

Protocol Title

Personnel Information

Protocol Director

Name:
Degree:
Title:
Email:
Phone:
Department:
Mail Code:

Yes No
 Human Subjects tutorial completed?

Administrative Contact

Name:
Degree:
Title:
Email:
Phone:
Department:
Mail Code:

Yes No
 Human Subjects tutorial completed?

Co-Protocol Director

Name:
Degree:
Title:
Email:
Phone:
Department:
Mail Code:

Yes No
 Human Subjects tutorial completed?

Other Contact

Name:
Degree:
Title:
Email:
Phone:
Department:
Mail Code:

Yes No
 Human Subjects tutorial completed?

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Faculty Sponsor

Name:

Degree:

Title:

Email:

Phone:

Department:

Mail Code:

Yes

No

Human Subjects tutorial completed?

Other Personnel:

Application Category/Type

In general, protocols submitted by an investigator in the School of Medicine (including Psychiatry and Behavioral Sciences) or at the VA should be marked with a category of *Medical*.

In general, protocols submitted by an investigator in Psychology, Education, Engineering, or th Humanities should be marked with a category of *Non-Medical*.

If you have questions about which protocol category to select, contact irbeducation@lists.stanford.edu or irbcoordinator@lists.stanford.edu.

Read more about [determining review type](#).

Select Protocol Category:

Medical Non-Medical

Select Protocol Review Type:

Regular Expedited Exempt

Subject Population(s) Checklist

- | <u>Yes</u> | <u>No</u> | |
|-----------------------|-----------------------|--|
| <input type="radio"/> | <input type="radio"/> | Minors (under 18) |
| <input type="radio"/> | <input type="radio"/> | Pregnant Women |
| <input type="radio"/> | <input type="radio"/> | Mentally Disabled |
| <input type="radio"/> | <input type="radio"/> | Decisionally Challenged |
| <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(s) Checklist

- Stanford University
- GCRC
- Stanford Hospital and Clinics
- Lucile Packard Children's Hospital
- VA (Specify PI at VA) _____
- San Mateo County
- Other (Specify other study locations) _____

General Checklist

- Training Grant
- Program Project Grant?
- Cooperating Institution(s)? _____
- Federally Sponsored Project?
- Human blood, cells, tissues, or body fluids (tissues)?
- Subjects will be paid for participation?

Funding Checklist

- Grants/Contracts**
 - Funding Administered by:
 - STANFORD
 - PAIRE
 - VA
 - Other
 - SPO# (if available): _____
 - Grant# (if available): _____
 - Funded by (include pending): _____
 - Principal Investigator: _____
 - Grant/Contract Title if different from Protocol Title _____

- | <u>Yes</u> | <u>No</u> | |
|-----------------------|-----------------------|---|
| <input type="radio"/> | <input type="radio"/> | For Federal project, are contents of this protocol the same as described in Federal proposal application? |
| <input type="radio"/> | <input type="radio"/> | Is this an Umbrella protocol? |
| <input type="radio"/> | <input type="radio"/> | Is this protocol under an Umbrella protocol? |

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Fellowships

Funding Administered by:

- STANFORD
- PAIRE
- VA
- Other

Fellowship Reference#

(if available):

Funded by:

Name of Fellow:

Fellowship Title if different
from Protocol Title

Yes

No

For Federal project, are contents of this protocol the same as described
in Federal proposal application?

Other

Gifts

Name of Donor:

Account#:

Department

Department Name:

Account#:

Other (e.g. OTL, URO)

Other Fund Name:

Account#:

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VA Checklist

When human research activities meet the criteria to be considered VA Research, the IRB must be made aware in order to meet its obligations to protect human subjects.

- The research recruits subjects at the VAPAHCS.
- The research involves the use of the VAPAHCSs nonpublic information to identify or contact human research subjects or prospective subjects or to use such data for research purposes.
- The research is sponsored (i.e., funded) by the VAPAHCS.
- The research is conducted by or under the direction of any employee or agent of VAPAHCS (full-time, part-time, intermittent, consultant, without compensation (WOC), on-station fee-basis, on-station contract, or on-station sharing agreement basis) in connection with her/his VAPAHCS responsibilities.
- The research is conducted using any property or facility of VAPAHCS.

