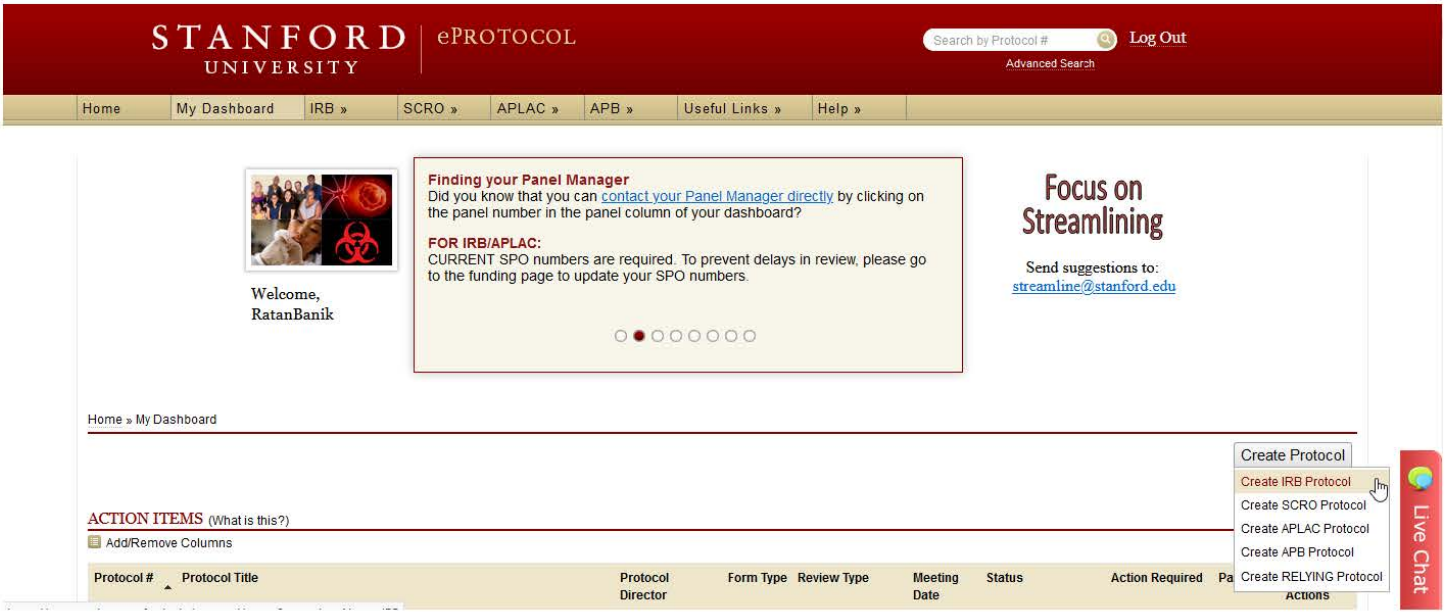


System Requirements:

- If using Windows, use Chrome 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, Investigator, or Other Contact.
- 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		**Mail Code**
Select Department		

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**
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: Select Department

Mail Code

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: Select Department

Mail Code

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: Select Department

Mail Code

CITI Training current ○ Yes ○ No

Next

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@lists.stanford.edu or (650) 724-7141 if you have questions.

Note: Use the Initial Submission Checklist for Investigators when preparing a new Medical application to ensure your protocol is complete and all required items are included.

( ) **Regular**	For greater than minimal risk studies
(●) **Expedited**	For minimal risk studies meeting specific criteria
( ) **Exempt**	Studies meeting specific criteria
( ) **Chart Review**	Chart review studies that only involve the use of data, documents, records
( ) **HSR Determination Form**	Projects that don't clearly qualify as human subjects research. Include the HSR Determination form in your submission.
( ) **Single IRB**	Studies where Stanford IRB is being asked to rely on an external IRB.
( ) **Single Patient IND/IDE**	Single patient treatment where the PD must obtain an IND from the FDA. Include FDA Form 3926 in your submission.
( ) **Humanitarian Use Device (HUD)**	Treatment using a device with a Humanitarian Device Exemption (HDE) issued by FDA.

Medical Expedited Review

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 paragraphs:

Select one or more of the following paragraphs:

☐ 1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

b) Research on medical devices for which

i) an investigational device exemption application (21 CFR Part 812) is not required; or
ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling

☐ 2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week

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

☐ 4. Collection of data through non invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples:

a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
b) weighing or testing sensory acuity;
c) magnetic resonance imaging;
d) electrocardiography, electroencephalography,thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

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

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

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

Create

Protocol Application Form

Protocol ID : 74095 (Ratan Banik)
Title : Expedited Sample

Medical | EXPEDITED

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

Instructions:

- You MUST select a name from Personnel Lookup to populate personnel.
- At minimum, Protocol Director (PD) and Admin Contact must be entered; this may be the same person.
- If the PD is a student (e.g., Undergraduate, Graduate, or Post-Doc), you must enter an Academic Sponsor. Those entered as Academic Sponsors must be listed under 1 or 2 of Admini Guide 23.
- To check CITI training review completion records.
- Only those entered in the following roles will have **edit access** to the Protocol application: PD, Admin Contact, Investigator and Other Contact.

Once all personnel have been entered and saved, click here to start the OPACS process.

Confirm Personnel

Protocol Director

Clear

View LDAP report

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	n/a	No Title
Email *	**Phone ***	**Fax**
rc-eprotocol-test@lists.stanfor	n/a	
Department		**Mail Code**
Vice Provost and Dean of Research and Graduate Policy - Re		

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	n/a	No Title
Email *	**Phone ***	**Fax**
rc-eprotocol-test@lists.stanfor	n/a	
Department		**Mail Code**
Vice Provost and Dean of Research and Graduate Policy - Re		

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

Academic Sponsor Review Form — Click here

Other Personnel

Click here to add Other Personnel

Click here to add Other Personnel

Once all personnel have been entered and saved, click here to start the OPACS process.

Confirm Personnel

Click the "Start" button once the Personnel section has been completed. The faculty investigators will receive an email asking them to disclose any outside 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 : 74095 (Ratan Banik)
Title : Expedited Sample

Medical EXPEDITED

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

Instructions:

Select 'Yes' if you will enroll children, pregnant women and fetuses, neonates, abortuses, prisoners, and International participants.
Select 'yes' for the remaining populations that are specifically targeted for this study.
For example:

- A researcher is conducting a study to compare two strategies designed to promote longer-term maintenance of smoking cessation. There may be students that smoke, however, the study is not designed to recruit students specifically as they are not the focus population. In this example, students would not be selected on the checklist.

Participant Population(s) Checklist

If using infants in Well Newborn Nursery, contact **GPRC.**

Yes	No	
◉	○	Children (under 18)
◉	○	Pregnant Women and Fetuses
◉	○	Neonates (0 - 28 days)
◉	○	Abortuses
◉	○	Prisoners
◉	○	International Participants Please enter the countries separated by comma
◉	○	Impaired Decision Making Capacity
◉	○	Cancer Subjects
◉	○	Laboratory Personnel
◉	○	Healthy Volunteers
◉	○	Students ☑ Stanford students ☐ Other students
○	◉	Employees
◉	○	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

If your study will focus on participants' status as a student at Stanford University (e.g. study pertains to academic performance, use of course work, use of academic data, student welfare, etc.), your protocol will first require submission to the Student Data Oversight Committee (SDOC) for review. Submit a PDF ("Print View") of your completed protocol to Tallie Caycen Wetzel at sdoc_review@lists.stanford.edu. Note that SDOC review usually takes 2 to 4 weeks.*Re-submit your protocol to IRB once SDOC has completed their review.*

OK

Protocol Application Form

Protocol ID : 74095 (Ratan Banik)
Title : Expedited Sample

Medical | EXPEDITED

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

Instructions:

The **study location** is where the Stanford researcher conducts any part of the research study. For example, a study in which specimens are collected at a community clinic and analyzed at Stanford would have both *Stanford* and *Other* selected.

