

Protocol Title

Personnel Information

Protocol Director

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

Yes No
 CITI Subjects tutorial completed?

Administrative Contact

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

Yes No
 CITI Subjects tutorial completed?

Co-Protocol Director

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

Yes No
 CITI Subjects tutorial completed?

Other Contact

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

Yes No
 CITI Subjects tutorial completed?

Faculty Sponsor

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

- Yes No
 CITI Subjects tutorial completed?

Other Personnel:

Application Category/Type

Protocol Application Category:

Select **Medical** for investigators in:

- Lucille Packard Children's Hospital (LPCH)
- Psychiatry & Behavioral Sciences
- School of Medicine
- Stanford Hospital and Clinics (SHC)
- Veteran's Affairs (VA) Hospital

Select **Non-Medical** for investigators in:

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

Protocol Application 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. Different review types result in different application forms. Submitting an application with an incorrect review type may require you to enter and submit a new protocol application with the correct review type.

Select Protocol Category:

- Medical Non-Medical

Select Protocol Review Type:

- Regular Expedited Exempt

When Non-Medical and Expedited are selected above, then the following is displayed:

Expedited Paragraph(s)

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 paragraphs.

Select one or more of the following paragraphs:

- 1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.**
 - a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
 - b) Research on medical devices for which
 - i) an investigational device exemption application (21 CFR Part 812) is not required; or
 - ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

- 2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:**
 - a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
 - b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

- 3) Prospective collection of biological specimens for research purposes by non invasive means.**

- 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. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)**

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) magnetic resonance imaging;
 - d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
 - e) 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(s) Checklist

- | <u>Yes</u> | <u>No</u> | |
|-----------------------|-----------------------|--|
| <input type="radio"/> | <input type="radio"/> | Children (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"/> | 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(s) Checklist

- Stanford University
- General Clinical Research Center (GCRC)
- Stanford Hospital and Clinics
- Lucile Packard Children's Hospital (LPCH)
- VA (Specify PI at VA) _____
- Other (Specify other study locations)
Location Name:
Contact Name:
Contact Phone:
Contact Email:

- | <u>Yes</u> | <u>No</u> | |
|-----------------------|-----------------------|---|
| <input type="radio"/> | <input type="radio"/> | Has the location granted permission for the research to be conducted? |
| <input type="radio"/> | <input type="radio"/> | Does the location have an IRB that will approve the research? |

General Checklist

- Yes** **No** **Multi-Site**
 Is this a multi-site study? A multi-site study is generally a study that involves one or more medical or research institutions in which one site takes a lead role.(e.g., multi-site clinical trial)
 Is Stanford the coordinating institution or are you the lead investigator for this multi-site study?

(if NO checked above)

Lead Site Name:
Contact Name:
Contact Phone:
Contact Email:

Yes **No**

- Has the location granted permission for the research to be conducted?
 Does the location have an IRB that will approve the research?

(if YES checked above)

Participating Site Name:
Contact Name:
Contact Phone:
Contact Email:

Yes **No**

- Has the location granted permission for the research to be conducted?
 Does the location have an IRB that will approve the research?

- Yes** **No** **Collaborating Institution(s)**
 Are there any collaborating institution(s)? A collaborating institution is generally an institution that collaborates equally on a research endeavor with one or more institutions.

Institution Name:
Contact Name:
Contact Phone:
Contact Email:

Yes **No**

- Has the location granted permission for the research to be conducted?
 Does the location have an IRB that will approve the research?

- Yes** **No** **Payment**
 Subjects will be paid for participation? See [payment considerations](#).

- Yes** **No** **Funding**
 Training Grant?
 Program Project Grant?
 Federally Sponsored Grant?
 Industry Sponsored Clinical Trial?

Funding Checklist

None

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 _____

Yes

No

- For Federal project, are contents of this protocol the same as described in Federal proposal application?
- Is this a Multiple Project Protocol (MPP)?
- Is this protocol under an MPP?

