IRB MEDICAL
REGULAR
FORM

Home » Protocol 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.

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, 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

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

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]

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]

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]

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		

Application Category: Select **Medical** for investigators in:
- Lucile Packard Children's Hospital (LPCH)
- Psychiatry & Behavioral Sciences
- School of Medicine (SoM)
- Stanford Hospital and Clinics (SHC)
- Veteran's Affairs (VA) Hospital

Select **Non-Medical** for investigators in:
- Business
- Education
- Engineering
- Humanities & Sciences
- Law
- Psychology (except MRI studies)

Application Category/Type			

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

Personnel Info:

Instructions:

- You MUST select an entry from the Personnel Lookup field to properly populate personnel information. Do NOT manually enter your name in the 'Name' field.
- At minimum, a Protocol Director (PD) and Administrative Contact must be entered; the same person may be entered for both roles if needed.
- If the PD is a student (e.g., Undergraduate, Graduate, or Post-Doc), you must also enter an Academic Sponsor. Those entered as Academic Sponsors should be listed in categories 1 and 2 of Administrative Guide 23.
- Only those entered in the following roles will have **edit access** to the Protocol application: PD, Admin Contact, Co-PD and Other Contact.
- Click the link in the *Other Personnel* section towards the bottom of the page to enter additional personnel (including persons without SUNetIDs).
- All users must take CITI training. If your training information is highlighted, it will be verified by IRB staff.
- You can click here to review completion records to ensure training has been completed.

Protocol Director

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

Name	Degree (Program/year	Title

	if student)	
E-mail	Phone	Fax
Dept	Mail Code	
[Drop Down Menu]		
CITI Training current (within last 2 years)〇Yes 〇No		

Co-Protocol Director [Clear]

Name	Degree (Program/year if student)	Title
E-mail	Phone	Fax

Dept	Mail Code
[Drop Down Menu]	
CITI Training current (within last 2 years)〇Yes 〇No	

Other Contact [Clear]

Name	Degree (Program/year if student)	Title
E-mail	Phone	Fax
Dept	Mail Code	
[Drop Down Menu]		
CITI Training current (within last 2 years)〇Yes 〇No		

Academic Sponsor [Clear]

Name	Degree (Program/year if student)	Title
E-mail	Phone	Fax
Dept	Mail Code	
[Drop Down Menu		
CITI Training current (within last 2 years) 〇Yes 〇No		

Other Personnel Click here to add Other Personnel

CITI "Stanford" Popup

If the CITI "Stanford" popup is clicked and the user has training, then:

Training Details [Close]

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

CITI "VA" popup

If the CITI "VA" popup is clicked and the user does not have training, then:

Training Details [Close]

Protocol ID:	User:
No training Details Available.	

"Click here to add Other Personnel" Popup

If the "Click here to add Other Personnel" popup was clicked, then:

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" Popup

If "Click here to add Other Personnel, if you are sure the SUNET ID does not exist for the person" popup was clicked, then:

Other Personnel Save

First Name:		Last Name:	
Degree:		Role:	
Email:		Phone:	
Fax:		Department:	(Drop Down)
Mail Code:			

Participant Population

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
○	○	Impared Decision Making Capacity
○	○	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
☐	Clinical & Translational Research Unit (CTRU)
☐	Stanford Hospital and Clinics
☐	Lucile Packard Children's Hospital (LPCH)
☐	VAPAHCS (Specify PI at VA)
☐	Other (Click ADD to specify details)

"Other Location Add" Popup

If “Other” was selected, then:

	[Add]
	Please Click on ‘Add’ to add Other Locations

If “Add” was selected, then:

Other Location [Save]

Location	○US ○International
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?

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?
		[Add] [Delete]

			Site Name	Contact Name	Contact Phone	Contact Email	Permission?	IRB?
		☐						

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.
		[Add] [Delete]

			Institution Name	Contact Name	Contact Phone	Contact Email	Permission?	IRB?

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 at http://cancer.stanford.edu/trials/admin/activation.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 for more information.
Yes	**No**	**Drug/Device**
○	○	Investigational drugs, biologics, reagents, or chemicals?
○	○	Commercially available drugs, reagents, or other chemicals administered to subjects (even if they are not being studied)?
○	○	Investigational Device / Commercial Device used off-label?
○	○	IDE Exempt Device (Commercial Device used according to label)
		For drug, device or biologic studies, click here for instructions regarding who must register a clinical trial at clinicaltrials.gov.
○		Click "yes" to confirm that you have accessed the website and read the clinicaltrials.gov reporting requirements provided.
○	○	This study will be registered on clinicaltrials.gov?
○	○	Protocol involves studying potentially addicting drugs?
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
Yes	**No**	**Biosafety (APB)**
○	○	Are you submitting a Human Gene Transfer investigation using biological agent or recombinant DNA vector? If yes, please complete and attach the Gene Transfer Protocol Application Supplemental Questions to section 16 of the eProtocol application. **APB #**

○	○	Are you submitting a Human study using biohazardous/infectious agents? If yes, refer to the Administrative Panel on BioSafety website prior to performing studies **APB #**
○	○	Are you submitting a Human study using samples from subjects that contain biohazardous/infectious agents? If yes, refer to the Administrative Panel on BioSafety website prior to performing studies. **APB #**
		IRB approval does not negate the need for APB approval, including the following issues: *use of rDNA, use of Biological/Infectious Agent, use of samples from patients/participants that are infected with a Biological/Infectious Agent.*

Yes	**No**	**Human Embryos or Stem Cells**
○	○	Human Embryos or gametes? **SCRO #**
○	○	Human Stem Cells (including hESC, iPSC, cancer stem cells, progenitor cells). **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.
○	○	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**	**Equipment**
○	○	Use of Patient related equipment? If Yes, equipment must meet the standards established by Hospital Instrumentation and Electrical Safety Committee (650-725-5000)
○	○	Medical equipment used for human patients/subjects also used on animals?
○	○	Radioisotopes/radiation-producing machines, even if standard of care?
Yes	**No**	**Payment**
○	○	Subjects will be paid for participation? See payment considerations.
Yes	**No**	**Funding**
○	○	Training Grant?
○	○	Program Project Grant?
○	○	Federally Sponsored Project?
○	○	Industry Sponsored Clinical Trial?