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

Study Location(s) Checklist

☑	Stanford University
☐	Clinical & Translational Research Unit (CTRU)
☐	Stanford Hospital and Clinics
☐	Lucile Packard Children's Hospital (LPCH)
☐	VAPAHCS (Specify PI at VA)
☑	Other (Click ADD to specify details)

Add

Please click on 'Add' to add Other Locations

Other Location

Save

Location	○ US ○ International
Location / Country *	
Contact Name	
Contact Phone	
Contact Email	

○ Yes	○ No	Has the location granted permission for the research to be conducted?
○ Yes	○ No	Is the site engaged in human subjects research? If yes, attach the site's IRB approval letter in Attachments Section

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

Instructions:

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

Reminder:
If this study is a clinical trial that must be registered on ClinicalTrials.gov and Stanford is responsible for the registration, contact clinicaltrials-gov@stanford.edu or ccto-website@stanford.edu (for cancer trials) to register the study.

General Checklist

Yes	No	
		1. Multi-site
○	○	Is this a multi-site study? A multi-site study is generally a study that involves one or more medical or research institutions in which one site takes a lead role.(e.g., multi-site clinical trial)
○	○	Is Stanford the coordinating institution or are you the lead investigator for this multi-site study?
Yes	No	**2. Collaborating Institution(s)**
○	○	Are there any collaborating institution(s)? A collaborating institution is generally an institution that collaborates equally on a research endeavor with one or more institutions.
Yes	No	**3. Cancer Institute**
○	○	Cancer-Related Studies (studies with cancer endpoints), Cancer Subjects (e.g., clinical trials, behavior/prevention) or Cancer Specimens (e.g., blood, tissue, cells, body fluids with a scientific hypothesis stated in the protocol).
		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://med.stanford.edu/cancer/research/trial-support/src.html for more information.
Yes	No	**4. Clinical Trials**
○	○	Investigational drugs, biologics, reagents, or chemicals?
○	○	Commercially available drugs reagents, or other chemicals administered to subjects that are being studied?
○	○	Investigational Medical Device / Commercial Medical Device used off-label or if being studied?
○	○	IDE Exempt Device (Commercial Medical Device used according to label, Investigational In Vitro Device or Assay, or Consumer Preference/Modifications/Combinations of Approved Medical Devices) if they are being studied.
○	○	Will this study be registered on clinicaltrials.gov? (See Stanford decision tree)
Yes	No	**5. Tissues and Specimens**
○	○	Human blood, cells, tissues, or body fluids (tissues)?
○	○	Tissues to be stored for future research projects?
○	○	Tissues to be sent out of this institution as part of a research agreement? For guidelines, please see https://sites.stanford.edu/ico/mtas
Yes	No	**6. Biosafety (APB)**
○	○	Are you submitting a Human Gene Transfer investigation using a biological agent or recombinant DNA vector? If yes, please complete the Gene Transfer Protocol Application Supplemental Questions and upload in Attachments section. **APB #**
○	○	Are you submitting a Human study using biohazardous/infectious agents? If yes, refer to the Administrative Panel on BioSafety website prior to performing studies. **APB #**

Yes	No	
○	○	Are you submitting a Human study using samples from subjects that are known or likely to contain biohazardous/infectious agents? If yes, refer to the Administrative Panel on BioSafety website prior to performing studies. **APB #**
		APB approval is needed in addition to IRB approval for protocols that include the following: 1. use of Recombinant DNA, RNA or synthetic Nucleic Acid molecules in humans; 2. use of Biological/Infectious Agent; 3. use of samples from participants that are known or likely to be infected with a Biological/Infectious Agent in a research lab.
Yes	No	**7. Human Embryos or Stem Cells**
○	○	Human Embryos or Gametes? **SCRO #**
○	○	Human Stem Cells (including hESC, iPSC, cancer stem cells, progenitor cells) **SCRO #**
Yes	No	**8. Veterans Affairs (VA)**
○	○	The research recruits participants at the Veterans Affairs Palo Alto Health Care System(VAPAHCS).
○	○	The research involves the use of VAPAHCS non-public information to identify or contact human research participants or prospective subjects or to use such data for research purposes.
○	○	The research is sponsored (i.e., funded) by VAPAHCS.
○	○	The research is conducted by or under the direction of a VA employee (VA-paid or VA Without Compensation (WOC) appointment) while on their VA time.
○	○	The research is conducted using any property or facility of VAPAHCS.
		Research done at or involving the VA must be reviewed and approved by the Research and Development Committee before any research is started. Please email the Research Administration office at the Palo Alto VA.
Yes	No	**9. Equipment**
○	○	Use of Patient related equipment? If Yes, equipment must meet the standards established by Biomedical Engineering (BME) (650-725-5000)
○	○	Medical equipment used for human patients/subjects also used on animals?
○	○	Radioisotopes/radiation-producing machines, even if standard of care? More Info
Yes	No	**10. Payment**
○	○	Subjects will be paid/reimbursed for participation? See payment considerations.
Yes	No	**11. Funding**
○	○	Training Grant?
○	○	Program Project Grant?
○	○	Federally Sponsored Project?
○	○	Industry Sponsored Clinical Trial?

General Checklist

Yes	No	1. Multi-site
◉	○	Is this a multi-site study? A multi-site study is generally a study that involves one or more medical or research institutions in which one site takes a lead role.(e.g., multi-site clinical trial)
◉	○	Is Stanford the coordinating institution or are you the lead investigator for this multi-site study?
		Add
		Please click on 'Add' to add Participating Site Information

Participating Site

Save

Site Name *	
Contact Name	
Contact Phone	
Contact Email	

○ Yes	○ No	Has the location granted permission for the research to be conducted?
○ Yes	○ No	Is the site engaged in human subjects research? If yes, attach the site's IRB approval letter in Attachments Section

Yes	No	2. **Collaborating Institution(s)**
◉	○	Are there any collaborating institution(s)? A collaborating institution is generally an institution that collaborates equally on a research endeavor with one or more institutions.

Add

Please click on 'Add' to add Cooperating Institution(s)

Cooperating Institution(s)

Save

Institution Name *	
Contact Name	
Contact Phone	
Contact Email	

○ Yes	○ No	Has the location granted permission for the research to be conducted?
○ Yes	○ No	Is the site engaged in human subjects research? If yes, attach the site's IRB approval letter in Attachments Section

Protocol Application Form

Protocol ID : 74095 (Ratan Banik)

Title : Expedited Sample

Medical

EXPEDITED

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

Submit Protocol

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., Med. Scholars)

Add

Please click on 'Add' to add Other Funding

Instructions:

If this is a Multiple Project Protocol (MPP), attach a listing of all protocols funded under this MPP in the Attachments section. Include the eProtocol number, PD, and initial approval date.

