System Requirements:

- If using Windows, use Internet Explorer (IE) or Firefox as your browser.
- If using Macintosh, use Safari or Firefox as your browser.
- Your browser must be configured to Allow Pop-ups while using eProtocol. See instructions for allowing pop-ups.

Before you begin:

If this is your first time *submitting a protocol for review, see* ***FAQs*** *for information to consider beforehand.*

The answers to many of your questions may be found on the IRB (Human Subjects) website.

What to expect:

- Your eProtocol application form will be created and an eProtocol number will be generated after you enter basic information (Protocol Title, Personnel Information, Form and Review Type) on the following screens.
- Once you have an eProtocol number, you may continue to complete the application, or you may exit the system and return at a later time to complete it. You must click the Save (Diskette) icon to save your work before exiting.

Study Title Next

Instructions:

- At minimum, a Protocol Director (PD) and Administrative Contact must be entered; the same person may be entered for both roles.
- If the PD is a student (e.g., Undergraduate, Graduate, or Post-Doc), you must also enter an Academic Sponsor. Those entered as Academic Sponsors should be listed in categories 1 and 2 of Administrative Guide 23.
- Only those entered in the following roles will have **edit access** to the Protocol application: PD, Admin Contact, Co-PD, Other Contact and Academic Sponsor.
- You will be prompted to add *Other Personnel* after you have selected the form type.
- All researchers must complete required human subjects training (CITI - Collaborative Institutional Training Initiative) prior to protocol approval.

Protocol Director *

Next

PERSONNEL LOOKUP

INSTRUCTIONS: Search by LastName, FirstName *(e.g., Smith, John)* or by SUNet ID.

Name *	Degree (Program/year if student) *	Position, e.g. Assistant Professor, Resident, etc. *
Email *	Phone *	Fax
Department: Select Department		Mail Code

CITI Training current ○ Yes ○ No

Admin Contact *

PERSONNEL LOOKUP

INSTRUCTIONS: Search by LastName, FirstName *(e.g., Smith, John)* or by SUNet ID.

Name *	Degree (Program/year if student) *	Position, e.g. Assistant Professor, Resident, etc. *
Email *	Phone *	Fax

Application Category:

Select **Medical** for investigators performing research in:

- School of Medicine (SoM)
- Lucile Packard Children's Hospital (LPCH)
- Stanford Hospital and Clinics (SHC)
- Veteran's Affairs (VA) Hospital
- Psychology fMRI studies

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

- Business
- Education
- Engineering
- Humanities & Sciences
- Law

Application Category/Type Create

Select Application Category :	○ Medical	◉ Non-Medical

Form Type:

Select a Form Type below to create the eProtocol application for IRB review. Learn more about different review types or contact IRBeducation@stanford.edu or (650) 724-7141 if you have questions.

○ **Regular**	For greater than minimal risk studies
◉ **Expedited**	For minimal risk studies meeting specific criteria
○ **Exempt**	Studies meeting specific criteria
○ **HSR Determination Form**	Projects that don't clearly qualify as human subjects research. Include the HSR Determination form in your submission.

Expedited Paragraphs

Create

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 categories.

Select one or more applicable expedited categories:

1. **Clinical studies of drugs and medical devices (medical studies only)**

2. **Collection of blood samples (medical studies only)**

3. **Prospective collection of biological specimens for research purposes by non invasive means.**
   Example: Collection of saliva or cheek swabs

4. **Collection of data through non invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing.**
   Examples:
   a) Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
   b) Weighing or testing sensory acuity;
   c) Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. **Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this paragraph may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)**

6. **Collection of data from voice, video, digital, or image recordings made for research purposes.**

7. **Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)**

Protocol Application Form

Protocol ID : 41676 (Ratan Banik)
Title : Expedited Nonmedical

Non-Medical **EXPEDITED**

- Personnel Info
- Participant Population
- Study Location
- General Checklist
- Funding
- Resources
- Protocol Information
- Obligations
- Check for Completeness
- Print View
- Event History

Submit Protocol

Instructions:

- You MUST select an entry from the Personnel Lookup field to properly populate personnel information. Do NOT manually enter your name in the 'Name' field.
- At minimum, a Protocol Director (PD) and Administrative Contact must be entered; the same person may be entered for both roles if needed.
- If the PD is a student (e.g., Undergraduate, Graduate, or Post-Doc), you must also enter an Academic Sponsor. Those entered as Academic Sponsors should be listed in categories 1 and 2 of Administrative Guide 23.
- Click the link in the *Other Personnel* section towards the bottom of the page to enter additional personnel.
- You can click here to review completion records to ensure training has been completed.
- Only those entered in the following roles will have **edit access** to the Protocol application: PD, Admin Contact, Co-PD and Other Contact.

