



Banik

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Home » Study Title

### System Requirements:

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

### Before you begin:

If this is your first time submitting a protocol for review, see <u>FAQs</u> 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





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Home » Protocol Title » Personnel Info

### Instructions:

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

PERSONNEL LOOK	UP NSTRUCTIONS: Search by LastName, First	Name (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	
	The state of the s		
CITI Training current		Yes No	
		○ Yes ○ No	
Admin Contact *			
CITI Training current  Admin Contact *  PERSONNEL LOOK  Name *	UP Q	Name (e.g., Smith, John) or by SUNet ID.	





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Home » Protocol Title » Personnel » Application Category/Type

### 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/Ty	ре		Create
Select Application Category :	Medical	0	Non-Medical
Form Type:			
Select a Form Type below to create to IRBeducation@stanford.edu or (65)	[18] - 18 아이들 아니라		more about different review types or contact
Regular	For greater than minimal r	risk studies	
Expedited	For minimal risk studies m	neeting specific crite	<u>ria</u>
Exempt	Studies meeting specific	criteria	
HSR Determination Form Projects that don't clearly qualify as human subjects research. Include the HSR Determination form in your submission.			



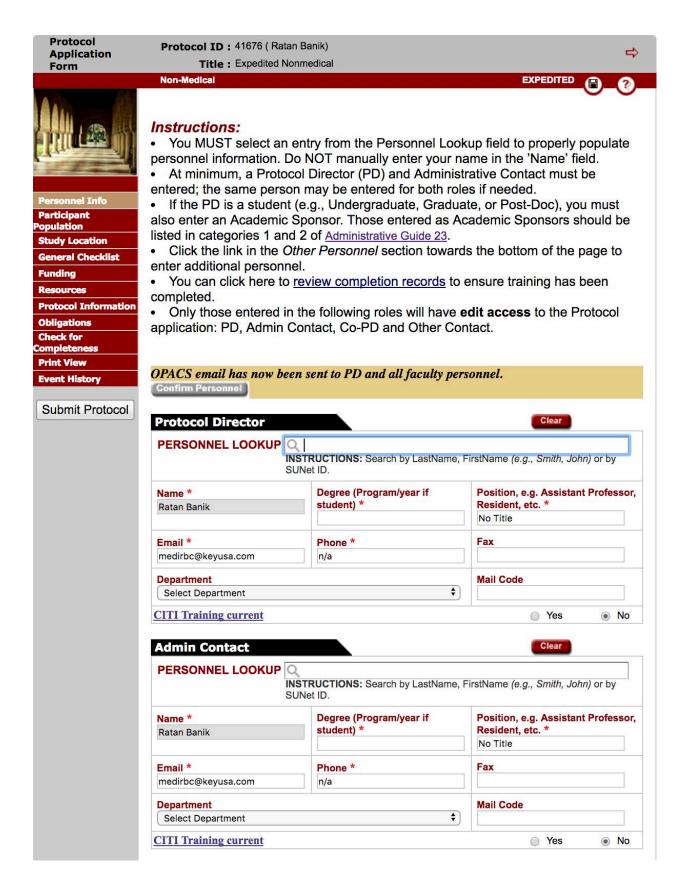


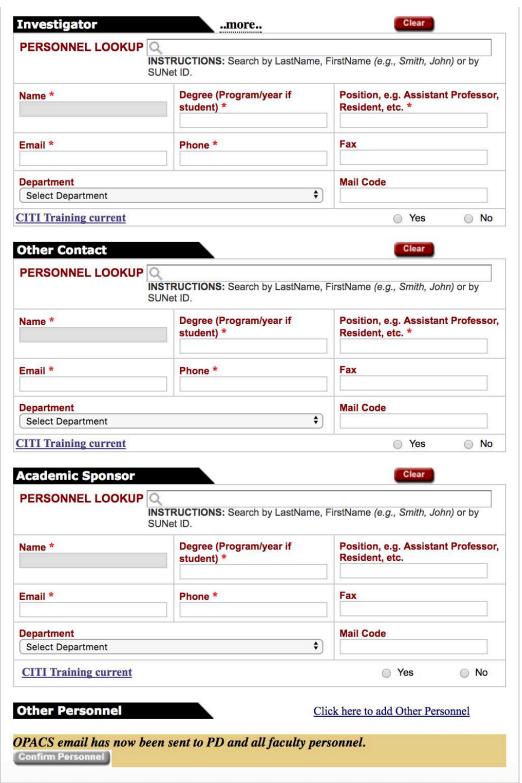
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Home » Protocol Title » Personnel » Application Category/Type » Expedited Review