Funding - Grants/Contracts Save

Funding Administered By	STANFORD

Search SPO Information by Principal Investigator or SPO Number

Principal Investigator	
○ SPO/RRA # (if available)	(e.g. 123456)
○ SPO # Pending	
Grant # (if available)	
Funded By/Partner (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?

○ Yes ○ No Is this a Multiple Project Protocol (MPP)?

○ Yes ○ No Is this protocol under a MPP?

STANFORD
- STANFORD
- PAVIR
- VA
- OTHER

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?

Gift Funding Save

Name of Donor *	

Dept. Funding Save

Department Name *	

Other Funding (e.g., Med. Scholars)

Save

Other Fund Name*	

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

Submit Protocol

Resources

Please demonstrate that you have adequate resources to conduct the project.

a. **Qualified staff.**

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

b. **Training.**

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

c. **Facilities.**

Provide the location(s) where the research will be conducted, including physical address if not conducted on site at Stanford University, Stanford Hospital on Pasteur Dr., Lucile Packard Children's Hospital on Welch Rd. or VAPAHCS. Describe the facilities and resources available to conduct the research at these sites.

d. **Sufficient time.**

Explain the time that you and your research team will allocate to perform the research activities, including data analysis.

e. **Access to target population.**

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

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

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

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

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

Expedited Paragraph(s) | 1-3 | 4 | 5,6 | 7 | 8(a-g) | 8(h-m) | 9(a-d) | 9(e) | 10, 11 | 12 | 13 | 14 | 15 | 16

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

Submit Protocol

Title

Expedited Sample

A protocol must be no more than minimal risk (i.e., "not greater than those ordinarily encountered in daily life") AND must only involve human subjects in one or more of the following paragraphs.

Select one or more of the following paragraphs:

☑ **1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.**

a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

b) Research on medical devices for which

i) an investigational device exemption application (21 CFR Part 812) is not required; or
ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

☐ **2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:**

a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

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

☐ **4. Collection of data through non invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)**

Examples:

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

b) weighing or testing sensory acuity;

c) magnetic resonance imaging;

d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;

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

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

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

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

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

Submit Protocol

Expedited Paragraph(s) | 1-3 | 4 | 5,6 | 7 | 8(a-g) | 8(h-m) | 9(a-d) | 9(e) | 10, 11 | 12 | 13 | 14 | 15 | 16

Complete Sections 1 - 16. Specify N/A as appropriate. Do not leave any required sections blank.

1. Purpose

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

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

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

2. Study Procedures

a) Please SUMMARIZE the research procedures, screening through closeout, which the research participant will undergo. Sections in the protocol attached in section 16 can be referenced, BUT do not copy the clinical protocol. Be clear on what is to be done for research and what is part of standard of care. For research involving collaborators, please specify the respective roles of Stanford and each collaborator on the protocol.

b) Explain how the above research procedures are the least risky that can be performed consistent with sound research design.

c) State if deception will be used. If so, provide the rationale and describe debriefing procedures. Since you will not be fully informing the participant in your consent process and form, complete an alteration of consent (in section 13). Submit a debriefing script (in section 16).

d) State if audio or video recording will occur. Describe what will become of the recording after use, e.g., shown at scientific meetings, erased. Describe the final disposition of the recordings.

e) Describe alternative procedures or courses of treatment, if any, that might be advantageous to the participant. Describe potential risks and benefits associated with these. Any standard treatment that is being withheld must be disclosed in the consent process and form. (i.e. standard-of-care drug, different interventional procedure, no procedure or treatment, palliative care, other research studies).

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

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

3. Background

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

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

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

Submit Protocol

Expedited Paragraph(s) | 1-3 | 4 | 5,6 | 7 | 8(a-g) | 8(h-m) | 9(a-d) | 9(e) | 10, 11 | 12 | 13 | 14 | 15 | 16

4. Radioisotopes or Radiation Machines

a) List all *standard of care* procedures using ionizing radiation (radiation dose received by a subject that is considered part of their normal medical care). List all *research* procedures using ionizing radiation (procedures performed due to participation in this study that is not considered part of their normal medical care). List each potential procedure in the sequence that it would normally occur during the entire study. More Info

Radiation Procedures Add

Please click on 'Add' to add Radiation Procedure

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

Identify the radionuclide(s) and chemical form(s).

For the typical subject, provide the total number of times the radioisotope and activity will be administered (mCi) and the route of administration.

If not FDA approved provide dosimetry information and reference the source documents (package insert, MIRD calculation, peer reviewed literature).

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

For well-established radiographic procedures describe the exam.

For the typical subject, identify the total number of times each will be performed on a single research subject.

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

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

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

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

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

Radiation Procedures Save

Identify Week/ Month of study	
Name of Exam *	
Identify if SOC or Research *	○ Standard of Care ○ Research

Protocol Application Form

Protocol ID : 74095 (Ratan Banik)

Title : Expedited Sample

Medical

EXPEDITED

Expedited Paragraph(s) | 1-3 | 4 | 5,6 | 7 | 8(a-g) | 8(h-m) | 9(a-d) | 9(e) | 10, 11 | 12 | 13 | 14 | 15 | 16

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

Submit Protocol

5. Devices

a) Please list in the table below all Investigational Devices (including Commercial Devices used off-label) to be used on participants.

Investigational Devices and Uses Add

Please click on 'Add' to attach Investigational devices

b) Please list in the table below all IDE Exempt Devices (Commercial Device used according to label, Investigational In Vitro Device or Assay, or Consumer Preference/Modifications/Combinations of Approved Devices) if they are being studied.

IDE Exempt Devices Add

Please click on 'Add' to attach IDE Exempt devices

6. Drugs, Reagents, or Chemicals and Devices

a) Please list in the table below all investigational drugs, reagents or chemicals to be administered to participants.

Investigational Drugs, Reagents, Chemicals Add

Please click on 'Add' to attach Investigational drugs

b) Please list in the table below all commercial drugs, reagents or chemicals to be administered to subjects.

Commercial Drugs, Reagents, Chemicals Add

Please click on 'Add' to attach Commercial drugs

Investigational Devices and Uses Save

Device Information

Describe the device and how it will be used.

Device Name *	
Manufacturer	

Risk * ◯ Significant ◯ Non-significant

See Significant and Non-Significant Risk Medical Devices guidance.

IDE Exempt Devices (Commercial Devices)

Save

Device Information

Describe the device to be used. *

Device Name *	
Manufacturer	

IDE Exemption

Select one of the following the IDE exemption categories: *

- ○ This is a legally marketed device being used in accordance with its labeling.
- ○ This is an *in vitro* diagnostic device that complies with the labeling requirements in 21 CFR 809.10(c), http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=809.10, and for the testing of the device all of the following statements are true:
  - It is non-invasive.
  - It does not require an invasive sampling procedure that presents significant risk.
  - It does not by design or intention introduce energy into a subject.
  - It is not used as a diagnostic procedure without confirmation by another medically established diagnostic product or procedure.
- ○ The study includes consumer preference testing, testing of a modification, or testing of a combination of devices that are legally marketed devices [that is, the device(s) have an approved PMA, cleared Premarket Notification (510k), or are exempt from 510k] AND the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk.