OPACS email has now been sent to PD and all faculty personnel.

Confirm Personnel

Protocol Director

Clear

PERSONNEL LOOKUP

INSTRUCTIONS: Search by LastName, FirstName *(e.g., Smith, John)* or by SUNet ID.

Name *	Degree (Program/year if student) *	Position, e.g. Assistant Professor, Resident, etc. *
Ratan Banik		No Title
Email *	**Phone ***	**Fax**
medirbc@keyusa.com	n/a	
Department		**Mail Code**
Select Department		

CITI Training current — Yes / No

Admin Contact

Clear

PERSONNEL LOOKUP

INSTRUCTIONS: Search by LastName, FirstName *(e.g., Smith, John)* or by SUNet ID.

Name *	Degree (Program/year if student) *	Position, e.g. Assistant Professor, Resident, etc. *
Ratan Banik		No Title
Email *	**Phone ***	**Fax**
medirbc@keyusa.com	n/a	
Department		**Mail Code**
Select Department		

CITI Training current — Yes / No

Investigator

..more..

Clear

PERSONNEL LOOKUP

INSTRUCTIONS: Search by LastName, FirstName *(e.g., Smith, John)* or by SUNet ID.

Name *	Degree (Program/year if student) *	Position, e.g. Assistant Professor, Resident, etc. *

Email *	Phone *	Fax

Department	Mail Code
Select Department	

CITI Training current — Yes — No

Other Contact

Clear

PERSONNEL LOOKUP

INSTRUCTIONS: Search by LastName, FirstName *(e.g., Smith, John)* or by SUNet ID.

Name *	Degree (Program/year if student) *	Position, e.g. Assistant Professor, Resident, etc. *

Email *	Phone *	Fax

Department	Mail Code
Select Department	

CITI Training current — Yes — No

Academic Sponsor

Clear

PERSONNEL LOOKUP

INSTRUCTIONS: Search by LastName, FirstName *(e.g., Smith, John)* or by SUNet ID.

Name *	Degree (Program/year if student) *	Position, e.g. Assistant Professor, Resident, etc.

Email *	Phone *	Fax

Department	Mail Code
Select Department	

CITI Training current — Yes — No

Other Personnel

Click here to add Other Personnel

OPACS email has now been sent to PD and all faculty personnel.

Confirm Personnel

Find User Find

Sunet ID:	
First Name:	
Last Name:	

Click the "Start" button once the Personnel section has been completed. The faculty investigators will receive an email asking them to disclose any financial interests related to this protocol. All faculty investigators must answer "Yes" or "No" before the protocol can be submitted.

Start Cancel

Protocol Application Form

Protocol ID : 41676 (Ratan Banik)
Title : Expedited Nonmedical

Non-Medical EXPEDITED

- Personnel Info
- Participant Population
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Submit Protocol

Instructions:

Select all populations (and only those) that are specifically ***targeted*** for this study. You must select at least one category.

For example:

- A researcher is conducting an internet survey asking about emotional responses to certain scenarios. Students may respond, but the study is not designed to recruit students specifically, so students would not be selected on the checklist.

