

**PROTOCOL  
 APPLICATION FORM  
 Human Subjects Research  
 Stanford University**

**Title:** The New Genetics: Electronic Tools for Educational Innovation  
**Protocol Director:** Sara L. Tobin  
**Approval Period:** 07/02/2009 - 12/31/2999

<b>Modification</b>
<b>1. Summarize the proposed changes to the protocol</b>
The project originally proposed to evaluate educational materials only in California undergraduate institutions. We wish to modify our evaluation plan so that we can carry out evaluation activities in selected undergraduate institutions in the United States.
<b>2. Indicate Level of Risk</b>
No Change
<b>3. Describe any Other Changes</b>

<b>Protocol Director</b>				
<b>Name</b> Sara L. Tobin		<b>Degree (program/year if student)</b> Ph.D., M.S.W.		<b>Title</b> Sr Research Scholar
<b>Dept</b> School of Medicine - Biomedical Ethics	<b>Mail Code</b> 5748	<b>Phone</b> (650) 725-2663	<b>Fax</b> (650) 725-6131	<b>E-mail</b> tobinsl@stanford.edu
<b>CITI Training current (within last 2 years for Stanford: within last year for VA)?</b>				Y

<b>Admin Contact</b>				
<b>Name</b> Sara L. Tobin		<b>Degree (program/year if student)</b>		<b>Title</b> Sr Research Scholar
<b>Dept</b> School of Medicine - Biomedical Ethics	<b>Mail Code</b> 5748	<b>Phone</b> (650) 725-2663	<b>Fax</b> (650) 725-6131	<b>E-mail</b> tobinsl@stanford.edu
<b>CITI Training current (within last 2 years for Stanford: within last year for VA)?</b>				Y

<b>Co-Protocol Director</b>				
<b>Name</b>		<b>Degree (program/year if student)</b>		<b>Title</b>
<b>Dept</b>	<b>Mail Code</b>	<b>Phone</b>	<b>Fax</b>	<b>E-mail</b>
<b>CITI Training current (within last 2 years for Stanford: within last year for VA)?</b>				

<b>Other Contact</b>				
<b>Name</b>		<b>Degree (program/year if student)</b>		<b>Title</b>
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<b>CITI Training current (within last 2 years for Stanford: within last year for VA)?</b>				

<b>Faculty Sponsor</b>		
<b>Name</b>	<b>Degree (program/year if student)</b>	<b>Title</b>

Dept	Mail Code	Phone	Fax	E-mail
<b>CITI Training Completed in the Last Two Years?</b>				

**Other Personnel**

**Participant Population(s) Checklist**

**Yes/No**

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

**Study Location(s) Checklist**

**Yes/No**

- |   |   |
|---|---|
| • Stanford University                       | Y |
| • General Clinical Research Center (GCRC)   | N |
| • Stanford Hospital and Clinics             | N |
| • Lucile Packard Children's Hospital (LPCH) | N |
| • Other (Click ADD to specify details)      | N |

**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) | N |
|--|---|

**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. | N |
|---|---|

**Payment**

**Yes/No**

- |  |   |
|--|---|
| • Subjects will be paid for participation? See payment considerations. | N |
|--|---|

**Funding**

**Yes/No**

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

### Funding

Funding - Grants/Contracts			
<b>Funding Administered By:</b>	STANFORD	<b>SPO # (if available):</b>	31658
<b>Grant # (if available):</b>		<b>Funded By (include pending):</b>	National Science Foundation
<b>Principal Investigator:</b>	Sara L. Tobin		
<b>Grant/Contract Title if different from Protocol Title:</b>			
Y	For Federal projects, are contents of this protocol the same as described in Federal proposal application?		
N	Is this an Umbrella protocol?		
N	Is this protocol under an Umbrella protocol?		

### Funding - Fellowships

### Gift Funding

### Dept. Funding

### Other Funding

### Resources:

a) **Qualified staff.**

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

The study staff include PI Tobin, assisted by an advisory board of two nationally known educators from University of Washington and Johns Hopkins University. There is an executive group composed of Tobin, Boughton (graphics and computer design), Huxley (California State Manpower Director), and Johnson (PI of Bio-Link, an NSF-funded Center). Staff also include Weiler, a professional evaluator experienced with NSF-funded projects. Project assistance is provided by Raina Glazener, who has assisted with a number of projects from the Stanford Center for Biomedical Ethics. All individual personnel were included by name and qualification in our original NSF application with the exception of Glazener.

