

**PROTOCOL
APPLICATION FORM
FOR EXPEDITED REVIEW
HUMAN SUBJECTS IN NON-MEDICAL RESEARCH
STANFORD UNIVERSITY**

Protocol ID: 9220
Title: Perceptual attack time listening experiments administered on subjects' own computers

Protocol Director				
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CITI Training Completed in the Last Two Years? Y				

Admin Contact				
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CITI Training Completed in the Last Two Years? Y				

Co-Protocol Director				
Name		Degree (MD/PhD):	Title	
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Other Contact				
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CITI Training Completed in the Last Two Years?				

Faculty Sponsor				
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CITI Training Completed in the Last Two Years? Y				

Other Personnel				
Name	Degree: MD/PhD	Role	Department	Required Training Completed

Participant Population(s) Checklist

Yes/No

- Children (under 18) N
- Pregnant Women N
- Mentally Disabled N
- Decisionally Challenged N
- Laboratory Personnel N
- Healthy Volunteers Y
- Students N
- Employees N
- Prisoners N
- Other (i.e., any population that is not specified above) 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
- Is Stanford the coordinating institution or are you the lead investigator for this multi-site study? 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? N

Funding

Yes/No

- Training Grant? N
- Program Project Grant? N
- Federally Sponsored Project? N
- Industry Sponsored Clinical Trial? 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
- San Mateo County N
- Other (Click ADD to specify details)

Funding

NONE

Y

Funding - Grants/Contracts

Funding - Fellowships

Gift Funding

Dept. Funding

Other Funding

Resources:

a) **Qualified staff.**

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

No staff; just me (Matt Wright) to do everything.

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.

No training required.

c) **Facilities.**

Please describe and justify.

The only facility needed is my personal laptop computer and some space on my CCRMA web site.

d) **Sufficient time.**

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

This research requires about one month of time for data collection and another week for data analysis. The software for the listening experiments has already been completed. I have at least through the end of the spring quarter to complete this research.

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.

I'm using an internet-based method to recruit volunteer participants. I will put out an email call for volunteers that will certainly reach hundreds, if not thousands, of potential participants. Even a small number (5-10) of participants would provide significant data.

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.

Not applicable.

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.

Expedited Form

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. N **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. N **Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:**
 - i) 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
 - ii) 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. N **Prospective collection of biological specimens for research purposes by non invasive means.**
4. N **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:

 - i) 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

- ii) weighing or testing sensory acuity;
 - iii) magnetic resonance imaging;
 - iv) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
 - v) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
5. N **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. N **Collection of data from voice, video, digital, or image recordings made for research purposes.**
7. Y **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.)**

1. Purpose

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

I want to gather data on the exact moment at which subjects perceive musical events (for example, the beginning of a note) to occur. Subjects will hear a musical excerpt along with one or more "click" sounds, and will be able to adjust the relative timing of the click(s) with respect to the music until they sound right (i.e., occurring at the same time). By comparing results on repeated trials with the same subject and across subjects I hope to make statistical models of perceptual attack time.

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

My hypotheses are

- 1) Subjects will not exactly replicate their response for repetitions of the same trial, but instead will fit a probability distribution.
- 2) The shapes of these probability distributions will vary based on the sharpness of attack and other characteristics of the musical material.
- 3) These probability distributions will be narrower (i.e., subjects will repeat the same results more accurately) when the sound of the click better matches the sound of the musical material.
- 4) Subjects will be more accurate when the musical material establishes an understandable and predictable rhythmic context.

In addition to testing these hypotheses, I hope to make statistical models of perceptual attack time.

2. Study Procedures

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

The subject downloads a computer program that I have written. When they open the program they're guided through an introductory sequence:

1) An online "consent form" explaining the purpose of the study, the potential risks, giving my email address if they have questions or want to discuss anything, asking them to attest that they are at least 18 years old, etc. They click "I agree" (to continue) or "No thanks" (to quit the program). (See my attached "Click-through consent screen".)

2) A short questionnaire asking about their level of musical training, etc., with no identifying information. (Each time the software is downloaded it generates a unique "subject ID" number that I will use to match responses from the same subject.) Subjects may leave any or all fields blank.

