

IRB NON-MED REGULAR 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 screenshot shows a web form with a large text input field labeled "Protocol Title" on the left and a "Next" button on the right. 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

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](#)

If the popup is clicked, then:

Find User

[Find]

SUNet ID:	
First Name:	
Last Name:	

Training Details

[Close]

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

Find User

[Find]

SUNet ID:	
First Name:	
Last Name:	

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

Other Personnel

[Save]

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

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)

Select Application Category:

Medical Non-Medical

Review Type:

Learn more about [determining review type](#). If you are not certain which review type applies to your protocol, contact the IRB education specialist at (650) 724-7141 or [IRBeducation@stanford.edu](#). Note that different review types result in different application forms.

Select Review Type:

Regular Expedited Exempt

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	

Choose one. For multiple sites, add each individually.

Other Location: **[SAVE]**

Within the US
 Location Name:

OR

Outside the US/International
 Location Name:


Note: 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.

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

Yes	No	Collaborating Institution(s) Generally, when one or more institutions work together equally on a research endeavor, it is a collaboration.
○	○	Are there any collaborating institutions?
		<div style="text-align: right;"></div>

Please click on add Collaborating Institution(s)



Pop Up Window

Collaborating Institution Name: [SAVE]

[Empty dashed text box]

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

Funding

Instructions:

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

NONE

Funding - Grants/Contracts [Add] [Delete]

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

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	[Drop down list]
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?	
<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] [Delete]

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

Funding Administered By	[Drop down list]
SPO # (if available)	
Fellowship Reference # (if available)	
Funded By	[Drop down list]
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?	

Funding - Other

Gift Funding [Add] [Delete]

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

Gift Funding [Save]

Name of Donor *	
Account Number *	

Dept. Funding [Add] [Delete]

	Department	Account Number

<input type="checkbox"/>		
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Dept. Funding [Save]

Department Name*	
Account Number*	

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

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

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

Other Fund Name*	
Account Number*	

Resources

a. Qualified staff

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

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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

Sections 1-3

Title

(Filled in this time)

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; complete an Alteration of Consent in Section 9, and attach a debriefing script in the *Attachments* section, or explain why debriefing would not be appropriate below.

3. Background

a) Describe what led to the formulation of the study.

Section 4(a-f)

4. Participant Population

- a) (i) How many participants do you expect to enroll at Stanford? (ii) How many participants do you expect to enroll outside Stanford? (iii) 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 potential vulnerable participants are needed (e.g., children, pregnant women, students, economically or educationally disadvantaged, homeless, or people with impaired decision making capacity).

- d) Will the research include women, minorities, or minors? Provide a rationale for not including these populations if the research might benefit these groups (e.g., if you choose not to include women in a survey study about salaries, explain why).

- e) Will any participants be your students, laboratory personnel and/or employees? See Stanford University policy RPH 5.5 [Use of Employees or Laboratory Personnel as Research Subjects](#).

- f) 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 APPROVAL.

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) For the following categories, describe any potential risks that can be reasonably anticipated. Estimate expected frequency and severity, and describe how you plan to minimize risks and protect study participants. If risks are not reasonably anticipated, enter 'none'.

- Physical well-being.

- Psychological well-being.

- Political status

- Economic well-being.

- Social well-being.

- b) How will you arrange for professional intervention if you believe it is necessary (e.g., interviews of participants with Post Traumatic Stress Disorder)? If not applicable, enter N/A.

- c) 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.

- d) Reserved for future use

- e) Children's Findings (OHRP)

If children are involved, select the category below that best describes your research, provide the rationale for your selection, and indicate whether parental permission will be obtained from one or both parents.

- 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 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. 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.
- 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.

Rationale:

Note: The IRB may determine that the permission of one parent is sufficient, or that permission of two parents is required, in which case the investigator must obtain the permission of both parents unless one parent is deceased, unknown, incompetent, not reasonably available or only one parent has legal responsibility for the care and custody of the child.

f) Data Safety and Monitoring Plan (DSMP)

Data should be closely monitored to ensure the safety of participants. The Protocol Director is responsible for monitoring data to identify problems that occur in the study.

Unanticipated problems that may occur in the course of your study need to be reported to the IRB.

I will monitor study data and report unanticipated problems and non-compliance to the IRB per the guidance on [Prompt Reporting](#).

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? If no identifiable data will be obtained, enter 'none.'