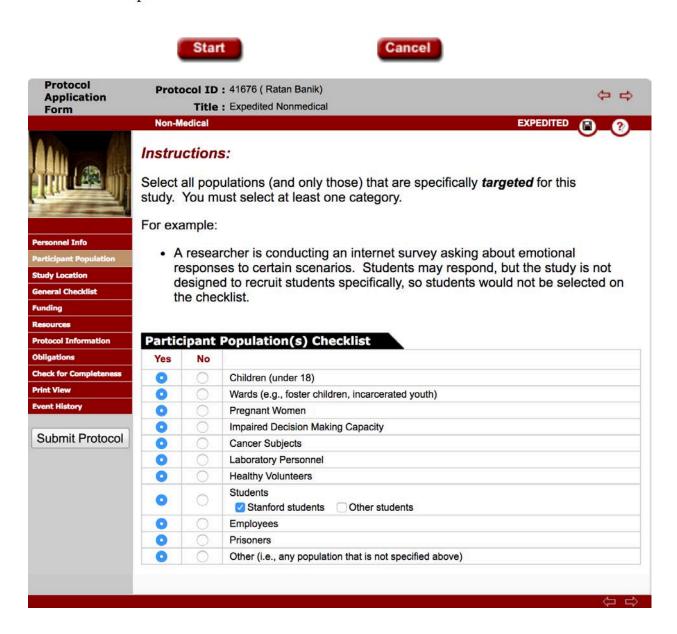
Expedite	ed Paragraphs Create
	must be no more than minimal risk (i.e., "not greater than those ordinarily encountered in daily life") only involve human subjects in one or more of the following categories.
Select o	ne or more applicable expedited categories:
□ 1.	Clinical studies of drugs and medical devices (medical studies only)
2.	Collection of blood samples (medical studies only)
□ 3.	Prospective collection of biological specimens for research purposes by non invasive means.  Example: Collection of saliva or cheek swabs
<b>4.</b>	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.
	<ul> <li>Examples:</li> <li>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;</li> <li>b) Weighing or testing sensory acuity;</li> </ul>
	c) Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
<u> </u>	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.
<b>7.</b>	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.)





Find User	Find
Sunet ID:	
First Name:	
Last Name:	

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

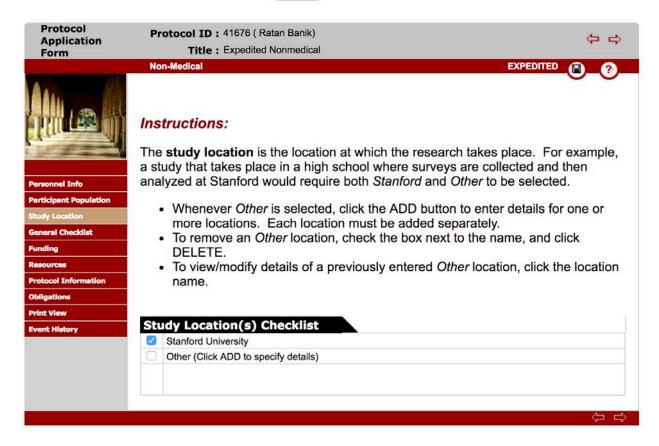


For all Cancer-related studies, see the submission instructions on the Cancer Clinical Trials website at <a href="http://med.stanford.edu/ccto.html">http://med.stanford.edu/ccto.html</a>

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.

