

USE FOR: chart review studies that only involve the use of materials (data, documents, records) that have been collected for research or non-research purposes, or will be collected for non-research purposes.

DO NOT USE: If a study involves interaction/intervention with participants, evaluating safety and effectiveness of a drug or device, or obtaining/analyzing specimens, (which must be submitted on an Expedited or Regular form.)

IRB CHART REVIEW

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 [FAQs](#) for information to consider beforehand.

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

What to expect:

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

Personnel Info

Instructions:



The image shows a screenshot of a web form. At the top left, there is a label 'Protocol Title' in white text on a black background. Below this is a large, empty rectangular text input field with a blue border. At the top right of the input field, there is a small red button with the word 'Next' in white text.

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

Protocol Director

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

PERSONNEL LOOKUP

Admin Contact

PERSONNEL LOOKUP

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		
Name	Degree (Program/year if student)	Title
Name	Degree (program/year if student)	Title
E-mail	Phone	Fax
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		
Name	Degree (Program/year if student)	Title
E-mail	Phone	Fax
Dept		Mail Code

Other

Contact

PERSONNEL LOOKUP [Clear]

Academic Sponsor **PERSONNEL LOOKUP** [Clear]

CITI "Stanford" Popup

If the CITI "Stanford" popup is clicked and the user has training, then: Training Details [Close]

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

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:

Name	Degree (program/year if student)	Title
E-mail	Phone	Fax
Dept		Mail Code
[Drop Down Menu]		

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

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		
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		

Application Category/Type **Create**

*This form type may only be used for studies involving materials (data, documents, records) that **have been** collected for research or non-research purposes, or materials that **will be** collected for non-research purposes.*

***Do not** use this form, if you plan on interaction or intervention with participants, if the chart review involves evaluating the safety and effectiveness of a drug or device, or if you are obtaining or analyzing specimens. Instead, submit an expedited or regular form.*

Chart Review Create

Expedited Category 5:

Yes No Research involving materials (data, documents, records) that 1) have been collected, or 2) will be collected solely for non-research purposes (such as medical treatment or diagnosis).

Personnel Info

Instructions:

- You **MUST** select an entry from the Personnel Lookup field to properly populate personnel information. Do **NOT** manually enter your name in the 'Name' field.

- At minimum, a Protocol Director (PD) and Administrative Contact must be entered; the same person may be entered for both roles if needed.
- If the PD is a student (e.g., Undergraduate, Graduate, or Post-Doc), you must also enter an Academic Sponsor. Those entered as Academic Sponsors should be listed in categories 1 and 2 of [Administrative Guide 23](#).
- Only those entered in the following roles will have **edit access** to the Protocol application: PD, Admin Contact, Co-PD and Other Contact.
- Click the link in the *Other Personnel* section towards the bottom of the page to enter additional personnel (including persons without SUNetIDs).
- All users must take CITI training. If your training information is highlighted, it will be verified by IRB staff.
- You can click here to [review completion records](#) to ensure training has been completed.

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

Confirm Personnel

Protocol Director

PERSONNEL LOOKUP

Admin Contact

PERSONNEL LOOKUP

Co-Protocol Director **PERSONNEL LOOKUP** [Clear]

Other

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		
Name	Degree (Program/year if student)	Title
E-mail	Phone	Fax
Name	Degree (program/year if student)	Title
Dept		Mail Code
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		
Name	Degree (Program/year if student)	Title
E-mail	Phone	Fax
Name	Degree (program/year if student)	Title
Dept		Mail Code
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		
Name	Degree (Program/year if student)	Title
E-mail	Phone	Fax
Dept		Mail Code

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		
Name	Degree (Program/year if student)	Title
Name	Degree (program/year if student)	Title
E-mail	Phone	Fax
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		
Name	Degree (Program/year if student)	Title
E-mail	Phone	Fax
Dept		Mail Code

Name	Degree (program/year if student)	Title
E-mail	Phone	Fax
Dept		Mail Code
[Drop Down Menu]		

PERSONNEL LOOKUP [Clear]

Academic Sponsor **PERSONNEL LOOKUP** [Clear]

CITI "Stanford" Popup

If the CITI "Stanford" popup is clicked and the user has training, then: Training Details [Close]

Name	Degree (program/year if student)	Title
E-mail	Phone	Fax
Dept		Mail Code

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

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

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

Confirm Personnel

Participant Population

Participant Population(s) Checklist	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		
	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		
Cancer Subjects popup	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		
For all Cancer-related studies, see the submission instructions on the Cancer Clinical Trials website at http://cancer.stanford.edu/trials/admin/newprotocol.html	[Drop Down Menu]		

IMPORTANT: Your study involves cancer, therefore review and approval by the Stanford Cancer Institute Scientific Review Committee (SRC) is required before accrual can begin. See <http://cancer.stanford.edu/trials/srctop.html> for more information.