Fellowships

Funding Administered by:

- STANFORD
- PAIRE
- VA
- Other

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 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#: _____

Resources

a. Qualified staff.

Please state and justify the number and qualifications of your study staff.

b. Training.

Describe the training you will provide to ensure that all persons assisting with the research are informed about the protocol and their research-related duties and functions.

c. Facilities.

Please describe and justify.

d. Sufficient time.

Explain whether you will have sufficient time to conduct and complete the research. Include how much time is required.

e. Access to target population

Explain and justify whether you will have access to a population that will allow recruitment of the required number of participants.

f. Access to resources if needed as a consequence of the research.

State whether you have medical or psychological resources available that participants might require as a consequence of the research when applicable. Please describe these resources.

g. Lead Investigator or Coordinating Institution in Multi-site Study.

Please explain (i) your role in coordinating the studies, (ii) procedures for routine communication with other sites, (iii) documentation of routine communications with other sites, (iv) planned management of communication of adverse outcomes, unexpected problems involving risk to participants or others, protocol modifications or interim findings.

Protocol Information

1. Purpose

- a) In layperson's language state the purpose of the study in 3-5 sentences.
- b) State what the Investigator(s) hope to learn from the study. Include an assessment of the importance of this new knowledge.

2. Study Procedures

- a) Describe all the procedures. 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 what will become of the recording after use, e.g., shown at scientific meetings, erased. Describe the final disposition of the recordings.
- c) State if deception will be used. If so, provide the rationale and describe debriefing procedures. Since you will not be fully informing the participant in your consent process and form, complete an alteration of consent (in section 9). Submit a debriefing script (in section 11).

3. Background

- a) Describe past experimental and/or clinical findings leading to the formulation of the study.

4. Subject Population

- a) State the following: (i) the number of participants expected to be enrolled at Stanford-affiliated site(s); (ii) the total number of participants expected to enroll at all sites; (iii) the type of participants (i.e. students, teachers, government officials) and the reasons for using such participants.
- b) State the age range, gender, and ethnic background of the participant population being recruited.
- c) State the number and rationale for involvement of potentially vulnerable subjects in the study (including children, pregnant women, economically and educationally disadvantaged, decisionally impaired, 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 children are not included, a clear compelling rationale must be provided (e.g., disease does not occur in children, drug or device would interfere with normal growth and development, etc.).
- e) State the number, if any, of participants who are laboratory personnel, employees, and/or students. They should render the same written informed consent. If payment 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 participants will be identified for recruitment (e.g., response to an ad, classroom recruitment, word of mouth, letters mailed home). Describe recruitment procedures. Attach recruitment materials in Section #11 (Attachments). You may not contact potential participants prior to IRB approval.
- g) 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 participants and that they do not constitute undue pressure on participants to volunteer for the research study. Include provisions for prorating payment. See [payment considerations](#).
- h) Costs. Please explain any costs that will be charged to the participant.
- i) Estimate the probable duration of the entire study. Also estimate the total time per participant for: (i) screening of participant; (ii) active participation in study; (iii) analysis of participant data.

5. Risks

- a) For the following categories, describe the potential risk(s) and estimate their frequency, severity, and reversibility.
 - Physical well-being.
 - Psychological well-being.
 - Political.
 - 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) Describe the planned procedures for protecting against and minimizing all potential risks. Include the means for monitoring to detect hazards to the participant (and/or to a potential fetus if applicable). Include steps to minimize risks to the confidentiality of identifiable information.
- d) Discuss plans for ensuring necessary medical or professional intervention in the event of a distressed participant.

e) **Children's Findings (OHRP)**

If children are involved in your research, please select the regulatory category below that your research falls under and provide the necessary rationale for this determination. See full [regulation citation](#).

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.