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.**

All staff persons report to the PI and do not have direct contact with any human subjects. The PI informs faculty at colleges and universities and community colleges that they are required to obtain administrative

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clearance from their institutions before they are permitted to use project modules in their classrooms and request evaluations from their students. They must submit an institutional letter signed by the appropriate official at their institution. This process is controlled by password protection of the website at which project educational modules and evaluation instruments are posted. In addition, the Stanford IRB application and approval letter and a template for an institutional approval letter are posted on the project website at: <http://bioethics.stanford.edu/research/TheNewGeneticsProjectPage.html>  
Go to the URL above and select "Enter Project Development Site"  
These documents are posted to assist prospective faculty to become familiar with the human subject aspects of the project and to provide documentation to their institutions.

c) **Facilities.**

**Please describe and justify.**

Only ordinary office and computer facilities are required for the execution of this project.

d) **Sufficient time.**

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

This project is currently funded for three years, but a no-cost extension for a fourth year is being requested. This project requires 25% of the PI time and is a significant part of her activities.

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.**

This project involves evaluation by undergraduate students so that educational modules can be improved before being finalized. Originally, we anticipated being able to recruit a sufficient number of faculty and students in California institutions, but were having problems achieving the numbers we need. Consequently, the reason for this modification request is to carry out national evaluation so that we can increase the number of evaluations.

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.**

This project involves only development of educational materials. We do not anticipate medical or psychological risk to participants. Students are actively enrolled in colleges or universities, so institutional resources would be available to them.

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.**

**Exempt Form**

Federal regulations state that certain research is exempt from review. However, under Stanford's Policy for the Protection of Human Subjects, a research protocol proposing the use of human subjects must be submitted to the Panel to determine if it qualifies for exempt status. EXEMPTIONS DO NOT APPLY TO RESEARCH CONDUCTED ON PRISONERS.

In order to qualify as Exempt, a protocol must be no more than minimal risk AND must only involve human subjects in one or more of the following paragraphs.

**Select one or more of the following paragraphs:**

1. Y **Research conducted in established educational settings, involving normal educational practices, such as:**
  - i) research on education instructional strategies, or
  - ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. N **Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), surveys, interviews, or observation of public behavior \***  
UNLESS
  - i) information is recorded with identifiers linked to the subjects AND
  - ii) subjects' responses could place subjects at risk (e.g., criminal or civil liability, financial standing, employability or reputation).
3. N **Research involving educational tests, surveys, interviews, or observation of public behavior is exempt if:**
  - i) the subjects are elected or appointed public officials or candidates for public office; or
  - ii) federal statute requires confidentiality of identifiable information to be maintained permanently
4. N **Research involving the collection or study of existing data, documents, or records. Sources must either be publicly available or information must be recorded without identifiers linked to the subjects.**

**Yes/No**

- N Are the data and/or specimens pre-existing, i.e., "on the shelf", as of today?
- N Is it correct that no one (including the researcher) can identify a subject from any information recorded for this research?

5. N **Research conducted by or subject to the approval of Federal Department or Agency head, and designed to study or evaluate:**
  - i) public benefit or service programs;
  - ii) procedures for obtaining benefits or services under those programs;
  - iii) possible changes in or alternatives to those programs; or
  - iv) changes in methods of payment for benefits under those programs.
6. N **Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.**

**1. Purpose**

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

This study is designed to create, produce, and evaluate an innovative set of educational materials about genetics and genomics for use in a broad spectrum of undergraduate courses and institutions. The intellectual merit of this project is its ability to engage student interest in cutting edge science by creating highly integrated educational materials that combine genetic and genomic science, technological concepts, environmental, agricultural,

and biomedical applications, and societal and ethical issues. Such materials can appeal to students at several stages of undergraduate education and may be effective in recruiting students into science careers.

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

We propose to test the effectiveness of these materials by carrying out rigorous educational evaluations in a wide variety of educational institutions that serve diverse student populations. We believe that these evaluations will enable us to detect workable educational approaches, to target needed improvements during revisions, and to identify strengths and weaknesses of the proposed materials.

## 2. Study Procedures

- a) **Describe all study procedures. Are the research procedures the least risky that can be performed consistent with sound research design?**

Study procedures involve construction of a programming shell for the project web site and production of draft versions of the following project deliverables: interactive courseware, workbook problem sets, exercises, image bank, debate questions, and materials to launch student research projects. Each deliverable will then be subjected to two cycles of evaluation and revision. The evaluations will take place in a wide variety of undergraduate educational institutions, including Stanford University, two four-year colleges, and 14 community colleges. Evaluations will consist of criterion-referenced assessment of knowledge gained by students, administered either by pencil and paper or computer-based. Instruments to develop each project deliverable will be developed by a professional evaluation consultant under the supervision of the projects's Executive Group. Early versions of these instruments will be pilot-tested by a few students and faculty. Students may also be asked to participate in informal discussions about how the materials could be improved. These procedures are 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 after transcription, etc. Describe the final disposition of the recordings.**

09/06. New Question. It is optional, at this time, whether you answer this new question during your Continuing Review submission. Note that the IRB may require you to answer it during the IRB review cycle, if any reviewer determines it is necessary.

