

# IRB NON-MED EXEMPT FORM

## **System Requirements:**

- If using Windows, use Internet Explorer (IE) or Firefox as your browser.
- If using Macintosh, use Safari or Firefox as your browser.
- Your browser must be configured to Allow Pop-ups while using eProtocol. See instructions for [allowing pop-ups](#).

## **Before you begin:**

*If this is your first time* submitting a protocol for review, see [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.



The image shows a screenshot of a web form. At the top left, there is a black tab labeled "Protocol Title". Below this is a large, empty rectangular text input field with a blue border. At the top right of the form, there is a small red button with the word "Next" written on it.

## **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

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

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

Admin Contact\*

PERSONNEL LOOKUP

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

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

Co-Protocol Director

PERSONNEL LOOKUP

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

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

Other Contact

PERSONNEL LOOKUP

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

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

[Drop Down Menu]	
CITI Training current (within last 2 years) <input type="radio"/> Yes <input type="radio"/> No	

Academic Sponsor

PERSONNEL LOOKUP 

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

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

Other Personnel

[Click here to add Other Personnel](#)

If the popup is clicked, then:

Find User  [Find]

SUNet ID:	<input type="text"/>
First Name:	<input type="text"/>
Last Name:	<input type="text"/>

Training Details (NOTFOUND) 

Protocol ID:	User:	<input type="text"/>
Module Name	Module Date Completion	Expiry Date

Find User  [Find]

SUNet ID:	<input type="text"/>
First Name:	<input type="text"/>
Last Name:	<input type="text"/>

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

First Name:	<input type="text"/>	Last Name:	<input type="text"/>
Degree:	<input type="text"/>	Role:	<input type="text"/>
Email:	<input type="text"/>	Phone:	<input type="text"/>
Fax:	<input type="text"/>	Department:	<input type="text"/>
Mail Code:	<input type="text"/>		<input type="text"/>

**Application Category:****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)

<b>Application Category/Type</b>		
<b>Select Application Category:</b>	<input type="radio"/> Medical	<input type="radio"/> Non-Medical
<b>Review Type:</b> Learn more about <a href="#">determining review type</a> . If you are not certain which review type applies to your protocol, contact the IRB education specialist at (650) 724-7141 or <a href="#">IRBeducation"at"stanford.edu</a> . Note that different review types result in different application forms.		
<b>Select Review Type:</b>	<input type="radio"/> Regular	<input type="radio"/> Expedited <input type="radio"/> Exempt

**Exempt Review**

Federal regulations state that certain research is exempt from review. However, under Stanford's Policy for the Protection of Human Subjects, a research protocol proposing the use of human subjects must be submitted to the IRB to determine if it qualifies for exempt status. All protocols must meet [Stanford HRPP ethical standards](#) governing the conduct of research.

Exempt status WILL NOT be granted when research:

- involves prisoners as participants
- involves children in category 2 below EXCEPT for the observation of public behavior when

- the researcher does not participate in the activity being observed
- involves significant physical invasions or intrusions upon the privacy of the participants

Select one or more applicable exempt categories:

- 1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:**
- i) research on regular and special education instructional strategies; or
  - ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods
- 2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior UNLESS:**
- i) information obtained is recorded such that, human subjects can be identified, directly or through identifiers linked to the subjects;  
**AND**
  - ii) any disclosure of the human subjects' responses outside the research could reasonably place subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- 3. Research involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is NOT exempt under 2 above, if:**
- i) the human subjects are elected or appointed public officials or candidates for public office; or
  - ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- 4. Research involving the collection or study of existing data, documents, or records, if these sources are publicly available OR if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.**
- |                                     |                          |                                                                                                                                   |
|-------------------------------------|--------------------------|-----------------------------------------------------------------------------------------------------------------------------------|
| YES                                 | NO                       |                                                                                                                                   |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | Are ALL the data, documents, or records pre-existing (on the shelf as of today)? If no, you do NOT qualify for Exempt Category 4. |

Note: Information must be recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

Provide the dates these data were collected (use mm/dd/yyyy to mm/dd/yyyy). Indicate where the data came from (e.g., public records, data collected for a non-research purpose, previous study records, teacher's personal records, registrar's office).