- 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 the permission of their parents or guardians. Please provide rationale for the above statement.
- 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. Please 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. Research that presents more than minimal risk to children that does not hold out the prospect of direct benefit for the individual subject, or is not likely to contribute to the well-being of the subject. Please provide rationale that: (a) the risk represents a minor increase over minimal risk; (b) the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations; (c) the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and (d) adequate provisions are made for soliciting assent of the children and permission of their parents or guardians.
- 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. Please provide rationale that: (a) the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; (b) the research will be conducted in accordance with sound ethical principles; (c) adequate provisions are made for soliciting assent of the children and permission of their parents or guardians.

Rationale for above selection:

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. Privacy and Confidentiality

Privacy Protections

- a) Describe how the conditions under which interactions will occur are adequate to protect the privacy interests of participants (e.g., privacy of physical setting for interviews or data collection, protections for follow-up interactions such as telephone, email and mail communications).

Confidentiality Protections

- b) Specify the individually identifiable data you will obtain, use or disclose to others.
- c) Describe: (i) how data will be maintained (e.g., paper or electronic spreadsheet, desktop computer, laptop or other portable device); (ii) how you will maintain the confidentiality and data security, (e.g., password protected computer, encrypted files, locked cabinet and office); and (iii) who will have access to the data (e.g., research team, sponsors, consultants)
- d) If you will be sharing data with others, describe how 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 <http://www.stanford.edu/group/security/securecomputing/iso-guidelines.html>.
- 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.
- f) How will you educate research staff to ensure they take appropriate measures to protect the privacy of participants and the confidentiality of data collected (e.g. conscious of oral and written communications, maintaining paper and electronic data)?

8. Potential Conflict of Interest

- a) Does anyone who:
- recruits, selects, consents, or treats participants
 - plans to analyze data
 - plans to serve as an author on any papers originating from this research
 - is an immediate family member (spouse, dependent child as defined by IRS, domestic partner) of any of the above
- Yes No have consulting arrangements, responsibilities or equity holdings in the Sponsoring company, vendor(s), provider(s) of goods, or subcontractor(s)?
- Yes No have a financial relationship with the Sponsoring company, vendor(s), provider(s) of goods, or subcontractor(s) including the receipt of honoraria, income, or stock/stock options as payment?
- Yes No serve as a member of an advisory board with the Sponsoring company, vendor(s), provider(s) of goods, or subcontractor(s)?
- Yes No receive any gift funds from the Sponsoring company, vendor(s), provider(s) of goods, or subcontractor(s)?
- Yes No have an ownership or royalty interest in any intellectual property utilized in this protocol?
- b) Yes No To your knowledge, does any one in a supervisory role to you have a conflict of interest related to this study?

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 Conflict of Interest (Col) disclosure. [See http://www.stanford.edu/dept/DoR/ad_hoc.html](http://www.stanford.edu/dept/DoR/ad_hoc.html) for more information. Contact Barbara Flynn at (650) 723-7226, or bflynn@stanford.edu.

- c) Yes No To your knowledge, does Stanford University have an ownership or royalty interest in any intellectual property utilized in this protocol?

9. Consent Background

Written, signed consent should always be sought unless there are compelling reasons to seek an alteration of consent, waiver of consent, or waiver of documentation (i.e., signature). See more information on [Informed Consent](#). A protocol 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.

- Consent
- Waiver of Consent (*e.g., retrospective chart reviews*)
- Waiver of Documentation (Signature) (*e.g., telephone screens, oral consent, web questionnaires, and cases when the primary risk is breach of confidentiality*)
- Alteration of Consent (*e.g., research involving deception or incomplete disclosure*)

9.1 Consent

Consent Information Type: *Consent*

Title:

Sponsor's Consent Version Number:

Consent Form (file name):

