Information About eProtocol Sections for Non-Medical Applications

Protocol Summary
Your protocol summary should be a thumbnail sketch of your purpose and procedures, and should be written for the layperson. You should cover everything, but not in great detail.

Example of purpose written in lay language for the IRB Non-Medical Application Process:

The purpose of this project is to create a classroom observation tool. We will refine and validate the tool through actual classroom observation. The measure will allow us to study aspects of classroom environments, such as type of instruction, physical classroom arrangements, and interactions between students, variables that may predict academic achievement for students who have limited English proficiency.

Study Procedures
Be sure to describe what data you plan to collect and how you will collect the data. Consider the following:

- **Location**: Are you choosing a site that protects your subjects’ privacy and/or security? If you’re working in an institutional setting, e.g. a school, do you have permission from the site?
- **Duration**: Over how long a period of time will subjects be involved? How many times are you going to be in contact with your subjects? How much time will they be asked to spend at each session? If there will be follow-ups, explain when and how you will contact the participants.
- **Rationale**: Do any of your procedures present risk to subjects? If so, explain why you need to do them.

Audio or Video Recording
If you intend to use audio or video recording, explain what you will do with the tapes following the study, i.e. will they be presented in conferences, etc.? If you will use the recordings in presentations, etc, please explain whether the tapes will include any identifying information about the participants and whether you will ask for explicit permission from the participants to show the tapes. Describe the final disposition of the tapes.

Subject Population
Who are your subjects? How many participants will you recruit? How will you decide who to approach? Will you include any vulnerable populations? If so, why?
Note that if you believe the project presents no more than minimal risk to children and it would be impracticable to obtain consent from parents, you may request a waiver of parental consent. (For more information, see Consent Procedures below.)

Recruitment
How will you make your first contact with subjects? If you'll be posting fliers, explain where fliers will be posted and provide the text of the fliers. If you'll be contacting subjects via email, explain how you will get their contact information and provide the email you will send to the potential participants. All final or revised recruitment materials, flyers, etc. must be submitted to the IRB for review and approval before use.

Payment
Will you pay the participants? If yes, state how much and explain whether you will pay them in cash, gift cards, etc.

Please note that if your research includes students and non-students, students must have the opportunity to get paid even if they usually complete studies for credit. Also, all participants should be compensated the same amount if they do the same task, even if some participants do the study online at home and some will have to come to the lab.

Please note that if you wish to have a drawing, you must allow anyone to enter your drawing, even if they do not want to participate or do not participate in your research study (e.g. do not complete the study task). This means you must state in your recruitment efforts (flyer, internet and/or email recruitment materials) and the consent form that anyone is eligible to enter your drawing by contacting you. There can be no obligation for anyone to actually participate in your research study in order to be eligible for the drawing. You must allow anyone to enter who would like to be in the drawing, per California law.

Risks
If there are potential risks involved in your study, specify them. Describe the precautions you will take to avoid these risks. If you are conducting research overseas and you have lived there previously, have friends/relatives living there, or if there are other reasons that you feel increase your knowledge of the area, please specify this.

Benefits
Be realistic and do not invent things. Please note that you should list the potential benefits to the participants, not to you. If there are no benefits to the participants, please state so.

Privacy
Explain where the data will be collected. This location should ensure that participants can complete the study tasks in a private setting.

Confidentiality
Describe the means by which you are able to ensure confidentiality of data. It is not enough to state that data will remain confidential; you must indicate how you are able to keep it confidential.

Confidentiality vs. Anonymity
"Anonymity" means that no one, not even the researcher, will be able to connect the subject's responses to his or her identity.

"Confidentiality" means that the researcher will be able to connect the subject's responses to his or her identity, but that the information will not be released to anyone else. Keep your data anonymous if you can, but be sure to use
Consent Procedures
Please follow the consent form templates [1].

If you are obtaining consent from more than one population, for example, students and parents, submit a consent form labeled for each population. Be sure to attach your consent form(s) in the consent section and your assent form(s) in the assent section of the protocol application.

If you are planning to obtain consent online or verbally, attach the online consent form as Waiver of Documentation (waiver of signature) and be sure to answer each of the questions within that section.

Copies of Questionnaires, Surveys, and Interview Questions
Copies should be provided for IRB review even if you are using "standard" instruments. These can be attached in the Attachments section of the protocol application. All final or revised questionnaires, surveys, etc. must be submitted to the IRB for review and approval before use.

WAIT for IRB Approval
You may not begin your project until you have been notified of the IRB's approval. Please allow time for the IRB to review and approve your protocol before you begin your research. Under no circumstances should you interpret a lack of communication from the IRB as an approval.

You can also contact the IRB Manager if you have questions, at (650) 723-2480 or by email [2].

Source URL: https://researchcompliance.stanford.edu/panels/hs/forms/for-researchers/nonmed-eprotocol
Links
[2] mailto:irb2-manager@lists.stanford.edu