System Requirements:

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

Before you begin:

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

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

What to expect:

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

Study Title Next

Instructions:

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

Protocol Director *

Next

PERSONNEL LOOKUP

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

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

CITI Training current ○ Yes ○ No

Admin Contact *

PERSONNEL LOOKUP

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

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

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

Stanford University | eProtocol

Non-Medical Exempt Protocol ID: 50123 (Ratan Banik) Protocol Title: Exempt Non-Medical

Save Exit

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- General Checklist
- Funding
- Resources

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- Participant Population(g-i)
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- Conflict Of Interest
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- Assent Background
- Attachments
- Obligations
- Check for Completeness
- Event History

Personnel Info Help Print Next →

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

Protocol Director

Clear

Search

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

Name * Ratan Banik

Degree (Program/year if student) * n/a

Position, e.g. Assistant Professor, Resident, etc. * n/a

E-mail * medirbc@keyusa.com

Phone * n/a

Fax

Department * -SHC

Mail Code

CITI Training current ○ Yes ◉ No

Admin Contact

Clear

Search

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

Name * Ratan Banik

Degree (Program/year if student) * n/a

Position, e.g. Assistant Professor, Resident, etc. * n/a

E-mail * medirbc@keyusa.com

Phone * n/a

Fax

Department * -SHC

Mail Code

CITI Training current ○ Yes ◉ No

Investigator

Clear

Search

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. *

E-mail *

Phone *

Fax

Department *

Mail Code

CITI Training current ○ Yes ○ No

Other Contact

Clear

Search

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. *

E-mail *

Phone *

Fax

Department *

Mail Code

CITI Training current ○ Yes ○ No

Academic Sponsor

Clear

Search

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. *

E-mail *

Phone *

Fax

Department *

Mail Code

CITI Training current ○ Yes ○ No

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

Instructions

Instructions:

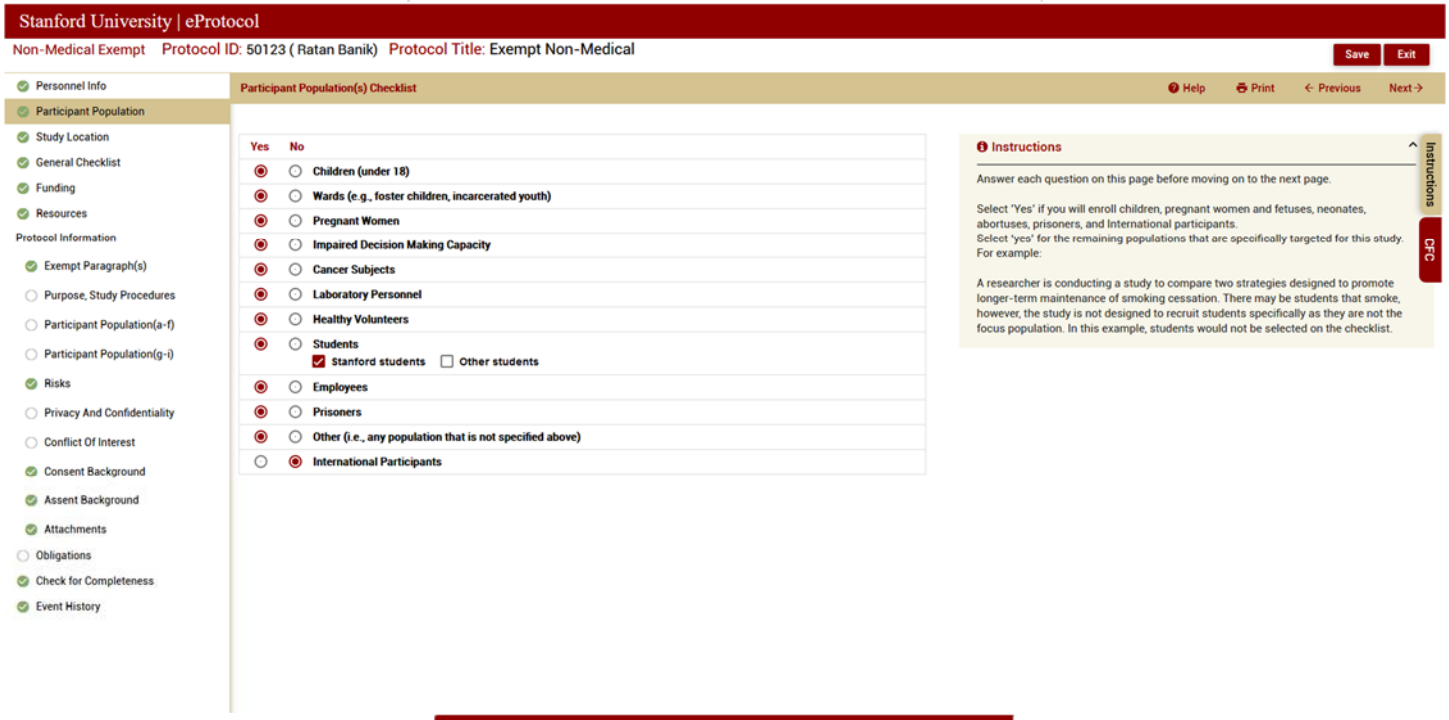
- You MUST select an entry from the Personnle Lookup field to properly populate personnel information. Do NOT manually enter your name in the 'Name' field.
- At minimum, a Protocol Director (PD) and Administrative Contact must be entered; the same person may be entered for both roles if needed.
- If the PD is a student (e.g., Undergraduate, Graduate, or Post-Doc), you must also enter an Academic Sponsor. Those entered as Academic Sponsors should be listed in categories 1 and 2 of Administrative Guide 23.
- Only those entered in the following roles will have **edit access** to the Protocol application: PD, Admin Contact, Investigator and Other Contact.
- Click the link in the *Other Personnel* section towards the bottom of the page to enter additional personnel (including persons without SUNetIDs).
- All users must take CITI training. If your training information is highlighted, it will be verified by IRB staff.
- You can click here to review completion records to ensure training has been completed.