Protocol Information

1. Purpose

a) Provide a 3-5 sentence lay summary of the purpose of the study.

b) What does the Investigator(s) hope to learn from the study? Provide an assessment of the importance of this new knowledge.

2. Study Procedures

a) Describe all study procedures. Are the research procedures the least risky that can be performed consistent with [sound research design](#)?

State if deception will be used. If so, provide a rationale and describe debriefing procedures. Since you will not be fully informing the subject in your consent form, complete an alteration of consent in section #9 (Consent Background). Submit a debriefing script in Section #11 (Attachments).

b) State if audio or video taping will occur. Describe what will become of the tapes after use, e.g., shown at scientific meetings, erased. Describe the final disposition of the tapes.

c) State if deception will be used. If so, provide a rationale and describe debriefing procedures. Since you will not be fully informing the subject in your consent form, complete an alteration of consent in section #9 (Consent Background). Submit a debriefing script in Section #11 (Attachments).

3. Background

Describe past findings leading to the formulation of the study.

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4. Subject Population

a) State how many subjects will be involved and describe the type of subjects (e.g., students, patients with cardiac problems, particular kind of cancer, etc.) and state the reason for using such subjects.

b) State the age range, gender, and ethnic background.

c) State the number and rationale for involvement of potentially vulnerable subjects to be entered into the study, including minors, pregnant women, economically and educationally disadvantaged, decisionally impaired, and homeless people, employees, and students. Specify the measures being taken to minimize the risks and the chance of harm to the potentially [vulnerable subjects](#) and the additional safeguards that have been included in the protocol to protect their rights and welfare.

d) If women, minorities, or minors are not included, a clear compelling rationale must be provided.

e) State the number, if any, of subjects who are laboratory personnel, employees, and/or students. They should render the same written informed consent. If compensation is allowed, they should also receive it. (Please see Stanford University policy at <http://www.stanford.edu/dept/DoR/rph/7-5.html>).

f) Describe how potential subjects will be identified for recruitment (e.g., chart review, referral from individual's treating physician, those individuals answering an ad). Describe how subjects will be recruited and how they will initially learn about the research, e.g., clinics, advertising (attach recruitment materials in Section #11 (Attachments)). You may not contact potential subjects prior to IRB approval.

g) Describe your recruitment procedures. Attach advertisements, flyers, etc. in Section #11 (Attachments).

h) Payment. Explain the amount and schedule of payment, if any, that will be paid for participation in the study. Substantiate that proposed payments are reasonable and commensurate with the expected contributions of participant and that they do not constitute undue pressure on the participant to volunteer for the research study. Include provisions for prorating payment.

i) Estimate the probable duration of the entire study as well as an estimate of the total time each subject is to be involved and data about the subject is to be collected (e.g., This is a 2 year study).

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5. Risks

If audio/video taping will be used, state if it could increase potential risk to subject's confidentiality.

a) For the following categories, include an estimate of the potential risk.

- Physical well-being.
- Psychological well-being.
- Political well-being.
- Economic well-being.
- Social well-being.

b) In case of overseas research, describe qualifications/preparations that enable you to estimate and minimize risks to subjects.

c) Discuss plans for ensuring necessary medical or professional intervention in the event of a distressed subject.

6. Benefits

Describe the potential benefit(s) to be gained by the subjects or by the acquisition of important knowledge which may benefit future subjects, etc.

7. Procedures to Maintain Confidentiality

a) Describe procedures protecting the privacy of the subjects and for maintaining confidentiality of data, as required by federal regulations, if applicable.

b) If information derived from the study will be provided to the subject's personal physician, a government agency, or any other person or group, describe to whom the information will be given and the nature of the information.

c) Specify where and under what conditions study data will be kept, how samples will be labeled, who has access to data, and what will be available to whom.

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RQ. Required Questions

Before submitting your protocol, you must complete the following [Required Questions](#). Once this form is completed and saved on your computer, please proceed to the *Attachments* section of your protocol application and attach.

PLEASE NOTE: Failure to complete and attach these questions will result in the return of your protocol and will delay its processing.