- c) Describe:

If no identifiable data will be obtained, enter N/A; otherwise, answer the following questions:

- (i) how you will manage the identifiable data (e.g., paper or electronic spreadsheet, desktop computer, laptop or other portable device)
- (ii) how you will ensure the security of identifiable data (e.g., password protected computer, encrypted files, locked cabinet, locked office);
- (iii) who will have access to the identifiable data (e.g., research team, sponsors, consultants)

- d) Describe how identifiable 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 the [Stanford Information Security Office](#) website. If not applicable, enter N/A.

- e) If you plan to code the data, describe the method in which it will be coded and indicate who will have access to the key to the code. If the data will not be coded, enter N/A

--

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. 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. Consent Information

A protocol should include at least one of the following consent options. More than one may be included. See more information on [Informed Consent](#), [Waiver of Consent](#), [Waiver of Documentation](#) and [Alteration of Consent](#).

Any consent form document (including information sheets used for consenting) should be attached by clicking the ADD button below, and then selecting the appropriate option in the drop-down menu.

- **Waiver of Consent**
Applicable for research involving identifiable data or records, when asking to waive parental permission, or other situations where consent is not possible
- **Consent**
Applicable for research involving *signed* consent or parental permission forms
- **Waiver of Documentation**
Applicable for internet research or oral consent when a signature is not obtained
- **Alteration of Consent**
Applicable when some required elements of consent are eliminated, such as incomplete disclosure of the purpose of the research (deception)

- a) Describe the informed consent process. Include the following: Who will obtain consent? When and how will this be done? If you are requesting to completely waive consent, enter "Waiver of Consent" in the text boxes a, b and c below.

Note: The person obtaining consent must be knowledgeable about the study. Sufficient time must be devoted to allow the participant to consider whether or not to participate. Steps must be taken to minimize the possibility of coercion or undue influence.

Note: If consent relates to children, the IRB will determine whether one or two parents' signatures are sufficient.

- b) What procedure will you use to assess if the participant understands the information contained in the consent? How will the information be provided to participants if they do not understand English? See [HRPP Chapter 14.6](#) for guidance.

- c) Are you planning to enroll participants who do not have the capacity to consent?

Any consent form document (including information sheets used for consenting) should be attached under the appropriate option below.

Instructions:

- Click ADD to enter information on one of the above categories and to attach relevant consent document(s). Once entered and saved, a row will be displayed in tabular form for each item entered (Alteration of Consent, Waiver of Documentation, Waiver of Consent, and Consent).

Consent Background		[Add]	[Delete]
	Title	Consent Type	Created Date
<input type="checkbox"/>			

Consent Background [Add]
 Please click on 'Add' to add Consent Background

Consent Background [Save]

Consent Type: *	[Drop down List]
Title: *	

Waiver of Consent

Waiver of Consent (or Waiver of Parental Permission)

- Applicable for research involving identifiable data or records, when asking to waive parental permission, or other situations where consent is not possible.
- Answer all questions as completely as possible.
- Click SAVE when done.

Consent Type: *	[Drop down List]
Title: *	

Address the following four regulatory criteria for a Waiver of Consent and provide protocol-specific reasons for each:

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

Examples: The research involves the analysis of secondary or existing identifiable data, such as student records; 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 will not adversely affect the rights and welfare of the participants.

Example: Participants will not be contacted and procedures are in place to protect the privacy of the participants and the confidentiality of their data.

Rationale for above selection:

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

Example: Without the waiver of consent, the research would require contacting former students who have graduated years ago. Accurate contact information is not available.

Rationale for above selection:

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

Example: We do not anticipate that there will be any pertinent information to share with study participants.

Rationale for above selection:

Consent

Consent (or Parental Permission)

- Attach consent or parental permission documents to be signed in this section. Enter a descriptive Title (e.g., use Consent for Controls instead of consentv1.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.

Consent Type: *	[Drop down List]
Title: *	
Consent Form (file name): *	[Browse file]

[Save]

Waiver of Documentation

Waiver of Documentation (Signature)

- Applicable for internet research, telephone interviews, oral consent, web surveys, OR where the primary risk is breach of confidentiality and the ONLY link to identifiable data is the signature on the consent form.
- Select the regulatory criterion below that is applicable to your study and provide rationale.

- Click SAVE when done.