Instructions CFC

Save ×

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

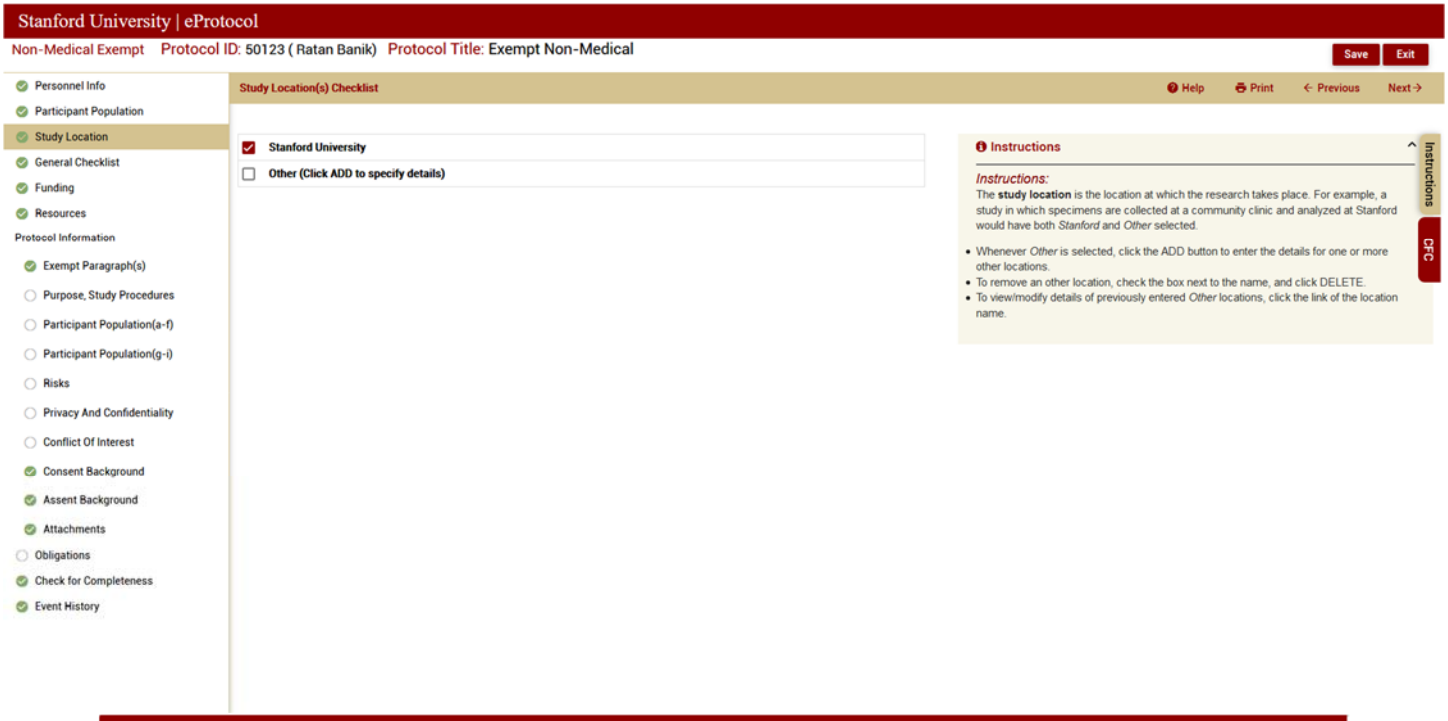
Start Cancel



×

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


Stanford University | eProtocol
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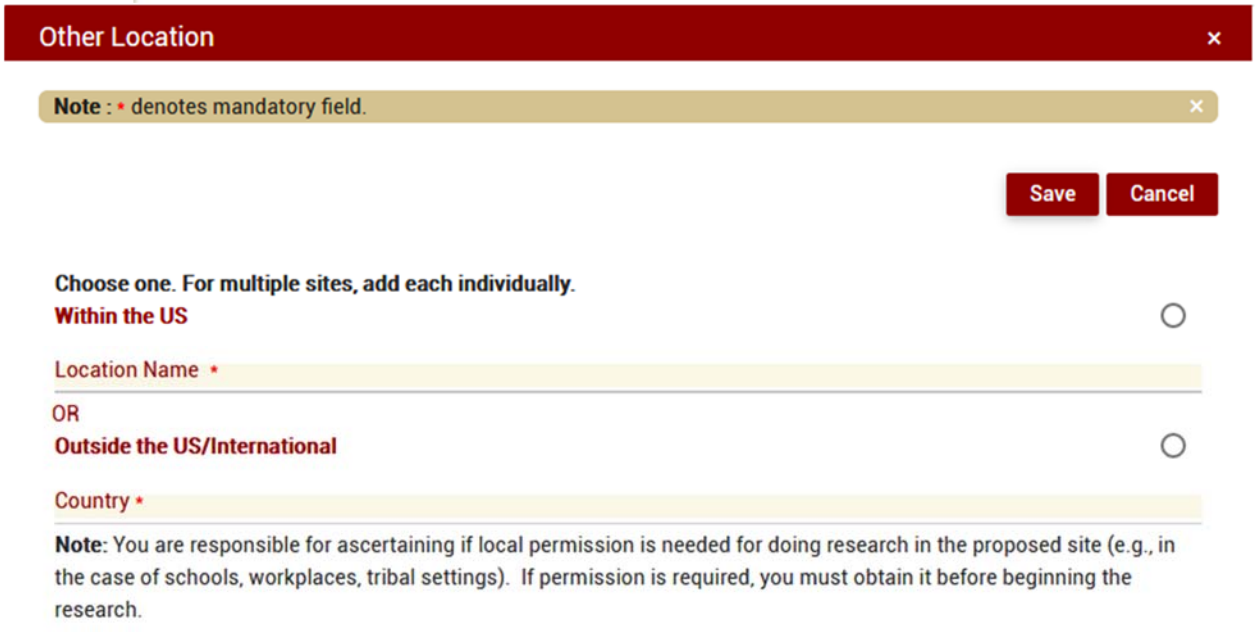
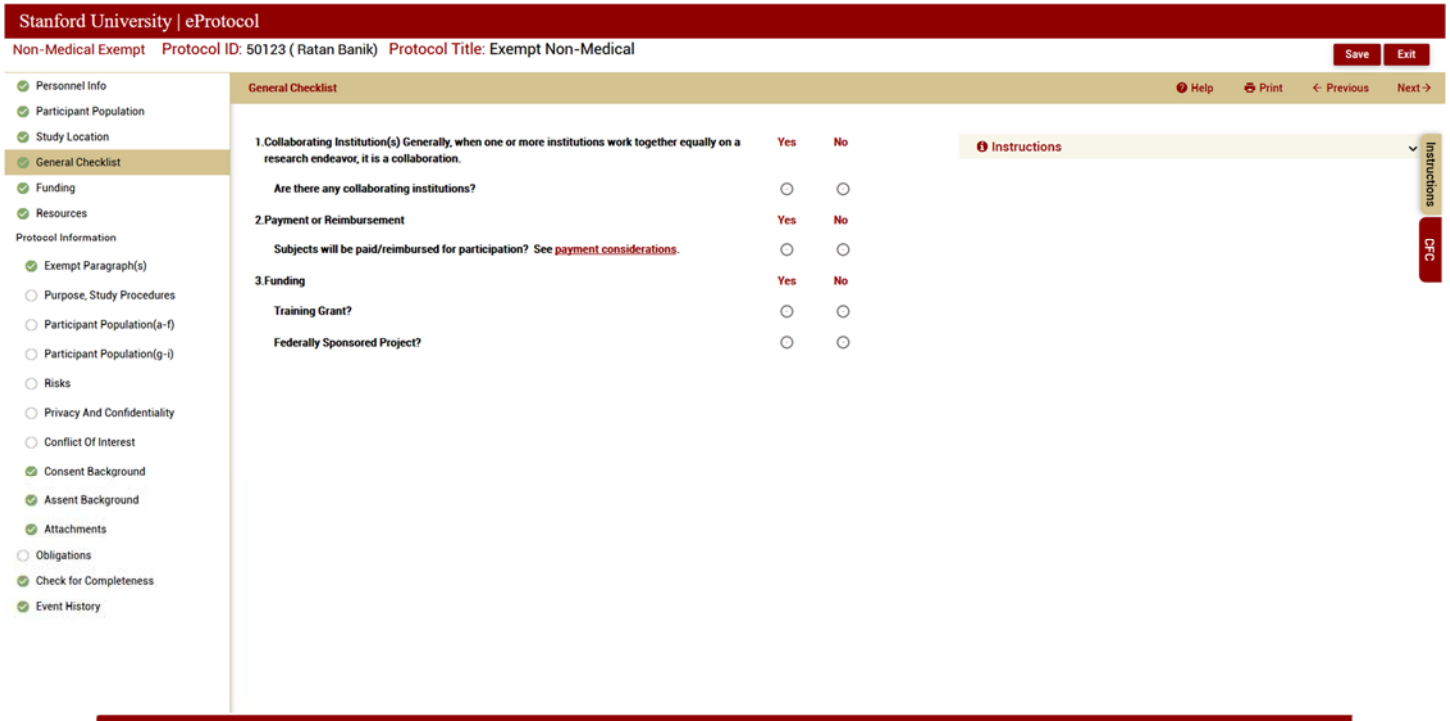
Other (Click ADD to specify details)
Instructions
Instructions:
The study location is the location at which the research takes place. For example, a study in which specimens are collected at a community clinic and analyzed at Stanford would have both Stanford and Other selected.
Whenever Other is selected, 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.
Instructions
CFC