- 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).**

09/06. New Question. It is optional, at this time, whether you answer this new question during your Continuing Review submission. Note that the IRB may require you to answer it during the IRB review cycle, if any reviewer determines it is necessary.

## 3. Background

- a) **Describe past findings leading to the formulation of the study.**

This study builds on the success of a pilot project in which 20 community college faculty and 1749 students used the multimedia, interactive CD-ROM courseware, "The New Genetics: Medicine and the Human Genome." This courseware was originally developed at Stanford by the PI on the basis of funding from the Department of Energy Human Genome Program. Faculty focus groups reflected enthusiastic feedback and developed the priority list for courseware revisions and ancillary materials presented in this proposal.

#### 4. 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.**

We estimate that approximately 2000 to 3000 students would be involved in evaluating the proposed educational materials.

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

The students are expected to be in the age range 18-75, with the majority in their twenties. Both genders are expected to participate in approximately equal proportions. The ethnic backgrounds of the students are expected to reflect the diverse populations of students in attendance at colleges, especially those attending community colleges.

- 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.**

Some students may be educationally or economically disadvantaged, but the evaluation activities should not impede their academic progress and may well enhance their educational experiences. Pregnant women may be present in this population, but will not be targeted for either recruitment or exclusion from the study. This study should not pose increased risks to women students who happen to be pregnant. Minors, decisionally impaired individuals, prisoners, and homeless people are unlikely to be registered as college students.

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

Women, minorities, and minors (students under the age of 21) are all invited to participate if they are enrolled in a class that is using one or more modules.

- 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>.**

All human subjects participants will be students. All students will receive an information sheet approved by the Stanford IRB before they decide whether to participate.

- 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. See guidance Advertisements: Appropriate Language for Recruitment Material.**

Potential participants will be given the opportunity to participate if their instructor is interested in the project and would like to use the educational modules that are being developed in their classrooms or in other student venues. No advertisements are being utilized. The instructor will announce the opportunity.

- 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**

09/06. New Question. It is optional, at this time, whether you answer this new question during your Continuing Review submission. Note that the IRB may require you to answer it during the IRB review cycle, if any reviewer determines it is necessary.

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

09/06. New Question. It is optional, at this time, whether you answer this new question during your Continuing Review submission. Note that the IRB may require you to answer it during the IRB review cycle, if any reviewer determines it is necessary.

- 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.**

The entire study will take three years. Each subject will be involved only for the duration of the particular course for which he or she has registered. It is possible that some students may be enrolled in more than one course using these materials. Limited demographic information will be collected on each student, but student identity will be known only to the instructor.

## 5. Risks

- a) For the following categories, describe the potential risk(s) and estimate their frequency, severity, and reversibility:

### Physical well-being.

09/06. New Question. It is optional, at this time, whether you answer this new question during your Continuing Review submission. Note that the IRB may require you to answer it during the IRB review cycle, if any reviewer determines it is necessary.

### Psychological well-being.

09/06. New Question. It is optional, at this time, whether you answer this new question during your Continuing Review submission. Note that the IRB may require you to answer it during the IRB review cycle, if any reviewer determines it is necessary.

### Political.

09/06. New Question. It is optional, at this time, whether you answer this new question during your Continuing Review submission. Note that the IRB may require you to answer it during the IRB review cycle, if any reviewer determines it is necessary.

### Economic well-being.

09/06. New Question. It is optional, at this time, whether you answer this new question during your Continuing Review submission. Note that the IRB may require you to answer it during the IRB review cycle, if any reviewer determines it is necessary.

### Social well-being.

09/06. New Question. It is optional, at this time, whether you answer this new question during your Continuing Review submission. Note that the IRB may require you to answer it during the IRB review cycle, if any reviewer determines it is necessary.

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

No overseas research is anticipated in this project.

- 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.**

09/06. New Question. It is optional, at this time, whether you answer this new question during your Continuing Review submission. Note that the IRB may require you to answer it during the IRB review cycle, if any reviewer determines it is necessary.

- d) **Discuss plans for ensuring necessary medical or professional intervention in the event of a distressed participant.**

09/06. New Question. It is optional, at this time, whether you answer this new question during your Continuing Review submission. Note that the IRB may require you to answer it during the IRB review cycle, if any reviewer determines it is necessary.

cycle, if any reviewer determines it is necessary.