Participant Population(s) Checklist

Yes	No	
◉	○	Children (under 18)
◉	○	Wards (e.g., foster children, incarcerated youth)
◉	○	Pregnant Women
◉	○	Impaired Decision Making Capacity
◉	○	Cancer Subjects
◉	○	Laboratory Personnel
◉	○	Healthy Volunteers
◉	○	Students ☑ Stanford students ☐ Other students
◉	○	Employees
◉	○	Prisoners
◉	○	Other (i.e., any population that is not specified above)

For all Cancer-related studies, see the submission instructions on the Cancer Clinical Trials website at http://med.stanford.edu/ccto.html

***IMPORTANT**: Your study involves cancer, therefore review and approval by the Stanford Cancer Institute Scientific Review Committee (SRC) is required before accrual can begin. See http://cancer.stanford.edu/trials/srctop.html for more information.*

OK

Protocol Application Form

Protocol ID : 41676 (Ratan Banik)
Title : Expedited Nonmedical

Non-Medical **EXPEDITED**

- Personnel Info
- Participant Population
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- Event History

Instructions:

The **study location** is the location at which the research takes place. For example, a study that takes place in a high school where surveys are collected and then analyzed at Stanford would require both *Stanford* and *Other* to be selected.

- Whenever *Other* is selected, click the ADD button to enter details for one or more locations. Each location must be added separately.
- To remove an *Other* location, check the box next to the name, and click DELETE.
- To view/modify details of a previously entered *Other* location, click the location name.

Study Location(s) Checklist

☑	Stanford University
☐	Other (Click ADD to specify details)

Choose one. For multiple sites, add each individually.

Other Location

Save

○ **Within the US**

Location Name :

OR

○ **Outside the US/International**

Country :

Note: You are responsible for ascertaining if local permission is needed for doing research in the proposed site (e.g., in the case of schools, workplaces, tribal settings). If permission is required, you must obtain it before beginning the research.

Protocol Application Form

Protocol ID : 41676 (Ratan Banik)
Title : Expedited Nonmedical

Non-Medical **EXPEDITED**

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Instructions:

- If you answer YES to *Collaborating Institution*, click the ADD button to enter the name of each institution.
- To remove an institution, check the box next to the name, and click DELETE.
- To view/modify previously entered institutions, click the institution name.

General Checklist

Yes	No	
		1. Collaborating Institution(s) Generally, when one or more institutions work together equally on a research endeavor, it is a collaboration.
○	○	Are there any collaborating institutions?
Yes	No	**2. Payment or Reimbursement**
○	○	Subjects will be paid/reimbursed for participation? See payment considerations.
Yes	No	**3. Funding**
○	○	Training Grant?
○	○	Federally Sponsored Project?

Collaborating Institution(s)

Save

Collaborating Institution Name: *

Protocol Application Form

Protocol ID : 41676 (Ratan Banik)
Title : Expedited Nonmedical

Non-Medical | EXPEDITED

- Personnel Info
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Submit Protocol

Instructions:

Remember to attach a copy of each applicable federal grant application, including competing renewals, in the *Attachments* section of this protocol application form.

Funding

☐ NONE

Funding - Grants/Contracts Add

Please click on 'Add' to add Grants/Contracts

Funding - Fellowships Add

Please click on 'Add' to add Fellowships

Funding - Other

Gift Funding Add

Please click on 'Add' to add Gift Funding

Dept. Funding Add

Please click on 'Add' to add Dept Funding

Other Funding (e.g., Undergraduate Funding) Add

Please click on 'Add' to add Other Funding

Instructions:

Remember to attach a copy of each applicable federal grant application, including competing renewals, in the *Attachments* section of this protocol application form.

If this is an umbrella protocol, attach in the *Attachments* section of this protocol application form, a listing of all protocols funded under this umbrella. Include protocol ID number, PI, and approval date.

Funding - Grants/Contracts Save

Funding Administered By	STANFORD
Search SPO Information by Principal Investigator or SPO Number	
Principal Investigator	
○ SPO # (if available)	**(e.g. 123456)**
○ SPO # Pending	
Grant # (if available)	
Funded By (include pending) *	
Grant/Contract Title if different from Protocol Title	

○ **Yes**	○ **No**	For Federal projects, are contents of this protocol consistent with the Federal proposal application?
○ **Yes**	○ **No**	Is this a Multiple Project Protocol (MPP)?
○ **Yes**	○ **No**	Is this protocol under a MPP?

Funding - Fellowships

Save

Funding administered by	STANFORD

Search SPO Information by Principal Investigator or SPO Number

Name of Fellow *

- ○ SPO # (if available) **(e.g. 123456)**
- ○ SPO # Pending
- ○ N/A

Fellowship Reference # (if available)	
Funded By	
Fellowship Title if different from Protocol Title	

○ **Yes** ○ **No** For Federal projects, are contents of this protocol consistent with the Federal proposal application?