Investigational Drugs, Reagents, Chemicals

Save

Drug, Reagent, Chemical Information

Drug Name *	
Source (i.e. Pharmacy, Sponsor, etc.,) *	

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

Manufacturer *	
IND # (if available)	
Dosage *	

Administration Route: *

Holder of IND

*** Indicate who holds the IND:**

○	The IND is held by the sponsor. Provide a copy of the investigator's brochure, the sponsor's protocol and the FDA letter issuing the IND number (attach in section #7). *The FDA letter does not have to be provided if the IND number is on the sponsor's protocol.*
○	The IND is held by the STANFORD (SHC, LPCH, VA) investigator. Provide a copy of the investigator's brochure (if available), the clinical protocol and a copy of the FDA letter issuing the IND number and all correspondence with the FDA on the IND (attach in section #7).
○	The IND is held by a non-STANFORD investigator. Provide a copy of the investigator's brochure (if available), the clinical protocol and a copy of the FDA letter issuing the IND number (attach in section #7).

Since your study involves an Investigational Drug/Biologic, indicate where the Investigational Drug/Biologic will be maintained and dispensed.

☐	SHC Investigational Drug Service(IDS), including outpatient pharmacies
☐	LPCH Investigational Drug Service(IDS), including outpatient pharmacies
☐	SHC or LPCH Nuclear Medicine
☐	Cellular Therapy Facility
☐	VAPAHCS
☐	Byers Eye Institute
☐	Stanford Medicine Outpatient Center in Redwood City
☐	Commercial compounding Pharmacy (e.g., Mariners)
☐	If none of the above, please contact the Senior Associate Dean for Research office, at sadrmedicine@stanford.edu for further instructions.

Commercial Drugs, Reagents, Chemicals

Save

Drug, Reagent, Chemical Information

Drug Name *	
Source (i.e. Pharmacy, Sponsor, etc.) *	

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

Manufacturer *	
IND# (if available)	
Dosage *	

Administration Route: *

IND Exemption

* ◯ Yes ◯ No	Is this new and different uses of this commercially available drug, reagent or chemical?
* ◯ Yes ◯ N/A	Are all of the IND statements shown below true?

Revising the IND Regulations section for consistency with the 21 CFR 312.2(b).

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

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

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

Submit Protocol

Expedited Paragraph(s) | 1-3 | 4 | 5,6 | 7 | 8(a-g) | 8(h-m) | 9(a-d) | 9(e) | 10, 11 | 12 | 13 | 14 | 15 | 16

7. Medical Equipment for Human Subjects and Laboratory Animals

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

Expedited Paragraph(s) | 1-3 | 4 | 5,6 | 7 | 8(a-g) | 8(h-m) | 9(a-d) | 9(e) | 10,11 | 12 | 13 | 14 | 15 | 16

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

Submit Protocol

8. Participant Population

a) State the following: (i) the number of participants expected to be enrolled at Stanford-affiliated site(s); (ii)the total number of participants expected to enroll at all sites; (iii) the type of participants (i.e. students, patients with certain cancer, patients with certain cardiac condition) and the reasons for using such participants.

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

c) State the number and rationale for involvement of potentially vulnerable subjects in the study (including children, pregnant women, economically and educationally disadvantaged, decisionally impaired, homeless people, employees and students). Specify the measures being taken to minimize the risks and the chance of harm to the potentially vulnerable subjects and the additional safeguards that have been included in the protocol to protect their rights and welfare.

d) If women, minorities, non-English speaking individuals, or children are not included, a clear compelling rationale must be provided (e.g., disease does not occur in children, drug or device would interfere with normal growth and development, etc.).

e) State the number, if any, of participants who are laboratory personnel, employees, and/or students. They should render the same written informed consent. If payment is allowed, they should also receive it. Please see Stanford University policy.

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

g) Describe your plan to identify and recruit potential participants including who will inform them about the study and how they will be initially contacted by the researchers (e.g., Research Engagement services; chart review; treating physician; ads including social media posts). All final or revised recruitment materials must be approved by the IRB before use. Contacting potential participants is not permitted prior to IRB approval. See Recruitment Guidance for additional information.

Expedited Paragraph(s) | 1-3 | 4 | 5,6 | 7 | 8(a-g) | 8(h-m) | 9(a-d) | 9(e) | 10, 11 | 12 | 13 | 14 | 15 | 16

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

Submit Protocol

8. Participant Population

h) Inclusion and Exclusion Criteria.

Identify inclusion criteria.

Identify exclusion criteria.

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

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

k) **Payment/reimbursement. Explain the amount and schedule of payment or reimbursement, 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

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

m) **Estimate the probable duration of the entire study. Also estimate the total time per participant for: (i) screening of participant; (ii) active participation in study; (iii) analysis of participant data.**

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

Submit Protocol

Expedited Paragraph(s) | 1-3 | 4 | 5,6 | 7 | 8(a-g) | 8(h-m) | 9(a-d) | 9(e) | 10,11 | 12 | 13 | 14 | 15 | 16

9. Risks

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

i. **The risks of the Investigational devices.**

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

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

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

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

vi. **The risks of the Physical well-being.**

vii. **The risks of the Psychological well-being.**

viii. **The risks of the Economic well-being.**

ix. **The risks of the Social well-being.**

b) If you are conducting international research, describe the qualifications/preparations that enable you to both estimate and minimize risks to participants. Provide an explanation as to why the research must be completed at this location and complete the **International Research Form**. If not applicable, enter N/A.

c) **Describe the planned procedures for protecting against and minimizing all potential risks. Include the means for monitoring to detect hazards to the participant (and/or to a potential fetus if applicable). Include steps to minimize risks to the confidentiality of identifiable information.**

d) **Explain the point at which the experiment will terminate. If appropriate, include the standards for the termination of the participation of the individual participant Also discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the participants.**

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

Submit Protocol

Expedited Paragraph(s) | 1-3 | 4 | 5,6 | 7 | 8(a-g) | 8(h-m) | 9(a-d) | 9(e) | 10,11 | 12 | 13 | 14 | 15 | 16

9. Risks

e) **Special Participant Populations**

Children

If your research includes children, complete the *Children's Findings* section entitled Children's Findings OHRP. (Regulatory citations 46.404 through 46.407)

If your research includes children and an investigational drug/device is being studied, complete the *Children's Findings* section entitled Children's Findings FDA (Regulatory citations 50.51 through 50.54) See memo for additional information on multiple children's findings on FDA studies.

- **Children's Findings OHRP. As children are involved in your research, please select one or more regulatory categories (46.404 through 46.407) below that your research falls under and provide the necessary rationale for each determination. See full regulation citation.**

☐ 46.404 Research not involving greater than minimal risk. The research must present no greater than minimal risk to children and adequate provisions must be made for soliciting the assent of the children and the permission of their parents or guardians. Please provide rationale for the above statement.

☐ 46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects. The research presents more than minimal risk to children, but holds out the prospect of direct benefit for the individual subject or is likely to contribute to the subject's well-being. Please provide rationale that: (a) the risk is justified by the anticipated benefit to the subjects; (b) the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and (c) adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.

☐ 46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition. Research that presents more than minimal risk to children that does not hold out the prospect of direct benefit for the individual subject, or is not likely to contribute to the well-being of the subject. Please provide rationale that: (a) the risk represents a minor increase over minimal risk; (b) the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations; (c) the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and (d) adequate provisions are made for soliciting assent of the children and permission of their parents or guardians.