- a) Describe the informed consent process. Include the following:
 - Who is obtaining consent and from whom will consent be obtained, e.g., participant, parent, legally authorized representative (LAR), conservator? (The person obtaining consent must be knowledgeable about the study).
 - When and where 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?
 - If consent relates to children and if you have a reason for obtaining only one parent signature, provide that rationale for IRB consideration.
 - Confirm that the information being communicated during the consent process will not include exculpatory language through which the participant or his LAR is made to waive or appear to waive any of the participant's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.
- b) 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.
- c) What steps are you taking to determine that potential subjects are competent to participate in the decision-making process? If your study may enroll adults who are unable to consent, describe (i) how you will assess the capacity to consent, (ii) what provisions will be taken if the participant regains the capacity to consent, (iii) who will be used as a legally authorized representative, and (iv) what provisions will be made for the assent of the participant.

9.2 Alteration of Consent

Consent Information Type: *Alteration of Consent*

Title:

Sponsor's Consent Version Number:

Consent Form (file name):

- a) Describe the informed consent process. Include the following:
 - Who is obtaining consent and from whom will consent be obtained, e.g., participant, parent, legally authorized representative (LAR), conservator? (The person obtaining consent must be knowledgeable about the study).
 - When and where 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?
 - If consent relates to children and if you have a reason for obtaining only one parent signature, provide that rationale for IRB consideration.
 - Confirm that the information being communicated during the consent process will not include exculpatory language through which the participant or his LAR is made to waive or appear to waive any of the participant's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

- b) 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.

- c) What steps are you taking to determine that potential subjects are competent to participate in the decision-making process? If your study may enroll adults who are unable to consent, describe (i) how you will assess the capacity to consent, (ii) what provisions will be taken if the participant regains the capacity to consent, (iii) who will be used as a legally authorized representative, and (iv) what provisions will be made for the assent of the participant.

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

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

Example: The research involves a review of medical records to determine the incidence of infection following hip replacement procedures. 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:

- True False **The waiver or alteration will not adversely affect the rights and welfare of the participants.**

Example: The Privacy Notice informs patients that their records may be used without their authorization if approved by the IRB, and because study procedures are in place to protect confidentially (including coding and restricted access to the key) information learned during the study will not affect the treatment of the participants who had infections in the pasts and thus will not adversely affect their welfare.

Rationale for above selection:

- True False **The research could not practically be carried out without the waiver or alteration.**

Example: If the IRB required informed consent of participants, this research would be impracticable to do because it would require contacting 1000 patients who had hip replacements one to four years ago; many are elderly and may have moved following their procedure, such that accurate contact information is not readily available and obtaining it for any of the target population would be unduly burdensome.

Rationale for above selection:

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

Example: The information expected to be learned from this retrospective chart review from patient cases one to four years ago will not affect participant's treatment in the future. Thus, it is not anticipated that there will be pertinent information for study participants, though the study may lead to articles about infection that may affect the treatment of future patients.

Rationale for above selection:

9.3 Waiver of Consent

Consent Information Type: *Waiver of Consent*

Title:

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

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

Example: The research involves a review of medical records to determine the incidence of infection following hip replacement procedures. 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:

- True False **The waiver or alteration will not adversely affect the rights and welfare of the participants.**

Example: The Privacy Notice informs patients that their records may be used without their authorization if approved by the IRB, and because study procedures are in place to protect confidentiality (including coding and restricted access to the key) information learned during the study will not affect the treatment of the participants who had infections in the pasts and thus will not adversely affect their welfare.

Rationale for above selection:

- True False **The research could not practically be carried out with out the waiver or alteration.**

Example: If the IRB required informed consent of participants, this research would be impracticable to do because it would require contacting 1000 patients who had hip replacements one to four years ago; many are elderly and may have moved following their procedure, such that accurate contact information is not readily available and obtaining it for any of the target population would be unduly burdensome.

Rationale for above selection:

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

Example: The information expected to be learned from this retrospective chart review from patient cases one to four years ago will not affect participant's treatment in the future. Thus, it is not anticipated that there will be pertinent information for study participants, though the study may lead to articles about infection that may affect the treatment of future patients.