Multi-site "Add" Popup

If the multi-site "Add" button was selected, then:

Participating Site [Save]

Site 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?

Collaborating Institution(s) "Add" popup

If the Collaborating Institution(s) "Add" button was selected, then:

Cooperating Institution(s) [Save]

Institution 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?

Funding

☐ NONE

Funding – Grants/Contracts [Add] [Delete]

	SPO#	Grant#	Administered By	Funded BY
☐				

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 "Add" popup

If the Funding – Grants/Contracts "Add" button was selected, then:

Instructions: Remember to attach a copy of each applicable federal grant application, including competing renewals, in the *Attachments* section of this protocol application form. If this is an umbrella protocol, attach in the *Attachments* section of this protocol application form, a listing of all protocols funded under this umbrella. Include protocol ID number, PI, and approval date.

Funding – Grants/Contracts [Save]

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

Funding – Fellowships "Add" popup

If the Funding – Fellowships "Add" button was selected, then:

Funding – Fellowships [Save]

Funding administered by	(Dropdown)
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?	

Gift Funding "Add" popup

If the Gift Funding "Add" button was selected, then:

Gift Funding [Save]

Name of Donor*	
Account Number*	

Department Funding "Add" popup

If the Dept. Funding "Add" button was selected, then:

Dept. Funding [Save]

Department Name*	
Account Number*	

Other Funding "Add" popup

If the Other Funding (e.g., OTL, URO) "Add" button was selected, then:

Other Funding [Save]
(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.

Protocol Information
Sections 1-3

Title

Complete Sections 1-16. 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 13). Submit a debriefing script (in section 16).

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.

e) Describe alternative procedures or courses of treatment, if any, that might be advantageous to the participant. Describe potential risks and benefits associated with these. Any standard treatment that is being withheld must be

disclosed in the consent process and form. (i.e. standard-of-care drug, different interventional procedure, no procedure or treatment, palliative care, other research studies).

☐

f) Will it be possible to continue the more (most) appropriate therapy for the participant(s) after the conclusion of the study?

☐

g) Study Endpoint. What are the guidelines or end points by which you can evaluate the different treatments (i.e. study drug, device, procedure) during the study? If one proves to be clearly more effective than another (or others) during the course of a study, will the study be terminated before the projected total participant population has been enrolled? When will the study end if no important differences are detected?

☐

3. Background

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

☐

b) Describe any animal experimentation and findings leading to the formulation of the study.

☐

Section 4

4. Radioisotopes or Radiation Machines

a) List all *standard of care* procedures using ionizing radiation (radiation dose received by a subject that is considered part of their normal medical care). List all *research* procedures using ionizing radiation (procedures performed due to participation in this study that is not considered part of their normal medical care). List each potential procedure in the sequence that it would normally occur during the entire study. More Info

Radiation Procedures [Add] [Delete]

	Procedure	Type
☐		

b) For **radioisotope** projects, provide the following radiation-related information:

Identify the radionuclide and chemical form.

Provide the number of times the radioisotope and activity that will be administered (mCi) and the route of administration.

If not FDA approved provide dosimetry information and reference the source documents (package insert, MIRD calculation, peer reviewed literature).

c) For radiation machine projects, provide the following diagnostic procedures:

For well-established radiographic procedures describe the exam.

Identify the number of times each will be performed on a single research subject

For each radiographic procedure, provide the setup and technique sufficient to permit research subject dose modeling. The chief technologist can usually provide this information.

For radiographic procedures not well-established, provide FDA status of the machine, and information sufficient to permit research subject dose modeling.

d) For research radiation machine projects, provide the following therapeutic procedures:

For a well-established therapeutic procedure, identify the area treated, dose per fraction and number of fractions. State whether the therapeutic procedure is being performed as a normal part of clinical management for the research participants's medical condition or whether it is being performed because the research participant is participating in this project.

For a therapeutic procedure that is not well-established, provide FDA status of the machine, basis for dosimetry, area treated, dose per fraction and number of fractions.

Section 4 "Add" Button

If "Add" button is selected, then:

Radiation Procedures [Save]

Procedures*	
Type	

Section 5, 6

5. Devices

a) Please list in the table below all **Investigational** Devices (and Commercial Devices used off-label) to be used on participants. [Add]

Please click on 'Add' to attach Investigational devices

Section 5a "Add" Button

If "Add" button is selected, then:

Investigational Devices and Uses [Save]

Device Information	
Describe the device to be used.	
Device Name*	
Manufacturer	
Risk* ○Significant ○Non-significant See Significant and Non-Significant Risk Medical Devices guidance.	

If the Significant risk button is selected then:

Investigational Devices and Uses [Save]

Device Information
Describe the device to be used.

Device Name*	
Manufacturer	
Risk* ○Significant ○Non-significant See Significant and Non-Significant Risk Medical Devices guidance.	
IDE#	
Holder of IDE	
* Indicate who holds the IDE:	
○	The IDE is held by the sponsor. Provide a copy of the sponsor's protocol, device manual and the FDA letter issuing the IDE number (attach in section #16). *The FDA letter does not have to be provided if the IDE number is on the sponsor's protocol.*
○	The IDE is held by the STANFORD (SU, SHC, LPCH, VA) Investigator. Provide a copy of the clinical protocol, device manual (if available) and a copy of the FDA letter issuing the IDE number and all correspondence with the FDA on the IND (attach in section #16).
○	The IDE is held by a non-STANFORD investigator. Provide a copy of the clinical protocol, device manual (if available) and a copy of the FDA letter issuing the IDE number (attach in section #16).
Ordering, Storage and Control	
To prevent the device being used by a person other than the investigator, and in someone other than a research participant: Confirm that the device will be handled according to the SCH/LPCH policy for Investigational New Devices or *as appropriate*, handled according to VAPAHCS memo 151-05-10. If no, please provide an explanation. **Confirm?** ○Yes ○No	

If the Non-significant risk button is selected, then:

Investigational Devices and Uses [Save]

Device Information	
Describe the device to be used.	
Device Name*	
Manufacturer	
Risk* ○Significant ○Non-significant See Significant and Non-Significant Risk Medical Devices guidance.	
Non-Significant Risk Device	

A non-significant risk device study is defined as the study of a device that does not present a potential for serious risk to the health, safety, or welfare of a subject and:

- Is not intended as an implant; or
- Is not used in supporting or sustaining human life; or
- Is not of substantial importance in diagnosing, curing, mitigating or treating

disease, or otherwise prevents impairment of human health; or
- Does not otherwise present a potential for serious risk to the health, safety, or welfare of a project.