3) An audio calibration step that plays a repeating tone starting at zero volume and asks the subject to gradually adjust the volume to a comfortable listening level.

4) A brief tutorial introduction to the program's user interface.

Then the subject performs the trials. (S)he can take a break at any time, can choose not to do any particular trial, and can take as long as (s)he likes on each trial.

When the set of trials is done, the program writes the results into an email message addressed to me and opens it in the subject's chosen email program. At this point my software recommends that they use an anonymous email service such as anonymousspeech.com if they don't want me to have their email address. The subject then sends the email to me.

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

The only possible risks are hearing damage from excessive listening volume and the normal ergonomic issues inherent in all computer use. The volume calibration step minimizes the risk of hearing damage by having users gradually turn up the volume to a comfortable listening level. The program ensures that no subsequent sounds will be louder than these. Also, the subject can always adjust the volume later, and can also always stop all sound instantaneously at any time just by hitting the space bar.

As for ergonomic issues, the program enforces a short break period (with no typing) about every 15 minutes, recommending that the subject stretch, stand up, etc.

- c) **State if deception will be used. If so, provide a rationale and describe debriefing procedures. Submit a debriefing script in Section #11 (Attachments).**

Deception will not be used.

- d) **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).**

N/A

3. Background

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

John Gordon's "The Perceptual Attack Time of Musical Tones." (Journal of the

Acoustical Society of America 82(1): 88-105) is the inspiration for this study. He used almost the exact same methodology, except that he brought a small number of subjects into a controlled environment in his lab, whereas I hope to recruit a larger number of subjects by doing everything via the Internet.

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.**

Participants will be volunteers contacted through the Internet and through word of mouth. I hope to find at least 10-20 subjects, hopefully many more. I will gladly take all the data I can get. By opening the experiment to all types of participants I expect to gather more data.

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

Recruitment will be blind to all such factors.

- 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.**

I will not seek out any potentially vulnerable subjects nor can I effectively prevent them from participating.

The only additional risk that this study poses to potentially vulnerable subjects is that they might not understand instructions well enough to protect themselves from damaging sound levels. However, potential subjects in this category will almost certainly not be able to download and install the software in the first place. In general, potential subjects with impaired decision-making abilities will be prevented from participation via technical challenges.

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

All are invited. If the IRB wants me to exclude minors then I will add language to that effect to the recruitment email and the consent screen.

- 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>.**

I have no employees or students of my own. Faculty, staff, and my fellow students at CCRMA will certainly all be invited to volunteer to participate, under the same consent policy as any other subjects.

- f) **Describe how potential participants will be identified for recruitment (e.g., responses to an ad, classroom recruitment, word of mouth). Describe how participants will be recruited and how they will initially learn about the research (e.g., announcements, letters mailed home, advertising). Attach recruitment materials in Section #11 (Attachments). You may not contact potential participants prior to IRB approval.**

I will send an email (which I will attach in Section #11) to a large number of people, including:

- All users at CCRMA (Stanford's Center for Computer Research in Music and Acoustics, the institution at which I am doing this research)
- My friends whom I think would be willing to participate
- Mailing lists of researchers interested in these topics
- Professional contacts in the computer music field.

The email will include an invitation for people to forward the message to other people or groups who may be interested, so that it can spread by word of mouth.

See the attached "recruitment email".

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

An email message; see 4f and the attachment. Once a subject chooses go to the web site and download the software he or she has been recruited.

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

No payment.

i) Costs. Please explain any costs that will be charged to the participant.

No costs.

j) 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 is likely to take about a month, though data might continue to come in after that as well.

(i) Participants will self-screen by choosing whether or not to respond to the email, download the software, etc. I estimate that this will take from 1 to 60 seconds.

(ii) Each set of subject trials is designed to take approximately 45 minutes, but could be more or less because the subject completely controls the pacing of the experiment.

(iii) I expect to take another few weeks to analyze participant data.

5. Risks

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

Physical well-being.

Potential for hearing damage from excess volume, the same as with playing any other audio (including video with sound, DVDs, etc) from a computer. Hearing damage is short-term unless the unsafe sound levels are very high and/or persist for a long time; both of these conditions are extremely any time to stop all sound.

The other category of potential physical risks are the normal ergonomic issues of any computer use. My software requires subjects to take a short break from working on the computer about every 15 minutes.