Gift Funding

Save

Name of Donor *	

Dept. Funding

Save

Department Name *	

Other Funding (e.g., Undergraduate Funding)

Save

Other Fund Name *	

Personnel Info
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Submit Protocol

Resources

a. Qualified staff

State your and/or your study staff's qualifications to conduct this study.

b. Training

Describe the training you have received regarding the research-related duties and functions of this protocol. Also, describe the training received by study staff assisting you with the research.

c. Facilities

Describe where the study will take place, including where data will be collected and where it will be analyzed.

d. Time

How much time will be needed to conduct and complete the research?

e. Participant access

Will you have access to a population that will allow recruitment of the required number of participants?

f. Access to resources

Will you have access to psychological resources that participants might need as a consequence of participating in the research? If yes, describe these resources. Enter N/A if the need for psychological resources is not anticipated.

Protocol Application Form

Protocol ID : 41676 (Ratan Banik)

Title : Expedited Nonmedical

Non-Medical **EXPEDITED**

Expedited Paragraph(s) | 1-3 | 4(a-f) | 4(g-i) | 5 | 6,7 | 8 | 9 | 10 | 11

- Personnel Info
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- Check for Completeness
- Print View
- Event History

Submit Protocol

Title

Expedited Nonmedical

Review your expedited paragraph selection(s) below. Make changes as applicable.

☐ **1. Clinical studies of drugs and medical devices (medical studies only)**

☐ **2. Collection of blood samples (medical studies only)**

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

Example: Collection of saliva or cheek swabs

☐ **4. Collection of data through non invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing.**

Examples:

a) Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;

b) Weighing or testing sensory acuity;

c) Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

☐ **5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this paragraph may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)**

☐ **6. Collection of data from voice, video, digital, or image recordings made for research purposes.**

☐ **7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)**

Protocol Application Form

Protocol ID : 41676 (Ratan Banik)

Title : Expedited Nonmedical

Non-Medical **EXPEDITED**

Expedited Paragraph(s): 1-3 | 4(a-f) | 4(g-i) | 5 | 6,7 | 8 | 9 | 10 | 11

- Personnel Info
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Submit Protocol

Complete Sections 1 - 11. Specify N/A as appropriate. Do not leave any required sections blank.

1. Purpose

a) **In 3-5 sentences, state the purpose of the study in lay language.**

b) **State what you hope to learn from the study and assess the importance of this new knowledge.**

2. Study Procedures

a) **Describe ALL the procedures human participants will undergo. Are the research procedures the least risky that can be performed consistent with sound research design?**

b) **State if audio or video recording will occur. Describe how the recordings will be used, e.g., shown at scientific meetings, used for transcription. Describe the final disposition of the recordings, e.g., erased, stored.**

c) **DECEPTION: Will participants be fully informed about the purpose of the study? If no: provide a rationale for deception; complete an Alteration of Consent in Section 9; and attach a debriefing script in Section 11, or explain why debriefing would not be appropriate below.**

3. Background

a) **Describe what led to the formulation of the study.**

Expedited Paragraph(s) | 1-3 | 4(a-f) | 4(g-i) | 5 | 6,7 | 8 | 9 | 10 | 11

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4. Participant Population

a) **(i) How many participants do you expect to enroll at Stanford? (ii) How many participants do you expect to enroll outside Stanford? (iii) What type of participants will you enroll (e.g., high school students, teachers, government officials)?**

b) **What are the age range, gender, and racial or ethnic background of the participant population being targeted?**

c) **If applicable, explain why potential vulnerable participants are needed (e.g., children, pregnant women, students, economically or educationally disadvantaged, homeless, or people with impaired decision making capacity).**

d) **Will the research include women, minorities, or minors? Provide a rationale for not including these populations if the research might benefit these groups (e.g., results of a survey study about salaries might benefit women, but if you choose not to include them, explain why).**

e) **Will any participants be your students, laboratory personnel and/or employees? See Stanford University policy at http://doresearch.stanford.edu/policies/research-policy-handbook/human-subjects-and-stem-cells-research/use-employees-or-laboratory).**

f) **How will you recruit participants (e.g., ads, classroom recruitment, word of mouth, letters mailed home, email)? Attach recruitment materials in the *Attachments* section. YOU MAY NOT CONTACT POTENTIAL PARTICIPANTS PRIOR TO IRB APPROVAL. ALL FINAL OR REVISED RECRUITMENT MATERIALS, FLYERS, ETC. MUST BE SUBMITTED TO THE IRB FOR REVIEW AND APPROVAL BEFORE USE.**