☐ I confirm the above are true

Rationale for the device being non-significant risk:
Sponsor of Project
* Indicate the project sponsor:

b) Please list in the table below all Commercial Devices to be used on participants.

IDE Exempt Devices (Commercial Devices) [Add]

Please click on 'Add' to attach Commercial devices

Section 5b "Add" Button

If "Add" button is selected, then:

IDE Exempt Devices (Commercial Devices) [Save]

Device Information	
Describe the device to be used.	
Device Name*	
Manufacturer	
IDE Exemption	
Select one of the following the IDE exemption categories ○ This is a legally marketed device being used in accordance with its labeling.	

○ This is an *in vitro* diagnostic device that complies with the labeling requirements in 21 CFR 809.10(c), and for the testing of the device all the following statements are true: ▪ It is non-invasive. ▪ It does not require an invasive sampling procedure that presents significant risk. ▪ It does not by design or intention introduce energy into a subject ▪ It is not used as a diagnostic procedure without confirmation by another medically established diagnostic product or procedure

○ The study includes consumer preference testing, testing of a modification, or testing of a combination of devices that are legally marketed devices [that is, the device(s) have an approved PMA, cleared Premarket notification (510k), or are exempt from 510k] AND the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk.

6. Drugs, Reagents, or Chemicals

a) Please list in the table below all **investigational** drugs, reagents or chemicals to be administered to participants. [Add]

Please click on 'Add' to attach Investigational drugs

Section 6a "Add" Button

If Investigational Drugs, Reagents, Chemicals "Add" button was selected, then:

Investigational Drugs, Reagents, Chemicals [Save]

Drug, Reagent, Chemical Information	
Drug Name*	
Source (i.e Pharmacy, Sponsor, etc.,)	
If not pre-mixed, where will the material be mixed and by whom:	
Manufacturer	
IND# (if available)	
Dosage	
Administration Route:	
Holder of IND	
*** Indicate who holds the IND:**	
	The IND is held by the sponsor. Provide a copy of the investigator's brochure, the

○	sponsor's protocol and the FDA letter issuing the IND number (attach in section #16). *The FDA letter does not have to be provided if the IND number is on the sponsor's protocol.*
○	The IND is held by the STANFORD (SHC, LPCH, VA) investigator. Provide a copy of the investigator's brochure (if available), the clinical protocol and a copy of the FDA letter issuing the IND number and all correspondence with the FDA on the IND (attach in section #16).
	The IND is held by a non-STANFORD investigator. Provide a copy of the investigator's brochure (if available), the clinical protocol and a copy of the FDA letter issuing the

○	IND number (attach in section #16).

If the IND is held by the sponsor or a non-STANFORD investigator, then:

Pharmacy Dispensing or Security and Controlled Access Plan.	
○✡♏♦ ○☠☐	Will the investigational drug/biologic be maintained and dispensed by a pharmacy or through an outpatient clinic monitored by a pharmacy?
Pharmacy Name	
Describe below (or attach in section 16) the procedures to be followed to prevent the investigational drug from being used by a person other than the investigator, and to prevent it from being used in someone other than a research participant	

If the IND is held by the STANFORD investigator, then:

Sponsor-Investigator Research You have indicated that the STANFORD (SHC, LPCH, VA) investigator holds the IND on this project. As the holder of the INDO, the investigator has FDA mandated responsibilities in conducting the research and in communicating information to the FDA about the study.

The IRB, in cooperation with SPCTRM and CCTO, will provide education, assistance and guidance towards complying with the investigator's FDA obligations as the holder of the IND. Upon submission of your protocol you will be contacted to arrange an education session.

Stanford IRB policies and procedures require the completion of an initial Compliance Review prior to recruiting and enrolling participants in a Sponsor-Investigator project and a follow-up review prior to Continuing Review (renewal).

Please read the following:
- IRB Requirements
- Memorandum from Dean of Research

If you would like further information on this process and/or assistance prior to submitting your protocol contact Stanford/Packard Center for Translational Research in Medicine (SPCTRM) at (650)498-6498

☐ I have read and understand the above, including the Memorandum from Dr. Arvin, Vice Provost and Dean of Research.

Pharmacy Dispensing or Security and Controlled Access Plan.	
○✡♏♦ ○☠☐	Will the investigational drug/biologic be maintained and dispensed by a pharmacy or through an outpatient clinic monitored by a pharmacy?
Pharmacy Name	
Describe below (or attach in section 16) the procedures to be followed to prevent the investigational drug from being used by a person other than the investigator, and to prevent it from being used in someone other than a research participant	

b) Please list in the table below all **commercial** drugs, reagents or chemicals to be administered to subjects [Add]

Please click on 'Add' to attach Commercial drugs

Section 6b "Add" Button

If Commercial Drugs, Reagents, Chemicals "Add" button is selected, then:

Commercial Drugs, Reagents, Chemicals [Save]