- RQ.1** Describe steps taken to minimize the possibility of coercion or undue influence.
- RQ.2** Provide an assessment of the importance of the knowledge expected to result from this study.
- RQ.3** If you have indicated **“Other”** as the study location, please provide the following information:
 - a. Name of the site,
 - b. Contact name for the site with phone number/email address,
 - c. Has the site granted permission for the research to be conducted?
 - d. Does the site have an IRB?
 - e. If yes, will that IRB approve the research?

Resources

- RQ.4** Will you have access to a population that will allow recruitment of the required number of participants? Please explain and justify.
- RQ.5** Will you have sufficient time to conduct and complete the research? Please explain the time required and justify.
- RQ.6** Will you have adequate numbers of qualified staff? Please explain and justify the number and qualifications of your study staff.
- RQ.7** Will you have adequate facilities to conduct the study? Please explain and justify.
- RQ.8** Will your process ensure that all persons assisting with the research are adequately informed about the protocol and their research related duties and functions? Please describe the training you will provide to meet this requirement.
- RQ.9** Will you have medical or psychological resources available that participants might require as a consequence of the research when applicable? Please describe these resources.

Privacy and Confidentiality

- RQ.10** For minimal risk studies, have you considered waiving the signature requirement since the only record linking the subjects and the research would be the consent document and the principal risk would be the potential harm to privacy? **YES** **NO**

If you decide to do so, please remember that each participant must be asked whether he/she wants documentation linking them with the research, and the participant's wishes will govern. (Common Rule 45 CFR 46.117(c))

- RQ.11** Please include a description of procedures for protecting the privacy interests of participants. Additionally, are the conditions affecting interaction with the participants and data collection adequate for the protection of privacy (for example, recording physical measurements of pre-teens in a school-setting, eliciting private medical or financial information in a quasi-public setting)?

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- RQ.12** Do personal identifiers (e.g., names, social security or medical record numbers) need to be recorded for potential participants during screening and recruitment and for actual participants?
- RQ.13** Will the private information you will be using be coded or be destroyed at some stage of the research?
- RQ.14** Will a code (e.g., number, letter, symbol replacing identifier) afford sufficient protection from deciphering? For instance, the use of initials or the last 4 digits of the social security number may not offer sufficient protection.
- RQ.15** Describe the steps you will take to ensure the security of the data or the codes linking information to an individual (including encryption, safe transmittal and storage, protection against loss, theft, or access by unauthorized persons).
- RQ.16** For this study, is it feasible to either not collect (e.g., anonymous data) or remove identifiers, substitute a code for identifiers, or separate identifiable portions of data from survey instruments?
- RQ.17** How will you dispose of electronic and paper documents containing private information?
- RQ.18** How will you educate research staff about (and impress on them) the importance of confidentiality, including being conscious of their communication, both verbally and in writing, in such situations as workplace conversation, insurance billing, lost or misplaced papers, and unsecured electronic documents?
- RQ.19** Describe how you will maintain research records in a secure manner (e.g., locked file cabinet), or use additional and more elaborate security (e.g., statistical techniques, encrypting electronic data) for research involving sensitive information.
- RQ.20** Describe the planned procedures for protecting against or minimizing risks, including risks to confidentiality.

Informed Consent Questions

- RQ.21** Respond to the questions concerning consent and provide more detail for any question that might raise an issue under the circumstances of your protocol:
1. Will legally effective informed consent be obtained from the participant or the participant's legally authorized representative or both? If LAR, is it clear who can serve as a LAR?
 2. Will the circumstances of the consent process provide the prospective participant or their representative sufficient opportunity to consider whether to participate?
 3. Will the circumstances of the consent process minimize the possibility of coercion or undue influence?
 4. Will the information being communicated to the participant or the representative during the consent process exclude any exculpatory language through which the participant or the representative is made to waive or appear to waive the participant's legal rights, or release or appear to release the investigator, the sponsor, the institution, or its agents from liability for negligence (e.g. I give up any property rights I may have in bodily fluids or tissue samples obtained in the course of the research)?

Multi-site Studies

- RQ.22** Is this a multi-site study? YES NO
- a. If "yes", are you the lead investigator for this study..... YES NO
- b. Is Stanford the coordinating site for this study?..... YES NO

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RQ.23 If you are the lead investigator for this multi-site study, what is your role in coordinating the participating sites?