Protocol Application Form

Protocol ID : 41676 (Ratan Banik)

Title : Expedited Nonmedical

Non-Medical **EXPEDITED**

Expedited Paragraph(s): 1-3 | 4(a-f) | 4(g-i) | 5 | 6,7 | 8 | 9 | 10 | 11

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Submit Protocol

4. Participant Population

g) **PAYMENT or REIMBURSEMENT. Will participants be paid or reimbursed for participation? If yes, how much, and explain why proposed payments/reimbursements are reasonable. Explain how payment will be prorated, if there is more than one study session. See payment considerations.**

h) **Explain what costs will be incurred by the participant. If none, enter none.**

i) **What is the total time that each participant will spend in the entire study (e.g., 20 minutes, 2 hours, 3 days)?**

Expedited Paragraph(s) | 1-3 | 4(a-f) | 4(g-i) | 5 | 6,7 | 8 | 9 | 10 | 11

Personnel Info
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Submit Protocol

5. Risks

a) **In order to qualify for expedited review, the protocol must present no more than minimal risk to participants. Describe any reasonably anticipated potential risks(s), including risk(s) to physical, psychological, political, economic or social well-being. If risks are not reasonably anticipated, enter "none"**

b) **If you are conducting research outside the US (international research), describe qualifications/ preparations that enable you to both estimate and minimize risks to participants. Then complete the International Research Form and attach it in the *Attachments* section. If not applicable, enter N/A.**

c) **Reserved for future use**

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

Confirm that your study meets the criteria for 46.404 below:

- ☐ 46.404 Research not involving greater than minimal risk. The research must present no greater than minimal risk to children and adequate provisions must be made for soliciting the assent of the children and permission of their parents or guardians.
- ☐ 46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit...(regular review only)
- ☐ 46.406 Research involving greater than minimal risk and no prospect of direct benefit...(regular review only)
- ☐ 46.407 Research not otherwise approvable...(regular review only)

Provide the rationale that this study presents no greater than minimal risk to children, and indicate whether parental permission will be obtained. If parental permission is to be obtained, indicate whether one or both parental signatures will be sought.

Rationale:

Expedited Paragraph(s) | 1-3 | 4(a-f) | 4(g-i) | 5 | 6,7 | 8 | 9 | 10 | 11

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Submit Protocol

6. Benefits

a) **Describe the potential benefit(s) to be gained by the participants and/or by society as a result of this study. If none, enter 'none.'**

7. Privacy and Confidentiality

Privacy

Privacy refers to the environment in which data are collected from participants (e.g., interviewing participants individually in a place where personal responses will not be seen or overheard).

a) **Explain where the research takes place (e.g., in a lab, online, at school). Describe how you will maintain privacy in this setting.**

Confidentiality

Confidentiality refers to your agreement with the participant about how the participant's identifiable personal information (i.e., identifiable data) will be handled, managed, stored, and disseminated.

b) **What identifiable data will you obtain from participants? Enter 'none' if identifiable data will not be obtained.**

c) **Describe if applicable:**

(i) how you will manage the identifiable data (e.g., paper or electronic spreadsheet, desktop computer, laptop or other portable device)
(ii) how you will ensure the security of identifiable data (e.g., password protected computer, encrypted files, locked cabinet, locked office);
(iii) who will have access to the identifiable data (e.g., research team, sponsors, consultants)
(iv) confirm that all devices on which data will be stored will also be encrypted

d) **Describe how identifiable 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 the Stanford Information Security Office website. If not applicable, enter 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.**

Protocol Application Form

Protocol ID : 41676 (Ratan Banik)
Title : Expedited Nonmedical

Non-Medical **EXPEDITED**

Expedited Paragraph(s) | 1-3 | 4(a-f) | 4(g-i) | 5 | 6,7 | 8 | 9 | 10 | 11

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Submit Protocol

8. Potential Conflict of Interest

STANFORD UNIVERSITY | OUTSIDE PROFESSIONAL ACTIVITIES CERTIFICATION SYSTEM (OPACS)

Investigators are required to disclose any financial interests that reasonably appear to be related to this protocol.