Drug, Reagent, Chemical Information

Drug Name*		
Source (i.e. Pharmacy, Sponsor, etc.)		
If not pre-mixed, where will the material be mixed and by whom:		
Manufacturer		
IND# (If available)		
Dosage		
Administration Route:		
IND Exemption		
○Yes	○No	Is this new and different uses of this commercially available drug, reagent or chemical?
○Yes	○No	Are all of the IND statements shown below true?
Investigational New Drug (IND) Regulations		
The IND Regulations (21 CFR 312.2(b)) state that clinical investigation of a drug product is exempt from requirements for an IND if all of the following apply: ▪ The Drug used in the investigation is lawfully marketed in the United States		

▪ The investigation is not intended to be reported to FDA in support of new indication for use or to support any other significant change in the labeling of the drug.
▪ The investigation is not intended to support a significant change in the advertising of the product.
▪ The investigation does not involve a route of administration or dosage level, use in a participant population, or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product.
▪ The investigation is conducted in compliance with the requirements for IRB review and informed consent [21 CFR parts 56 and 50]
▪ The investigation is conducted in compliance with the requirements concerning the promotion and sale of drugs [21 CFR part 312.7] e.g., the drug may not be represented as safe or effective for the purposes for which it is under investigation, nor may it be commercially distributed or sold.

Section 7

7. Medical Equipment for Human Subjects and Laboratory Animals

If medical equipment used for human patients/participants is also used on animals, describe such equipment and disinfection procedures.

Section 8(a-g)

8. 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) 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.

f) State the number, if any, of participants who are healthy volunteers. Provide rationale for the inclusion of healthy volunteers in this study. Specify any risks to which participants may possibly be exposed. Specify the measures being taken to minimize the risks and the chance of harm to the volunteers and the additional safeguards that have been included in the protocol to protect their rights and welfare.

g) Describe how potential participants will be identified for recruitment (e.g., chart review, referral from individual's treating physician, responses to an ad). Describe how participants will be recruited and how they will initially learn about the research (e.g., clinics, advertising). If this is a clinical trial, indicate the recruitment option selected in registering the trial on the Stanford Clinical Trials web site-whether recruitment is limited to "invitation only" (e.g. your own patients), or whether recruitment will be open to the general public. Attach recruitment materials in Section #16 (Attachments). You may not contact potential participants prior to IRB approval. See guidance Advertisements: Appropriate Language for Recruitment Material.

Section 8(h-m)

8. Participant Population

h) Inclusion and Exclusion Criteria

Identify inclusion criteria.

Identify Exclusion criteria.

i) 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 15).

j) Describe how you will be cognizant of other protocols in which participants might be enrolled. Please explain if participants will be enrolled in more than one study.

k) 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

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

m) 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.

Section 9(a-e)

9. Risks

a) For **the following categories include a scientific estimate of the frequency, severity, and reversibility of potential risks. Wherever possible, include statistical incidence of complications and the mortality rate of proposed procedures. Where there has been insufficient time to accumulate significant data on risk, a statement to this effect should be included. (In describing these risks in the consent form to the it is helpful to use comparisons which are meaningful to persons unfamiliar with medical terminology.)**

- Investigational devices.

▪ Investigational drugs. Information about risks can often be found in the Investigator's brochure.

☐

▪ Commercially available drugs, reagents or chemicals. Information about risks can often be found in the package insert.

☐

▪ Procedures to be performed. Include all investigational, non-investigational and non-invasive procedures (e.g., surgery, blood draws, treadmill tests).

☐

▪ Radioisotopes/radiation-producing machines (e.g., X-rays, CT scans, fluoroscopy) and associated risks.

☐

▪ Physical well-being.

☐

▪ Psychological well-being.

☐

▪ Economic well-being.

☐

▪ Social well-being

☐

Overall evaluation of Risk.

○ **Low** - innocuous procedures such as phlebotomy, urine or stool collection, no therapeutic agent, or safe therapeutic agent such as the use of an FDA approved drug or device.
○ **Medium** - therapy with chemotherapy, antibodies, or a non-FDA approved potentially toxic drug, invasive procedures such some organ biopsies or catheter procedures, and some studies using biological agents
○ **High** - some organ biopsies, novel therapeutic procedures, first-time-in-humans drug or device studies, some biological agents or Recombinant DNA Vector studies

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

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) Explain **the point at which the experiment will terminate. If appropriate, include the standards for the termination of the participation of the individual participant Also discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the participants.**

e)

Data Safety and Monitoring Plan (DSMP). See guidance on Data Safety and Monitoring.

A Data and Safety Monitoring Plan (DSMP) is required for studies that present Medium or High risk to participants. (See Overall Evaluation of Risk above). If Low Risk, a DSMP may not be necessary. Multi-site Phase III clinical trials funded by NIH require the DSM Plan to have a Data Safety Monitoring Board or Committee (DSMC or DSMB). The FDA recommends that all multi-site clinical trials that involve interventions that have potential for greater than minimal risk to study participants also have a DSMB or DSMC.

The role of the DSMC or DSMB is to ensure the safety of participants by analyzing pooled data from all sites, and to oversee the validity and integrity of the data. Depending on the degree of risk and the complexity of the protocol, monitoring may be performed by an independent committee, a board (DSMC/DSMB), a sponsor's Data Safety Committee (DSC), a Medical Monitor, a sponsor's safety officer, or by the Protocol Director (PD). *more...*

Describe the following:

Describe the following:

- **What type of data and/or events will be reviewed under the monitoring plan,** e.g. adverse events, protocol deviations, aggregate data? *more...*

- **Identify who will be responsible for Data and Safety Monitoring for this study,** e.g. Stanford Cancer Institute DSMC, an independent monitoring committee, the sponsor, Stanford investigators independent of the study, the PD, or other person(s). *more...*

▪ **Provide the scope and composition of the monitoring board, committee, or safety monitor,** e.g., information about each member's relevant experience or area of expertise. If the Monitor is the Stanford Cancer Center DSMC or the PD, enter N/A. *more...*

▪ If applicable, how frequently will the Monitoring Committee meet? Will the Monitoring Committee provide written recommendations about continuing the study to the Sponsor and IRB? *more...*

▪ Specify triggers or stopping rules that will dictate when the study will end, or when some action is required. If you specified this in Section 2g [Study Endpoints], earlier in this application enter 'See 2g'.