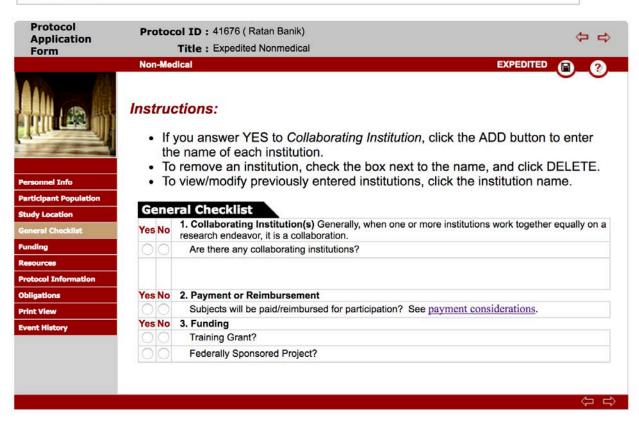




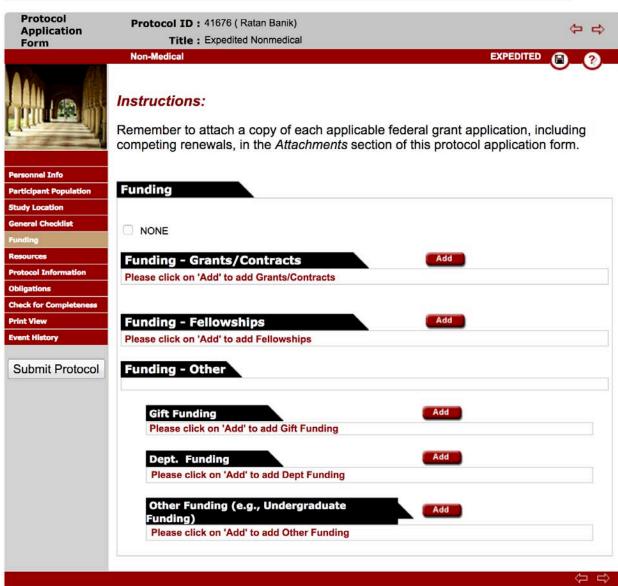
### Choose one. For multiple sites, add each individually.

# Other Location Within the US Location Name: OR Outside the US/International Country:

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



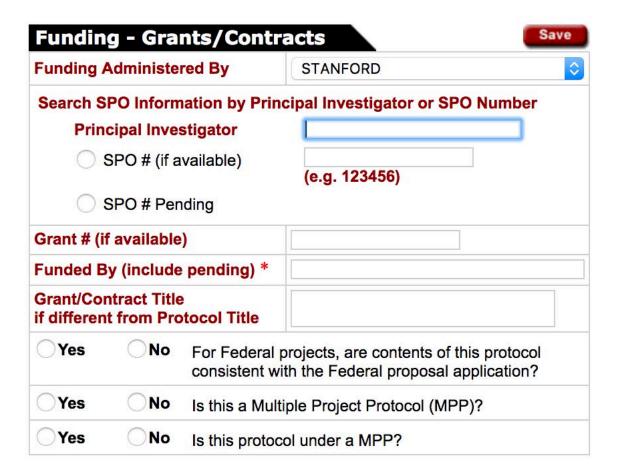




## Instructions:

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

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



Funding - 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			
	jects, are contents of this protocol the Federal proposal application?		
Gift Funding	Save		
Name of Donor *			
Dept. Funding	Save		
Department Name *			
Other Funding (e.g., Under	graduate Funding) Save		
Other Fund Name *			

Protocol Application Form

Protocol ID: 41676 (Ratan Banik)