You will be unable to submit this protocol until all financial interest tasks are completed. Click here to send reminder emails.

Financial Interest Tasks

Investigators	Role	Email	Has Financial Interest?	Date Financial Interest Answered	Date OPACS Disclosure Submitted	Date OPACS Review Completed
Ratan Banik	PD	medirbc@keyusa.com	Incomplete	Incomplete	Incomplete	Pending

INSTRUCTIONS FOR ADMIN CONTACT

- Please reload this page to see updated financial interest information.
- Issues submitting protocol? Hover over information icons.
- Incomplete tasks must be completed by the investigator. Forward instructions below.

To Disclose Financial Interests for this protocol:

1. Log on to your dashboard at https://OPACSprd.stanford.edu
2. Click the red "enter response" button for this protocol
3. If you enter "yes", you will need to disclose related financial interests

Issues? Please submit an OPACS HelpSU ticket.

Expedited Paragraph(s) | 1-3 | 4(a-f) | 4(g-i) | 5 | 6,7 | 8 | 9 | 10 | 11

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Submit Protocol

9. Consent Information

A protocol should include at least one of the following consent options. More than one may be included. See more information on Informed Consent, Waiver of Consent, Waiver of Documentation and Alteration of Consent.

- **Waiver of Consent**
  Applicable for research involving identifiable data or records, when asking to waive parental permission, or other situations where consent is not possible
- **Consent**
  Applicable for research involving *signed* consent or parental permission forms
- **Waiver of Documentation**
  Applicable for internet research or oral consent when a signature is not obtained
- **Alteration of Consent**
  Applicable when some required elements of consent are eliminated, such as incomplete disclosure of the purpose of the research (deception)

For IRB consent form templates, please click here

a) Describe the informed consent process. Include the following: Who will obtain consent? When and how will this be done? If you are requesting to completely waive consent, enter "Waiver of Consent" in the text boxes a, b and c below.

Note: The person obtaining consent must be knowledgeable about the study. Sufficient time must be devoted to allow the participant to consider whether or not to participate. Steps must be taken to minimize the possibility of coercion or undue influence.

Note: If consent relates to children, the IRB will determine whether one or two parents' signatures are sufficient.

b) What procedure will you use to assess if the participant understands the information contained in the consent? How will the information be provided to participants if they do not understand English? See HRPP Chapter 14.6 for guidance.

c) Are you planning to enroll participants who do not have the capacity to consent?

Any consent form document (including information sheets used for consenting) should be attached by clicking the ADD button below, and then selecting the appropriate option in the drop-down menu.

Instructions:

- Click ADD to enter information on one of the above categories and to attach relevant consent document(s). Once entered and saved, a row will be displayed in tabular form for each item entered (Alteration of Consent, Waiver of Documentation, Waiver of Consent, and Consent).

Consent Background Add

Please click on 'Add' to add Consent Background

Consent Background

Save

Waiver of Consent (or Parental Permission)

- Applicable for research involving identifiable data or records, when asking to waive parental permission, or other situations where consent is not possible.
- Answer all questions as completely as possible.
- Click SAVE when done.

Consent Type: * Waiver of Consent

Title: *

Address the following four regulatory criteria for a Waiver of Consent and provide protocol-specific reasons for each:

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

Examples: The research involves the analysis of secondary or existing identifiable data, such as student records; participant information will be coded, and the key linking identities to the code will be kept in a locked cabinet to which only the Protocol Director and one co-investigator have access.

Rationale for above selection:

2) ○ True ○ False **The waiver will not adversely affect the rights and welfare of the participants.**

Example: Participants will not be contacted and procedures are in place to protect the privacy of the participants and the confidentiality of their data.

Rationale for above selection:

3) ○ True ○ False **The research could not practicably be carried out without the waiver.**

Example: Without the waiver of consent, the research would require contacting former students who have graduated years ago. Accurate contact information is not available.