- 5. Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:**
- i) public benefit or service programs;
  - ii) procedures for obtaining benefits or services under those programs;
  - iii) possible changes in or alternatives to those programs or procedures; or

iv) possible changes in methods or levels of payment for benefits or services under those programs.

**6. Taste and food quality evaluation and consumer acceptance studies:**

- i) if wholesome foods without additives are consumed or
- ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

## Participant Population

### *Instructions:*

Select all populations (and only those) that are specifically **targeted** for this study. You must select at least one category.

For example:

- A researcher is conducting an internet survey asking about emotional responses to certain scenarios. Students may respond, but the study is not designed to recruit students specifically, so students 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"/>	Wards (e.g., foster children, incarcerated youth)
<input type="radio"/>	<input type="radio"/>	Pregnant Women
<input type="radio"/>	<input type="radio"/>	Impaired Decision-Making Capacity
<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 at which the research takes place. For example, a study that takes place in a high school where surveys are collected and then analyzed at Stanford would require both *Stanford* and *Other* to be selected.

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

#### Study Location(s) Checklist

<input type="checkbox"/>	Stanford University
<input type="checkbox"/>	Other (Click ADD to specify details)

If “Other” was selected, then:

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

<b><u>Other Location:</u></b>	<b>[SAVE]</b>
<p><input type="radio"/> Within the US          Location Name: <input style="border: 1px dashed black; width: 400px; height: 20px;" type="text"/></p> <p><b>OR</b></p> <p><input type="radio"/> Outside the US/International          Location Name: <input style="border: 1px dashed black; width: 400px; height: 20px;" type="text"/></p>	
<p><b>Note:</b> You are responsible for ascertaining if local permission is needed for doing research in the proposed site (e.g., in the case of schools, workplaces, tribal settings). If permission is required, you must obtain it before beginning the research.</p>	

### General Checklist

#### ***Instructions:***

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

#### General Checklist

		Last Revision Date: 2/08/2014
--	--	-------------------------------

**Yes**   **No**   **Collaborating Institution(s)** Generally, when one or more institutions work together equally on a research endeavor it is a collaboration.

<input type="radio"/>	<input type="radio"/>	Are there any collaborating institutions?
-----------------------	-----------------------	-------------------------------------------

Add

Save

Pop Up Window

Collaborating Institution Name:  [SAVE]

Yes	No	Payment
<input type="radio"/>	<input type="radio"/>	Subjects will be paid or reimbursed for participation? See <a href="#">payment</a> .
Yes	No	Funding
<input type="radio"/>	<input type="radio"/>	Training Grant?
<input type="radio"/>	<input type="radio"/>	Federally Sponsored Project?

**Instructions:**

Remember to attach a copy of each applicable federal grant application, including competing renewals, in the Attachments section of this protocol application form.

**Funding** NONE

Funding - Grants/Contracts [Add] [Delete]

	SPO#	Grant#	Administered By	Funded By
<input type="checkbox"/>				

Please click on 'Add' to add Grants/Contracts

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., Undergraduate Funding) [Add] [Delete]

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

### Funding – Grants/Contracts

#### Instructions:

Remember to attach a copy of each applicable federal grant application, including competing renewals, in the *Attachments* section of this protocol application form.

If this is an umbrella protocol, attach in the *Attachments* section of this protocol application form, a listing of all protocols funded under this umbrella. Include protocol ID number, PI, and approval date.

Funding Administered By	
SPO # (if available)	
Grant # (if available)	
Funded By (include pending)	
Principal Investigator	
Grant/Contract Title if different from Protocol Title	
<input type="radio"/> Yes <input type="radio"/> No   For Federal projects, are contents of this protocol consistent with the Federal proposal application?	

### Funding – Fellowships

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 consistent with the Federal proposal application?	

### Gift Funding

Gift Funding [Save]

Name of Donor	
Account Number	

**Department Funding**

Dept. Funding [Save]

Department Name	
Account Number	

**Other Funding**Other Funding [Save]  
(e.g., Undergraduate funding)

Other Fund Name	
Account Number	

**Resources****a. Qualified staff**

State your and/or your study staff's qualifications to conduct this study.

**b. Training**

Describe the training you have received regarding the research-related duties and functions of this protocol. Also, describe the training received by study staff assisting you with the research.