Title: Expedited Nonmedical





**EXPEDITED** 





**Personnel Info** 

**Participant Population** 

Study Location

General Checklist

Funding

tesources

**Protocol Information** 

**Obligations** 

**Check for Completeness** 

**Print View** 

**Event History** 

Submit Protocol

R	e	S	0	Ш	r	C	e	C

Non-Medical

### a. Qualified staff

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

### b. Training

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

### c. Facilities

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

### d. Time

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

### e. Participant access

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

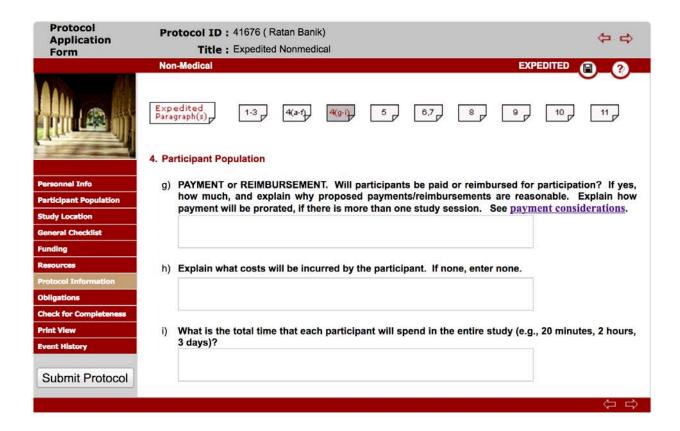
### f. Access to resources

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

Protocol	Protocol ID: 41676 (Ratan Banik)
Application	Title: Expedited Nonmedical
Form	Non-Medical EXPEDITED (a)
	Expedited Paragraph(s) 1-3 4(a-1) 4(g-1) 5 6.7 8 9 10 11  Title Expedited Nonmedical
Personnel Info	
Participant Population	
Study Location	Review your expedited paragraph selection(s) below. Make changes as applicable.
General Checklist	
Funding	Clinical studies of drugs and medical devices (medical studies only)
Resources	
Protocol Information	Collection of blood samples (medical studies only)
Obligations	
Check for Completeness	3. Prospective collection of biological specimens for research purposes by non invasive means.
Print View	Example: Collection of saliva or cheek swabs
Event History	Example. Collection of Saliva of Crieek Swabs
Submit Protocol	4. Collection of data through non invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing.
	Examples:
	<ul> <li>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;</li> </ul>
	<ul><li>b) Weighing or testing sensory acuity;</li></ul>
	c) Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
	5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this paragraph may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
	6. Collection of data from voice, video, digital, or image recordings made for research purposes.
	7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

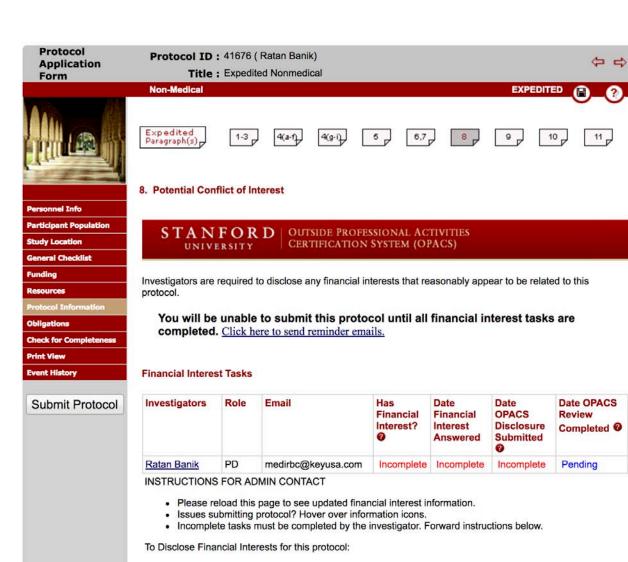
Protocol	Protocol ID: 41676 (Ratan Banik)
Application Form	Title: Expedited Nonmedical
rom	Non-Medical EXPEDITED
	Expedited Paragraph(s) 1-3 4(a-f) 4(g-i) 5 6,7 8 9 10 11 Complete Sections 1 - 11. Specify N/A as appropriate. Do not leave any required sections blank.
Personnel Info	1. Purpose
Participant Population	
Study Location	a) In 3-5 sentences, state the purpose of the study in lay language.
General Checklist	
Funding	
Resources	
Protocol Information	b) State what you hope to learn from the study and assess the importance of this new knowledge.
Obligations	
Check for Completeness	
Print View	2. Study Procedures
Event History	2. Study Procedures
Submit Protocol	a) Describe ALL the procedures human participants will undergo. Are the research procedures the least risky that can be performed consistent with sound research design?  b) State if audio or video recording will occur. Describe how the recordings will be used, e.g., shown at scientific meetings, used for transcription. Describe the final disposition of the recordings, e.g., erased, stored.
	c) DECEPTION: Will participants be fully informed about the purpose of the study? If no: provide a rationale for deception; complete an Alteration of Consent in Section 9; and attach a debriefing script in Section 11, or explain why debriefing would not be appropriate below.  3. Background  a) Describe what led to the formulation of the study.