▪ Indicate to whom the data and safety monitoring person, board, or committee will disseminate the outcome of the review(s), e.g., to the IRB, the study sponsor, the investigator, or other officials, as appropriate. *more...*

Select One:

☐ The Protocol Director will be the only monitoring entity for this study.

☐ This protocol will utilize a board, committee, or safety monitor as identified in question #2 above.

Section 9(f)

9. Risks

f) Special Participant Populations

	Children

	If your research includes children but does not include an investigational drug/device or the research is not studying a commercial drug/device, complete the *Children's Findings* section entitled Children's Findings OHRP. (Regulatory citations 46.404 through 46.407)
	If your research includes children and an investigational drug/device is being studied, complete the *Children's Findings* section entitled Children's Findings FDA (Regulatory citations 50.51 through 50.54) See memo for additional information on multiple children's findings on FDA studies.

• Children's Findings OHRP. As children are involved in your research, please select one or more regulatory categories (46.404 through 46.407) below that your research falls under and provide the necessary rationale for each determination. See full regulation citation.

		46.404 Research not involving greater than minimal risk. The research must present no greater than minimal risk to children and adequate

		provisions must be made for soliciting the assent of the children and the permission of their parents or guardians. Please provide rationale for the above statement.

		46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects. The research presents more than minimal risk to children, but holds out the prospect of direct benefit for the individual subject or is likely to contribute to the subject's well-being. Please provide rationale that: (a) the risk is justified by the anticipated benefit to the subjects; (b) the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and (c) adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.
		46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition. Research that presents more than minimal risk to children that does not hold out the prospect of direct benefit for the individual subject, or is not likely to contribute to the well-being of the subject. Please provide rationale that: (a) the

		risk represents a minor increase over minimal risk; (b) the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations; (c) the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and (d) adequate provisions are made for soliciting assent of the children and permission of their parents or guardians.
		46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. Please provide rationale that: (a) the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; (b) the research will be conducted in accordance with sound ethical principles; (c) adequate provisions are made for soliciting assent of the children and permission of their parents or guardians.
	Rationale for category selected above:	

• Children's Findings FDA. As your research includes children and an investigational drug/device or a commercial device is being studied, please select one or more regulatory categories (50.51 through 50.54) below that your research falls under and provide the necessary rationale for each determination. See full regulation citation.

		50.51 Research not involving greater than minimal risk. The research must present no greater than minimal risk to children and adequate provisions must be made for soliciting the assent of the children and the permission of their parents or guardians. Please provide rationale for the above statement.

		50.52 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects. The research presents more than minimal risk to children, but holds out the prospect of direct benefit for the individual subject or is likely to contribute to the subject's well-being. Please provide rationale that: (a) the risk is justified by the anticipated benefit to the subjects; (b) the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and (c) adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.

		50.53 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition. Research that presents more than minimal risk to children that does not hold out the prospect of direct benefit for the individual subject, or is not likely to contribute to the well-being of the subject. Please provide rationale that: (a) the risk represents a minor increase over minimal risk; (b) the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations; (c) the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and (d) adequate provisions are made for soliciting assent of the children and permission of their parents or guardians.
		50.54 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. Please provide rationale that: (a) the research presents a reasonable opportunity to further the understanding, prevention, or

		alleviation of a serious problem affecting the health or welfare of children; (b) the research will be conducted in accordance with sound ethical principles; (c) adequate provisions are made for soliciting assent of the children and permission of their parents or guardians.
	Rationale for category selected above:	

	Pregnant Women or Fetuses
	As pregnant women or fetuses are included in your research, please confirm that all of the following conditions are met. See full regulation citation.

		Met		N/A	(a) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data assessing potential risks to pregnant women and fetuses;

		Met		N/A	(b) The risk

					to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;
		Met		N/A	(c) Any risk is the least possible for achieving the objectives of the research;
		Met		N/A	(d) If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the

					pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means , her consent is obtained in accord with the informed consent provisions of subpart A of this part;
		Met		N/A	(e) If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of subpart A of

					this part, except that the father's consent need not be obtained if he is unable to consent because of` unavailability , incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.
		Met		N/A	(f) Each individual providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;
		Met		N/A	(g) For children as defined in Sec. 46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of

					subpart D of this part;
		Met		N/A	(h) No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
		Met		N/A	(i) Individual engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy;
		Met		N/A	(j) Individual engaged in the research will have no part in determining the viability of a neonate.

Section 10, 11

10. 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.

11. 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 • Social Security numbers • Telephone numbers • 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 • 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 • Fax numbers • Electronic mail addresses • Medical record numbers • Health plan beneficiary numbers • Account numbers • Certificate/license numbers

	• Vehicle identifiers and serial numbers, including license plate numbers • Device identifiers and serial numbers • Web Universal Resource Locations (URLs). • Internet Protocol (IP) address numbers • Biometric identifiers, including finger and voice prints • Full face photographic images and any comparable images; and • 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). 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

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)

You are required to comply with University Policy that states that ALL electronic devices: computers (laptops and desktops; OFFICE or HOME); smart phones; tablets; external hard disks, USB drives, etc. that may hold identifiable participant data will be password protected, backed up, and encrypted. See http://med.stanford.edu/datasecurity/ for more information on the Data Security Policy and links to encrypt your devices.

Provide any additional information on ALL data security measures you are taking. You must use secure databases such as RedCap https://clinicalinformatics.stanford.edu/services/redcap.html. If you are unsure of the security of the system, check with your Department IT representative. Please see http://med.stanford.edu/irt/security/ for more information on IRT Information Security Services and http://www.stanford.edu/group/security/securecomputing/mobile_devices.html for more information for securing mobile computing devices. Additionally,any PHI data on paper must be secured in an locked environment.

By checking this box, You affirm the aforementioned.

☐

d) Describe how data or specimens will be labeled (e.g. name, medical record number, study number, linked coding system) or de-identified. If you are de-identifying data or specimens, who will be responsible for the de-identification? If x-rays or other digital images are used, explain how and by whom the images will be de-identified.