Study Location

Instructions:

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

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

Study Location(s) Checklist

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		
Name	Degree (program/year if student)	Title
E-mail	Phone	Fax
Dept		Mail Code
[Drop Down Menu]		

“Other Location Add” Popup

If “Other” was selected, then:

If “Add” is selected, then: Other Location [Save]

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		
Name	Degree (Program/year if student)	Title
E-mail	Phone	Fax
Dept		Mail Code
[Drop Down Menu]		

General Checklist

Instructions:

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

Reminder: If your study meets the [ICMJE definition](#) of a clinical trial, regardless of the funding source, you must register your study at <http://clinicaltrials.stanford.edu>.

Reminder: If your study meets the [ICMJE definition](#) of a clinical trial, regardless of the funding source, you must register your study at <http://clinicaltrials.stanford.edu>.

General Checklist

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		
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		
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		

Collaborating Institution(s) "Add" popup

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

[Save]

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

Funding

NONE

Funding – Grants/Contracts [Add]

Funding – Fellowships [Add]

Funding – Other [Add]

Gift Funding [Add]

Dept. Funding [Add]

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

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 consistent with those 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

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		
Name	Degree (Program/year if student)	Title
E-mail	Phone	Fax
Dept	Mail Code	
[Drop Down Menu]		

[Save]

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

Other Fund Name	
Account Number	

Protocol Information

Expedited Category 5

Title

Confirm that this project constitutes research under:

Expedited Category 5:

1. Yes No Research involving materials (data, documents, records) that 1) have been collected, or 2) will be collected solely for non-research purposes (such as medical treatment or diagnosis).

Purpose

- a) In layperson's language, state the purpose of the study and what you hope to learn in 3-5 sentences.
- b) Estimate the approximate number of medical charts you expect to review for this study
- c) Describe the source of the data that you will be studying, e.g., STRIDE, CERNER, EPIC, etc.

Participant Population

- a) Indicate if you will target the medical records data or documents of any vulnerable populations not already listed in the Participant Population section, e.g., economically or educationally disadvantaged, or homeless people. Enter N/A if these populations are not targeted.
- b) Identify the inclusion criteria for the medical records you will study. Provide the age range of the persons whose charts you will be reviewing.
- c) If you intend to exclude a particular age group, ethnic group, or gender, provide a rationale for doing so, e.g., the disease does not occur in children. If children are involved in your research, confirm that the following regulation applies.

If children are involved in your research, confirm that the following regulation applies

✂ Yes ✂ No 45 CFR 46.404: 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. [Note: IRB Waivers of Assent and Consent are considered adequate provisions. See Section 5]

Confidentiality Protections

Before answering the following questions, [click here](#) to learn about HIPAA and the authorized use of identifiable protected health information (PHI).

- a) Specify the PHI (protected health information) or other individually identifiable data you will obtain, use, or disclose to others. List both the type of health information you will obtain from the medical record (e.g., diagnosis, X-ray reports, H&P, lab reports, progress notes, billing records) and the HIPAA identifiers that are needed (e.g., name, Medical Record Number or MRN, SSN, dates of birth, death, admission, surgery, or treatment, geographic location smaller than a state.) Be very specific.(Note: this section must be consistent with the Waiver of HIPAA Authorization in Section 5.)

- b) Describe how the data will be maintained (e.g., paper or electronic spreadsheet, desktop computer, laptop or other portable device).

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

Provide any additional information on ALL data security measures you are taking. You must use a secure database such as STRIDE, RedCap, or Medrio. If you are unsure of the security of the system, check with your Department IT representative.

Please see [this link](#) for more information on IRT Information Security Services and [this link](#) for more information for securing mobile computing devices. Additionally, any PHI data on paper must be secured in a locked environment.

