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# Overview of the IRB Application

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. Please see the full list of Guidances [1]for more information on selec topics.

If you have any questions, please contact your Panel Manager [2] (if assigned), call (650) 724-7141, or email IRB Education [3].

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**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 [4] to correct this.

For NIH-funded studies:

- NIH guidelines [5] 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**

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

> *Sample summary for a Medical protocol*: "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."
>
> *Sample summary for a Non-Medical protocol*: ?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.?

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

**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, 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:

> What are you going to do? Interviews? Surveys? Observations? Participant observations? Experiments? Summarize your procedures in as much detail as needed.

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 recordings following the study, (i.e. will they be presented in conferences, etc.?) If you will include the recordings in presentations, etc, please explain whether they will include any identifying information about the participants and whether you will ask for explicit permission from the participants to show the recordings. Describe the final disposition of the recordings.

**Subject Population**

Consider the following:

- Who are your subjects? Are there specific inclusion/exclusion criteria?
- How will you decide who to enroll?
- 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**

- How will you make your first contact with subjects?
- If you will 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. Please review the Recruitment Language Guidance [6].

**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 these terms accurately.

**Risks**

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.

**Benefits**

Be realistic, do not overstate the benefits. Include the prospect for individual benefit, if any, as well as the benefit to the subject population, society, etc.

**Consent Procedures**

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. Please see Stanford consent/assent templates [7]. If you are planning to obtain consent verbally or online, select ?Waiver of Documentation [8]? as the consent type. You will also need to attach the oral consent script or online consent form for IRB review.

> For obtaining consent form non-English speaking participants, refer to the Short-Form Guidance [9].
>
> For obtaining signed consent online (eConsent), refer to the Online Consent Guidance (coming soon...)

**Payment**

Will you pay the participants? If yes, state how much and explain whether you will pay them in cash, gift cards, etc. Please review the Ethical Considerations for Payment [10].

**Translation**

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**

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.

**International Studies**

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.

## Special Considerations for Medical Applications

**Data and Safety Monitoring Plans/Boards**

Please reivew the Data and Safety Monitoring guidance documents on the Guidances [1]page.

**Risks**

Please do not include the entire risk section from the Investigator?s Brochure. All risks should be listed, included risks of commercial drugs, study procedures, radiation, etc.

**Attachments**

Please include all of the following (as applicable):

- Investigator?s Brochures/Device Manuals
- Package inserts for commercial drugs/devices
- Sponsor?s protocol and any amendments
- FDA documentation/correspondence

**(MORE MEDICAL GUIDANCE TO COME...)**

## Special Considerations for Non-Medical Applications

**Payment**

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.

**(MORE NON-MEDICAL GUIDANCE TO COME...)**

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**Links**

[1] https://researchcompliance.stanford.edu/panels/hs/policies/guidances
[2] https://researchcompliance.stanford.edu/panels/hs/about/contacts
[3] mailto:irbeducation@lists.stanford.edu
[4] https://remedyweb.stanford.edu/helpsu/helpsu
[5] http://grants.nih.gov/grants/policy/senior_key_personnel_faqs.htm
[6] https://stanfordmedicine.box.com/shared/static/bslih2a9odsgfauvblzxdluf06nbykkt.pdf
[7] https://researchcompliance.stanford.edu/panels/hs/forms/forms-templates
[8] https://stanfordmedicine.box.com/shared/static/6s5bimwuqdan2k5zxr3kbzdghctjgbx8.pdf
[9] https://researchcompliance.stanford.edu/panels/hs/consent/forms/short-form-consent-process
[10] https://stanfordmedicine.box.com/shared/static/gpbjsk4avx04zqhtynetytiyi1o9py59.pdf