Rationale for above selection:

9.4 Waiver of Documentation

Consent Information Type: *Waiver of Documentation*

Title:

Sponsor's Consent Version Number:

- a) Describe the informed consent process. Include the following:
 - Who is obtaining consent and from whom will consent be obtained, e.g., participant, parent, legally authorized representative (LAR), conservator? (The person obtaining consent must be knowledgeable about the study).
 - When and where 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?
 - If consent relates to children and if you have a reason for obtaining only one parent signature, provide that rationale for IRB consideration.
 - Confirm that the information being communicated during the consent process will not include exculpatory language through which the participant or his LAR is made to waive or appear to waive any of the participant's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.
- b) 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.
- c) What steps are you taking to determine that potential subjects are competent to participate in the decision-making process? If your study may enroll adults who are unable to consent, describe (i) how you will assess the capacity to consent, (ii) what provisions will be taken if the participant regains the capacity to consent, (iii) who will be used as a legally authorized representative, and (iv) what provisions will be made for the assent of the participant.

Select one of the following regulatory criteria for a waiver of documentation (signature) and provide a protocol-specific justification:

- 45 CFR 46.117(c)(1). 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.
- 45 CFR 46.117(c)(2) and 21 CFR 56.109(c)(1). Research (whether it is or is not subject to FDA regulation) 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:

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

All children capable of providing assent should assent to participation. If the PD believes that some or all of the children are not capable of assenting because of age, maturity, psychological state, or other factors, this information should be provided to the IRB. 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.

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

10.1 Assent

Assent Information Type: *Assent*

Title:

Sponsor's Assent Version Number:

Assent Form (file name):

- a) Describe the assent process. Include the following:
 - Who is obtaining child assent? (The person must be knowledgeable about the study.)
 - When and where will assent be obtained?
 - Will a parent or guardian be present when assent is obtained?
 - How much time will be devoted to the assent discussion?
 - 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?
- b) 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?
- c) 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.

10.2 Waiver of Assent

Consent Information Type: *Waiver of Assent*

Title:

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

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

Rationale for above selection:

True False **The waiver or alteration will not adversely affect the rights and welfare of the participants.**

Rationale for above selection:

True False **The research could not practically be carried out without the waiver or alteration.**

Rationale for above selection:

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

Rationale for above selection:

10.3 Assent Not Applicable

Consent Information Type: *Waiver of Assent*

Title:

Please explain why assent is not applicable to this study.

11. Attachments

11.1 Advertisements

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

11.2 Cooperating Institution(s) Approval

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

11.3 Federal Grant/Sub-contract

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

11.4 Information Sheets/Brochures

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

11.5 Package Inserts

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

11.6 Phone Scripts

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

11.7 Program Project Grant/List

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

11.8 Questionnaires

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

11.9 Sponsor's Protocol

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

11.10 Sponsor's Protocol Amendments

Attachment Name:
Attached Date:

Attached By:
Submitted Date:

11.11 Training Grant/List

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

11.12 Un-sponsored Research Approval

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

11.13 VA Required Questions

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

11.14 Other

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

Obligations

The Protocol Director agrees to:

- Adhere to principles of [sound scientific research](#) designed to yield valid results
- Conduct the study according to the protocol approved by the IRB
- Be appropriately qualified to conduct the research and be trained in Human Research protection ethical principles, regulations, policies and procedures
- Ensure all research personnel are adequately trained and supervised
- Ensure that the rights and welfare of participants are protected including privacy and confidentiality of data
- Disclose to the appropriate departments 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. 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 IRBCoordinator@lists.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.

PLEASE NOTE: List all items (verbatim) that you want to be reflected in your approval letter (e.g., Amendment, Investigator's Brochure, consent form(s), advertisement, etc.) in the box below. Include number and date when appropriate.

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