☐

e) Indicate who will have access to the data or specimens (e.g., research team, sponsors, consultants) and describe levels of access control (e.g., restricted access for certain persons or groups, access to linked data or specimens).

☐

f) If data or specimens will be coded, describe the method in which they will be coded so that study participants' identities cannot be readily ascertained from the code.

g) If data or specimens will be coded, indicate who will maintain the key to the code and describe how it will be protected against unauthorized access.

h) 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/. Additionally, if you will be using or sharing PHI see http://hipaa.stanford.edu/policy_security.html.

i) How will you educate research staff to ensure they take appropriate measures to protect the privacy of participants and the confidentiality of data or specimens collected (e.g. conscious of oral and written communications, conducting insurance billing, and maintaining paper and electronic data)?

Section 12

12. 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 faculty investigators will receive an email notifying them of the OPACS requirement. They may either answer "No" to the Financial Interest question from the email, or go to their OPACS dashboard to answer the question.
Investigators who have not received an email from 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, & S/B 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 below.
Review of this protocol by IRB will occur when all investigators listed below have answered Yes or No to the Financial Interest question in OPACS.
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 the COI Manager.
Note: If any changes to disclosures are made while this page is open, simply reload the page to see current information.

Section 13

13. Consent Background

Written, signed consent should always be sought unless there are compelling reasons to seek an alteration of consent, waiver of consent, or waiver of documentation (i.e., signature). See more information on Informed Consent. A protocol should include **at least one** of the following. Depending on the nature of the research and the subject population, more than one may be included.

- Consent (Click HERE for consent form templates)
- Waiver of Consent *(e.g., retrospective chart reviews)*
- Waiver of Documentation (signature) *(e.g., telephone screens, oral consent, web questionnaires, and cases when the primary risk is breach of confidentiality)*
- Alteration of Consent *(e.g., research involving deception or incomplete disclosure)*
- Short Form Consent *(e.g., when you anticipate consenting patients that speak a language other than the language in which the Consent form is written)*

Instructions

- Click ADD to enter detailed information on one of the above categories, and attach relevant consent documents. Once entered and saved, a row will be displayed in tabular form for each item (Consent, Waiver of Consent, etc.) entered.
- To view/modify the details of previously entered information or to **replace a consent document** with an updated version, click the link in the *Consent Type* column for the desired item.
- To view the current consent document, click the link in the *Title* column for the desired item.
- To remove an item, check the box next to the *Title* and click DELETE.

Consent Background [Add] [Delete]

	Title	Consent Type	Created Date
☐			

Section 13 "Add" Button

If "Add" was selected, then:

Consent Information Type:* [----------Please Select--------⇳]
Title:*

If "Consent" was selected under "Consent Information Type", then:

Consent

• Enter a descriptive *Title* rather than a filename. For example, instead of entering *consent.v1.doc* you should enter *consent for controls*. Also, do not use any special characters or symbols in the title.
• Click BROWSE to locate and attach a file from your desktop.
• Answer all questions as completely as possible.
• Click SAVE when done.

NOTE: VA Consent form must be used when any of the research activity is conducted on VA property, including recruitment of study subjects.

Consent Information Type:* [----------Please Select--------⇳]
Title:*
Sponsor's Consent Version Number:
(if any)
Consent Form (file name):* [Choose File]no file selected

Check if VA related ☐

a) Describe the informed consent process. Including 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.

[Save]

If "Waiver of Consent" was selected under "Consent Information Type", then:

• An example of when a waiver of consent would be applicable is for retrospective chart reviews.

- Answer all questions as completely as possible.
- Click SAVE when done.

Consent Information Type:* [----------Please Select--------⇳]
Title:*

Address the following four regulatory criteria for an alteration of consent and provide protocol-specific justification for each:

1) ○ True ○ False The research involves no more than minimal risk to the participants

Example: The research involves a review of medical records to determine the incidence of infection following hip replacement procedures. Participant information will be coded, and the key linking identities to the code will be kept in a locked cabinet to which only the Protocol Director and one co-investigator have access.

Rationale for above selection:

2) ○True ○False The waiver of alteration will not adversely affect the rights and welfare of the participants.

Example: The Privacy Notice informs patients that their records may be used without their authorization if approved by the IRB, and because study procedures are in place to protect confidentiality (including coding and restricted access to the key) information learned during the study will not affect the treatment of the participants who had infections in the pasts and thus will not adversely affect their welfare.

Rationale for above selection:

3) ○True ○False The research could not practically be carried out with out the waiver or alteration.

Example: If the IRB required informed consent of participants, this research would be impracticable to do because it would require contacting 1000 patients who had hip replacements one to four years ago; many are elderly and may have moved following their procedure, such that accurate contact information is not readily available and obtaining it for any of the target population would be unduly burdensome.

Rationale for above selection:

4) ○True ○False Whenever appropriate, the participants will be provided with additional pertinent information after participation.

Example: The information expected to be learned from this retrospective chart review from patient cases one to four years ago will not affect participant's treatment in the future. Thus, it is not anticipated that there will be pertinent information for study participants, though the study may lead to articles about infection that may affect the treatment of future patients.

Rationale for above selection:

[Save]
If "Waiver of Documentation" was selected under "Consent Information Type", then:

• Is applicable for telephone screens , oral consent , web questionnaires, and cases where the primary risk is breach of confidentiality
• Enter a descriptive *Title* rather than a filename. For example, instead of entering *consent.v1.doc* you should enter *consent for controls*. Also, do not use any special characters or symbols in the title.
• Click BROWSE to locate and attach a file from your desktop.
• Answer all questions as completely as possbile.
• Click SAVE when done.

Consent Information Type:* [----------Please Select--------⇳]
Title:*
Sponsor's Consent Version Number:
(if any)
Consent Form (file name):* [Choose File]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.

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.