Other Location
Note : * denotes mandatory field.
Save
Cancel
Choose one. For multiple sites, add each individually.
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.


Stanford University | eProtocol
Non-Medical Exempt Protocol ID: 50123 (Ratan Banik) Protocol Title: Exempt Non-Medical
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1.Collaborating Institution(s) Generally, when one or more institutions work together equally on a research endeavor, it is a collaboration.
Yes
No
Are there any collaborating institutions?
2.Payment or Reimbursement
Yes
No
Subjects will be paid/reimbursed for participation? See payment considerations.
3.Funding
Yes
No
Training Grant?
Federally Sponsored Project?
Instructions
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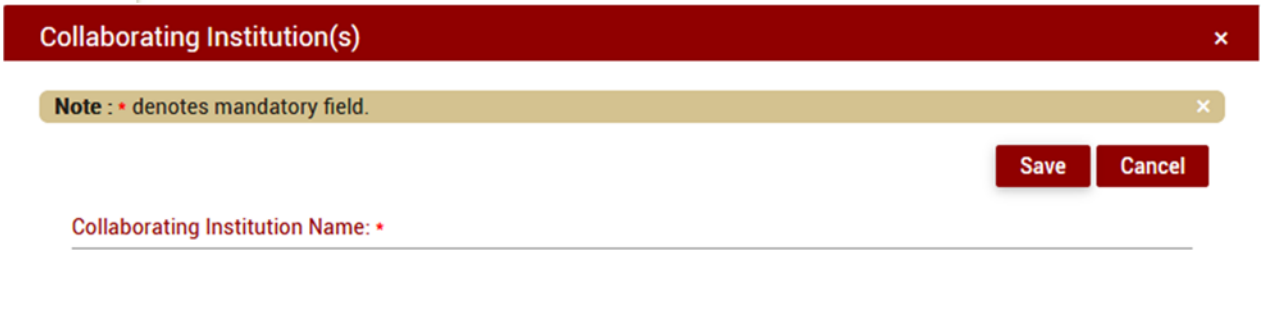
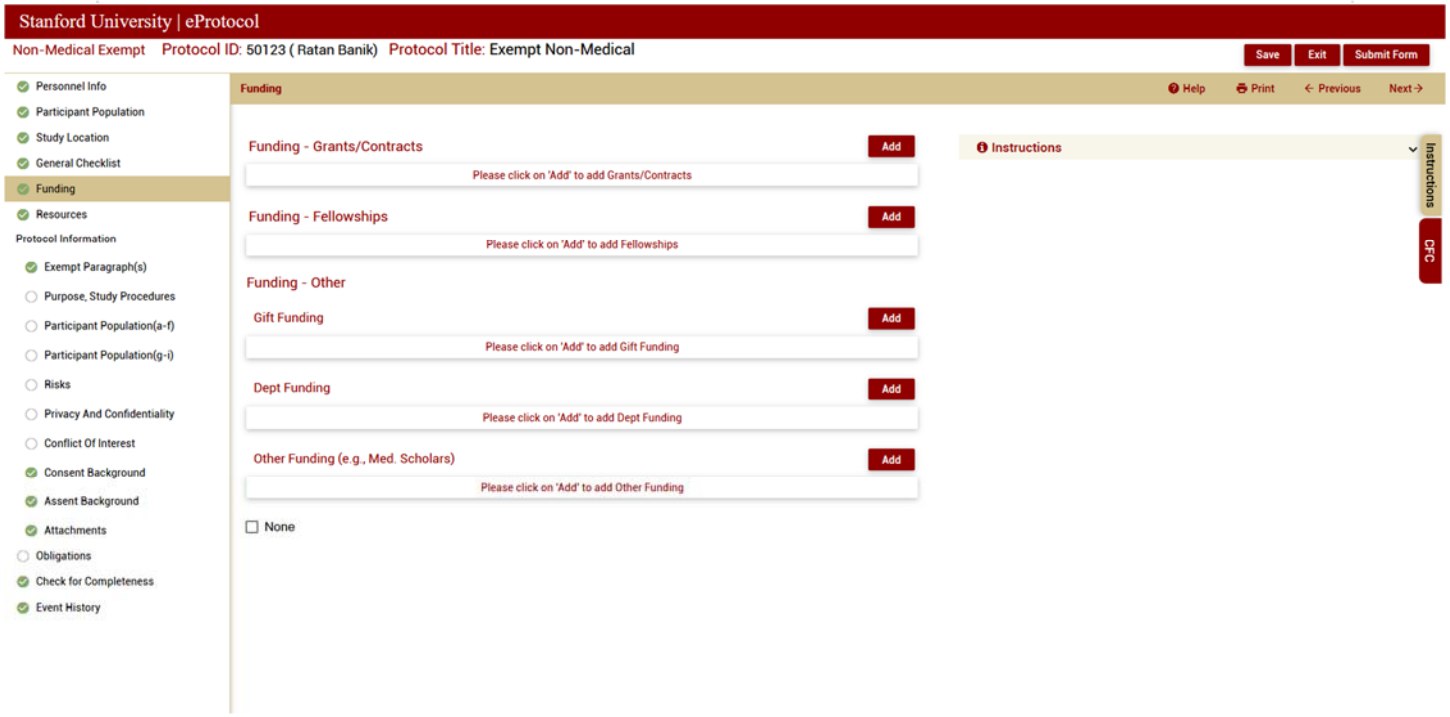
CFC


Collaborating Institution(s)
Note : * denotes mandatory field.
Save
Cancel
Collaborating Institution Name: *


Stanford University | eProtocol
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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
None
Instructions
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CFC

Funding - Grants/Contracts

Note : • denotes mandatory field.