Consent Type: *	[Drop down List]
Title: *	
Consent Form (file name): *	[Browse file]

Select one of the following regulatory criteria for a Waiver of Documentation and provide a protocol-specific justification:

- 45 CFR 46.117(c)(1) For research 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 of confidentiality. Each participant will be asked whether he/she wants documentation linking the participant with the research, and the participant's wishes govern.
- 45 CFR 46.117(c)(2) Research that 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:

Alteration of Consent

Alteration of Consent

- Applicable when some required elements of consent are eliminated, such as incomplete disclosure of the purpose of the research (deception).
- Answer all questions as completely as possible. Be sure to include which consent elements you wish to alter in the Rationale text boxes below.
- Click SAVE when done.

Consent Type: *	[Drop down List]
Title: *	
Consent Form (file name): *	[Browse file]

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

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

Examples: The research does not reveal the entire purpose of the study to avoid response bias; the participants will complete a minimal risk survey regarding their preferences; participant information will be coded, and only the Protocol Director and one co-investigator will have access to the data.

Rationale for above selection:

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

Example: The research involves no greater than minimal risk and does not involve any activity that would be harmful to any rights the participant would be eligible for.

Rationale for above selection:

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

Example:

If the participants knew the entire purpose of the study, their responses would be biased and the data would be compromised.

Rationale for above selection:

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

Example:

Participants will be debriefed following the study, and will be given the opportunity to withdraw their data if they wish OR debriefing will not add any benefit or pertinent information, and might even cause unnecessary discomfort.

Rationale for above selection:

Section 10

10. Assent Background (17 years old or younger)

Children must assent to participating in research unless 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 by clicking the ADD button below and then selecting the appropriate option from the drop-down menu.

- Assent
- Waiver of Assent (*used when assent will not be sought for some or all children who are capable of assenting*)
- Assent Not Applicable (*used when all children are not capable of assenting*)

a) Describe the assent process. Include the following: Who will obtain assent? When and how will this be done? If assent will not be obtained, enter "Waiver of Assent" or "Assent not Applicable" in questions a, b, and c below, depending on which is appropriate.

Note: The person obtaining assent must be knowledgeable about the study. Sufficient time must be devoted to allow the child to consider whether or not to participate. Steps must be taken to minimize the possibility of coercion or undue influence.

b) What procedure will you use to assess if the child understands the information contained in the assent? How will the information be provided to children if they do not understand English? See [Guidance](#).

c) Are you planning to enroll children ages 7-17 who do not have the capacity to assent? If not applicable, enter N/A.

Instructions:

- Click ADD to enter information on one of the above assent options, and to attach relevant assent documents. Once entered and saved, a row will be displayed in tabular form for each item (Assent, Waiver of Assent, Assent Not Applicable) entered.

	Assent Background	[Add]	[Delete]
	Title	Consent Type	Created Date
<input type="checkbox"/>			

Assent Background

[Add]

Please click on 'Add' to add Assent Background

Assent Background (17 years old or younger)

[Save]

Assent Type: * [Drop down List]

Assent

- Enter a descriptive Title (e.g., use Assent 7-10 years instead of assentv1.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.

Assent Type: *	[Drop down List]
Title: *	
Assent Form (file name): *	[Browse file]

Waiver of Assent

- Applicable only when children are capable of assenting
- Answer all questions as completely as possible.
- Click SAVE when done.

Assent Type: *

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

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

Rationale for above selection:

[Dashed box for rationale]

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

Rationale for above selection:

[Dashed box for rationale]

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

- Be appropriately qualified to conduct the research and be trained in Human Research

Rationale for above selection:

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

Rationale for above selection:

Assent Not Applicable

- Applicable only when children are incapable of assenting
- Answer the question as completely as possible.
- Click SAVE when done.

Assent Type: *	Assent Not Applicable
----------------	-----------------------

Explain why assent is not applicable to this research (e.g., the children are too young to assent).

Section 11

11. Attachments

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

Type:	
Title: *	
Attachment(File Name):	[Browse file]

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
 - Be appropriately qualified to conduct the research and be trained in Human Research
 - 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 submitted to the IRB for review prior to the implementation of such change. 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.

IRB approval of any project is at the discretion of the IRB and is usually from 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 several weeks prior to the expiration date of the protocol.

The Department Chair must approve faculty and staff research that is not part of a sponsored project. The Scientific & Scholarly Review forms and instructions for submission will be provided once the protocol is assigned to an IRB for review.

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

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