RQ.24 Since Stanford is the coordinating site for this study, please describe what procedures are in place for routine communication with the other participating sites. Additionally, please explain how you will document these routine communications with the participating sites (e.g., telephone conferences, planned meetings, email communications, etc.).

RQ.25 Since Stanford is the coordinating site, explain how you will manage the communication of adverse outcomes, unexpected problems involving risk to participants or others, protocol modifications or interim findings.

DSM Plans

RQ.26 If your protocol is more than minimal risk, please include a DSM Plan and explain below. The monitoring plan must be commensurate with the level of risk. See the Guidance on Data Safety and Monitoring Plans at <http://humansubjects.stanford.edu/research/documents/DSMBGuidance.pdf>.

Chair Approval

RQ.27 If your study is unsponsored (i.e., department funding, gift funding, or no funding), please request that your Department Chair respond to the following comments regarding your study:

- a. Are the research procedures the least risky procedures that can be performed consistent with sound research design?
- b. Is the research likely to achieve its aims?
- c. Is the proposed research of sufficient scientific importance to justify the risks entailed?
- d. Are there adequate resources (e.g., facilities, qualified staff, access to population that will allow recruitment of the required number of participants)?

Please email responses from the Department Chair to IRBCoordinator@lists.stanford.edu. (If you are an undergraduate, please have your faculty sponsor respond to the above questions as well.)

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8. Potential Conflict of Interest

Please answer the following questions as though f:

- a) Yes No
 Do any of the involved investigators or their immediate family (as described below) have consulting arrangements, management responsibilities or equity holdings in the sponsoring company, vendor(s), provider(s) of goods, or subcontractor(s)?
- b) Do any investigators or their immediate family have any financial relationship with the sponsoring company, including the receipt of honoraria, income, or stock/stock options as payment?
- c) Is any Investigator(s) a member of an advisory board with the sponsoring company?
- d) Do any investigators receive gift funds from the sponsoring company?
- e) Do any investigators or their immediate family have an ownership or royalty interest in any intellectual property utilized in this protocol?
- f) Does Stanford University have an ownership or royalty interest in any intellectual property utilized in this protocol?

"Immediate family" means a spouse, dependent children as defined by the IRS, or a domestic partner.

If one or more of the above relationships exist, please include a statement in the consent form to disclose this relationship, i.e., a paid consultant, a paid member of the Scientific Advisory Board, has stock or stock options, or receives payment for lectures given on behalf of the sponsor (see sample consent form). The consent form should disclose what institution(s) or companies are involved in the study through funding, cooperative research, or by providing study drugs or equipment (see sample consent form).

If you answer yes to any of the questions above, you must file a Col disclosure with your School Dean. If you are a faculty member in the School of Medicine, contact Barbara Flynn @ 723-7226, or email bflynn@stanford.edu. http://www.stanford.edu/dept/DoR/ad_hoc.html .

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9. Consent Background

You can add different Consent Forms, Alteration Forms, and Waivers. Provide consent process background information, in the table below.

If the study involves deception of subjects, you must complete an alteration of consent.

If this is a parental consent, please also see the Assent Background in the next section.

9.1 Consent Form

Title:

Consent Information Type: *Consent Form*

Consent Form:

- Stanford Non-Medical Template
- Attachment (file name :_____)

If you use a consent form template, please edit it to be applicable to your study.

[Video-Use Consent Form Consent Form Template](#)

Describe the process of consent. Include the following:

- Who is obtaining consent? (The person obtaining consent must be knowledgeable about the study).
- Where and when will consent be obtained?
- How much time will be devoted to consent discussion?
- Will these periods provide sufficient opportunity for the participant to consider whether or not to participate and sign the written consent?
- What steps are you taking to minimize the possibility of coercion and undue influence?

What is the procedure to assess understanding of the information contained in the consent? How will the information be provided to participants if they do not understand English or if they have a hearing impairment? See [HRPP Chapter 14.5](#) for guidance.