Instructions :

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.

Save Cancel

Funding Administered By

STANFORD

Search SPO Information by Principal Investigator or SPO Number

Principal Investigator

○ SPO # (if available) ○ SPO # Pending

(e.g. 123456)

Grant # (if available)

Funded By (include pending) •

Grant/Contract Title if different from Protocol Title

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

Funding - Fellowships

Note : • denotes mandatory field.

Save Cancel

Funding administered by

STANFORD

Search SPO Information by Principal Investigator or SPO Number

Name of Fellow •

○ SPO # (if available) ○ SPO # Pending ○ N/A

(e.g. 123456)

Fellowship Reference # (if available)

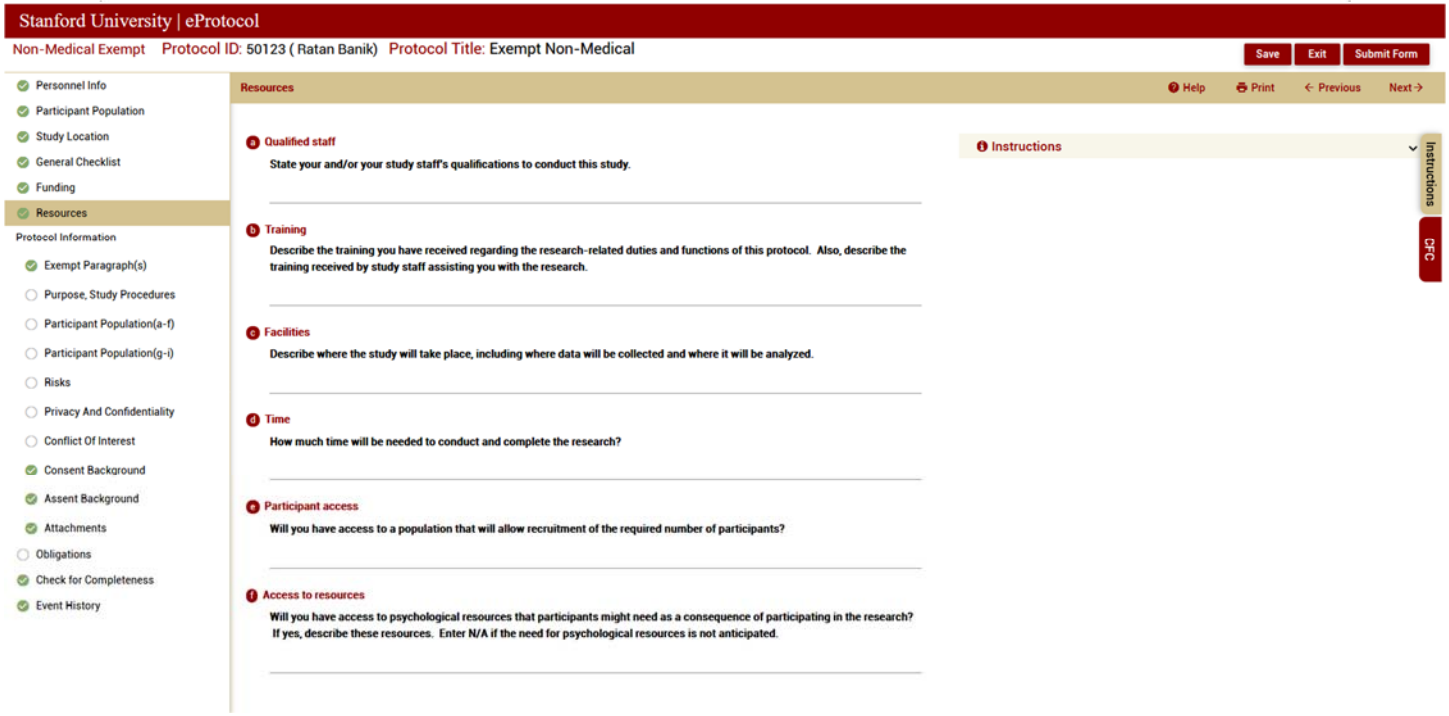
Funded By

Fellowship Title if different from Protocol Title

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


Gift Funding
Note : * denotes mandatory field.
Save
Cancel
Name of Donor *


Other Funding (e.g., Med. Scholars)
Note : * denotes mandatory field.
Save
Cancel
Other Fund Name *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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.
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CFC

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  - Risks
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  - Assent Background
  - Attachments
- Obligations
- Check for Completeness
- Event History

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Title

Exempt Non-Medical

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

Select one or more of the following paragraphs:

☑ **1. Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.**

☐ **2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:**

- ☐ **i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;**
- ☐ **ii) Any disclosure of the human subjects responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, educational advancement, or reputation; or**
- ☐ **iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § .111(a)(7)**

☐ **3. (i)Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:** See (3)(ii) below for more on the definition of a benign behavioral intervention.

- ☐ **A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;**
- ☐ **B) Any disclosure of the human subjects responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, educational advancement, or reputation; or**
- ☐ **C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § .111(a)(7).**

ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

Is deception involved? ○ Yes ○ No

☐ **4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:**

- ☐ **i) The identifiable private information or identifiable biospecimens are publicly available;**
- ☐ **ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;**

iii) Reserved for future use.

