Information About eProtocol Sections for Medical Applications

Topics with the relevant protocol section are listed below. Remember, you can come back to a section later by saving it. You do not have to answer the sections in the order they appear in the protocol application.

If you have any questions, please contact your Panel Manager [1] (if assigned), call (650) 724-7141, or email IRB Education [2].

- Personnel Info
- Protocol Summary (Protocol Section 2)
- Study Procedures (Protocol Section 2)
- Subject Population (Protocol Section 8)
- Recruitment (Protocol Section 8(g), 13, and 15)
- Confidentiality vs. Anonymity (Protocol Section 11)
- Risks (Protocol Section 9)
- Benefits (Protocol Section 10)
- Consent Procedures (Protocol Section 13 and 15)
- Translation (Protocol Section 13)
- Copies of Questionnaires, Interview Questions (Protocol Section 16)

Personnel Info

The Protocol Director (PD) should consider the following when adding personnel:

- **Key personnel** should be listed in eProtocol, including all persons who are responsible for the design, conduct, data analysis or reporting for the study.
- The IRB expects that personnel who are involved in the consent process, other aspects of human subject protection, or handling private health information will also be listed.
- Ultimately, it is the PD's decision to decide who constitutes key personnel, but whether or not a person working on the protocol is listed, human subject training is still required, and it is the PD's responsibility to verify that the training has been completed.
- The first four people listed on the protocol (Protocol Director, Admin Contact, Investigator, and Other Contact) can edit the application. All others listed have view access only.
- When there is a change to personnel, a modification should be submitted.
- CITI records are available through eProtocol and via the IRB website.
  - If the ‘Yes’ answer in the CITI question is highlighted in yellow, it means that the CITI records are not available, or there is a mismatch between your SUNet ID and your CITI User ID: Contact HelpSU [3] to correct this.
For NIH-funded studies:

- **NIH guidelines** [4] state, “Key personnel are defined as participants in a grant or application who contributes substantively to the scientific development or execution of a project. Key personnel contribute a specified level of time, whether or not earning a salary. Key personnel include the principal investigator as well as any consultants who meet the definition above.”

**Protocol Summary** (Protocol Section 2)

Your protocol summary should be a thumbnail sketch of your purpose and procedures, and should be written for the layperson.

For example, “This project will be a retrospective study of the long-term effects of eating disorders in adolescent girls. Adult subjects will be recruited through flyers posted in community centers, and data will primarily be gathered through questionnaires distributed at these community centers. Follow-up interviews will be conducted with interested subjects. We hope to determine if eating disorders in adolescents are related to long-term problems with weight and nutrition.”

You may want to write this section after you have written the rest of your protocol.

**Study Procedures** (Protocol Section 2)

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, do you have permission from the institution?

**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?

**Procedures:**

**Rationale:**
Do any of your procedures present risk to subjects? If so, explain why you need to do them.

**Subject Population** (Protocol Section 8)

Consider the following:

- Who are your subjects?
- How will you decide who to approach?
- Will you include any vulnerable populations? If so, why?
- Are there groups of people that could benefit from the research but that aren't included? If so, provide rationale for exclusion.
- When it comes to children, difficulty obtaining parental consent is not necessarily a sufficient rationale for exclusion. If you believe the project presents no more than minimal risk to children, you may wish to request a waiver of parental consent. (For more information, see **Consent Procedures** below.)

**Recruitment** (Protocol Section 8(g), 13, and 15)

- 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 by phone, explain how you will get their contact information and provide a script for the phone call.

Keep in mind that recruitment materials are considered part of the consent process, so any revisions to them need to be reviewed and approved by the IRB.

Confidentiality vs. Anonymity (Protocol Section 11)

"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 these terms accurately.

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.

Risks (Protocol Section 9)

If there are potential risks involved in your study, specify them even if you believe they can and will be avoided. 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 there are other reasons that you feel increase your knowledge of the area, please specify this.

Benefits (Protocol Section 10)

Be realistic. Do not invent things, but try to design your procedures so that there is some potential benefit for your subjects.

Consent Procedures (Protocol Section 13 and 15)

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 orally, be sure to choose Waiver of Documentation (i.e., waiver of signature) as your consent type and to answer each of the questions for the waiver, not just respond "yes" to each. You will also need to attach your oral consent script for IRB review.

Translation (Protocol Section 13)

When research is being conducted in a language other than English, it is important that consent forms be translated accurately. Procedures for ensuring accurate translation should be described in detail. The IRB recommends the use of professional translators, although the use of back-translations by native-speakers is acceptable.

Copies of Questionnaires, Interview Questions (Protocol Section 16)

Copies of surveys, questionnaires and interview questions 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.

Source URL: https://researchcompliance.stanford.edu/panels/hs/forms/for-researchers/tips-medical

Links

[1] https://researchcompliance.stanford.edu/panels/hs/about/contacts