

**PROTOCOL  
APPLICATION FORM  
MEDICAL REGULAR  
HUMAN SUBJECTS IN MEDICAL RESEARCH  
STANFORD UNIVERSITY**

|   |
|---|
| <b>Protocol ID:</b> 9039                            |
| <b>Title:</b> Sample Medical Regular Protocol Title |

**Protocol Director**

|  |                           |                                 |                          |   |
|--|---------------------------|---------------------------------|--------------------------|---|
| <b>Name</b><br>Ratan Banik   |                           | <b>Degree (MD/PhD):</b><br>M.D. | <b>Title</b><br>Test     |   |
| <b>Dept</b><br>Vice Provost and Dean of Research and Graduate Policy - Research Compliance | <b>Mail Code</b><br>77777 | <b>Phone</b><br>(650) 333 4444  | <b>Fax</b><br>6501236666 | <b>E-mail</b><br>doctor.test@stanford.edu |
| <b>CITI Training Completed in the Last Two Years?</b> Y                                    |                           |                                 |                          |   |

**Admin Contact**

|  |                           |                                 |                          |  |
|--|---------------------------|---------------------------------|--------------------------|--|
| <b>Name</b><br>Ratan Banik   |                           | <b>Degree (MD/PhD):</b><br>M.D. | <b>Title</b><br>Test     |  |
| <b>Dept</b><br>Vice Provost and Dean of Research and Graduate Policy - Research Compliance | <b>Mail Code</b><br>77777 | <b>Phone</b><br>(650) 333 4444  | <b>Fax</b><br>6501236666 | <b>E-mail</b><br>kmgarcia@stanford.edu |
| <b>CITI Training Completed in the Last Two Years?</b> Y                                    |                           |                                 |                          |  |

**Co-Protocol Director**

|   |                  |                         |              |               |
|---|------------------|-------------------------|--------------|---------------|
| <b>Name</b>   |                  | <b>Degree (MD/PhD):</b> | <b>Title</b> |               |
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| <b>CITI Training Completed in the Last Two Years?</b> |                  |                         |              |               |

**Other Contact**

|   |                  |                         |              |               |
|---|------------------|-------------------------|--------------|---------------|
| <b>Name</b>   |                  | <b>Degree (MD/PhD):</b> | <b>Title</b> |               |
| <b>Dept</b>   | <b>Mail Code</b> | <b>Phone</b>            | <b>Fax</b>   | <b>E-mail</b> |
| <b>CITI Training Completed in the Last Two Years?</b> |                  |                         |              |               |

**Faculty Sponsor**

|   |                  |                         |              |               |  |
|---|------------------|-------------------------|--------------|---------------|--|
| <b>Name</b>   |                  | <b>Degree (MD/PhD):</b> | <b>Title</b> |               |  |
| <b>Dept</b>   | <b>Mail Code</b> | <b>Phone</b>            | <b>Fax</b>   | <b>E-mail</b> |  |
| <b>CITI Training Completed in the Last Two Years?</b> |                  |                         |              |               |  |

| <b>Other Personnel</b> |                       |             |                   |                                    |
|------------------------|-----------------------|-------------|-------------------|------------------------------------|
| <b>Name</b>            | <b>Degree: MD/PhD</b> | <b>Role</b> | <b>Department</b> | <b>Required Training Completed</b> |

**Participant Population(s) Checklist**

**Yes/No**

- Children (under 18) Y
- Pregnant Women Y
- Fetuses Y
- Abortuses Y
- Mentally Disabled Y
- Decisionally Challenged Y
- Cancer Subjects Y
- Laboratory Personnel Y
- Healthy Volunteers Y
- Students Y
- Employees Y
- Prisoners Y
- Other (i.e., any population that is not specified above) Y

**General Checklist**

**Multi-site**

**Yes/No**

- 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) Y
- Is Stanford the coordinating institution or are you the lead investigator for this multi-site study? Y