- ☐ **iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.**

☐ **5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.**

i) Each Federal department or agency conducting or supporting the research and (i) demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

ii) [Reserved]

☐ **6. Taste and food quality evaluation and consumer acceptance studies:**

- ☐ **i) If wholesome foods without additives are consumed, or**
- ☐ **ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.**

7. Reserved for future use.
8. Reserved for future use.

Instructions

Instructions CFC

Federal Regulations State That Certain Research Is Exempt From Irb Review. However, under Stanford's Human Research Protection Program (HRPP), a research protocol proposing the use of human subjects must be submitted to the IRB to determine if it qualifies for exempt status.All protocols must meet Stanford HRPP ethical standards governing the conduct of research. Exempt status WILL NOT be granted when research:

- involves prisoners as participants, EXCEPT for research aimed at involving a broader subject population that only incidentally includes prisoners
- involves children in category 1, EXCEPT for educational tests or the observation of behavior when the investigator does not participate in the activities being observed
- involves children in category 2, EXCEPT for educational tests or the observation of public behavior when the investigator does not participate in the activities being observed under paragraphs (2)(i) and (ii); paragraph (2)(iii) may not be applied to children
- involves children in category 3

1 Purpose

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

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

2 Study Procedures

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

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

c) Does the study involve deception? Deception occurs when information about the study is deliberately withheld from subjects, or when subjects are intentionally misled about the study. If this study includes deception:
(i) Explain and justify the deception
(ii) Explain the debriefing procedure (ensure a debriefing document is attached to the protocol) OR explain why debriefing would not be appropriate

3 Reserved for future use

Instructions

Instructions

CFC

Stanford University | eProtocol

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Protocol Information / Purpose, Study Procedures

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1 Purpose

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3 Reserved for future use

Instructions

Instructions

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Stanford University | eProtocol

Non-Medical Exempt Protocol ID: 50123 (Ratan Banik) Protocol Title: Exempt Non-Medical

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4 Participant Population

a) How many participants do you expect to enroll? What type of participants will you enroll (e.g., high school students, teachers, government officials)?

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

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

d) Reserved for future use

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

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

Instructions

Instructions CFC

Stanford University | eProtocol

Non-Medical Exempt Protocol ID: 50123 (Ratan Banik) Protocol Title: Exempt Non-Medical

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Protocol Information / Participant Population(g-i)

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4 Participant Population

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

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

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

Instructions

Instructions CFC

Stanford University | eProtocol

Non-Medical Exempt Protocol ID: 50123 (Ratan Banik) Protocol Title: Exempt Non-Medical

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- Privacy And Confidentiality
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Protocol Information / Risks

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5 Risks

a) Describe any reasonably anticipated potential risks(s), including risk(s) to physical, psychological, political, economic or social well-being. If risks are not reasonably anticipated, enter 'none'.

b) If you are conducting research outside the US (international research), describe qualifications/ preparations that enable you to both estimate and minimize risks to participants. Please review the Listing of Social-Behavioral Research Standards, to ensure that your research complies with all applicable standards. Then complete the International Research Form and attach it in the *Attachments* section. If not applicable, enter N/A.

c) Will you be working with any Political Action Committees or other political organizations that are involved in partisan activities? If yes, describe below. See Admin Guide 1.5.1 for restrictions on doing research involving partisan organizations.

d) Children's Findings (OHRP)

Select the category below that best describes your research, if children are involved.

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

Rationale:

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Protocol Information / Privacy And Confidentiality

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6 Benefits

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

7 Privacy and Confidentiality

Privacy

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

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

Confidentiality

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

b) What identifiable data will you obtain from participants? Enter 'none' if identifiable data will not be obtained. Discuss how you will protect the participants' identity, if applicable.