Psychological well-being.

Potential for slight boredom, entirely reversible by pausing or quitting the experiment.

Political.

None.

Economic well-being.

Subject could conceivably choose to spend time on this experiment instead of doing paid work. Subjects like that would find some other distraction from work if they didn't have my experiment to do.

Social well-being.

No more risk than from any other computer use.

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

I will not seek out overseas participants, nor can I effectively screen them out. I cannot imagine how any of

the slight potential risks would apply differentially to overseas participants.

- 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.**

My main concern is with unsafe excessive listening volume levels. My software has no control over the loudness of the subject's sound system, so I calibrate the audio level at the onset by instructing the subject to gradually increase a tone's volume from zero to a comfortable listening level.

While trials are in progress, the user can always stop all sound with a single press of the space bar, as well as adjust the volume (with the arrow keys).

I do not ask for any identifiable information, although I rely on the subjects to use email to send me back their results. Subjects are invited to send their email via an anonymous email service such as anonymousspeech.com if they don't want me to have their real email address.

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

Not applicable.

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.**

No direct benefits to participants. Improved understanding of the statistical behavior of subjects' perceptual attack time judgements will lead to improved machine listening systems with benefits described above.

7. 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).**

Subjects do not have to provide any identifying or confidential information. Subjects are recommended to send their results back to me using an anonymous email service if they don't want me to have their email address.

- 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?**

There will be no private, sensitive, or confidential information. I will store the results as digital files on my personal laptop with backups on CCRMA's file servers.

- 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?**

No research staff.

- 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)?**

Yes; I use only anonymous data.

- 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.**

The software does not ask for any identifiers.

- 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?**

No, except that I will maintain whatever email addresses subjects use to send me their data. I would be able to send an email back to any subject who chooses to send me data via a non-anonymous email address.

- 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.**

Not needed.

- h) **Explain whether you will code or destroy PHI or other individually identifiable information at some stage of the research. How will you dispose of or destroy these electronic and/or paper documents?**

N/A

- 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.**

N/A

8. Potential Conflict of Interest

- a) N 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) N 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) N Is any Investigator(s) a member of an advisory board with the Sponsoring company?
- d) N Do any investigators receive gift funds from the Sponsoring company?
- e) N 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.

- N 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 Consent

Click-through consent screen

- 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.

When the user downloads and runs my software, the first thing they see is the "consent" screen, an image of which I have attached as my "Click-through consent screen" as if it were a form. If the user clicks "No, Thanks" then the program quits. Only by clicking "Yes, I accept" does the program proceed. The user can also click "Send Matt an email" to open an empty email message addressed to me; this is the channel for any discussions of consent. Consent is therefore obtained immediately when the program begins, by the subject himself or herself. The subject can take as long as he or she likes to read the agreement, including waiting for an email exchange with me. This software provides no mechanism for coercion or undue influence. The consent has nothing to do with children.

- 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.

Participants who do not understand English will not be able to follow instructions to download the software in the first place. Hearing is not required to understand the consent. I will trust my subjects to assess their own understanding of the text, or to email me with questions.

- 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.

Again, potential participants not competent to participate in the decision-making process will probably not be able to download and run the software in the first place, much less click on "Yes, I accept."

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

10.1 Assent

Assent for minors is the same as consent for adult

- a) Describe the assent process. Include the following:
- (i) Who is obtaining child assent? (The person must be knowledgeable about the study.)
 - (ii) When and where will assent be obtained?
 - (iii) Will a parent or guardian be present when assent is obtained?
 - (iv) How much time will be devoted to the assent discussion?
 - (v) Will these periods provide sufficient opportunity for the child to consider whether to assent?
 - (vi) What steps are you taking to minimize the possibility of coercion and undue influence?

Same as for "consent".

- 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., oral response, signature on form, combination of methods, other)?

Same as for "consent".

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

Same as for "consent".

11. Attachments

Attachment Name	Attached Date	Attached By	Submitted Date
Recruitment Email	03/30/2007	mjwright	
Click-through consent screen	03/30/2007	mjwright	

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. Email the Department Chair approval to Lauri.Kanerva@stanford.edu.

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

I have attached my recruitment email and my on-screen click-through consent.

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