**Collaborating Institution(s)**

**Yes/No**

- 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. Y

| <b>Institution Name</b> | <b>Contact Name</b> | <b>Contact Phone</b> | <b>Contact Email</b> | <b>Permission?</b> | <b>IRB?</b> |
|-------------------------|---------------------|----------------------|----------------------|--------------------|-------------|
| Sample Institution      | Sample Name         | 12345678910          | test@stanford.edu    | Y                  | Y           |

**Cancer Center** **Yes/No**

- Cancer Subjects (e.g., clinical trials, behavior/prevention) or Cancer Tissues (e.g., blood, cells, body fluids). Y

**Drug /Device** **Yes/No**

- Protocol involves studying potentially addicting drugs? Y
- Investigational drugs, reagents, or chemicals? Y
- Commercially available drugs, reagents, or other chemicals administered to subjects (even if they are not being studied)? Y
- Investigational Device? Y
- Commercially available device? Y

**Tissues and Specimens** **Yes/No**

- Human blood, cells, tissues, or body fluids (tissues)? Y
- Tissues to be stored for future research projects? Y
- Tissues to be sent out of this institution as part of a research agreement? For guidelines, please see <http://otl.stanford.edu> Y

**Human Embryos or Embryonic Stem Cells** **Yes/No**

- Human Embryos? Y
- Human Embryonic Stem Cells? Provide NIH Code Number(s) or state that no federal funding will be used to support this research. Y

12345

**Veterans Affairs (VA)** **Yes/No**

- The research recruits participants at the Veterans Affairs Palo Alto Health Care System(VAPAHCS). Y
- The research involves the use of VAPAHCS non-public information to identify or contact human research participants or prospective subjects or to use such data for research purposes. Y
- The research is sponsored (i.e., funded) by VAPAHCS. Y
- 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. Y
- The research is conducted using any property or facility of VAPAHCS. Y

**Equipment** **Yes/No**

- Use of Patient related equipment? If Yes, equipment must meet the standards established by Hospital Instrumentation and Electrical Safety Committee (650-725-5000) Y
- Medical equipment used for human patients/subjects also used on animals? Y
- Radioisotopes/radiation-producing machines, even if standard of care? Y

**Payment**

**Yes/No**

- Subjects will be paid for participation? Y

**Funding**

**Yes/No**

- Training Grant? Y
- Program Project Grant? Y
- Federally Sponsored Project? Y
- Industry Sponsored Clinical Trial? Y

**Study Location(s) Checklist**

**Yes/No**

- Stanford University Y
- General Clinical Research Center (GCRC) Y
- Stanford Hospital and Clinics Y
- Lucile Packard Children's Hospital (LPCH) Y
- VA (Specify PI at VA) Y

Sample

- San Mateo County Y
- Other (Click ADD to specify details) Y

| Location Name   | Contact Name  | Contact Phone | Contact Email     | Permission? | IRB? |
|-----------------|---------------|---------------|-------------------|-------------|------|
| Sample Location | Sample Person | 16502344567   | test@stanford.edu | Y           | Y    |

**Funding**

NONE

| <b>Funding - Grants/Contracts</b>                             |  |                                     |                |
|---|--|-------------------------------------|----------------|
| <b>Funding Administered By:</b>                               | OTHER  | <b>SPO # (if available):</b>        | 12345          |
| <b>Grant # (if available):</b>                                | 12345  | <b>Funded By (include pending):</b> | sample funding |
| <b>Principal Investigator:</b>                                | Dr. Sample Ph.D.   |                                     |                |
| <b>Grant/Contract Title if different from Protocol Title:</b> | Sample Protocol  |                                     |                |
| Y   | For Federal projects, are contents of this protocol the same as described in Federal proposal application? |                                     |                |

|   |  |
|---|--|
| Y | Is this an Umbrella protocol?                |
| Y | Is this protocol under an Umbrella protocol? |

