

IRB MEDICAL

EXPEDITED

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.



The screenshot shows a web form with a text input field. The label "Protocol Title" is positioned at the top left of the field. A "Next" button is located at the top right of the field. The input field is currently empty.

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***PERSONNEL LOOKUP**

Name	Degree (program/year if student)	Title
E-mail	Phone	Fax
Dept	Mail Code	
[Drop Down Menu]		
CITI Training current (within last 2 years)? <input type="radio"/> Yes <input type="radio"/> No		

*Admin Contact***PERSONNEL LOOKUP**

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

*Co-Protocol Director***PERSONNEL LOOKUP**

[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) <input type="radio"/> Yes <input type="radio"/> No		

Other Contact

PERSONNEL LOOKUP

APP-1m-exped
[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) <input type="radio"/> Yes <input type="radio"/> No		

Academic Sponsor

PERSONNEL LOOKUP

[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) <input type="radio"/> Yes <input type="radio"/> No		

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.		

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 .

Create

Select Application Category:	<input type="radio"/> Medical	<input type="radio"/> 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:	<input type="radio"/> Regular	<input type="radio"/> Expedited	<input type="radio"/> Exempt

Medical Expedited Review

A protocol must be no more than minimal risk (i.e., "not greater than those ordinarily encountered in daily life") AND must only involve human subjects in one or more of the following paragraphs:

Select one or more of the following paragraphs:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
- a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
 - b) Research on medical devices for which
 - i) an investigational device exemption application (21 CFR Part 812) is not required; or
 - ii) the medical device is cleared/approved for marketing and

the medical device is being used in accordance with its cleared/approved labeling

- 2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
 - b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week
- 3. Prospective collection of biological specimens for research purposes by non invasive means.
- 4. Collection of data through non invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples:

- a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
 - b) weighing or testing sensory acuity;
 - c) magnetic resonance imaging;
 - d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
 - e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
- 5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this paragraph may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only

to research that is not exempt.)

- 6. Collection of data from voice, video, digital, or image recordings made for research purposes.
- 7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

Personnel Info

Instructions:

- You **MUST** select an entry from the auto-complete choices under the Name field to properly populate personnel information. Do **NOT** manually enter your name.
- 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, Other Contact and Academic Sponsor. • Click the link in the Other Personnel section towards the bottom of the page to enter additional personnel (including persons without SUNetIDs).
- All personnel must take CITI training. If your training information is highlighted, it must 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)? <input type="radio"/> Yes <input type="radio"/> 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) <input type="radio"/> Yes <input type="radio"/> 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) <input type="radio"/> Yes <input type="radio"/> 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) <input type="radio"/> Yes <input type="radio"/> 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) <input type="radio"/> Yes <input type="radio"/> No		

Other Personnel

[Click here to add other personnel](#)

SUNet ID

First Name

Last Name

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

[Click here to add Other Personnel, if you are sure the SUNet ID does not exist for the person](#)

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.			

Participant Population

Instructions:

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

- A researcher is conducting a study to compare to strategies designed to promote a 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	
<input type="radio"/>	<input type="radio"/>	Children (under 18)
<input type="radio"/>	<input type="radio"/>	Pregnant Women and Fetuses

<input type="radio"/>	<input type="radio"/>	Neonates (0 - 28 days)
<input type="radio"/>	<input type="radio"/>	Abortuses
<input type="radio"/>	<input type="radio"/>	Mentally Disabled
<input type="radio"/>	<input type="radio"/>	Decisionally Challenged
<input type="radio"/>	<input type="radio"/>	Cancer Subjects
<input type="radio"/>	<input type="radio"/>	Laboratory Personnel
<input type="radio"/>	<input type="radio"/>	Healthy Volunteers
<input type="radio"/>	<input type="radio"/>	Students
<input type="radio"/>	<input type="radio"/>	Employees
<input type="radio"/>	<input type="radio"/>	Prisoners
<input type="radio"/>	<input type="radio"/>	Other (i.e., any population that is not specified above)

Study Location

Instructions:

The **study location** is the location is 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 details for one or more 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

<input type="checkbox"/>	Stanford University
<input type="checkbox"/>	General Clinical Research Center (GCRC)
<input type="checkbox"/>	Stanford Hospital and Clinics
<input type="checkbox"/>	Lucile Packard Children's Hospital (LPCH)
<input type="checkbox"/>	VAPAHCS (Specify PI at VA)
<input type="checkbox"/>	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 Name*	
Contact Name	
Contact Phone	

Contact Email		
<input type="radio"/> Yes	<input type="radio"/> No	Has the location granted permission for the research to be conducted?
<input type="radio"/> Yes	<input type="radio"/> 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 on <http://clinicaltrials.stanford.edu> prior to enrolling any research participants.