Select one of the following regulatory criteria for a waiver of documentation (signature) and provide a protocol-specific justification:

○ 45 CFR 46.117(c)(1). For research that is not subject to FDA regulation, the only record linking the participants and the research would be the consent document,and the principal risk would be potential harm resulting from a breach on confidentiality; each participant will be asked whether he/she wants documentation linking the participant with the research, and the participant's wishes govern.

○ 45CFR46.117(c)(2). Research (whether it is or is not a subject to FDA regulation) presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.

Rationale for above selection:

[Save]

If "Alteration of Consent" is selected under "Consent Information Type", then:

Alteration of Consent

• Is applicable for research involving deception or incomplete disclosure.
• Enter a descriptive *Title* rather than a filename. For example, instead of entering *consent.v1.doc* you should enter *consent for controls*. Also, do not use any special characters or symbols in the title.

• Click BROWSE to locate and attach a file from your desktop.
• Answer all questions as completely as possbile.
• Click SAVE when done.

Consent Information Type:* [----------Please Select--------⇳]
Title:*
Sponsor's Consent Version Number:
(if any)
Consent Form (file name):* [Choose File]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.

a) 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.

b) 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.

Address the following four regulatory criteria for an alteration of consent and provide protocol-specific justification for each:

1) ○True ○False The research involves no more than minimal risk to the participants.

Example: The research involves a review of medical records to determine the incidence of infection following hip replacement procedures. Participant information will be coded, and the key linking identities to the code will be kept in a locked cabinet to which only the Protocol Director and one co-investigator have access.
Rationale for above selection:

2) ○True ○False The waiver or alteration will not adversely affect the rights and welfare of the participants.

Example: The Privacy Notice informs patients that their records may be used without their authorization if approved by the IRB, and because study procedures are in place to protected confidentiality (including coding and restricted access to the key) information learned during the study will not affect the treatment of the participants who had infections in the pasts and thus will not adversely affect their welfare.

Rationale for above selection:

3) ○True ○False The research could not practically be carried out with out the waiver or alteration.

Example: If the IRB required informed consent of participants, this research would be impracticable to do because it would require contacting 1000 patients who had hip replacements one to four years ago; many are elderly and may have moved following their procedure,such that accurate contact information is not readily available and obtaining it for any of the target population would be unduly burdensome.

Rationale for above selection:

4) ○True ○False Whenever appropriate, the participants will be provided with additional pertinent information after participation.

Example: The information expected to be learned from this retrospective chart review from patient cases one to four years ago will not affect participant's treatment in the future. Thus, it is not anticipated that there will be pertinent information for study participants, though the study may lead to articles about infection that may affect the treatment of future patients.

Rationale for above selection:

[Save]

If "Short Form Consent Process" is selected under "Consent Information Type", then:

• Download the short form consent in required language and add to the header: Study Title, Protocol Director. Contact Information. If the participant speaks a language other than one available on our website, you must submit a short form version in that language to the IRB for approval before enrolling the participant.
• Add lines to the full English consent form for Witness Signature and Date.
• If the Person Obtaining Consent does not speak the participant's language, you must use a translator/interpreter. A family member may act as the translator/interpreter if the participant has declined the services of a hospital translator/interpreter.
• A witness, who is bi-lingual in English and the participant's language, must be present during the entire consent process. The translator/interpreter can act as the witness. After the study is describe to the participant by the translator/interpreter, the participant and witness must sign the short form consent and the Person Obtaining Consent and the witness must sign the full English consent.

☐ I have read and will follow the above procedures.

Consent Form (file name): [Choose File]no file selected

[Save]

Section 14

14. Assent Background (less than 18 years of age)

All children must assent to participating by signing an assent form, unless the investigator(s) provides evidence to the IRB that the children are not capable of assenting because of age, maturity, psychological state, or other factors. See more information on Assent. A protocol that involves children should include **at least one** of the following. Depending on the nature of the research and the subject population, more than one may be included.

- Assent (Click HERE for assent template)
- Waiver of Assent (used when assent will not be sought for some or all of the children **capable** of assenting)
- Assent Not Applicable (used to describe why some or all of children are **not capable** of assenting)

Instructions

- Click ADD to enter detailed information on one of the above categories, and attach relevant assent documents. Once entered and saved, a row will be displayed in tabular form for each item (Assent, Waiver of Assent, etc.) entered.
- To view/modify the details of previously entered information or to **replace an assent document** with an updated version, click the link in the *Assent InformationType* column for the desired item.
- To view the current assent document, click the link in the *Title* column for the desired item.
- To remove an item, check the box next to the *Title* and click DELETE.

Assent Background [Add] [Delete]

	Title	Assent Information Type	Created Date
☐			

Section 14 "Add" Button

If "Add" was selected, then:

Assent Background [Save]

Assent Information Type:* [----------Please Select------⇳]
Title:*

If "Assent" was selected under "Assent Information Type", then:

Assent
• Enter a descriptive *Title* rather than a filename. For example, instead of entering *assent.v1.doc* you should enter *assent for 7 to 10 yr old*. Also, do not use any special characters or symbols in the title.
• Click BROWSE to locate and attach a file from your desktop.
• Answer all questions as completely as possbile.
• Click SAVE when done.

Assent Information Type:* [----------Please Select------⇳]
Title:*
Sponsors Assent Version Nbr: (if any)
Assent Form(file name):* [Choose File]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 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.

[Save]

If "Waiver of Assent" was selected under "Assent Information Type", then:

Waiver of Assent
• Answer all questions as completely as possbile.
• Click SAVE when done.

Assent Information Type:* [----------Please Select------⇳]
Title:*

Address the following four regulatory criteria for a waiver of assent and provide a protocol-specific justification for each:

1) ○True ○False The research involves no more than minimal risk to the participants.

Rationale for above selection:

2) ○True ○False The waiver will not adversely affect the rights and welfare of the participants.

Rationale for above selection:

3) ○True ○False The research could not practicably be carried out without the waiver.

Rationale for the above selection:

4) ○True ○False Whenever appropriate, the participants will be provided with additional pertinent information after participation.