**Funding - Fellowships**

|   |  |   |            |
|---|--|---|------------|
| <b>Funding administered by:</b>                           | OTHER  | <b>Fellowship Reference # (if available):</b> | 12345      |
| <b>Funded By:</b>   | Sample Fellowship  | <b>Name of Fellow:</b>                        | Mr. Sample |
| <b>Fellowship Title if different from Protocol Title:</b> |  |   |            |
| <input type="text" value="Sample Protocol"/>              |  |   |            |
| Y   | For Federal projects, are contents of this protocol the same as described in Federal proposal application? |   |            |

**Gift Funding**

|                       |            |                        |         |
|-----------------------|------------|------------------------|---------|
| <b>Name of Donor:</b> | Test Donor | <b>Account Number:</b> | 1234567 |
|-----------------------|------------|------------------------|---------|

**Dept. Funding**

|                         |                   |                        |         |
|-------------------------|-------------------|------------------------|---------|
| <b>Department Name:</b> | Sample Department | <b>Account Number:</b> | 1234567 |
|-------------------------|-------------------|------------------------|---------|

**Other Funding**

|                         |             |                        |         |
|-------------------------|-------------|------------------------|---------|
| <b>Other Fund Name:</b> | Test Funder | <b>Account Number:</b> | 1234567 |
|-------------------------|-------------|------------------------|---------|

**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.**

Sample Access

- 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.**

Sample 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.**

Sample Investigator

## 1. Purpose

- a) **In layperson's language state the purpose of the study in 3-5 sentences.**

Sample Purpose

- b) **State what the Investigator(s) hope to learn from the study. Include an assessment of the importance of this new knowledge.**

Sample Response

- c) **Explain why human subjects must be used for this project. (i.e. purpose of study is to test efficacy of investigational device in individuals with specific condition; purpose of study is to examine specific behavioral traits in humans in classroom or other environment)**

Sample Reason

## 2. Study Procedures

- a) **Describe all the procedures, from screening through closeout, which the human subject must undergo in the research project, including study visits, drug treatments, randomization and the procedures that are part of standard of care.**

Sample procedures

- b) **Explain how the above research procedures are the least risky that can be performed consistent with /research/documents/SoundStudyDesignMedical.pdf sound research design.**

Sample Response

- 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 13). Submit a debriefing script (in section 16).**

Sample Response

- d) **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.**

Sample response

- e) **Describe alternative procedures or courses of treatment, if any, that might be advantageous to the participant. Describe potential risks and benefits associated with these. Any standard treatment that is**

being withheld must be disclosed in the consent process and form. (i.e. standard-of-care drug, different interventional procedure, no procedure or treatment, palliative care, other research studies).

Sample Procedures

- f) Will it be possible to continue the more (most) appropriate therapy for the participant(s) after the conclusion of the study?

Sample Response

- g) **Study Endpoint.** What are the guidelines or end points by which you can evaluate the different treatments (i.e. study drug, device, procedure) during the study? If one proves to be clearly more effective than another (or others) during the course of a study, will the study be terminated before the projected total participant population has been enrolled? When will the study end if no important differences are detected?

Sample response

### 3. Background

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

Sample background

- b) Describe any animal experimentation and findings leading to the formulation of the study.

Sample response

### 4. Radioisotopes or Radiation Machines

- a) State whether the radiation procedures are performed as a normal part of clinical management for the medical condition that is under study or whether they are being performed because the research subject is participating in this project (extra CT scans, more fluoroscopy time, additional Nuclear Medicine Studies, etc.). If some are Standard of Care and some are Not Standard of Care, check both boxes.

**Y NOT STANDARD OF CARE**  
If it is not standard of care,  
complete the rest of this section.

**STANDARD OF CARE**  
If it is only standard of care, skip the rest  
of this section.

Note: Only applications from the faculty of the Stanford School of Medicine or senior medical staff at the Veterans Affairs Palo Alto Health Care System will be accepted. In general the Protocol Director must be a licensed clinician; however, in the unusual circumstance that the protocol director is not a physician, collaboration and appropriate assistance by such a physician is mandatory and both names must appear.

