# IRB NON-MED
# EXPEDITED
# FORM

***System Requirements:***

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

***Before you begin:***

***If this is your first time*** *submitting a protocol for review, see* ***FAQs*** *for information to consider beforehand.*

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

***What to expect:***

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

  (Diskette) icon to save your work before exiting.


**Personnel Info:**

***Instructions:***

- At minimum, a Protocol Director (PD) and Administrative Contact must be entered; the same person may be entered for both roles.

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

Protocol Director

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

Admin Contact

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

Co-Protocol Director [Clear]

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

Other Contact [Clear]

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

Academic Sponsor [Clear]

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

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

Other Personnel Click here to add Other Personnel

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"at"stanford.edu. Note that different review types result in different application forms.

**Select Review Type:**

○ Regular ○ Expedited ○ Exempt

## Expedited Paragraphs

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

**Select one or more applicable expedited categories:**

☐ **1. Clinical studies of drugs and medical devices (medical studies only)**

☐ **2. Collection of blood samples (medical studies only)**

☐ **3. Prospective collection of biological specimens for research purposes by non invasive means.**
Example: Collection of saliva or cheek swabs

☐ **4. Collection of data through non invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing.**

Examples:

a) Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;

b) Weighing or testing sensory acuity;

c) Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

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

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

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

## 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 | |
|---|---|---|
| ○ | ○ | Children (under 18) |
| ○ | ○ | Wards (e.g., foster children, incarcerated youth) |
| ○ | ○ | Pregnant Women |
| ○ | ○ | Impaired Decision Making Capacity |
| ○ | ○ | Cancer Subjects |
| ○ | ○ | Laboratory Personnel |
| ○ | ○ | Healthy Volunteers |
| ○ | ○ | Students |
| ○ | ○ | Employees |
| ○ | ○ | Prisoners |
| ○ | ○ | Other (i.e., any population that is not specified above) |

## Study Location

***Instructions:***

The **study location** is the location at which the research takes place. For example, a study 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

| | |
|---|---|
| ☐ | Stanford University |
| ☐ | 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? |

Add Save

Pop Up Window

**Collaborating Institution Name:** **[SAVE]**

| Yes | No | **Payment** |
|---|---|---|

| | | |
|---|---|---|
| ○ | ○ | Subjects will be paid for participation? See payment considerations. |
| **Yes** | **No** | **Funding** |

| | | |
|---|---|---|
| ○ | ○ | Training Grant? |
| ○ | ○ | 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 |
|---|---|---|---|---|
| ☐ | | | | |

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 Menu] |
| SPO # (if available) | |
| Grant # (if available) | |
| Funded By (include pending) * | |
| Principal Investigator | |
| Grant/Contract Title if different from Protocol Title | |
| ○Yes ○No | For Federal projects, are contents of this protocol consistent with the Federal proposal application? |
| ○Yes ○No | Is this a Multiple Project Protocol (MPP), e.g., a training grant? |
| ○Yes ○No | Is this protocol under a MPP? |

**Funding – Fellowships**

Funding – Fellowships [Add] [Delete]

| | Fellow | Title | Administered By | Funded By |
|---|---|---|---|---|
| ☐ | | | | |

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 | |
| ○Yes ○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 |
|---|---|---|
| ☐ | | |

Dept. Funding [Add] [Delete]

| | Department | Account Number |
|---|---|---|
| ☐ | | |

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

| | Other Funding | Account Number |
|---|---|---|
| ☐ | | |

**Gift Funding**

Gift Funding [Save]

| | |
|---|---|
| Name of Donor * | |
| Account Number * | |

**Department Funding**

Dept. Funding [Save]

| | |
|---|---|
| Department Name * | |

| | |
|---|---|
| Account Number * | |

## Other Funding

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.

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 –

Title

(Filled in)

Review your expedited paragraph selection(s) below. Make changes as applicable.

☐ 1. Clinical studies of drugs and medical devices (medical studies only)

☐ 2. Collection of blood samples (medical studies only)

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

Example: Collection of saliva or cheek swabs

☐ 4. Collection of data through non invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing.

Examples:

a) Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
b) Weighing or testing sensory acuity;
c) Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

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

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

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

## Protocol Information
## Sections 1-3

Complete Sections 1-11. Specify N/A 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 Section 11, 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., results of a survey study about salaries might benefit women, but if you choose not to include them, 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) In order to qualify for expedited review, the protocol must present no more than minimal risk to participants. 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)

Confirm that your study meets the criteria for 46.404 below:

○ 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)

Provide the rationale that this study presents no greater than minimal risk to children, and indicate whether parental permission will be obtained. If parental permission is to be obtained, indicate whether one or both parental signatures will be sought.

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.

c) Describe if applicable:

(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.

## 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.

- 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 by clicking the ADD button below, and then selecting the appropriate option in the drop-down menu.

## 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 |
|---|---|---|---|
| ☐ | | | |

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 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 (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 (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 (or Parental Permission)

- 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 (less than 18 years of age)

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?

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.

## 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 |
|---|---|---|---|
| ☐ | | | |

**Assent Background** [Add]

| Please click on 'Add' to add Assent Background |
|---|

**Assent Background (18 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:

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

Rationale for above selection:

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

Rationale for 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
- 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 participants 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.