- e) **Children's Findings.** 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.

Rationale for category selected above:

## 6. 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.

09/06. New Question. It is optional, at this time, whether you answer this new question during your Continuing Review submission. Note that the IRB may require you to answer it during the IRB review cycle, if any reviewer determines it is necessary.

## 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).

Privacy protections have not been modified.

### Confidentiality Protections

- b) Specify the individually identifiable data you will obtain, use or disclose to others.

N/A. Researchers will not obtain identifiable data.

- 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)

N/A

- 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> .

N/A

- e) If you plan to code the data, describe the method in which it will be coded and indicate who will have access to the key to the code.

N/A

- f) How will you educate research staff to ensure they take appropriate measures to protect the privacy of participants and the confidentiality of data or specimens collected (e.g. conscious of oral and written communications, conducting insurance billing, and maintaining paper and electronic data)?

N/A

## 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)
- Y i) have consulting arrangements, responsibilities or equity holdings in the Sponsoring company, vendor(s), provider(s) of goods, or subcontractor(s)?
- N ii) 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?
- N iii) serve as a member of an advisory board with the Sponsoring company, vendor(s), provider(s) of goods, or subcontractor(s)?
- N iv) receive any gift funds from the Sponsoring company, vendor(s), provider(s) of goods, or subcontractor(s)?
- N v) have an ownership or royalty interest in any intellectual property utilized in this protocol?
- b) N 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 (CoI) 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 'mailto:bflynn@stanford.edu'bflynn@stanford.edu.

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

## 9. Consent Background

### 9.1 Waiver of Consent version 1

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

This project involves research conducted in established educational settings, involving normal educational practices as innovative educational approaches are evaluated. An information sheet will be provided with all the information of a consent but signatures will not be collected. A Waiver of Documentation of Informed Consent under 46.117 (c)(2) is requested. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

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

The waiver will not adversely affect the rights and welfare of the subjects because they can freely decide whether or not to participate and can withdraw without penalty at any time. No sensitive information on participants will be gathered.

- 3) Y **The research could not practically be carried out with out the waiver or alteration.**

For such a complex project involving a large number of participating instructors at many institutions, a waiver of consent would permit the research to go forward without significant risks to participants. The logistics of handling written informed consent for thousands of students in different courses at multiple institutions would be daunting and might dissuade instructors from participating in evaluation activities.

- 4) Y **Whenever appropriate, the participants will be provided with additional pertinent information after participation(See relevant consent regulations at: <http://humansubjects.stanford.edu/consentregs.html>.) (See also section #11.)**

Subjects will be informed of the aggregate results of this project as each phase of evaluation activity is completed. These results will be made available on a public section of the project website, and participants will be encouraged to check on the progress of the project often.

**9.2 Consent tng consent/information sheet**

- a) **Describe the informed consent process. Include the following.**
- i) **Who is obtaining consent? (The person obtaining consent must be knowledgeable about the study.)**
  - ii) **When and where will consent be obtained?**
  - iii) **How much time will be devoted to consent discussion?**
  - iv) **Will these periods provide sufficient opportunity for the participant to consider whether or not to participate and sign the written consent?**
  - v) **What steps are you taking to minimize the possibility of coercion and undue influence?**
  - vi) **If consent relates to children and if you have a reason for only one parent signing, provide that rationale for IRB consideration.**

This project has been declared exempt, so formal consent procedures will not be used. However, each student will be given an information sheet about the project that summarizes the elements of consent, such as voluntariness or ability to withdraw at any time. Please refer to the attached information sheet for detailed information.

- 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 Chapter14.5 for guidance.**

Instructors will ask students if they are interested in participating in the study and will answer questions. The classes are at the college level and are conducted in English, so students are very likely to understand English well. Students with hearing impairments will use the strategies and accommodations that permit them to participate in their classes successfully.

- c) **What steps are you taking to determine that potential participants 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.**

Students will be at least 18. The college students who are being recruited to participate in this study are generally presumed to be competent.

**10. Assent Background (less than 18 years of age)**

**11. Attachments**

Attachment Name	Attached Date	Attached By	Submitted Date
/Sally's G4/Users/tobinsl/ Sally's Files/Education	06/05/2006	tobinsl	

**Obligations**

The Protocol Director agrees to:

- Adhere to principles of

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<http://humansubjects.stanford.edu/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  
<http://humansubjects.stanford.edu/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. Email the Department Chair approval to [Lauri.Kanerva@stanford.edu](mailto: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, )

Amendment to exempt review application to delete word "California" from items 1b, 2a, 4b. No other study documents require changes.
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Y The Protocol Director has read and agrees to abide by the above obligations.