- b) For radioisotope projects, provide the following radiation-related information:

**Identify the radionuclide and chemical form.**

Sample answer

**For each dosage, provide the route of administration and the amount administered (mCi).**

Sample Answer

**Provide dosimetry information and reference the source documents (package insert, MIRD calculation, peer reviewed literature).**

Sample Information

- c) For radiation machine projects, provide the following diagnostic procedures:

**For well-established radiographic procedures, identify the procedures and the number of times each will be performed on a single research participant.**

sample procedures

For each radiographic procedure, provide the setup and technique sufficient to permit dose modeling. The chief technologist can usually provide this information.

Sample setup

For radiographic procedures that are not well-established, provide FDA status of the machine, and information sufficient to permit dose modeling.

Sample status

d) For radiation machine projects, provide the following therapeutic procedures:

For a well-established therapeutic procedure, identify the area treated, dose per fraction and number of fractions. State whether the therapeutic procedure is being performed as a normal part of clinical management for the research participants' medical condition or whether it is being performed because the research participant is participating in this project.

sample response

For a therapeutic procedure that is not well-established, provide FDA status of the machine, basis for dosimetry, area treated, dose per fraction and number of fractions.

sample status

## 5. Devices

### a) Investigational Devices

#### 5.1 Device Name: Sample device

Describe the device to be used.

Sample Description

Manufacturer

Sample Manufacturer

Significant:

Y

IDE #:

1234567

Non-significant

Rationale for the device being non-significant risk:

#### Holder of IDE:

Y

Is IDE held by the sponsor? If yes, provide a copy of the sponsor's protocol, the device manual, and the FDA letter granting the IDE# (attach in section 16).:

Y

Is IDE held by the investigator? If yes, provide a copy of the letter submitted to the FDA and the FDA's response (attach in section 16).

#### Ordering, Storage and Control

To prevent the device being used by a person other than the investigator, and in someone other than a research participant: Confirm that the device will be handled according to the SHC/LPCH policy for Investigational New Devices (ordered through SHC/LPCH Materials Management and stored in the SHC/LPCH unit where it will be used) or as appropriate, handled according to VAPAHCS memo 151-05-10. Enter "confirmed", else provide an explanation.

Sample response

### b) Commercial Devices

#### 5.1 Device Name: Sample Commercial Device

Describe the device to be used.

Sample description

Manufacturer Sample manufacturer

IDE Exemption

Y Is this a new and different use of this commercially available device?

Y Are all of the IDE statements shown below true?

## 6. Drugs, Reagents, or Chemicals

### a) Investigational Drugs

6.1 Drug Name: Sample Drug

Source (i.e. Pharmacy, Sponsor, Sample Pharmacy etc.):

If not pre-mixed, where will the material be mixed and by whom:

Sample response

Manufacturer: sample manufacturer

IND # (if available): 1234567

Dosage: sample dose

Administration Route:

sample route

#### Holder of IND

Y Is IND held by the sponsor? If yes, provide a copy of the investigator's brochure and the sponsor's protocol, and the FDA letter granting the IND# (Attach in Section #16).

Y Is IND held by the investigator? If yes, provide a copy of the letter submitted to the FDA and the FDA's response(attach in section 16).

#### Pharmacy Dispensing or Security and Controlled Access Plan.

Y Will the investigational drug/biologic be maintained and dispensed by a pharmacy or through an outpatient clinic monitored by a pharmacy?

Pharmacy Name: sample pharmacy

Describe below (or attach in section 16) the procedures to be followed to prevent the Investigational drug from being used by a person other than the investigator, and to prevent it from being used in someone other than a research participant

### b) Commercial Drugs

6.1 Drug Name: sample commercial drug

Source (i.e. Pharmacy, Sponsor, sample pharmacy

etc.):

**If not pre-mixed, where will the material be mixed and by whom:**

sample response

**Manufacturer:** sample manufacturerer

**IND# (if available):** 1234567

**Dosage:** sample dose

**Administration Route:**

sample route

### **IND Exemption**

- Y** Is this new and different uses of this commercially available drug, reagent or chemical?  
**Y** Are all of these IND Statements true?