☐ 46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. Please provide rationale that: (a) the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; (b) the research will be conducted in accordance with sound ethical principles; (c) adequate provisions are made for soliciting assent of the children and permission of their parents or guardians.

Rationale for category selected above:

- **Children's Findings FDA. As your research includes children and an investigational drug/device or a commercial device is being studied, please select one or more regulatory categories (50.51 through 50.54) below that your research falls under and provide the necessary rationale for each determination. See full regulation citation.**

☐ 50.51 Clinical Investigations not involving greater than minimal risk. The research must present no greater than minimal risk to children and adequate provisions must be made for soliciting the assent of the children and the permission of their parents or guardians. Please provide rationale for the above statement.

☐ 50.52 Clinical Investigations involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects. The research presents more than minimal risk to children, but holds out the prospect of direct benefit for the individual subject or is likely to contribute to the subject's well-being. Please provide rationale that: (a) the risk is justified by the anticipated benefit to the subjects; (b) the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and (c) adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.

☐ 50.53 Clinical Investigations involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition. Research that presents more than minimal risk to children that does not hold out the prospect of direct benefit for the individual subject, or is not likely to contribute to the well-being of the subject. Please provide rationale that: (a) the risk represents a minor increase over minimal risk; (b) the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations; (c) the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and (d) adequate provisions are made for soliciting assent of the children and permission of their parents or guardians.

☐ 50.54 Clinical Investigations not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. Please provide rationale that: (a) the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; (b) the research will be conducted in accordance with sound ethical principles; (c) adequate provisions are made for soliciting assent of the children and permission of their parents or guardians.

Rationale for category selected above:

Pregnant Women or Fetuses

As pregnant women or fetuses are included in your research, please confirm that all of the following conditions are met. See full regulation citation.

◯ **Met** ◯ **N/A** (a) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data assessing potential risks to pregnant women and fetuses;

◯ **Met** ◯ **N/A** (b) The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;

◯ **Met** ◯ **N/A** (c) Any risk is the least possible for achieving the objectives of the research;

◯ Met	◯ N/A	(d) If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means , her consent is obtained in accord with the informed consent provisions of subpart A of this part;
◯ Met	◯ N/A	(e) If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of subpart A of this part, except that the father's consent need not be obtained if he is unable to consent because of unavailability , incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.
◯ Met	◯ N/A	(f) Each individual providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;
◯ Met	◯ N/A	(g) For children as defined in Sec. 46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of subpart D of this part;
◯ Met	◯ N/A	(h) No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
◯ Met	◯ N/A	(i) Individual engaged in the research will have no part in any decisions as to the timing, method or procedures used to terminate a pregnancy;
◯ Met	◯ N/A	(j) Individual engaged in the research will have no part in determining the viability of a neonate.

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

Submit Protocol

Expedited Paragraph(s) | 1-3 | 4 | 5,6 | 7 | 8(a-g) | 8(h-m) | 9(a-d) | 9(e) | 10, 11 | 12 | 13 | 14 | 15 | 16

10. Benefits

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

11. Privacy and Confidentiality

Most medical research must comply with the Health Insurance Portability and Accountability Act (HIPAA) regulations if it uses *protected health information* (PHI). See more information on HIPAA.

PHI is health information with one or more of the following identifiers:

1. Names
2. Social Security numbers
3. Telephone numbers
4. All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if, according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combing all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000s
5. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older
6. Fax numbers
7. Electronic mail addresses
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers, including license plate numbers
13. Device identifiers and serial numbers
14. Web Universal Resource Locations (URLs).
15. Internet Protocol (IP) address numbers
16. Biometric identifiers, including finger and voice prints
17. Full face photographic images and any comparable images; and
18. Any other unique identifying number, charactristic, or code (except the unique code assigned by the Investigator(s) to code the research data, unless the code was derived from other identifiable information, such as the SSN).

Privacy Protections

a) **Describe the setting and method (e.g. crowded waiting room, patient exam room, telephone or email communication) in which interactions will occur and how the privacy interests of participants will be maintained. Note, high risk data such as PHI must be sent via "Secure:" email per Stanford policy.**

Confidentiality Protections

b) Specify PHI (Protected Health Information). PHI is health information linked to HIPAA identifiers (see above). List BOTH health information AND HIPAA identifiers. If you are using **STARR** , use the **Data Privacy Attestation** to ensure that your request will match your IRB-approved protocol. Be consistent with information entered in section 15a.

c) You are required to comply with University Policy that states that ALL electronic devices: computers (laptops and desktops; OFFICE or HOME); smart phones; tablets; external hard disks, USB drives, etc. that may hold identifiable participant data will be password protected, backed up, and encrypted.

Stanford University IT approved platforms (**https://uit.stanford.edu/guide/riskclassifications**) should be used for data management. Consult with your Department IT representative for more information.

For data security policies and links to encrypt your devices see **http://med.stanford.edu/irt/security** and **http://www.stanford.edu/group/security/securecomputing/mobile_devices.html**. Additionally, any PHI data on paper must be secured in a locked environment.

By checking this box, You affirm the aforementioned. ☐

d) Describe how data or specimens will be labeled (e.g. name, medical record number, study number, linked coding system) or de-identified. If you are de-identifying data or specimens, who will be responsible for the de-identification? If x-rays or other digital images are used, explain how and by whom the images will be de-identified.

e) Indicate who will have access to the data or specimens (e.g., research team, sponsors, consultants) and describe levels of access control (e.g., restricted access for certain persons or groups, access to linked data or specimens).

f) If data or specimens will be coded, describe the method in which they will be coded so that study participants' identities cannot be readily ascertained from the code.

g) If data or specimens will be coded, indicate who will maintain the key to the code and describe how it will be protected against unauthorized access.

h) If sharing data with others, describe how data will be transferred or transmitted (e.g., file transfer software, file sharing, email). If transmitted via electronic networks, confirm a Stanford University IT approved platform will be used (see **https://uit.stanford.edu/guide/riskclassifications**) or that data will be encrypted while in transit. Additionally, confirm appropriate agreements are in place to allow for the sharing (see **https://ico.stanford.edu/stanford-researchers/who-will-handle-my-agreement**).

If using or sharing PHI, refer to the following policies: **https://uit.stanford.edu/security/hipaa**.

i) 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)?

Expedited Paragraph(s) | 1-3 | 4 | 5,6 | 7 | 8(a-g) | 8(h-m) | 9(a-d) | 9(e) | 10, 11 | 12 | 13 | 14 | 15 | 16

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

Submit Protocol

12. Potential Conflict of Interest

STANFORD UNIVERSITY | OUTSIDE PROFESSIONAL ACTIVITIES CERTIFICATION SYSTEM (OPACS)

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

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

Outside Interest Tasks

Investigators	Role	Potential COI?	Date Outside Interest Answered	Date OPACS Disclosure Submitted	COI Review Determination
Ratan Banik	PD	Incomplete	Incomplete	Incomplete	

INSTRUCTIONS FOR ADMIN CONTACT

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

To Disclose Outside 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 outside interests

Issues? Please submit an OPACS HelpSU ticket.