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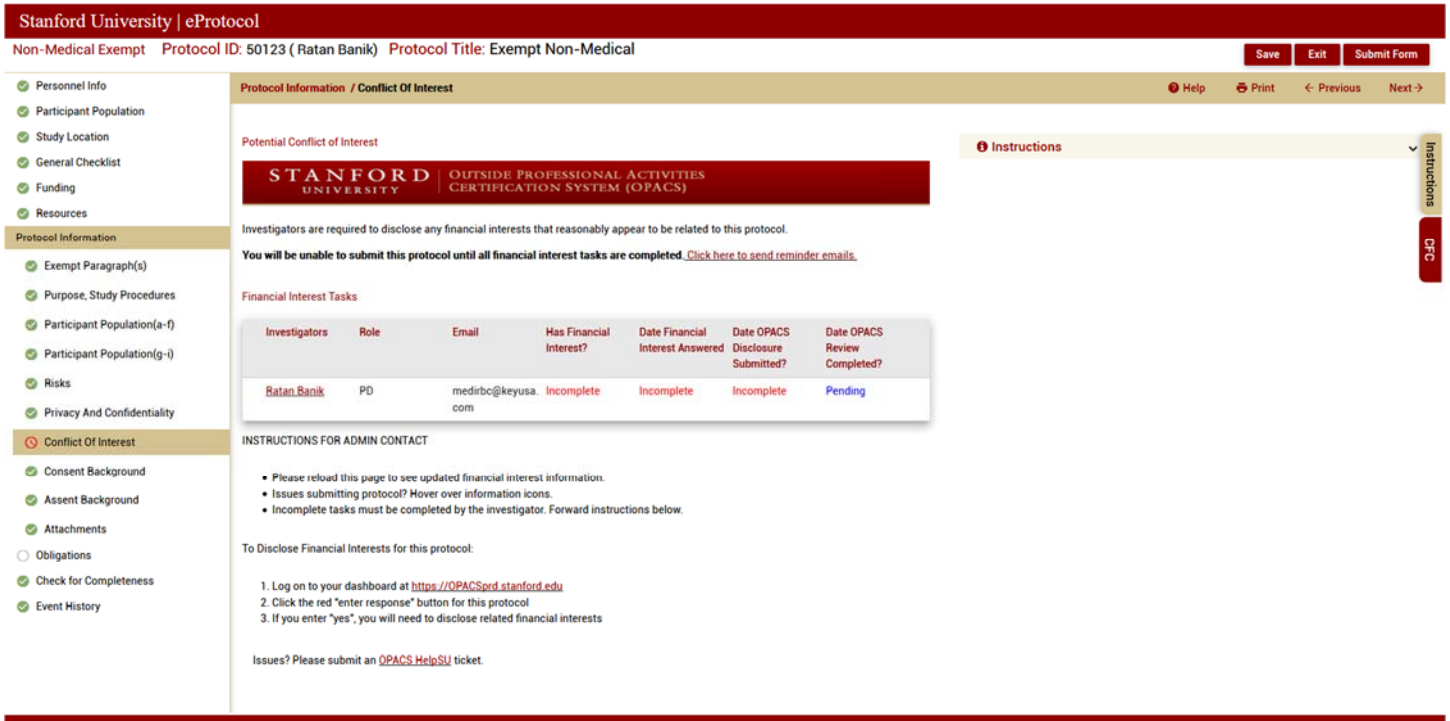
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Potential Conflict of Interest
STANFORD UNIVERSITY | OUTSIDE PROFESSIONAL ACTIVITIES CERTIFICATION SYSTEM (OPACS)
Investigators are required to disclose any financial interests that reasonably appear to be related to this protocol.
You will be unable to submit this protocol until all financial interest tasks are completed. Click here to send reminder emails.
Financial Interest Tasks
Investigators
Role
Email
Has Financial Interest?
Date Financial Interest Answered
Date OPACS Disclosure Submitted?
Date OPACS Review Completed?
Ratan Banik
PD
medirbc@keyusa.com
Incomplete
Incomplete
Incomplete
Pending
INSTRUCTIONS FOR ADMIN CONTACT
Please reload this page to see updated financial interest information.
Issues submitting protocol? Hover over information icons.
Incomplete tasks must be completed by the investigator. Forward instructions below.
To Disclose Financial Interests for this protocol:
1. Log on to your dashboard at https://OPACSprd.stanford.edu
2. Click the red "enter response" button for this protocol
3. If you enter "yes", you will need to disclose related financial interests
Issues? Please submit an OPACS HelpSU ticket.
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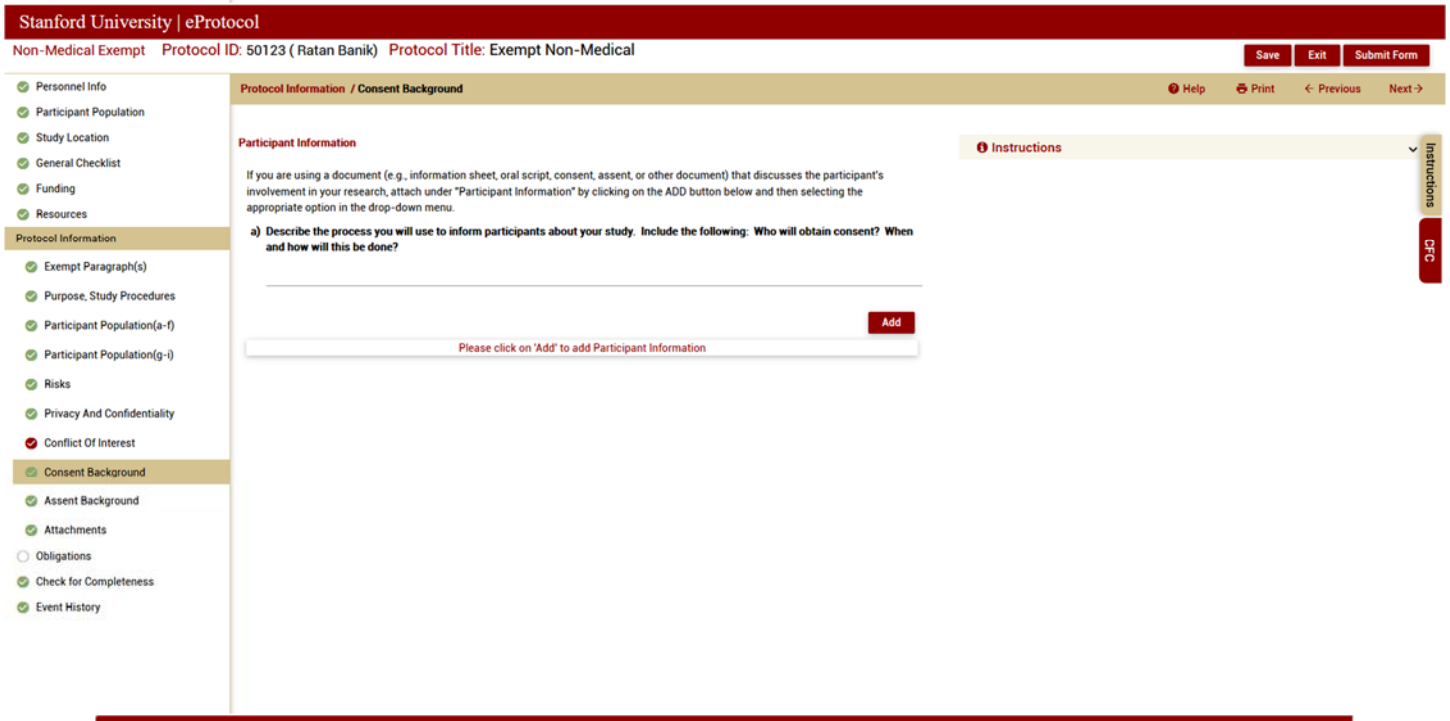
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Participant Information
If you are using a document (e.g., information sheet, oral script, consent, assent, or other document) that discusses the participant's involvement in your research, attach under "Participant Information" by clicking on the ADD button below and then selecting the appropriate option in the drop-down menu.
a) Describe the process you will use to inform participants about your study. Include the following: Who will obtain consent? When and how will this be done?
Add
Please click on 'Add' to add Participant Information
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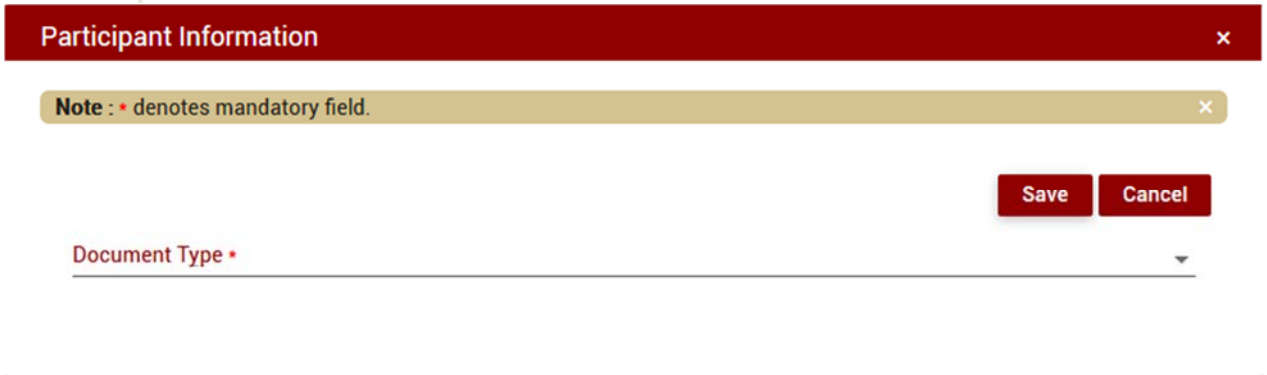
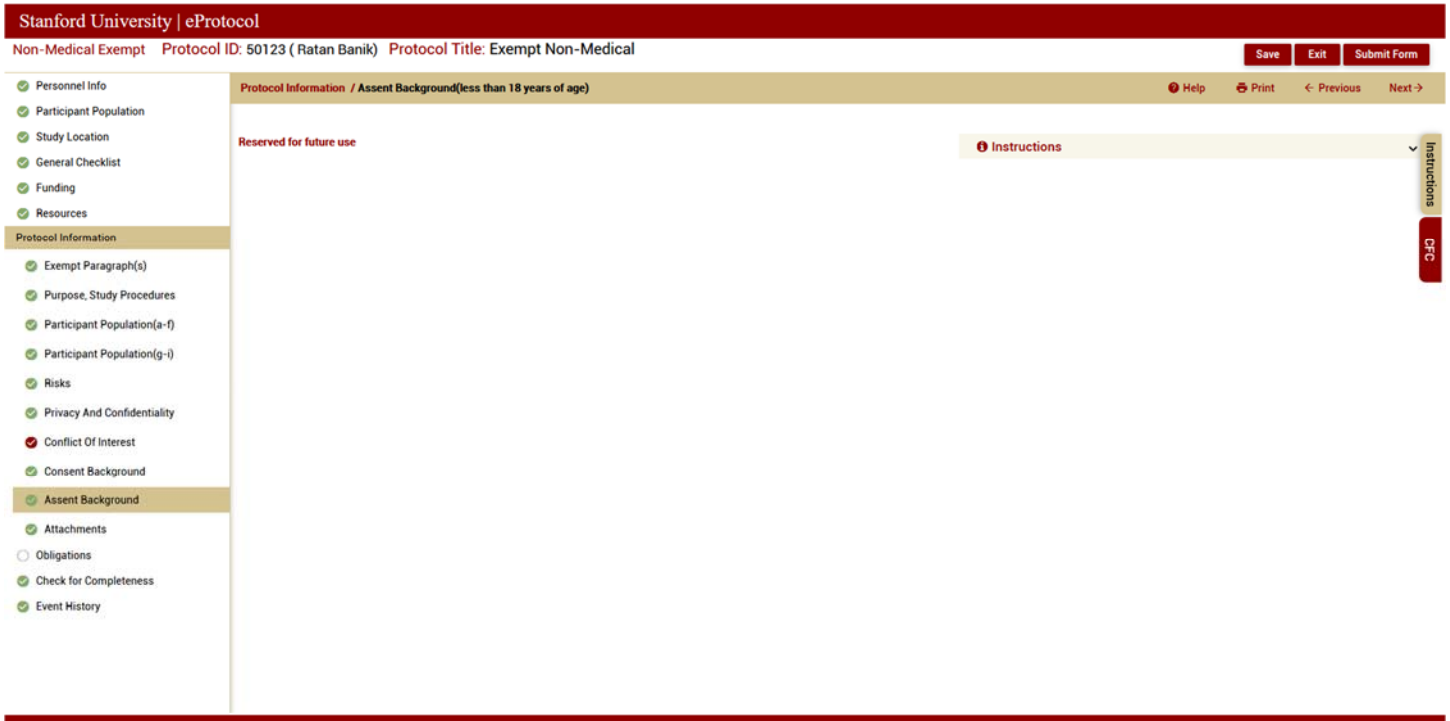