### **Investigational New Drug (IND) Regulations**

The IND Regulations [21 CFR 312.2(b)] state that clinical investigation of a drug product is exempt from the requirements for an IND if all of the following apply:

- The Drug used in the investigations is lawfully marketed in the United States.
- The investigation is not intended to be reported to FDA in support of new indication for use or to support any other significant change in the labeling for the drug.
- The investigation is not intended to support a significant change in the advertising of the product.
- The investigation does not involve a route of administration or dosage level, use in a participant population, or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product.
- The investigation is conducted in compliance with the requirements for IRB review and informed consent [21 CFR parts 56 and 50].
- The investigation is conducted in compliance with the requirements concerning the promotion and sale of drugs [21 CFR part 312.7], e.g., the drug may not be represented as safe or effective for the purposes for which it is under investigation, nor may it be commercially distributed or sold.

## **7. Medical Equipment for Human Subjects and Laboratory Animals**

**If medical equipment used for human patients/participants is also used on animals, describe such equipment and disinfection procedures.**

Sample response

## **8. Participant 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, patients with certain cancer, patients with certain cardiac condition) and the reasons for using such participants.**

sample response

- b) **State the age range, gender, and ethnic background of the participant population being recruited.**

sample response

- 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.**

sample response

- 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.).**

sample response

- 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>).**

sample response

- f) **State the number, if any, of participants who are healthy volunteers. Provide rationale for the inclusion of healthy volunteers in this study. Specify any risks to which participants may possibly be exposed. Specify the measures being taken to minimize the risks and the chance of harm to the volunteers and the additional safeguards that have been included in the protocol to protect their rights and welfare.**

sample response

- g) **Describe how potential participants will be identified for recruitment (e.g., chart review, referral from individual's treating physician, responses to an ad). Describe how participants will be recruited and how they will initially learn about the research (e.g., clinics, advertising). Attach recruitment materials in Section #16 (Attachments). You may not contact potential participants prior to IRB approval.**

sample response

- h) **Inclusion and Exclusion Criteria.**

**Identify inclusion criteria.**

sample criteria

**Identify exclusion criteria.**

sample criteria

- i) **Describe your screening procedures, including how qualifying laboratory values will be obtained. If you are collecting personal health information prior to enrollment (e.g., telephone screening), please request a limited waiver of authorization (in section 15).**

sample procedures

- j) **Describe how you will be cognizant of other protocols in which participants might be enrolled. Please explain if participants will be enrolled in more than one study.**

sample response

- k) **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.**

sample response

- l) **Costs. Please explain any costs that will be charged to the participant.**

sample response

- m) **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.**

sample response

## 9. Risks

- a) For the following categories include a scientific estimate of the frequency, severity, and reversibility of potential risks. Wherever possible, include statistical incidence of complications and the mortality rate of proposed procedures. Where there has been insufficient time to accumulate significant data on risk, a statement to this effect should be included. (In describing these risks in the consent form to the participant it is helpful to use comparisons which are meaningful to persons unfamiliar with medical terminology.)