What steps are you taking to determine that potential subjects are competent to participate in the decision-making process? For adults who are unable to consent, please describe how you will assess the capacity to consent, what provisions will be taken if the participant regains the capacity to consent, who will be used as a legally authorized representative, and what provisions will be made for the assent of the participant.

New Protocol Application: Non-Medical Regular (text only sample)

9.2 Alteration of Consent

Title:

Consent Information Type: *Alteration of Consent*

Consent Form:

- Stanford Non-Medical Template
- Attachment (file name : _____)

If you use a consent form template, please edit it to be applicable to your study.

[Sample Oral Consent Form](#)

[Consent Form Template](#)

[Alterations/Waivers of Consent Regulations](#)

Describe the process of consent. Include the following:

- Who is obtaining consent? (The person obtaining consent must be knowledgeable about the study).
- Where and when will consent be obtained?
- How much time will be devoted to consent discussion?
- Will these periods provide sufficient opportunity for the participant to consider whether or not to participate and sign the written consent?
- What steps are you taking to minimize the possibility of coercion and undue influence?

What is the procedure to assess understanding of the information contained in the consent? How will the information be provided to participants if they do not understand English or if they have a hearing impairment? See [HRPP Chapter 14.5](#) for guidance.

What steps are you taking to determine that potential subjects are competent to participate in the decision-making process? For adults who are unable to consent, please describe how you will assess the capacity to consent, what provisions will be taken if the participant regains the capacity to consent, who will be used as a legally authorized representative, and what provisions will be made for the assent of the participant.

Address the following four points. A yes/no response is not adequate.

Provide protocol-specific justification for an alteration of the consent process. The Institutional Review Board (IRB) will not consider an alteration request unless you explain specifically how this protocol meets each of the following regulatory criteria.

Yes

No

- The research involves no more than minimal risk to the subjects.

- The alteration will not adversely affect the rights and welfare of the subjects.

- The research could not practicably be carried out without the alteration.

Explain why this research would not be possible to conduct if the IRB required informed consent of participants by completing the following statement, If the IRB required informed consent of participants, this research would not be possible because...Also, estimate the number or percentage of participants for whom obtaining consent is anticipated to be impracticable.

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- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

9.3 Waiver of Consent

Title:

Consent Information Type: *Waiver of Consent*

[Alterations/Waivers of Consent Regulations](#)

Address the following four points. A yes/no response is not adequate.

Provide protocol-specific justification for a waiver of the consent process. The Institutional Review Board (IRB) will not consider a waiver request unless you explain specifically how this protocol meets each of the following regulatory criteria.

Yes

No

- The research involves no more than minimal risk to the subjects.

- The waiver will not adversely affect the rights and welfare of the subjects.

- The research could not practicably be carried out without the waiver.

Explain why this research would not be possible to conduct if the IRB required informed consent of participants by completing the following statement, If the IRB required informed consent of participants, this research would not be possible because...Also, estimate the number or percentage of participants for whom obtaining consent is anticipated to be impracticable.

- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

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9.4 Waiver of Documentation

Title:

Consent Information Type: *Waiver of Documentation*

[Alterations/Waivers of Consent Regulations](#)

Address the following points. A yes/no response is not adequate.

Provide protocol-specific justification for a waiver of documentation of consent. The Institutional Review Board (IRB) will not consider such a request unless you explain specifically why the protocol meets one of the following sets of regulatory criteria:

Yes

No

For research that is not subject to FDA regulation, the only record linking the participants and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality; each participant will be asked whether he/she wants documentation linking the participant with the research, and the participant's wishes govern.

For research whether it is or is not subject to FDA regulation, the research 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.

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10. Assent Background (Less than 18 years of age)

You can add different Assent Forms or Waivers. Provide assent process background information in the table below.

All children must assent to participating by signing an assent form, unless the investigator(s) provides evidence to the IRB that the children are not capable of assenting because of age, maturity, psychological state, or other factors.

Assent for children age 7 – 17 is generally expected. If assent will not be sought for some or all of the children, you will need to add a waiver request.

10.1 Assent Form

Title:

Assent Information Type: *Alteration of Consent*

Consent Form:

- Stanford Non-Medical Template
- Attachment (file name :_____)

If you use a consent form template, please edit it to be applicable to your study.