General Checklist

Yes	No	Multi-site						
<input type="radio"/>	<input type="radio"/>	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)						
<input type="radio"/>	<input type="radio"/>	Is Stanford the coordinating institution or are you the lead investigator for this multi-site study?						
		[Add] [Delete]						
		<input type="checkbox"/>	Site Name	Contact Name	Phone	Email	Permission?	IRB?
Yes	No	Collaborating Institution(s)						
<input type="radio"/>	<input type="radio"/>	Are there any collaborating institutions? A collaborating institution is generally an institution that collaborates equality on a research endeavor with one or more institutions.						
		[Add] [Delete]						
		<input type="checkbox"/>	Site Name	Contact Name	Phone	Email	Permission?	IRB?
Yes	No	Cancer Institute						
<input type="radio"/>	<input type="radio"/>	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).						
		<i>For all Cancer-related studies, see the submission instructions on the Cancer Clinical Trials website</i>						

		<i>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.</i>
Yes	No	Drug/Device
<input type="radio"/>	<input type="radio"/>	Investigational drugs, biologics, reagents, or chemicals?
<input type="radio"/>	<input type="radio"/>	Commercially available drugs, reagents, or other chemicals administered to subjects (even if they are not being studied)?
<input type="radio"/>	<input type="radio"/>	Investigational Device / Commercial Device used off-label?
<input type="radio"/>	<input type="radio"/>	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 .
<input type="radio"/>		Click "yes" to confirm that you have accessed the website and read the clinicaltrials.gov reporting requirements provided.
<input type="radio"/>	<input type="radio"/>	This study will be registered on clinicaltrials.gov ?
<input type="radio"/>	<input type="radio"/>	Protocol involves studying potentially addicting drugs?
Yes	No	Tissues and Specimens
<input type="radio"/>	<input type="radio"/>	Human blood, cells, tissues, or body fluids (tissues)?
<input type="radio"/>	<input type="radio"/>	Tissues to be stored for future research projects?
<input type="radio"/>	<input type="radio"/>	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)
<input type="radio"/>	<input type="radio"/>	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 # <input type="text"/>
<input type="radio"/>	<input type="radio"/>	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 # <input type="text"/>
<input type="radio"/>	<input type="radio"/>	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 # <input type="text"/>
		<i>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.</i>
Yes	No	Human Embryos or Stem Cells
<input type="radio"/>	<input type="radio"/>	Human Embryos or gametes? SCRO # <input type="text"/>
<input type="radio"/>	<input type="radio"/>	Human Stem Cells (including hESC, iPSC, cancer stem cells, progenitor cells).

		SCRO # <input type="text"/>
Yes	No	Veterans Affairs (VA)
<input type="radio"/>	<input type="radio"/>	The research recruits participants at the Veterans Affairs Palo Alto Health Care System (VAPAHCS)
<input type="radio"/>	<input type="radio"/>	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.
<input type="radio"/>	<input type="radio"/>	The research is sponsored (i.e., funded) by VAPAHCS
<input type="radio"/>	<input type="radio"/>	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.
<input type="radio"/>	<input type="radio"/>	The research is conducted using any property or facility of VAPAHCS.
<i>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 and Administration office at the Palo Alto VA at 650-493-5000 ext. 65418</i>		
Yes	No	Equipment
<input type="radio"/>	<input type="radio"/>	Use of Patient related equipment? If Yes, equipment must meet the standards established by Hospital Instrumentation and Electrical Safety Committee (650-725-5000)
<input type="radio"/>	<input type="radio"/>	Medical equipment used for human patients/subjects also used on animals?
<input type="radio"/>	<input type="radio"/>	Radioisotopes/radiation-producing machines, even if standard of care?
Yes	No	Payment
<input type="radio"/>	<input type="radio"/>	Subjects will be paid for participation? See payment considerations .
Yes	No	Funding
<input type="radio"/>	<input type="radio"/>	Training Grant?
<input type="radio"/>	<input type="radio"/>	Program Project Grant?
<input type="radio"/>	<input type="radio"/>	Federally Sponsored Project?
<input type="radio"/>	<input type="radio"/>	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		
<input type="radio"/> Yes <input type="radio"/> No	Has the location granted permission for the research to be conducted?	
<input type="radio"/> Yes <input type="radio"/> 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		
<input type="radio"/> Yes <input type="radio"/> No	Has the location granted permission for the research to be conducted?	
<input type="radio"/> Yes <input type="radio"/> 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
<input type="checkbox"/>				

Funding – Fellowships [Add] [Delete]

	Fellow	Title	Administered By	Funded By
<input type="checkbox"/>				

Funding – Other

Gift Funding [Add] [Delete]