○ By checking this button, you affirm that you will comply with the aforementioned. d) Indicate who will have access to the data (e.g., research team, sponsors, consultants).

e) If data will be de-identified after it is collected, describe who will be responsible for the de-identification, and confirm that none of the [HIPAA identifiers](#) listed in this hyperlink will be linked to the data.

f) If data will be coded, describe the code you will use so that the identity of the subjects cannot be readily ascertained from the code (e.g., the code should not contain initials, last 4 numbers of the SSN, date of birth, or dates of treatment). Indicate who will maintain the key to the code, and describe how the key will be protected.

Potential Conflict of Interest

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

When the Personnel section of this protocol is completed, the faculty investigators will receive an email notifying them of the OPACS requirement. They may either answer "No" to the Financial Interest question from the email, or go to their OPACS dashboard to answer the question.

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

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

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

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

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

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

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

Waivers of Consent, Assent, HIPAA Authorization

Instructions

- A waiver of consent AND a waiver of HIPAA authorization is required for all medical chart reviews. Both should be added below. Add a waiver of assent if you are accessing the information of children (<18 years old)
- Click ADD to enter detailed information on each of the above waivers. Once entered and saved, a row will be displayed in tabular form for each item (Waiver of Consent, Waiver of HIPPA Authorization, etc.) entered.
- To view/modify the details of previously entered information, click the link in the *WaiversType* column for the desired item.
- To remove an item, check the box next to the *Title* and click DELETE.

Waivers [Save]

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

Title: *

Waiver of Consent

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

- 1) ✕ True ✕ False The research involves no more than minimal risk to the participants because it involves materials (data, documents, records) that have been or will be collected, and precautions will be taken to ensure that confidentiality is maintained
- 2) ✕ True ✕ False The waiver will not adversely affect the rights and welfare of the participants because procedures are in place to protect confidentiality, and information learned during the study will not affect the treatment of participants.

- 3) True False The research could not practically be carried out without the waiver because it would require contacting patients, and contact information is not readily available.
- 4) True False Whenever appropriate, the participants will be provided with additional pertinent information after participation. We do not anticipate that there would be any information to share with participants.

Waiver of Assent

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

Title: *

Complete only for children ages 7-17 or adults with limited decision-making capacity.

- 1) True False The research involves no more than minimal risk to the participants because it involves materials (data, documents, records) that have been or will be collected, and precautions will be taken to ensure that confidentiality is maintained.
- 2) True False The waiver will not adversely affect the rights and welfare of the participants because procedures are in place to protect confidentiality, and information learned during the study will not affect the treatment of participants.
- 3) True False The research could not practically be carried out without the waiver because it would require contacting patients, and contact information is not readily available.
- 4) True False Whenever appropriate, the participants will be provided with additional pertinent information after participation. We do not anticipate that there will be any information to share with participants.

Waiver of HIPAA Authorization

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

Title: *

- a) Specify the PHI (protected health information) or other individually identifiable data you will obtain, use, or disclose to others. List both the type of health information you will obtain from the medical record (e.g., diagnosis, X-ray reports, H&P, lab reports, progress notes, billing records) and the HIPAA identifiers that are needed (e.g., name, Medical Record Number or MRN, SSN, dates of birth, death, admission, surgery, or treatment, geographic location smaller than a state.) Be very specific. Your answer should be consistent with information provided in 3a.

b) Complete the following:

- Yes No Do you certify that the use or disclosure of the protected health information involves no more than a minimal risk to the privacy of individuals?
- Yes No Do you certify that the research could not practically be conducted without the waiver?
- Yes No Do you certify that you have adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted?
- Yes No Do you certify that the research could not practically be conducted without access to and use of the protected health information?

c) Describe an adequate plan to protect any identifiers from improper use and disclosure.

d) 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.

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).
- 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.

Type:

- Cooperating Institution(s) Approval
- Federal Grant/Sub-contract
- Program Project Grant/List
- Training Grant/List
- Academic Sponsor Forms
- VA required questions
- Other

Title: *

Attachment (File Name):

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
- Ensure adequate resources are available to conduct the study.
- Be appropriately qualified to conduct the research and be trained in Human Research protection, ethical principles, regulations, policies and procedures
- Ensure all research personnel are adequately trained and supervised
- Ensure that the rights and welfare of participants are protected including privacy and confidentiality of data
- Ensure that, when de-identified materials are obtained for research purposes, no attempt will be made to re-identify them.
- Disclose to the appropriate entities any potential conflict of interest
- Report promptly any new information, modification, or [unanticipated problems that involve risks to participants or others](#)
- Apply relevant professional standards.

VA Protocol Directors also certify that:

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

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

IRB approval of any project is for a period of one to three years. 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.

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

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