Participant Information
Note : * denotes mandatory field.
Save
Cancel
Document Type *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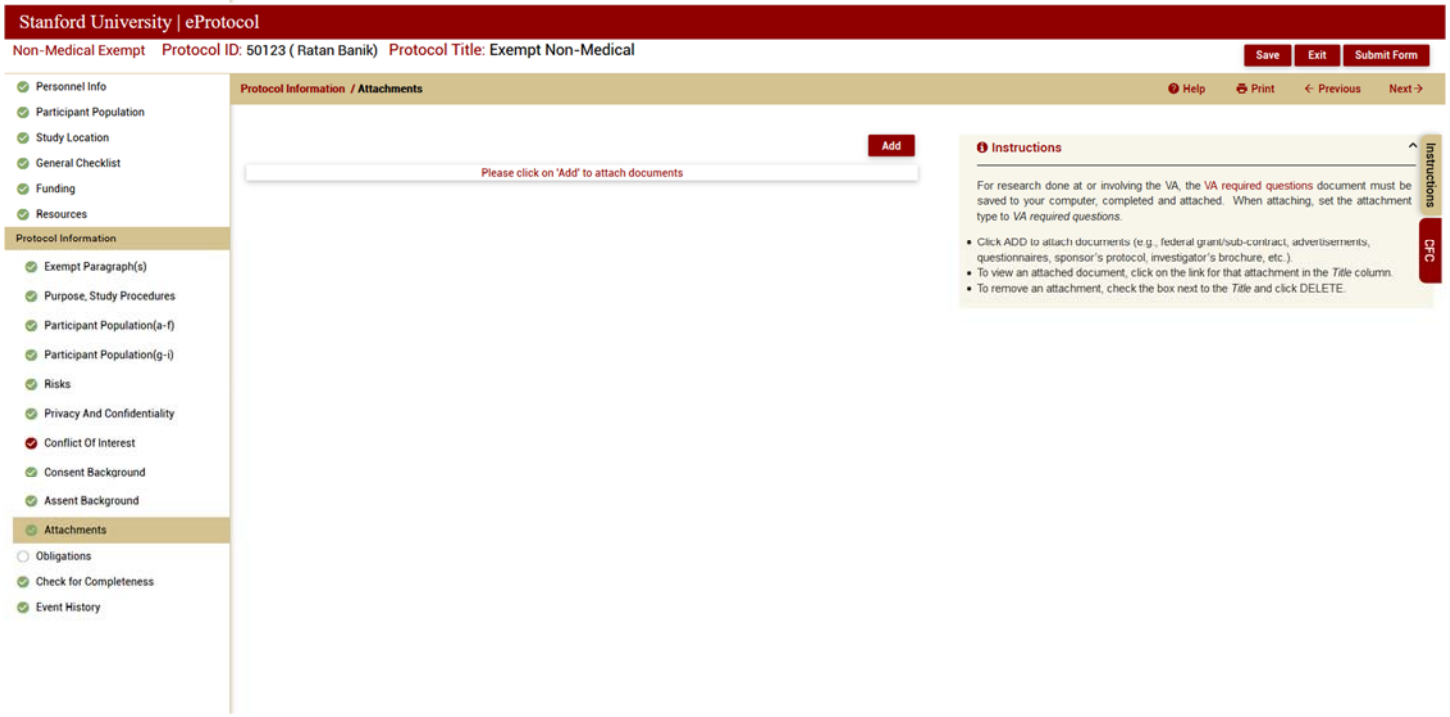
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Add
Please click on 'Add' to attach documents
Instructions
For research done at or involving the VA, the VA required questions document must be saved to your computer, completed and attached. When attaching, set the attachment type to VA required questions.
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.
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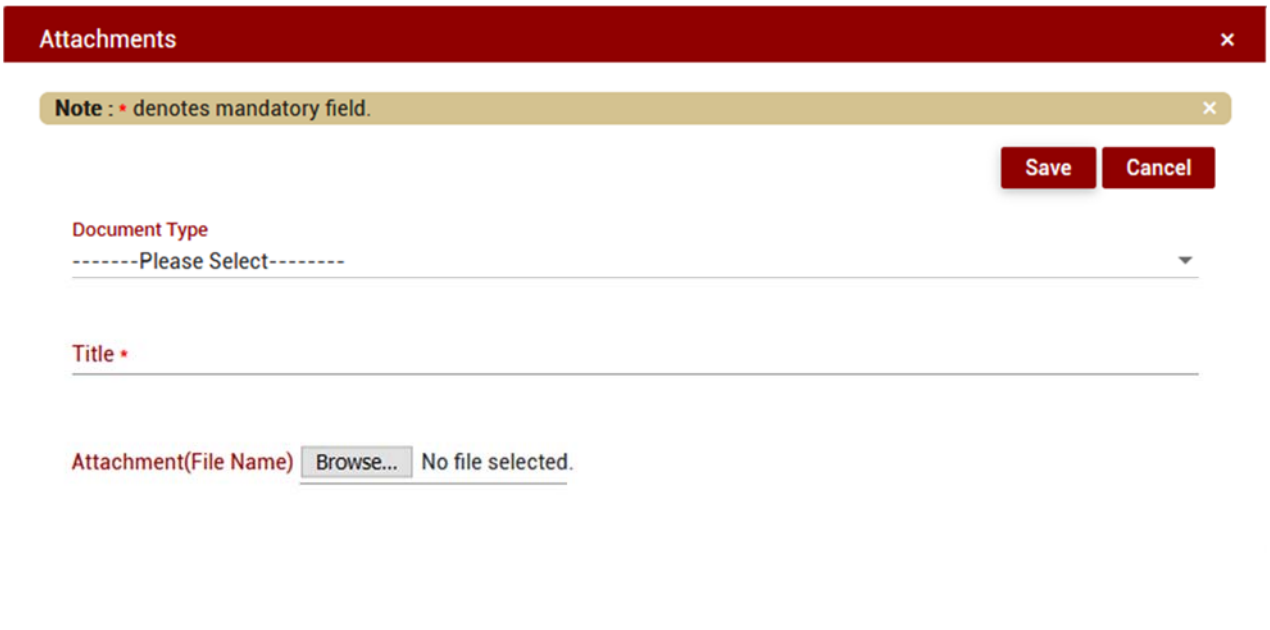
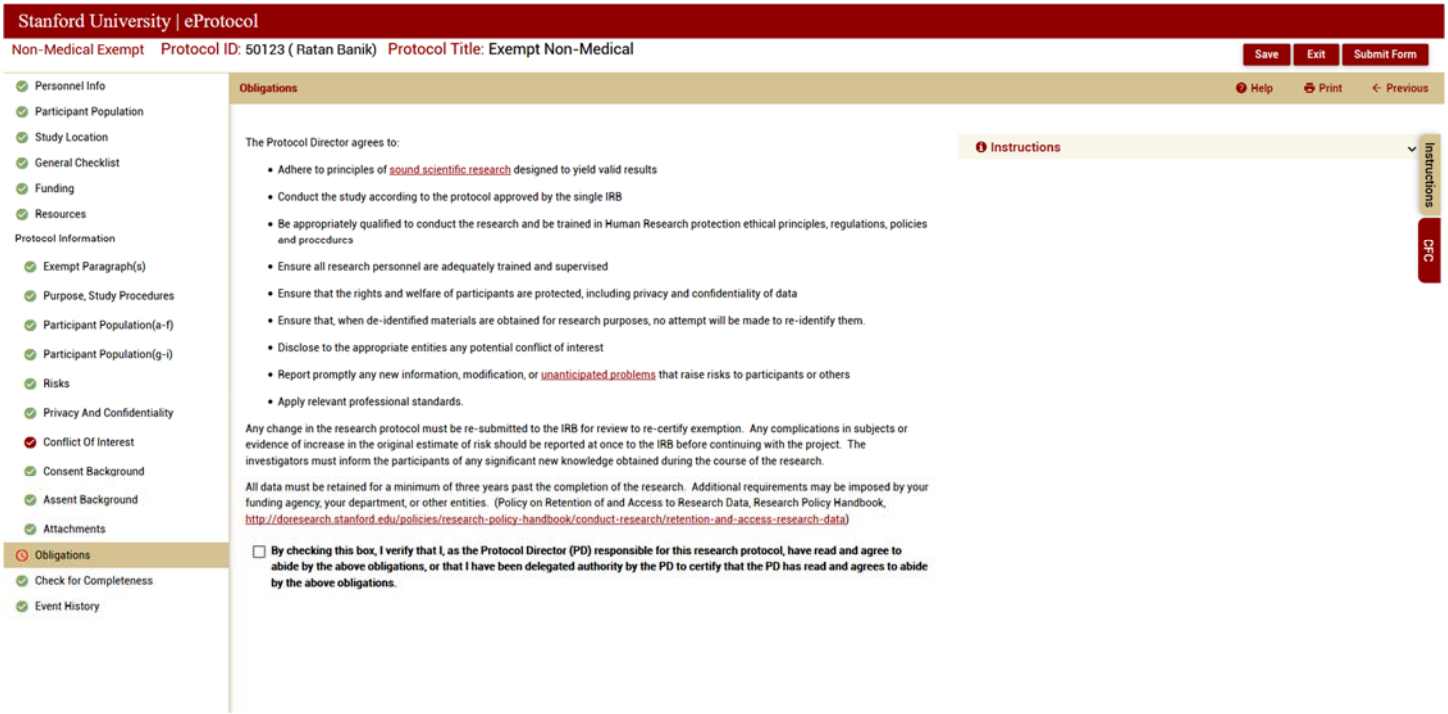