**Investigational devices.**

sample device

**Investigational drugs. Information about risks can often be found in the Investigator's brochure.**

sample drug

**Commercially available drugs, reagents or chemicals. Information about risks can often be found in the package insert.**

sample commercial drug

**Procedures to be performed. Include all investigational, non-investigational and non-invasive procedures (e.g., surgery, blood draws, treadmill tests).**

sample procedure

**Radioisotopes/radiation-producing machines (e.g., X-rays, CT scans, fluoroscopy) and associated risks.**

sample machines

**Physical well-being.**

sample response

**Psychological well-being.**

sample response

**Economic well-being.**

sample response

**Social well-being.**

sample response

**Overall evaluation of Risk.**

High

Select all that apply:

- Y    Chemotherapy  
Y    Potential toxic drug  
Y    Other (explain below)  
sample risk

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

sample qualifications

- 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.**

sample procedures

- d) **Explain the point at which the experiment will terminate. If appropriate, include the standards for the termination of the participation of the individual participant Also discuss plans for ensuring necessary**

**medical or professional intervention in the event of adverse effects to the participants.**

sample response

- e) **Data Safety and Monitoring Plan (DSMP). See guidance on Data Safety and Monitoring.**

**Describe the following:**

**The type of data or events that are to be captured under the monitoring plan.**

sample data

**The Monitoring Entity (ME) that will be responsible for monitoring the data collected, including data related to unanticipated problems and adverse events, and their respective roles (e.g., Stanford Cancer Center, GCRC, investigator, sponsor, coordinating or statistical center, independent medical monitor, DSMB/DSMC, or some other entity). If there is no ME, then the Protocol Director (PD) is responsible for this function.**

sample response

**If the ME is not the Stanford Cancer Center or GCRC, provide information about the ME's members (e.g., name, credentials, title, organization, contact information).**

sample response

**The time frames for reporting adverse events and unanticipated problems to the ME.**

sample response

**The frequency of assessments of data or events captured by the monitoring plan.**

sample response

**Specific triggers or stopping rules that will dictate when some action is required.**

sample response

**As appropriate, procedures for communicating to the IRB, the study sponsor, and other appropriate entities the outcome of the reviews by the ME.**

sample response

**Select One:**

Y This protocol will not utilize a Monitoring Entity. I understand that as Protocol Director, it is my responsibility to assess events and new information, and to report to the IRB as specified in the guidance /research/documents/GuidanceUnanticipatedProblems.pdf Events and Information that Require Prompt Reporting to the IRB.

This protocol will utilize a Monitoring Entity. I understand as Protocol Director, it is my responsibility to review reports from the Monitoring Entity and to report to the IRB those identified as unanticipated problems involving risks to participants or others according to the criteria of being unexpected, related, and harmful, as specified in the guidance Events and Information that Require Prompt Reporting to the IRB.

- f) **Special Participant Populations**

**Children's Findings FDA. As your research includes an investigational drug/device and children, please select the category below that your research falls under and provide the necessary rationale for this determination. See full regulation citation.**

Y 50.51 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.

**Rationale for category selected above**

sample rationale

### **Pregnant Women or Fetuses**

**As pregnant women are included in your research, please confirm that all of the statements below are true. See full regulation citation.**

- Y a) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data assessing potential risks to pregnant women and fetuses;
- Y b) The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;
- Y c) Any risk is the least possible for achieving the objectives of the research;
- Y d) If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions of subpart A of this part;
- Y e) If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of subpart A of this part, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.
- Y f) Each individual providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;
- Y g) For children as defined in Sec. 46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of subpart D of this part;
- Y h) No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
- Y i) Individual engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy;
- Y j) Individual engaged in the research will have no part in determining the viability of a neonate.

### **10. Benefits**

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

sample response

### **11. Procedures to Maintain Confidentiality**

- a) **Describe procedures for protecting the privacy interests of participants. Additionally, include whether the conditions affecting interaction with the participants and data collection are adequate to protect privacy (e.g., recording physical measurements of pre-teens in a school-setting, eliciting private medical or financial information in a quasi-public setting).**

sample procedures

- b) **Describe how you will maintain the confidentiality of research records in a secure manner. Include (i) where and under what conditions study data will be kept; (ii) how samples and records will be labeled; (iii) who has access to data, and whether there are levels of access (e.g., restricted access to sensitive information); (iv) what security measures will be used for private information and sensitive information (e.g., locked file cabinet, safe transmittal and storage, protection against loss, theft, or access by unauthorized persons, statistical techniques, encryption); and (v) if a code is used, what measures will be taken to protect against deciphering?**