Protocol Application Form	Pro	otocol ID: 41676 (Ratan Banik)  Title: Expedited Nonmedical	
	Non	n-Medical EXPEDITED 👩 👩	
	Para	edited 1.3 4(a-f) 4(g-i) 5 6.7 8 9 10 11 rticipant Population	
Personnel Info Participant Population Study Location General Checklist Funding	a)	(i) How many participants do you expect to enroll at Stanford? (ii) How many participants do you expect to enroll outside Stanford? (iii) What type of participants will you enroll (e.g., high schoo students, teachers, government officials)?	
Resources	b)	What are the age range, gender, and racial or ethnic background of the participant population	
The state of the s	D)	being targeted?	•
Protocol Information			
Obligations			
Check for Completeness			
Event History  Submit Protocol	c)	If applicable, explain why potential vulnerable participants are needed (e.g., children, pregnam women, students, economically or educationally disadvantaged, homeless, or people with impaired decision making capacity).	
	d)	Will the research include women, minorities, or minors? Provide a rationale for <u>not</u> including these populations if the research might benefit these groups (e.g., results of a survey study about salaries might benefit women, but if you choose not to include them, explain why).	
	e)	Will any participants be your students, laboratory personnel and/or employees? See Stanford University policy at <a href="http://doresearch.stanford.edu/policies/research-policy-handbook/human-subjects-and-stem-cells-research/use-employees-or-laboratory">http://doresearch.stanford.edu/policies/research-policy-handbook/human-subjects-and-stem-cells-research/use-employees-or-laboratory</a> ).	
	f)	How will you recruit participants (e.g., ads, classroom recruitment, word of mouth, letters mailed home, email)? Attach recruitment materials in the <i>Attachments</i> section. YOU MAY NOT CONTACT POTENTIAL PARTICIPANTS PRIOR TO IRB APPROVAL. ALL FINAL OR REVISED RECRUITMENT MATERIALS, FLYERS, ETC. MUST BE SUBMITTED TO THE IRB FOR REVIEW AND APPROVAL BEFORE USE.	r r



Protocol	Protocol ID: 41676 ( Ratan Banik)	44
Application Form	Title: Expedited Nonmedical	~ ~
	Non-Medical EXPEDITED	0
	Expedited Paragraph(s) 1-3 4(a-f) 4(g-i) 5 6.7 8 9 10 5. Risks	11,
Personnel Info	a) In order to qualify for expedited review, the protocol must present no more than minima	
Participant Population	participants. Describe any reasonably anticipated potential risks(s), including risk(s) to psychological, political, economic or social well-being. If risks are not reasonably ant	
Study Location  General Checklist	enter "none"	
Funding		
Resources		
Protocol Information Obligations Check for Completeness Print View Event History	b) If you are conducting research outside the US (international research), describe qualify preparations that enable you to both estimate and minimize risks to participants. Then the International Research Form and attach it in the Attachments section. If not applicate N/A.	complete
Event matery		
Submit Protocol	c) Reserved for future use	
	d) Children's Findings (OHRP)	
	Confirm that your study meets the criteria for 46.404 below:	
	46.404 Research not involving greater than minimal risk. The research must present no than minimal risk to children and adequate provisions must be made for soliciting the ass the children and permission of their parents or guardians.	T. (2007) 100 (2007)
	46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit(regular review only)	
	46.406 Research involving greater than minimal risk and no prospect of direct benefit(review only)	egular
	☐ 46.407 Research not otherwise approvable(regular review only)	
	Provide the rationale that this study presents no greater than minimal risk to children, and whether parental permission will be obtained. If parental permission is to be obtained, indicate one or both parental signatures will be sought.	
	Rationale:	

Protocol Application	Protocol ID: 41676 ( Ratan Banik)	
Form	Title: Expedited Nonmedical	
	Non-Medical EXPEDITED (1)	
	Expedited Paragraph(s) 1.3 4(a-f) 4(g-i) 5 6.7 8 9 10 11 6. Benefits	
Personnel Info	a) Parariba the anti-still benefit(a) to be united by the modificants and/or by society or a result of	
Participant	<ul> <li>a) Describe the potential benefit(s) to be gained by the participants and/or by society as a result of this study. If none, enter 'none.'</li> </ul>	
Population		
Study Location		
General Checklist		
Funding	7. Privacy and Confidentiality	
Resources	Privacy	
Protocol Information	Filvacy	
Obligations Check for	Privacy refers to the environment in which data are collected from participants (e.g., interviewing participants	
Completeness	individually in a place where personal responses will not be seen or overheard).	
Print View	a) Explain where the research takes place (e.g., in a lab, online, at school). Describe how you will	
Event History	maintain privacy in this setting.	
Submit Protocol		
	Confidentiality refers to your agreement with the participant about how the participant's identifiable personal information (i.e., identifiable data) will be handled, managed, stored, and disseminated.  b) What identifiable data will you obtain from participants? Enter 'none' if identifiable data will not be obtained.	
	<ul> <li>c) Describe if applicable:</li> <li>(i) how you will manage the identifiable data (e.g., paper or electronic spreadsheet, desktop computer, laptop or other portable device)</li> <li>(ii) how you will ensure the security of identifiable data (e.g., password protected computer, encrypted files, locked cabinet, locked office);</li> <li>(iii) who will have access to the identifiable data (e.g., research team, sponsors, consultants)</li> </ul>	
	(iv) confirm that all devices on which data will be stored will also be encrypted	
	d) Describe how identifiable data will be transferred (e.g., courier, mail) or transmitted (e.g., file transfer software, file sharing, email). If transmitted via electronic networks, describe how you will secure the data while in transit. See the <a href="Stanford Information Security Office">Stanford Information Security Office</a> website. If not applicable, enter N/A.	
	e) If you plan to code the data, describe the method in which it will be coded and indicate who will have access to the key to the code.	