Attachments
Note : * denotes mandatory field.
Save
Cancel
Document Type
-------Please Select--------
Title *
Attachment(File Name)
Browse...
No file selected.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The Protocol Director agrees to:
Adhere to principles of sound scientific research designed to yield valid results
Conduct the study according to the protocol approved by the single IRB
Be appropriately qualified to conduct the research and be trained in Human Research protection ethical principles, regulations, policies and procedures
Ensure all research personnel are adequately trained and supervised
Ensure that the rights and welfare of participants are protected, including privacy and confidentiality of data
Ensure that, when de-identified materials are obtained for research purposes, no attempt will be made to re-identify them.
Disclose to the appropriate entities any potential conflict of interest
Report promptly any new information, modification, or unanticipated problems that raise risks to participants or others
Apply relevant professional standards.
Any change in the research protocol must be re-submitted to the IRB for review to re-certify exemption. Any complications in subjects 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.
All data must be retained for a minimum of three years past the completion of the research. Additional requirements may be imposed by your funding agency, your department, or other entities. (Policy on Retention of and Access to Research Data, Research Policy Handbook, http://doresearch.stanford.edu/policies/research-policy-handbook/conduct-research/retention-and-access-research-data)
By checking this box, I verify that I, as the Protocol Director (PD) responsible for this research protocol, have read and agree to abide by the above obligations, or that I have been delegated authority by the PD to certify that the PD has read and agrees to abide by the above obligations.
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