sample response

- c) **How will you educate research staff to ensure they appreciate the importance of confidentiality including being conscious of their oral and written communications in such situations as workplace conversation, insurance billing, lost or misplaced papers, and unsecured electronic documents?**  
 sample response
- d) **For this study, is it feasible to not collect and record protected health information (PHI) or other individually identifiable information (e.g., use anonymous data)?**  
 sample response
- e) **If you are using de-identified data or specimens, will you receive the data or specimens without identifiers? Who will be responsible for the de-identification? If x-rays or other digital images are used, explain how the images will be de-identified.**  
 sample response
- f) **Are the data coded in such a manner that you would be re-identify the participant if you needed to? Who maintains the key to this code? Does anyone on your research team have access to this code?**  
 sample response
- g) **If PHI or other individually identifiable information is needed, explain at what stage of the research you will collect and record it (e.g., screening and recruitment, or actual enrollment, before or after obtaining informed consent). Describe what PHI or other individually identifiable information you will need.**  
 sample response
- h) **Explain whether you will code or destroy PHI or other individually identifiable information at some stage of the research.**  
 sample response
- i) **List any outside parties to whom you may need to disclose PHI or other individually identifiable information collected in or derived from the study. Include, for example, a participant's personal physician(s), other participating study sites and research teams, insurer(s), the sponsor, government agency(ies) (including FDA if this is FDA-regulated research), the institutional review board or other oversight bodies, or any other person or group. Include the nature of the PHI or other individually identifiable information that may be disclosed.**  
 sample response

## 12. Potential Conflict of Interest

- a) Y 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) Y 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) Y Is any Investigator(s) a member of an advisory board with the Sponsoring company?
- d) Y Do any investigators receive gift funds from the Sponsoring company?
- e) Y Do any investigators or their immediate family 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 CoI 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](http://www.stanford.edu/dept/DoR/ad_hoc.html).

- Y To your knowledge, does Stanford University have an ownership or royalty interest in any intellectual property utilized in this protocol?

### 13. Consent Background

#### 13.1 Waiver of Consent sample title

- 1) Y **The research involves no more than minimal risk to the participants.**  
sample rationale
- 2) Y **The waiver or alteration will not adversely affect the rights and welfare of the participants.**  
sample rationale
- 3) Y **The research could not practically be carried out with out the waiver or alteration.**  
sample rationale
- 4) Y **Whenever appropriate, the participants will be provided with additional pertinent information after participation.**  
sample rationale

### 14. Assent Background (less than 18 years of age)

#### 14.1 Waiver of Assent test title

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

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

sample rationale

- Y **The waiver will not adversely affect the rights and welfare of the participants.**

sample rationale

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

sample rationale

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

sample rationale

### 15. HIPAA Background

#### 15.1 Waiver of Authorization sample name

- a) **Please describe the protected health information needed to conduct screening or recruitment.**

sample information

- b) Please Answer:

- Y Do you certify that the use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals?
  - Y Do you certify that the research could not practically be conducted with out the waiver?
  - Y Do you certify that you have adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted?
  - Y Do you certify that the research could not practically be conducted with out access to and use of the protected health information?
- c) Please describe an adequate plan to protect any identifiers from improper use and disclosure.

sample plan

- d) Please describe an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.

sample plan

## 16. Attachments

| Attachment Name    | Attached Date | Attached By | Submitted Date |
|--------------------|---------------|-------------|----------------|
| sample VA document | 06/06/2007    | ratanb      |                |

## Obligations

The Protocol Director agrees to:

- Adhere to principles of /research/documents/SoundStudyDesignMedical.pdf 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 /research/documents/GuidanceUnanticipatedProblems.pdf 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. 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>)

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.

|                 |
|-----------------|
| sample response |
|-----------------|

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