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

Issues? Please submit an OPACS HelpSU ticket.



Protocol Application	Protocol ID: 41676 (Ratan Banik)	<b>44</b>
Form	Title: Expedited Nonmedical	·ED
44.	Non-Medical EXPEDIT	
	Expedited Paragraph(s) 1.3 4(a-f) 4(g-i) 5 6.7 8 9 9. Consent Information	10 11
Personnel Info		
Participant Population	A protocol should include <u>at least one</u> of the following consent options. More than one may more information on <u>Informed Consent</u> , <u>Waiver of Consent</u> , <u>Waiver of Documentation</u> a <u>Consent</u> .	
Study Location		
General Checklist Funding	<ul> <li>Waiver of Consent         Applicable for research involving identifiable data or records, when asking to waive par or other situations where consent is not possible     </li> </ul>	ental permission,
Resources Protocol Information	<ul> <li>Consent         Applicable for research involving signed consent or parental permission forms     </li> </ul>	
Obligations	<ul> <li>Waiver of Documentation</li> <li>Applicable for internet research or oral consent when a signature is not obtained</li> </ul>	
Check for Completeness	Alteration of Consent	
Print View	Applicable when some required elements of consent are eliminated, such as incomplete	te disclosure of
Event History	the purpose of the research (deception)	
Submit Protocol	For IRB consent form templates, please click <u>here</u>	
	a) Describe the informed consent process. Include the following: Who will obtain c and how will this be done? If you are requesting to completely waive consent, en Consent" in the text boxes a, b and c below.	
	Note: The person obtaining consent must be knowledgeable about the study. Su be devoted to allow the participant to consider whether or not to participate. Step to minimize the possibility of coercion or undue influence.  Note: If consent relates to children, the IRB will determine whether one or two pa	ps must be taken
	are sufficient.	Tonio oignaturo
	b) What procedure will you use to assess if the participant understands the informat the consent? How will the information be provided to participants if they do not u English? See <u>HRPP Chapter 14.6</u> for guidance.	
	c) Are you planning to enroll participants who do not have the capacity to consent?	
	Any consent form document (including information sheets used for consenting) should be at the ADD button below, and then selecting the appropriate option in the drop-down menu.	ttached by clicking
	Instructions:	
	<ul> <li>Click ADD to enter information on one of the above categories ar relevant consent document(s). Once entered and saved, a row we displayed in tabular form for each item entered (Alteration of Con- of Documentation, Waiver of Consent, and Consent).</li> </ul>	vill be
	Consent Background	1
	Please click on 'Add' to add Consent Background	

- Waiver of Consent (or Parental Permission)

   Applicable for research involving identifiable data or records, when asking to waive parental permission,

10 m (10 m) (10 m) (10 m)	when done			
nsent Type	: *	Waiver of Consent		J
tle: *				J
ddress the pecific reas		ur regulatory criteria for a Waiv า:	er of Consent and provid	e protocol-
)   True	False	The research involves no more	than minimal risk to the	participants.
		Examples: The research involver identifiable data, such as student and the key linking identities to the which only the Protocol Director a	records; participant informatic code will be kept in a lock	ation will be code ked cabinet to
Rationa	le for abov	selection:		
)   True	⊚ False	The waiver will not adversely a participants.	ffect the rights and welfa	re of the
		Example: Participants will not be protect the privacy of the participate		
Rationa	le for abov	selection:		
)   True	⊚ False	The research could not practic	ably be carried out withou	ut the waiver.
		Example: Without the waiver of contacting former students who hinformation is not available.		
Rationa	le for abov	selection:		
4)  True	⊚ False	Whenever appropriate, the part pertinent information after part		with additional
		Example: We do not anticipate the share with study participants.	nat there will be any pertine	nt information to
Rationa	le for abov	selection:		