Protocol Application Form

Protocol ID : 74095 (Ratan Banik)
Title : Expedited Sample

Medical | EXPEDITED

Expedited Paragraph(s): 1-3 | 4 | 5,6 | 7 | 8(a-g) | 8(h-m) | 9(a-d) | 9(e) | 10, 11 | 12 | 13 | 14 | 15 | 16

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

Submit Protocol

13. Consent Background

Written, signed consent should always be sought unless there are compelling reasons to seek an alteration of consent, waiver of consent, or waiver of documentation (i.e., signature). See more information on Informed Consent. A protocol should include **at least one** of the following. Depending on the nature of the research and the subject population, more than one may be included.

- Consent (Click HERE for consent form templates)
- Waiver of Consent *(e.g., retrospective chart reviews)*
- Waiver of Documentation (signature) *(e.g., telephone screens, oral consent, web questionnaires, and cases when the primary risk is breach of confidentiality)*
- Alteration of Consent *(e.g., research involving deception or incomplete disclosure)*
- Short Form Consent *(e.g., when you anticipate consenting patients that speak a language other than the language in which the Consent form is written)*

Instructions

• Click ADD to enter detailed information on one of the above categories, and attach relevant consent documents. Once entered and saved, a row will be displayed in tabular form for each item (Consent, Waiver of Consent, etc.) entered.
• To view/modify the details of previously entered information or to **replace a consent document** with an updated version, click the link in the *Consent Type* column for the desired item.
• To view the current consent document, click the link in the *Consent (editable)* column for the desired item.
• To remove an item, check the box next to the *Consent (editable)* and click DELETE.

Consent Background Add

Please click on 'Add' to add Consent Background

Consent Background Save

Consent Information Type: * ---------- Please Select ----------

Title: *

- ---------- Please Select ----------
- Consent
- Waiver of Consent
- Waiver of Documentation
- Alteration of Consent
- Short Form Consent Process

Consent Background

Save

Consent

- Enter a descriptive *Title* rather than a filename. For example, instead of entering *consent.v1.doc* you should enter *consent for controls*. Also, do not use any special characters or symbols in the title.
- Click BROWSE to locate and attach a file from your desktop.
- Answer all questions as completely as possbile.
- Click SAVE when done.

NOTE: *VA Consent form must be used when any of the research activity is conducted on VA property, including recruitment of study subjects.*

Consent Information Type: * Consent

Title: *

Sponsor's Consent Version Number: (if any)

Consent Form (file name): * Browse... No file selected.

Check if VA related

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.

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 Chapter12.2 for guidance.

c) What steps are you taking to determine that potential participants have the capacity 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.

Consent Background

Save

Waiver of Consent

- An example of when a waiver of consent would be applicable is for retrospective chart reviews.
- Answer all questions as completely as possible.
- Click SAVE when done.

Consent Information Type: * Waiver of Consent

Title: *

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

1) ○ True ○ False **The research/clinical investigation involves no more than minimal risk (as defined in 45 CFR 46.102(j), 21 CFR 50.3(k), or 21 CFR 56.102(i)) to the participants. [45 CFR 46.116(f)(3)(i) and/or 2017 FDA Guidance IV.1]**

Example: The research involves a review of medical records to determine the incidence of infection following hip replacement procedures. Participant information will be coded, and the key linking identities to the code will be kept in a locked cabinet to which only the Protocol Director and one co-investigator have access.

Rationale for above selection(s):

2) ○ True ○ False **The waiver or alteration will not adversely affect the rights and welfare of the participants. [45 CFR 46.116(f)(3)(iv) and/or 2017 FDA Guidance IV.2]**

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

Rationale for above selection(s):

3a) ○ True ○ False **The research/clinical investigation could not practicably be carried out without the requested waiver or alteration. [45 CFR 46.116(f)(3)(ii) and/or 2017 FDA Guidance IV.3]**

3b) ◯ True ◯ False **For research using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format. [45 CFR 46.116(f)(3)(iii)]**

Example: If the IRB required informed consent of participants, this research would be impracticable to do because it would require contacting 1000 patients who had hip replacements one to four years ago; many are elderly and may have moved following their procedure, such that accurate contact information is not readily available and obtaining it for any of the target population would be unduly burdensome. Without access to the identifiers the researchers would not be able to collect information from the various sources.

Rationale for above selection(s):

4) ◯ True ◯ False **Whenever appropriate, the participants or legally authorized representatives will be provided with additional pertinent information after participation. [45 CFR 46.116(f)(3)(v) and/or 2017 FDA Guidance IV.4)]**

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

Rationale for above selection(s):

Save

Consent Background

Save

Waiver of Documentation

- Is applicable for telephone screens , oral consent , web questionnaires, and cases where the primary risk is breach of confidentiality
- Enter a descriptive *Title* rather than a filename. For example, instead of entering *consent.v1.doc* you should enter *consent for controls*. Also, do not use any special characters or symbols in the title.
- Click BROWSE to locate and attach a file from your desktop.
- Answer all questions as completely as possbile.
- Click SAVE when done.

Consent Information Type: * Waiver of Documentation

Title: *

Sponsor's Consent Version Number: (if any)

Consent Form (file name): * Browse... No file selected.

Check if VA related

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.

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 Chapter12.2 for guidance.

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

Select ALL applicable regulatory criteria for a Waiver of Documentation and provide a protocol-specific justification:

An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all participants if it finds any of the following:

- [ ] 45 CFR 46.117(c)(1)(i)., that 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 (or legally authorized representative) 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)(1)(ii)., that the research 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.

- [ ] 45 CFR 46.117(c)(1)(iii)., if participants or legally authorized representatives (LAR) are members of a distinct cultural group in which signing forms is not the norm, the research presents no more than minimal risk and there is an appropriate alternative mechanism for documenting that informed consent was obtained.

For a FDA regulated clinical investigation, the IRB may, for some or all participants, waive the requirement that the participant, or the participant's legally authorized representative, sign a written consent form if it finds that the research

- [ ] 21 CFR 56.109(c)(1)., 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:

Consent Background

Save

Alteration of Consent

- Is applicable for research involving deception or incomplete disclosure.
- Enter a descriptive *Title* rather than a filename. For example, instead of entering *consent.v1.doc* you should enter *consent for controls*. Also, do not use any special characters or symbols in the title.
- Click BROWSE to locate and attach a file from your desktop.
- Answer all questions as completely as possbile.
- Click SAVE when done.

Consent Information Type: * Alteration of Consent

Title: *

Sponsor's Consent Version Number: (if any)

Consent Form (file name): * Browse... No file selected.

Check if VA related

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.

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 Chapter12.2 for guidance.

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

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

1) ◯ True ◯ False **The research/clinical investigation involves no more than minimal risk (as defined in 45 CFR 46.102(j), 21 CFR 50.3(k), or 21 CFR 56.102(i)) to the participants. [45 CFR 46.116(f)(3)(i) and/or 2017 FDA Guidance IV.1]**

Example: The research involves a survey that in addition to purpose of asking questions about videogame playing, researchers want to study aggression but do not want to reveal this purpose. This is incomplete disclosure. Responses are collected and maintained in accordance with Stanford IT security standards.

Rationale for above selection(s):

2) ◯ True ◯ False **The waiver or alteration will not adversely affect the rights and welfare of the participants. [45 CFR 46.116(f)(3)(iv) and/or 2017 FDA Guidance IV.2]**

Example: The research team is storing the data according to Stanford IT standards and coding data with the code key in a separate location to protect subject data.