**c. Facilities**

Describe where the study will take place, including where data will be collected and where it will be analyzed.

**d. Time**

How much time will be needed to conduct and complete the research?

**e. Participant access**

Will you have access to a population that will allow recruitment of the required number of participants?

**f. Access to resources**

Will you have access to psychological resources that participants might need as a consequence of participating in the research? If yes, describe these resources. Enter N/A if the need for psychological resources is not anticipated.

## Protocol Information

### Exempt Paragraph(s)

Title

(Filled in)

**Federal** regulations state that certain research is exempt from review. However, under Stanford's Policy for the Protection of Human Subjects, a research protocol proposing the use of human subjects must be submitted to the IRB to determine if it qualifies for exempt status. All protocols must meet [Stanford HRPP ethical standards](#) governing the conduct of research.

#### **Exempt status WILL NOT be granted when research:**

- involves prisoners as participants
- involves children in category 2 below EXCEPT for the observation of public behavior when the researcher does not participate in the activity being observed
- involves significant physical invasions or intrusions upon the privacy of the participants

**Review your exempt category selection(s) below. Make changes as applicable.**

#### 1. **Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:**

- i) research on regular and special education instructional strategies; or
- ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

#### 2. **Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior UNLESS:**

i) information obtained is recorded, such that human subjects can be identified directly or through identifiers linked to the subjects;

AND

ii) any disclosure of the human subjects' responses outside the research could reasonably place subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

#### 3. **Research involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is NOT exempt under 2 above, if:**

i) the human subjects are elected or appointed public officials or candidates for public office;  
or

ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. **Research, involving the collection or study of existing data, documents, or records, if these sources are publicly available OR if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.**

Yes	No	Are the data, documents, or records pre-existing (on the shelf as of today)? If no, you do NOT qualify for Exempt Category 4.
<input type="radio"/>	<input type="radio"/>	

**Note: Information must be recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.**

Provide the dates these data were collected (use mm/dd/yyyy to mm/dd/yyyy). Indicate where the data came from (e.g., public records, data collected for a non-research purpose, previous study records, teacher's personal records, registrar's office).

5. **Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:**

- i) public benefit or service programs;
- ii) procedures for obtaining benefits or services under those programs;
- iii) possible changes in or alternatives to those programs or procedures; or
- iv) possible changes in methods or levels of payment for benefits or services under those programs.

6. **Taste and food quality evaluation and consumer acceptance studies:**

- i) if wholesome foods without additives are consumed or
- ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

## Protocol Information

### Sections 1-3

Complete Sections 1-11. Specify N/A or 'none' as appropriate. Do not leave any required sections blank.

#### 1. Purpose

- a) In 3-5 sentences, state the purpose of the study in lay language.

b) State what you hope to learn from the study and assess the importance of this new knowledge.

## 2. Study Procedures

a. Describe ALL the procedures human participants will undergo. Are the research procedures the least risky that can be performed consistent with sound research design?

b. State if audio or video recording will occur. Describe how the recordings will be used, e.g., shown at scientific meetings, used for transcription. Describe the final disposition of the recordings, e.g., erased, stored.

c. DECEPTION: Will participants be fully informed about the purpose of the study? If no: provide a rationale for deception.

## 3. Reserved for future use

## Section 4(a-f)

## 4. Participant Population

a) How many participants do you expect to enroll? What type of participants will you enroll (e.g., high school students, teachers, government officials)?

b) What are the age range, gender, and racial or ethnic background of the participant population being targeted?

c) If applicable, explain why potentially vulnerable participants are needed (e.g., children, pregnant women, students, economically or educationally disadvantaged, homeless, people with impaired decision making capacity).

d) Reserved for future use.

a) Will any participants be your students, laboratory personnel and/or employees? See Stanford University policy at <http://www.stanford.edu/dept/DoR/rph/7-5.html>)



- e) How will you recruit participants (e.g., ads, classroom recruitment, word of mouth, letters mailed home, email)? Attach recruitment materials in the *Attachments* section.  
**YOU MAY NOT CONTACT POTENTIAL PARTICIPANTS PRIOR TO IRB NOTICE OF EXEMPTION.**

## Section 4(g-i)

### 4. Participant Population

- g) PAYMENT or REIMBURSEMENT. Will participants be paid or reimbursed for participation? If yes, how much, and explain why proposed payments/reimbursements are reasonable. Explain how payment will be prorated, if there is more than one study session. See [payment considerations](#).