[Assent Form Template](#)

Describe the process of assent. Include the following:

- Will the assent of some or all children be obtained? If only some, how will those be determined and are the others not capable or is a waiver being sought?
- Who is obtaining child assent and parental consent? (The person obtaining consent must be knowledgeable about the study).
- Where and when will assent be obtained?
- Will a parent or guardian be present when assent is obtained?
- How much time will be devoted to assent discussion?
- How much time will be allowed for assent decision?
- Will these periods provide sufficient opportunity for the child to consider whether to assent?
- What steps are you taking to minimize the possibility of coercion and undue influence?

What is the procedure to assess the child's understanding of the information contained in the assent? How will the information be provided to the child if he/she does not understand English or has a hearing impairment? How will affirmative assent be obtained, e.g., documented by signature on assent form, oral response, combination of methods, or other?

What steps are you taking to determine that the child has the capacity to participate in the decision-making process? Will consent be obtained from both parents (unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child), or from just one parent? Provide a rationale if only one parent will consent.

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10.2 Waiver of Assent

Title:

Consent Information Type: *Waiver of Consent*

[More Information on Assent](#)

Address the following four points. A yes/no response is not adequate.

Provide rationale for waiver of child assent.

Yes

No

The research involves no more than minimal risk to the subjects.

The waiver will not adversely affect the rights and welfare of the subjects.

The research could not practicably be carried out without the waiver.

Explain why this research would not be possible to conduct if the IRB required assent of children by completing the following statement, If the IRB required assent of children, this research would not be possible because...Also, estimate the number or percentage of children for whom obtaining assent is anticipated to be impracticable.

Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

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11. Attachments

11.1 Advertisements

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

11.2 Checklists

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

11.3 Cooperating Institution(s) Approval

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

11.4 Federal Grant/Sub-contract

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

11.5 HIPPA Authorization Form

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

11.6 Information Sheets/Brochures

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

11.7 Package Inserts

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

11.8 Phone Scripts

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

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11.9 Program Project Grant/List

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

11.10 Questionnaires

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

11.11 Sponsor's Protocol

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

11.12 Sponsor's Protocol Amendments

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

11.13 Training Grant/List

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

11.14 Other

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

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Obligations

The Protocol Director agrees to:

- Adhere to principles of [sound scientific research](#) designed to yield valid results
- Conduct the study according to the protocol approved by the IRB
- Be appropriately qualified to conduct the research and be trained in Human Research protection ethical principles, regulations, policies and procedures
- Ensure all research personnel are adequately trained and supervised
- Ensure that the rights and welfare of participants are protected including privacy and confidentiality of data
- Disclose to the appropriate departments any potential conflict of interest
- Report promptly any new information, modification, or [unanticipated problems](#)
- 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. Inasmuch as the Institutional Review Board (IRB) include faculty, staff, legal counsel, public members, and students, protocols should be written in language that can be understood by all Panel members. The investigators must inform the participants of any significant new knowledge obtained during the course of the research.

IRB approval of any project is for a maximum period of one year. For continuing projects and activities, it is the responsibility of the investigator(s) to resubmit the project to the IRB for review and re-approval prior to the end of the approval period. A Notice to Renew Protocol is sent to the Protocol Director 7 weeks prior to the expiration date of the protocol.

Department Chair must approve faculty and staff research that is not part of a sponsored project. VA applicants must have Division Chief or Ward Supervisor approval. E-mail the Department Chair approval to Lauri.Kanerva@stanford.edu.

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

List all items (verbatim) you want to be reflected in your approval letter, i.e. Amendment, Investigator's Brochure, consent form(s), advertisement, telephone script, diary card, etc. Include number and date when appropriate.

Approval Includes:

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

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Check for Completeness *(text that displays when all sections completed)*

The Protocol Form appears to be complete. However, you will need to manually check to make sure that you have attached any necessary documents ([Required Questions](#), Consent forms, etc.) using the attachments feature in the final page of the *Protocol Information* Section.

PLEASE NOTE: Failure to complete and attach the Required Questions document will result in the return of your protocol and may delay its processing.

Please close this window to return to the protocol form. Click on the *Submit Protocol* menu option when you are ready to submit your protocol.