Rationale for above selection(s):

3a) ◯ True ◯ False **The research/clinical investigation could not practicably be carried out without the requested waiver or alteration. [45 CFR 46.116(f)(3)(ii) and/or 2017 FDA Guidance IV.3]**

3b) ◯ True ◯ False **For research using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format. [45 CFR 46.116(f)(3)(iii)]**

Example: If the IRB required informed consent of participants, this research would be impracticable to do because it could challenge the validity of results if participants knew the purpose of identifying aggression in video game playing as they could conceal their aggression in their responses.

Rationale for above selection(s):

4) ◯ True ◯ False **Whenever appropriate, the participants or legally authorized representatives will be provided with additional pertinent information after participation. [45 CFR 46.116(f)(3)(v) and/or 2017 FDA Guidance IV.4)]**

Example: The information expected to be learned from the surveys will not likely provide pertinent information directly about participants; however, if pertinent information is discovered, participants will be provided with them.

Rationale for above selection(s):

Consent Background

Save

Short Form Consent Process

Consent Information Type: * Short Form Consent Process

Title: *

- Download the short form consent in required language and add to the header: Study Title, Protocol Director, and Contact Information. If the participant speaks a language other than one available on our website, you must submit a short form version in that language to the IRB for approval before enrolling the participant.
- Add lines to the full English consent form for Witness Signature and Date.
- If the Person Obtaining Consent does not speak the participant's language, you must use a translator/interpreter. A family member may act as the translator/interpreter if the participant has declined the services of a hospital translator/interpreter.
- A witness must be present during the entire consent process. The translator/interpreter can act as the witness. The person obtaining consent can not be the witness. After the study is described to the participant by the translator/interpreter, the participant and witness must sign and date the short form consent and the Person Obtaining Consent and the witness must sign and date the full English consent.
- The IRB may require that a participant be given a fully translated consent in the participant's language within 30-days of enrollment for certain high risk studies (e.g., first-in-human).

☐ **I have read and will follow the above procedures.**

Select one or both as applicable to the study:

☐ **Short Form Consent Process FDA 21 CFR 50.27(b)(2)**

☐ **Short Form Consent Process OHRP (federally funded research or non-FDA regulated research) 45 CFR 46.117(b)(2).**

Consent Form (file name): Browse... No file selected.

Save

Protocol Application Form

Protocol ID : 74095 (Ratan Banik)
Title : Expedited Sample

Medical | EXPEDITED

Expedited Paragraph(s) | 1-3 | 4 | 5,6 | 7 | 8(a-g) | 8(h-m) | 9(a-d) | 9(e) | 10, 11 | 12 | 13 | 14 | 15 | 16

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

Submit Protocol

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

All children must assent to participating by signing an assent form, unless the investigator(s) provides evidence to the IRB that 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.

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

Instructions

- Click ADD to enter detailed information on one of the above categories, and attach relevant assent documents. Once entered and saved, a row will be displayed in tabular form for each item (Assent, Waiver of Assent, etc.) entered.
- To view/modify the details of previously entered information or to **replace an assent document** with an updated version, click the link in the *Assent InformationType* column for the desired item.
- To view the current assent document, click the link in the *Title* column for the desired item.
- To remove an item, check the box next to the *Title* and click DELETE.

Assent Background | Add

Please click on 'Add' to add Assent Background

Assent Background | Save

Assent Information Type: *

Title *

---------- Please Select ----------

---------- Please Select ----------
Assent
Waiver of Assent
Assent Not Applicable

Assent Background

Save

Assent

- Enter a descriptive *Title* rather than a filename. For example, instead of entering *assent.v1.doc* you should enter *assent for 7 to 10 yr old*. Also, do not use any special characters or symbols in the title.
- Click BROWSE to locate and attach a file from your desktop.
- Answer all questions as completely as possbile.
- Click SAVE when done.

Assent Information Type: * Assent

Title *

Sponsors Assent Version Nbr: (if any)

Assent Form (file name): * Browse... No file selected.

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?

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)? Is there a possibility that the intervention or procedure involved in the research/clinical investigation holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research/clinical investigation and therefore assent may not be necessary?**

c) **What steps are you taking to determine that the child has the capacity to participate in the decision-making process?**

Save

Assent Background

Save

Waiver of Assent

- Answer all questions as completely as possbile.
- Click SAVE when done.

Assent Information Type: * Waiver of Assent

Title *

Address the following regulatory criteria for a waiver of assent and provide a 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:

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

3b) ○ **True** ○ **False** **For research using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format**

Rationale for above selection(s):

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

Rationale for above selection:

Assent Background

Save

Assent Not Applicable

- Answer the question as completely as possbile.
- Click SAVE when done.

Assent Information Type: * Assent Not Applicable

Title *

Please explain why assent is not applicable to this study:

Save

Protocol Application Form

Protocol ID : 74095 (Ratan Banik)
Title : Expedited Sample

Medical EXPEDITED

Expecited Paragraphis) | 1-3 | 4 | 5,6 | 7 | 8(a-g) | 8(h-r) | 8(a-d) | 9(e) | 10,11 | 12 | 13 | 14 | 15 | 16

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

Submit Protocol

15. HIPAA Background

If your protocol involves Protected Health Information (PHI) you must include one or more of the following unless your consent form(s) contain embedded HIPAA language. In cases where HIPAA language is included in the consent(s), you may still need to include a Waiver of Authorization for Recruitment.

- **HIPAA Authorization** (Click HERE for HIPAA Authorization template)
- **Waiver of Authorization** *(e.g., retrospective chart reviews)*
- **Waiver of Authorization for Recruitment** *(e.g., telephone screens that include questions eliciting PHI, chart reviews to determine elligibility)*
- **Alteration of Authorization** *allow for a waiver of the signature requirement for HIPAA authorization (e.g. for studies conducted over the telephone or by mail)*

Instructions

- Click ADD to enter detailed information on one of the above categories, and attach relevant documents. Once entered and saved, a row will be displayed in tabular form for each item (HIPAA Authorization, Waiver of Authorization, etc.) entered.
- To view/modify the details of previously entered information or to replace a document with an updated version, click the link in the HIPAA Information Type column for the desired item.
- To view the current authorization document, click the link in the Title column for the desired item.
- To remove an item, check the box next to the Title and click DELETE

HIPAA Background Add

Please click on 'Add' to add HIPAA Background

HIPAA Background

Save

HIPAA Information Type:* ---------- Please Select ----------

Title:*

- ---------- Please Select ----------
- Authorization
- Waiver of Authorization
- Waiver of Authorization for Recruitment
- Alteration of Authorization

HIPAA Background

Save

Authorization

HIPAA Information Type:* Authorization

Title:*

Authorization (file name): Browse... No file selected.