Rationale for above selection:

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

Example: We do not anticipate that there will be any pertinent information to share with study participants.

Rationale for above selection:

Save

Consent Background

Save

Consent (or Parental Permission)

- Attach consent or parental permission documents to be signed in this section.
- Enter a descriptive Title (e.g., use *Consent for Controls* instead of *consentv1.doc)*. Do NOT use special characters or symbols in the title.
- Click BROWSE to locate and attach a file from your desktop.
- Click SAVE when done.

Consent Type: *

Consent

Title: *

Consent Form (file name): *

Choose File | No file chosen

Save

Consent Background

Save

Waiver of Documentation (Signature)

- Applicable for internet research, telephone interviews, oral consent, web surveys, OR where the primary risk is breach of confidentiality and the ONLY link to identifiable data is the signature on the consent form.
- Select the regulatory criterion below that is applicable to your study and provide rationale.
- Click SAVE when done.

Consent Type: * Waiver of Documentation

Title: *

Consent Form (file name): * Choose File No file chosen

Select one of the following regulatory criteria for a Waiver of Documentation and provide a protocol-specific justification:

- **45 CFR 46.117(c)(1) For research not subject to FDA regulation, the only record linking the participants and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality; each participant will be asked whether he/she wants documentation linking the participant with the research, and the participant's wishes govern.**

- **45 CFR 46.117(c)(2) For research that is not subject to FDA regulation, presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.**

Rationale for above selection:

Save

Consent Background

Save

Alteration of Consent (or Parental Permission)

- Applicable when some required elements of consent are eliminated, such as incomplete disclosure of the purpose of the research (deception).
- Answer all questions as completely as possible. Be sure to include which consent elements you wish to alter in the Rationale text boxes below.
- Click SAVE when done.

Consent Type: * Alteration of Consent

Title: *

Consent Form (file name): * Choose File | No file chosen

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

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

Example: The research does not reveal the entire purpose of the study to avoid response bias; the participants will complete a minimal risk survey regarding their preferences; participant information will be coded, and only the Protocol Director and one co-investigator will have access to the data.

Rationale for above selection:

2) ○ True ○ False **The Alteration of Consent will not adversely affect the rights and welfare of the participants.**

Example: The research involves no greater than minimal risk and does not involve any activity that would be harmful to any rights the participant would be eligible for.

Rationale for above selection:

3) ○ True ○ False **The research could not practicably be carried out without the alteration.**

Example: If the participants knew the entire purpose of the study, their responses would be biased and the data would be compromised.

Rationale for above selection:

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

Example: Participants will be debriefed following the study, and will be given the opportunity to withdraw their data if they wish **OR** debriefing will not add any benefit or pertinent information, and might even cause unnecessary discomfort.

Rationale for above selection:

Save

Protocol Application Form

Protocol ID : 41676 (Ratan Banik)
Title : Expedited Nonmedical

Non-Medical **EXPEDITED**

Expedited Paragraph(s) | 1-3 | 4(a-f) | 4(g-i) | 5 | 6,7 | 8 | 9 | 10 | 11

- Personnel Info
- Participant Population
- Study Location
- General Checklist
- Funding
- Resources
- Protocol Information
- Obligations
- Check for Completeness
- Print View
- Event History

Submit Protocol

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

Children must assent to participating in research unless the children are not capable of assenting because of age, maturity, psychological state, or other factors. See more information on Assent. A protocol that involves children should include at least one of the following. Depending on the nature of the research and the subject population, more than one may be included by clicking the ADD button below and then selecting the appropriate option from the drop-down menu.

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

a) Describe the assent process. Include the following: Who will obtain assent? When and how will this be done?

Note: The person obtaining assent must be knowledgeable about the study. Sufficient time must be devoted to allow the child to consider whether or not to participate. Steps must be taken to minimize the possibility of coercion or undue influence.

b) What procedure will you use to assess if the child understands the information contained in the assent? How will the information be provided to children if they do not understand English? See Guidance.

Instructions:

- Click ADD to enter information on one of the above assent options, and to attach relevant assent documents. Once entered and saved, a row will be displayed in tabular form for each item (Assent, Waiver of Assent, Assent Not Applicable) entered.