	Gift Name	Account Number
<input type="checkbox"/>		

Dept. Funding [Add] [Delete]

	Department	Account Number
<input type="checkbox"/>		

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

	Other Funding	Account Number
<input type="checkbox"/>		

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		
SPO # (if available)		
Grant # (if available)		
Funded By (include pending)*		
Principal Investigator		
Grant/Contract Title if different from Protocol Title		
<input type="radio"/> Yes <input type="radio"/> No For Federal projects, are contents of this protocol the same as described in Federal proposal application?		
<input type="radio"/> Yes <input type="radio"/> No Is this a Multiple Project Protocol (MPP)?		
<input type="radio"/> Yes <input type="radio"/> 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		
SPO# (if available)		
Fellowship Reference #(if available)		
Funded By		
Name of Fellow*		
Fellowship Title if different from Protocol Title		
<input type="radio"/> Yes <input type="radio"/> 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 (e.g., OTL, URO)	[Save]
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

Section Expedited Paragraph(s)

Title

A protocol must be no more than minimal risk (i.e., "not greater than those ordinarily encountered in daily life") AND must only involve human subjects in one or more of the following paragraphs.

Select one or more of the following paragraphs:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
- a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
- b) Research on medical devices for which
- I) an investigational device exemption application (21 CFR Part 812) is not required; or
- II) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

- a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
- b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by non invasive means.

4. Collection of data through non invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples:

- a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
- b) weighing or testing the sensory acuity;
- c) magnetic resonance imaging;
- d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
- e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this paragraph may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior(including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human

subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

Sections 1-3

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 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. Include the total number of times each procedure may be performed.

Radiation Procedures		[Add]	[Delete]
	Procedure		Type
<input type="checkbox"/>			

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

Identify the radionuclide and chemical form.

For each dosage, provide the number of times the radioisotope will be administered, the route of administration, and the activity that will be administered (mCi).

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, identify the procedures and the number of times each will be performed on a single research participant

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

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

- d) For 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' 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	<input type="radio"/> Standard of Care <input type="radio"/> Research

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.

Investigational Devices and Uses [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*	<input type="radio"/> Significant <input type="radio"/> 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*	<input type="radio"/> Significant <input type="radio"/> Non-significant See Significant and Non-Significant Risk Medical Devices guidance.
IDE#	
Holder of IDE	
* Indicate who holds the IDE:	
<input type="radio"/>	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). <i>The FDA letter</i>

	<i>does not have to be provided if the IDE number is on the sponsor's protocol.</i>
<input type="radio"/>	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).
<input type="radio"/>	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 <i>as appropriate</i> , handled according to VAPAHCS memo 151-05-10. If no, please provide an explanation.	
Confirm? <input type="radio"/> Yes <input type="radio"/> 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* <input type="radio"/> Significant <input type="radio"/> 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:	
<ul style="list-style-type: none"> ▪ 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. 	
<input type="checkbox"/> I confirm the above are true	
Rationale for the device being non-significant risk:	

Sponsor of Project	
* Indicate the project sponsor:	
<input type="radio"/>	The sponsor is the device manufacturer.
<input type="radio"/>	The sponsor is the STANFORD (SU, SHC, LPCH, VA) investigator.
<input type="radio"/>	The sponsor is a non-STANFORD investigator.
Ordering, Storage, 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 SHC/LPCH policy for Investigational New Devices <i>or as appropriate</i> , handled according to VAPAHCS memo 151-05-10. If no, please provide an explanation.	
Confirm? <input type="radio"/> Yes <input type="radio"/> No	

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	
<input type="radio"/> This is a legally marketed device being used in accordance with its labeling.	
<input type="radio"/> This is an <i>in vitro</i> 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:	
<ul style="list-style-type: none"> ▪ 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.

Investigational Drugs, Reagents, Chemicals [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:	
	<p>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). <i>The FDA letter does not have to be provided if the IND number is</i></p> <p>○</p>

	<i>on the sponsor's protocol.</i>
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Pharmacy Dispensing or Security and Controlled Access Plan.	
<input type="radio"/> Yes <input type="radio"/> No	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	

	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).
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b) Please list in the table below all commercial drugs, reagents or chemicals to be administered to subjects.

Commercial Drugs, Reagents, Chemicals	[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	
<input type="radio"/> Yes <input type="radio"/> No	Is this new and different uses of this commercially available drug, reagent or chemical?
<input type="radio"/> Yes <input type="radio"/> No	Are all of the IND statements shown below true?
<u>Investigational New Drug (IND) Regulations</u>	
<p>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:</p> <ul style="list-style-type: none"> ▪ 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.

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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 RPH 5.5 [Use of Employees or Laboratory Personnel as Research Subjects](#))

- 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-d)

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 subject 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.