# Consent (or Parental Permission) • Attach consent or parental permission documents to be signed in this section. • Enter a descriptive Title (e.g., use Consent for Controls instead of consentv1.doc). Do NOT use special characters or symbols in the title. • Click BROWSE to locate and attach a file from your desktop. • Click SAVE when done. Consent Type: \* Consent Type: \* Consent Form (file name): \* Choose File No file chosen

Save

## Consent Background

### Waiver of Documentation (Signature)

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

Consent Type: *	Waiver of Documentation		•
Title: *			
Consent Form (file name): *	Choose File	No file chosen	

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

- 45 CFR 46.117(c)(1) For research not subject to FDA regulation, the only record linking the participants and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality; each participant will be asked whether he/she wants documentation linking the participant with the research, and the participant's wishes govern.
- 45 CFR 46.117(c)(2) For research that is not subject to FDA regulation, presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.

Rationale for above selection:				

Save

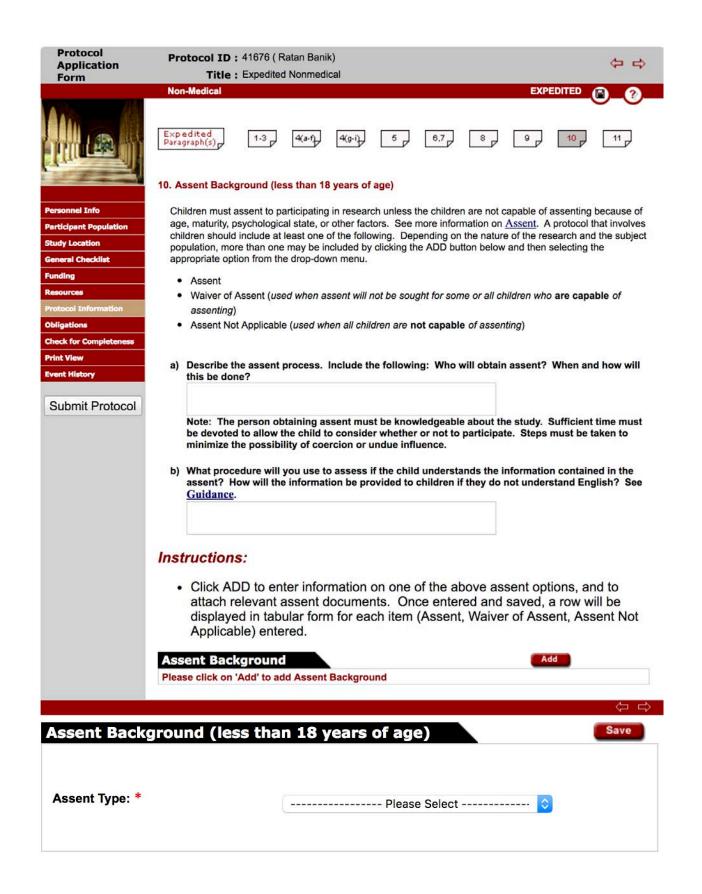
- Alteration of Consent (or Parental Permission)

  Applicable when some required elements of consent are eliminated, such as incomplete disclosure of the purpose of the research (deception).

  Answer all questions as completely as possible. Be sure to include which consent elements you wish to alter in the Rationale text boxes below.

  Click SAVE when done.

Cons	ent Type	*	ſ	Alteration of	Consent	•	
Title:							
Consent Form (file name): *			a· *	Choose File	No file chosen		
CONS	ent i onn	(ine name	,.	Choose The	140 IIIe Chosen		
		following fo ons for eac		y criteria for a	n alteration of co	nsent and prov	ride protocol-
1)	True	False	The researc	h involves no	more than minim	al risk to the p	articipants.
	avoid resp regarding t			ise bias; the pa eir preferences	es not reveal the e rticipants will com participant inform o-investigator will	plete a minimal ration will be cod	isk survey ed, and only the
2)	◯ True	○ False	The Alteration		will not adversel	y affect the rig	nts and welfare
					olves no greater the lid be harmful to a		
	Rational	e for abov	e selection:				
	Rational	e ioi abov	e selection.				
3)	True	False	The researc	h could not pr	acticably be carr	ied out without	the alteration.
					knew the entire p and the data would		
	Rational	e for abov	e selection:				
4)	<b>◯</b> True	False			e participants wil	l be provided w	rith additional
			pertinent in	formation afte	r participation.		
			the opportun	ity to withdraw	be debriefed follow their data if they w rmation, and migh	ish OR debriefin	ng will not add
	Rationale for above selection:						