Assent Background Add

Please click on 'Add' to add Assent Background

Assent Background (less than 18 years of age)

Save

Assent Type: * ---------- Please Select ----------

Assent Background (less than 18 years of age)

Save

Assent

- Enter a descriptive Title (e.g., use *Assent 7-10 years* instead of *assentv1.doc*). Do NOT use special characters or symbols in the title.
- Click BROWSE to locate and attach a file from your desktop.
- Click SAVE when done.

Assent Type: *

Assent

Title: *

Assent Form (file name): *

Choose File | No file chosen

Save

Assent Background (less than 18 years of age)

Save

Waiver of Assent

- Applicable only when children are capable of assenting
- Answer all questions as completely as possible.
- Click SAVE when done.

Assent Type: * Waiver of Assent

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

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

Rationale for above selection:

2) ○ True ○ False **The waiver will not adversely affect the rights and welfare of the participants.**

Rationale for above selection:

3) ○ True ○ False **The research could not practicably be carried out without the waiver.**

Rationale for above selection:

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

Rationale for above selection:

Save

Assent Background (less than 18 years of age)

Save

Assent Not Applicable

- Applicable only when children are incapable of assenting
- Answer the question as completely as possible.
- Click SAVE when done.

Assent Type: *

Assent Not Applicable

Explain why assent is not applicable to this research (e.g., the children are too young to assent).

Save

Protocol Application Form

Protocol ID : 41676 (Ratan Banik)

Title : Expedited Nonmedical

Non-Medical **EXPEDITED**

Expedited Paragraph(s) | 1-3 | 4(a-f) | 4(g-i) | 5 | 6,7 | 8 | 9 | 10 | 11

- Personnel Info
- Participant Population
- Study Location
- General Checklist
- Funding
- Resources
- Protocol Information
- Obligations
- Check for Completeness
- Print View
- Event History

Submit Protocol

11. Attachments

Click ADD to attach relevant study documents to this section (e.g., surveys, questionnaires, federal grants). All final or revised recruitment materials, flyers, questionnaires, surveys, etc. must be submitted to the IRB for review and approval before use.

Add

Please click on 'Add' to attach documents

Attachments

Save

Type:	----------Please Select----------
Title: *	
Attachment(File Name):	Choose File No file chosen

- Advertisements
- Cooperating Institution(s) Approval
- Federal Grant(s)
- Questionnaires
- Training Grant/List
- Academic Sponsor Oversight/Scientific Review
- Scientific and Scholarly Review
- FDA Documents
- Other

Personnel Info
Participant Population
Study Location
General Checklist
Funding
Resources
Protocol Information
Obligations
Check for Completeness
Print View
Event History

Submit Protocol

Obligations

The Protocol Director agrees to:

- Adhere to principles of sound scientific research designed to yield valid results
- Conduct the study according to the protocol approved by the IRB
- Be appropriately qualified to conduct the research and be trained in Human Research protection ethical principles, regulations, policies and procedures
- Ensure all research personnel are adequately trained and supervised
- Ensure that the rights and welfare of participants are protected, including privacy and confidentiality of data
- Ensure that, when de-identified materials are obtained for research purposes, no attempt will be made to re-identify them.
- Disclose to the appropriate entities any potential conflict of interest
- Report promptly any new information, modification, or unanticipated problems that raise risks to participants or others
- Apply relevant professional standards.

Any change in the research protocol must be submitted to the IRB for review prior to the implementation of such change. Any complications in participants or evidence of increase in the original estimate of risk should be reported at once to the IRB before continuing with the project. The investigators must inform the participants of any significant new knowledge obtained during the course of the research.

IRB approval of any project is at the discretion of the IRB and is usually from one to three years. 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 several weeks prior to the expiration date of the protocol.

The Department Chair must approve faculty and staff research that is not part of a sponsored project. The Scientific & Scholarly Review forms and instructions for submission will be provided once the protocol is assigned to an IRB for review.

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://doresearch.stanford.edu/policies/research-policy-handbook/conduct-research/retention-and-access-research-data)

☐ By checking this box, I verify that I, as the Protocol Director (PD) responsible for this research protocol, have read and agree to abide by the above obligations, or that I have been delegated authority by the PD to certify that the PD has read and agrees to abide by the above obligations.