- h) Explain what costs will be incurred by the participant. If none, enter 'none'.

- i) What is the total time that each participant will spend in the entire study (e.g., 20 minutes, 2 hours, 3 days)?

## Section 5

### 5. Risks

- a) Describe any reasonably anticipated potential risks(s), including risk(s) to physical, psychological, political, economic or social well-being. If risks are not reasonably anticipated, enter 'none'.

- b) If you are conducting research outside the US (international research), describe qualifications/preparations that enable you to both estimate and minimize risks to participants. Then complete the [International Research Form](#) and attach it in the *Attachments* section. If not applicable, enter N/A.

- c) Reserved for future use.

## d) Children's Findings (OHRP)

Select the category below that best describes your research, if children are involved.

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 permission of their parents or guardians.

46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit... (regular review only)

46.406 Research involving greater than minimal risk and no prospect of direct benefit...(regular review only)

46.407 Research not otherwise approvable...(regular review only)

Rationale:

## Section 6, 7

### 6. Benefits

a) Describe the potential benefit(s) to be gained by the participants and/or by society as a result of this study. If none, enter 'none.'

### 7. Privacy and Confidentiality

#### Privacy

Privacy refers to the environment in which data are collected from participants (e.g., interviewing participants individually in a place where personal responses will not be seen or overheard).

a) Explain where the research takes place (e.g., in a lab, online, at school). Describe how you will maintain privacy in this setting.

#### Confidentiality

Confidentiality refers to your agreement with the participant about how the participant's identifiable personal information (i.e., identifiable data) will be handled, managed, stored, and disseminated.

b) What identifiable data will you obtain from participants? Enter 'none' if identifiable data will not be obtained. Discuss how you will protect the participants' identity, if applicable.

## Section 8

### 8. Potential Conflict of Interest

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

When the Personnel section of this protocol is completed, the 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](http://opacsprd.stanford.edu). They should contact their school's [COI Manager](#) with any issues with OPACS.

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

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

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

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

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

## Section 9

### 9. Participant Information

If you are using a document (e.g., information sheet, oral script, consent, assent, or other document) that discusses the participant's involvement in your research, attach under "Participant Information" by clicking on the ADD button below and then selecting the appropriate option in the drop-down menu.

- a) Describe the process you will use to inform participants about your study. Include the following: Who will obtain consent? When and how will this be done?

#### Instructions:

- Click ADD to enter relevant document(s). Once entered and saved, a row will be displayed in tabular form for each item entered.
- To view/modify the details of previously entered information or to replace a document with an updated version, click the link in the Document Type column for the desired item.
- To view the current document, click the link in the Title column for the desired item.
- To remove an item, click the box next to the Title and DELETE.

Participant Information		[Add]	[Delete]
	Title	Document Type	Created Date
<input type="checkbox"/>			

### Section 9 "Add" Button

#### Participant Information

##### Information Sheet/Oral Script/Other Document

- Attach ALL documents you will use to inform participants about your research and to obtain agreement to participate in this section (e.g., information sheets, oral scripts, other documents).
- Enter a descriptive Title (e.g., use Oral Script instead of scriptv1.doc). Do NOT use special characters or symbols in the title.
- Click BROWSE to locate and attach a file from your desktop.
- Click SAVE when done.

Document Type:

Title:

Document (file name):

## 10. Reserved for future use

## Section 11

### 11. Attachments

Click ADD to attach relevant study documents to this section (e.g., surveys, questionnaires, federal grants).

#### **Advertisements**

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

#### **Cooperating Institution(s) Approval**

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

#### **Federal Grant(s)**

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

#### **Questionnaires**

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

#### **Training Grant/List**

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

#### **Faculty Sponsor Oversight / Scientific Review**

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

**Other**

Attachment Name:

Attached Date:

Attached By:

Submitted Date:

**Obligations**

The Protocol Director agrees to:

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

Any change in the research protocol must be re-submitted to the IRB for review to re-certify exemption. Any complications in subjects or evidence of increase in the original estimate of risk should be reported at once to the IRB before continuing with the project. The investigators must inform the participants of any significant new knowledge obtained during the course of the research.

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.