Section 9(e)

9. Risks

- e) Special Participant Populations

Children

If your research includes children but does not include an investigational 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)

- Children's Findings OHRP. As children are involved in your research, please select one regulatory category (46.404 through 46.407) below that your research falls under and provide the necessary rationale for this 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:

[IRB MEDICAL EXPEDITED FORM AS OF 02/04/2013]

-
- Children's Findings FDA. As your research includes an investigational drug/device and children, please select one regulatory category (50.51 through 50.54) below that your research falls under and provide the necessary rationale for this 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](#).

<input type="radio"/> Met	<input type="radio"/> 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;
<input type="radio"/> Met	<input type="radio"/> 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;
<input type="radio"/> Met	<input type="radio"/> N/A	(c) Any risk is the least possible for achieving the objectives of the research;
<input type="radio"/> Met	<input type="radio"/> 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;
<input type="radio"/> Met	<input type="radio"/> 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.
<input type="radio"/> Met	<input type="radio"/> 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;
<input type="radio"/> Met	<input type="radio"/> 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;
<input type="radio"/> Met	<input type="radio"/> N/A	(h) No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
<input type="radio"/> Met	<input type="radio"/> 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;
<input type="radio"/> Met	<input type="radio"/> N/A	(j) Individual engaged in the research will have no part in

	determining the viability of a neonate.
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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
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 combining 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, characteristic, or code (except the unique code assigned by the Investigator(s) to code the research data, unless the code was derived from other identifiable information, such as the 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 how data will be maintained (e.g., paper or electronic spreadsheet, desktop computer, laptop or other portable device) and how you will maintain the confidentiality and data security, (e.g. password protected computer, encrypted files, locked cabinet and office).

- 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 [ISO website](#). Additionally, if you will be using or sharing PHI see the Stanford HIPAA website.

- 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 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.

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**
- **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]
<input type="checkbox"/>	Title	Consent Type	Created Date
<input type="checkbox"/>			

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 Background

[Save]

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:

Waiver of Consent

- 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:

Waiver of Documentation

- 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 possible.
- 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 possible.
- 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 Chapter 12.2](#) 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 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 without 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:

Short Form Consent Process

Consent Information Type:* [-----Please Select-----⇅]

Title:*

- 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

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**
- **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]
<input type="checkbox"/>	Title	Assent Information Type	Created Date
<input type="checkbox"/>			

Section 14 "Add" Button

If "Add" was selected, then:

Assent Background [Save]

[IRB MEDICAL EXPEDITED FORM AS OF 02/04/2013]

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 possible.
- Click SAVE when done

Assent Information Type:* [Assent ⇅]
 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 possible.
- Click SAVE when done.

Assent Information Type:* [Waiver of Assent ⇅]
Title:*

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 possible.
- Click SAVE when done.

Assent Information Type:* [Assent Not Applicable ⇅]
Title:*

Please explain why assent is not applicable to this study:

--

[Save]

Section 15

15. HIPAA Background

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 eligibility*)
- **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
<input type="checkbox"/>			Created Date

Section 15 "Add" Button

If "Add" was selected, then:

HIPAA Background

[Save]

[IRB MEDICAL EXPEDITED FORM AS OF 02/04/2013]

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

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

Authorization

HIPAA Information Type:* [Authorization ↕]
 Title:*

Authorization (file name): [Chose File]no file selected

[Save]

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

Waiver of Authorization

HIPAA Information Type:* [Waiver of Authorization ↕]
 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:

<input type="radio"/> Yes	<input type="radio"/> 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?
<input type="radio"/> Yes	<input type="radio"/> No	Do you certify that the research could not practically be conducted with out the waiver?
<input type="radio"/> Yes	<input type="radio"/> 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?
<input type="radio"/> Yes	<input type="radio"/> 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:

Waiver of Authorization for Recruitment

HIPAA Information Type:* [Waiver of Authorization for Recruitment-⌵]
 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:

<input type="radio"/> Yes	<input type="radio"/> 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?
<input type="radio"/> Yes	<input type="radio"/> No	Do you certify that the research could not practically be conducted with out the waiver?
<input type="radio"/> Yes	<input type="radio"/> 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?
<input type="radio"/> Yes	<input type="radio"/> 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:

Alteration of Authorization

HIPAA Information Type:* [Alteration of Authorization ⇅]

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:

<input type="radio"/> Yes	<input type="radio"/> 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?
<input type="radio"/> Yes	<input type="radio"/> No	Do you certify that the research could not practically be conducted with out the waiver?
<input type="radio"/> Yes	<input type="radio"/> 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?
<input type="radio"/> Yes	<input type="radio"/> 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
- 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@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.