Save

HIPAA Background

Save

Waiver of Authorization

HIPAA Information Type:* Waiver of Authorization

Title:*

a) **Describe the Protected Health Information (PHI) needed to conduct the research. PHI is health information linked to HIPAA identifiers. List BOTH health information AND HIPAA identifiers. If you are using STARR , use the Data Privacy Attestation to ensure that your request will match your IRB-approved protocol.**

b) **Please Answer:**

- ○ Yes ○ No **Do you certify that the use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals?**
- ○ Yes ○ No **Do you certify that the research could not practically be conducted with out the waiver?**
- ○ Yes ○ No **Do you certify that you have adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted?**
- ○ Yes ○ No **Do you certify that the research could not practically be conducted with out access to and use of the protected health information?**

c) **Please describe an adequate plan to protect any identifiers from improper use and disclosure.**

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

Save

HIPAA Background

Save

Waiver of Authorization for Recruitment

HIPAA Information Type:* Waiver of Authorization for Recruitment

Title:*

a) **Describe the protected health information (PHI) needed to conduct screening or recruitment. PHI is health information linked to one or more of the HIPAA identifiers. List BOTH health information AND HIPAA identifiers. If you are using STARR , use the Data Privacy Attestation to ensure that your request will match your IRB-approved protocol.**

b) **Please Answer:**

- ○ Yes ○ No **Do you certify that the use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals?**
- ○ Yes ○ No **Do you certify that the research could not practically be conducted with out the waiver?**
- ○ Yes ○ No **Do you certify that you have adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted?**
- ○ Yes ○ No **Do you certify that the research could not practically be conducted with out access to and use of the protected health information?**

c) **Please describe an adequate plan to protect any identifiers from improper use and disclosure.**

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

Save

HIPAA Background

Save

Alteration of Authorization

HIPAA Information Type:* Alteration of Authorization

Title:*

Attachment (optional) Browse... No file selected.

a) **Describe the Protected Health Information (PHI) needed to conduct the research. PHI is health information linked to HIPAA identifiers. List BOTH health information AND HIPAA identifiers. If you are using STARR , use the Data Privacy Attestation to ensure that your request will match your IRB-approved protocol.**

b) **Please Answer:**

- ○ Yes ○ No **Do you certify that the use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals?**
- ○ Yes ○ No **Do you certify that the research could not practically be conducted with out the waiver?**
- ○ Yes ○ No **Do you certify that you have adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted?**
- ○ Yes ○ No **Do you certify that the research could not practically be conducted with out access to and use of the protected health information?**

c) **Please describe an adequate plan to protect any identifiers from improper use and disclosure.**

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

Save

Protocol Application Form

Protocol ID : 74095 (Ratan Banik)
Title : Expedited Sample

Medical EXPEDITED

Expedited Paragraph(s) | 1-3 | 4 | 5,6 | 7 | 8(a-g) | 8(h-m) | 9(a-d) | 9(e) | 10, 11 | 12 | 13 | 14 | 15 | 16

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

Submit Protocol

16. Attachments

Instructions

- Click ADD to attach documents (e.g., federal grant/sub-contract, advertisements, questionnaires, sponsor's protocol, investigator's brochure, etc.).
- To view an attached document, click on the link for that attachment in the *Title* column.
- To remove an attachment, check the box next to the *Title* and click DELETE.

Scientific and Scholarly Validity (SSV) Review

If this study requires review of scientific and scholarly validity by your Department Chair, Division Chief, School Dean or their designee, send them the following link and a copy of your protocol to complete this review. If the Department Chair is a researcher on the protocol, submit the application and the IRB Manager will request this review as appropriate.

- Scientific and Scholarly Validity Review

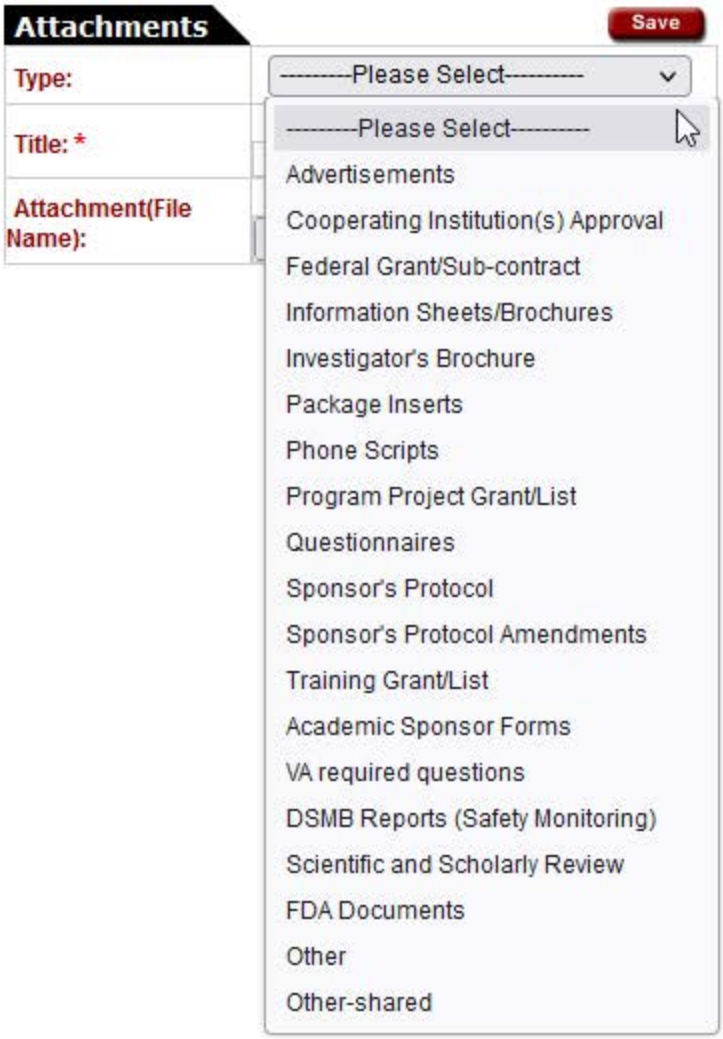
Academic Sponsor Review of Scientific and Scholarly Validity (SSV) and Oversight

If the Protocol Director is a student, Resident, Fellow or Post-Doc and requires an Academic Sponsor, review of scientific and scholarly review and oversight should be completed by the Academic Sponsor using the following link:

- Academic Sponsor Review

Add

Please click on 'Add' to attach documents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Information Sheets/Brochures
Investigator's Brochure
Package Inserts
Phone Scripts
Program Project Grant/List
Questionnaires
Sponsor's Protocol
Sponsor's Protocol Amendments
Training Grant/List
Academic Sponsor Forms
VA required questions
DSMB Reports (Safety Monitoring)
Scientific and Scholarly Review
FDA Documents
Other
Other-shared

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 Stanford 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
- Apply relevant professional standards.

Additional Responsibilities

- Any change or modification in the research protocol must be submitted to and approved by the IRB prior to the implementation of such change, except when necessary to eliminate apparent immediate hazards to the participant.
- For studies with expiration dates, submit a Continuing Review prior to the end of the approval period. An IRB Continuing Review (Renewal) Notice to Renew Protocol is sent to the Protocol Director prior to the expiration date of the protocol.
- Report promptly any new information, complaints, possibly serious and/or continuing noncompliance, or unanticipated problems involving risks to participants or others.

Record Retention

All data, including signed consent forms when applicable, 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 (e.g. 6 years for studies conducted under HIPAA or VAPAHCS). (See also Research Policy Handbook Retention of and Access to 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.

APPROVAL LETTER/NOTICE NOTE: List all items (verbatim) that you want to be included in your approval letter (e.g., Amendment date, Investigator's Brochure version, consent form(s) version(s), advertisement name, etc.) in the box below.