Consent Information Type: Co
Title:
Sponsor's Consent Version Number (if any)
Consent Form (file nar
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.

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 Chapter12.2 for guidance.

c) What steps are you taking to determine that potential participants 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.

Additional VA Questions (if VA checked above)

(i) List the people to whom you have formally delegated responsibility to obtain informed consent, and state whether they have the appropriate training to perform this activity.

(ii) Will legally effective informed consent be obtained from the participant or the participant's legally authorized representative (LAR) or both? If LAR, is it clear who can serve as LAR?

(iii) Will the circumstances of the consent process minimize the possibility of coercion or undue influence and provide the prospective participant or their representative sufficient opportunity to consider whether to participate?

(iv) Will the circumstances of the consent process minimize the possibility of coercion or undue influence?

(v) Will the information being communicated to the participant or the representative during the consent process exclude any exculpatory language through which the participant or the representative is made to waive or appear to waive the participant's legal rights, or release or appear to release the investigator, the sponsor, the institution, or its agent from liability for negligence (e.g. I give up any property rights I may have in bodily fluids or tissue samples obtained in the course of the research)?

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

Assent Background

Title	Assent Information Type	Created Date

Please click on 'Add' to add Assent Background

(After user clicks on Add button the pop up dialog box opens as described in 10.1 below)

10.1 Assent Background

Assent Information Type: Assent

Title:

Sponsor's Assent Version Nbr: (if any):

Assent Form (file name): Browse

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 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., oral response, signature on form, combination of methods, other)?

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

11. Attachments

NOTE: 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.

Instructions

- Click ADD to attach documents (e.g., federal grant/sub-contract, advertisements, 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.

Please click on 'Add' to attach documents

1. Advertisements
   a. Title:
   b. Attached Date:
   c. Attached By:
   d. Submitted Date:

2. Cooperating Institution(s) Approval
   a. Title:
   b. Attached Date:
   c. Attached By:

d. Submitted Date:

3. Federal Grant/Sub-contract
    a. Title:
    b. Attached Date:
    c. Attached By:
    d. Submitted Date:

4. Information Sheets/Brochures
    a. Title:
    b. Attached Date:
    c. Attached By:
    d. Submitted Date:
5. Investigator's Brochure
    a. Title:
    b. Attached Date:
    c. Attached By:
    d. Submitted Date:

6. Package Inserts
    a. Title:
    b. Attached Date:
    c. Attached By:
    d. Submitted Date:

7. Phone Scripts
    a. Title:
    b. Attached Date:
    c. Attached By:
    d. Submitted Date:

8. Program Project Grant/List
    a. Title:
    b. Attached Date:
    c. Attached By:
    d. Submitted Date:

9. Questionnaires
    a. Title:
    b. Attached Date:
    c. Attached By:
    d. Submitted Date:

10. Sponsor's Protocol
    a. Title:
    b. Attached Date:
    c. Attached By:

d. Submitted Date:

11. Sponsor's Protocol Amendments
    a. Title:
    b. Attached Date:
    c. Attached By:
    d. Submitted Date:

12. Training Grant/List
    a. Title:
    b. Attached Date:
    c. Attached By:
    d. Submitted Date:

13. Un-sponsored Research Approval
    a. Title:
    b. Attached Date:
    c. Attached By:
    d. Submitted Date:

14. VA Required Questions
    a. Title:
    b. Attached Date:
    c. Attached By:
    d. Submitted Date:

15. Other
    a. Title:
    b. Attached Date:
    c. Attached By:
    d. 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.

VA Protocol Directors also certify that:

- All unanticipated internal or local SAEs, whether related or unrelated to the research, will be/have been reported to the IRB
- All subjects entered onto the master list of subjects for the study will sign/have signed an informed consent form prior to undergoing any study interactions or interventions, unless granted a waiver by the IRB.

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. 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”at”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. (Research Policy Handbook, RPH 1.6 Retention of and Access to Research Data)

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.