# Assent • Enter a descriptive Title (e.g., use Assent 7-10 years instead of assentv1.doc). Do NOT use special characters or symbols in the title. • Click BROWSE to locate and attach a file from your desktop. • Click SAVE when done. Assent Type: \* Title: \* Assent Form (file name): \* Choose File No file chosen

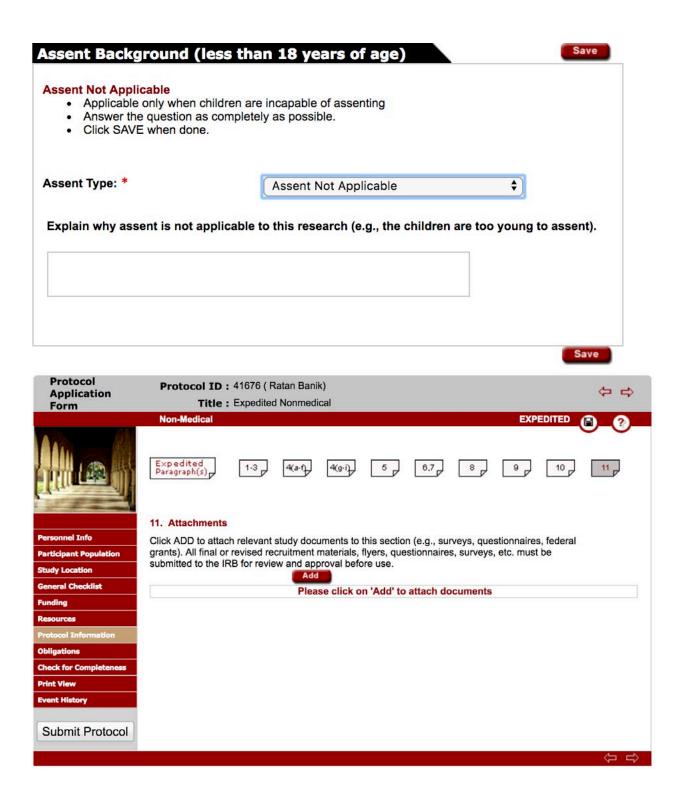
# Assent Background (less than 18 years of age)

Save

### Waiver of Assent

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

As	ssent Type:	*	Waiver of Assent	•
	ddress the f asons for e		egulatory criteria for a waiver of assent and	provide protocol-specific
1)	○ True Rationale f	○ False For above select	The research involves no more than minin	nal risk to the participants.
2)	True	○ False or above selec	The waiver will not adversely affect the rig participants. tion:	hts and welfare of the
3)	True  Rationale f	○ False or above select	The research could not practicably be card	ried out without the waiver.
4)	True  Rationale f	○ False	Whenever appropriate, the participants wi additional pertinent information after partition:	
	N = -	P 44.5 3.73		



Attachments				
Type:				
Title: *				
Attachment(File Name):	Choose File No file chosen			
Advertisements Cooperating Institution(s) Appropriate Federal Grant(s) Questionnaires Training Grant/List Academic Sponsor Oversight				

Scientific and Scholarly Review

FDA Documents

Other

Protocol **Application** Form

Protocol ID: 41676 (Ratan Banik)

Title: Expedited Nonmedical











Personnel Info

Participant Population

Study Location

neral Checklist

**Check for Complete** 

**Event History** 

Submit Protocol

### **Obligations**

Non-Medical

The Protocol Director agrees to:

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

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

IRB approval of any project is at the discretion of the IRB and is usually from one to three years. For continuing projects and activities, it is the responsibility of the investigator(s) to resubmit the project to the IRB for review and re-approval prior to the end of the approval period. A Notice to Renew Protocol is sent to the Protocol Director several weeks prior to the expiration date of the protocol.

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

All data, including signed consent form documents, must be retained for a minimum of three years past the completion of the research. Additional requirements may be imposed by your funding agency, your department, or other entities. (Policy on Retention of and Access to Research Data, Research Policy http://doresearch.stanford.edu/policies/research-policy-handbook/conduct-

research/retention-and-access-research-data)

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