Rationale for above selection:

[Save]
If "Assent Not Applicable" is selected under "Assent Information Type", then:

Assent Not Applicable
• Answer the question as completely as possbile.
• Click SAVE when done.

Assent Information Type:* [----------Please Select------⇳]
Title:*

Please explain why assent is not applicable to this study:

[Save]
Section 15

15. HIPAA Background

If your protocol involves Protected Health Information (PHI) you must include one or more of the following unless your consent form(s) contain embedded HIPAA

language. In cases where HIPAA language is included in the consent(s), you may still need to include a Limited Waiver of Authorization.
• **HIPAA Authorization**
• **Waiver of Authorization** *(e.g., retrospective chart reviews)*
• **Waiver of Authorization for Recruitment** (*e.g., telephone screens that include questions eliciting PHI, chart reviews to determine elligibility*)
• **Alteration of Authorization** *allow for a waiver of the signature requirement for HIPAA authorization (e.g for studies conducted over the telephone or by mail)*

Instructions
• Click ADD to enter detailed information on one of the above categories, and attach relevant documents. Once entered and saved, a row will be displayed in tabular form for each item (HIPAA Authorization, Waiver of Authorization, etc.) entered.
• To view/modify the details of previously entered information or to replace a document with an updated version, click the link in the HIPAA Information Type column for the desired item.
• To view the current authorization document, click the link in the Title column for the desired item.
• To remove an item, check the box next to the Title and click DELETE.

HIPAA Background [Add] [Delete]

	Title	HIPAA Information Type	Created By	Created Date
☐				

Section 15 "Add" Button

If "Add" was selected, then:

HIPAA Background [Save]

HIPAA Information Type:* [----------Please Select----⇳]
Title:*

If "Authorization" was selected under "HIPAA Information Type", then:

HIPAA Information Type:* [----------Please Select----⇳]
Title:*
Authorization (file name): [Chose File]no file selected

[Save]

If “Waiver of Authorization” was selected under “HIPAA Information Type”, then:

HIPAA Information Type:* [----------Please Select----⇳]
Title:*

a) Please describe the Protected Health Information (PHI) needed to conduct the study. PHI is health information linked to one or more of the HIPAA identifiers listed in section 11. List BOTH health information AND identifiers (e.g., lab report (health information) AND patient name (identifier)). Be consistent with information entered in section 11b.

b) Please Answer:

○ Yes	○ No	Do you certify that the use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals?
○ Yes	○ No	Do you certify that the research could not practically be conducted with out the waiver?
○ Yes	○ No	Do you certify that you have adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research which the use or disclosure of protected health information would be permitted?
○ Yes	○ No	Do you certify that the research could not practically be conducted with out access to and use of the protected health information?

c) Please describe an adequate plan to protect identifiers from improper use and disclosure.

d) Please describe an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.

[Save]

If “Waiver of Authorization for Recruitment” is selected under “HIPAA Information Type”, then:

HIPAA Information Type:* [----------Please Select----⇳]
Title:*

a) Please describe the protected health information (PHI) needed to conduct screening or recruitment. PHI is health information linked to one or more of the HIPAA identifiers listed in section 11. List BOTH health information AND identifiers (e.g., lab report (health information) AND patient name (identifier)). Be consistent with information entered in section 11b.

b) Please Answer:

○ Yes	○ No	Do you certify that the use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals?
○ Yes	○ No	Do you certify that the research could not practically be conducted with out the waiver?
○ Yes	○ No	Do you certify that you have adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research which the use or disclosure of protected health information would be permitted?
○ Yes	○ No	Do you certify that the research could not practically be conducted with out access to and use of the protected health information?

c) Please describe an adequate plan to protect identifiers from improper use and disclosure.

d) Please describe an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.

[Save]

If “Alteration of Authorization” is selected under “HIPAA Information Type”, then:

HIPAA Information Type:* [----------Please Select----⇳]
Title:*
Attachment (optional) [Choose File]no file selected

a) Please describe the Protected Health Information (PHI) needed to conduct the study. PHI is health information linked to one or more of the HIPAA identifiers listed in section 11. List BOTH health information AND identifiers (e.g., lab report (health information) AND patient name (identifier)). Be consistent with information entered in section 11b.

b) Please Answer:

○ Yes	○ No	Do you certify that the use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals?
○ Yes	○ No	Do you certify that the research could not practically be conducted with out the waiver?
○ Yes	○ No	Do you certify that you have adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research which the use or disclosure of protected health information would be permitted?
○ Yes	○ No	Do you certify that the research could not practically be conducted with out access to and use of the protected health information?

c) Please describe an adequate plan to protect identifiers from improper use and disclosure.

d) Please describe an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.

[Save]

Section 16

16. 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.**

[Add]

Please click on 'Add' to attach documents

Section 16 "Add" Button

If "Add" is selected, then:

Attachments [Save]

Type:	[Drop down menu]
Title:*	
Attachment(File Name):	[Choose File]no file selected

Under the drop down menu there are the following options

- IRB Administrative Use Only
- Advertisements
- Cooperating Institution(s) Approval
- Federal Grant/Sub-contract
- Information Sheets/Brochures
- Investigator's Brochure
- Package Inserts
- Phone Scripts
- Program Project Grant/List
- Questionnaires
- Sponsor's Protocol
- Sponsor's Protocol Amendments
- Training Grant/List
- Un-sponsored Research Approval
- VA required questions
- Other

Obligations

The Protocol Director agrees to:

- Adhere to principles of sound scientific research designed to yield valid results
- Conduct the study according to the protocol approved by the IRB
- Be appropriately qualified to conduct the research and be trained in Human Research protection, ethical principles, regulations, policies and procedures
- Ensure all research personnel are adequately trained and supervised
- Ensure that the rights and welfare of participants are protected including privacy and confidentiality of data
- Ensure that, when de-identified materials are obtained for research purposes, no attempt will be made to re-identify them.
- Disclose to the appropriate entities any potential conflict of interest
- Report promptly any new information, modification, or unanticipated problems that raise risks to participants or others
- Apply relevant professional standards.

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) 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 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)

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.