X. What do the Reviewers Want? Things to Consider when Submitting a Protocol

The IREC Application/ Protocol Form

The IREC evaluates every research protocol according to the ethical principles described in the Belmont Report. This means the IREC considers whether the risks and benefits of a study are acceptable and managed appropriately, and whether individuals being asked to participate are adequately informed about the research and its possible risks.

Considered another way, investigators could look at their plans from the point of view of a subject, or an observer concerned about responsible research. Who are the subjects and how are they recruited? Could they be lured or coerced into participation? Is the research being conducted through an institution that may have responsibilities toward them (e.g., a school or hospital) and should be consulted? Do they understand, in advance, what they are agreeing to participate in and give their consent willingly? What will they actually do, and what is done to them during the study? Is it possible that the experience might be injurious, painful, uncomfortable, needlessly boring, embarrassing, offensive, or otherwise stressful?
Might there be long-term consequences? Could the subject be endangered, compromised or embarrassed if collected information were leaked?

There are many possible considerations, but they should not be difficult to understand if one assumes the subject's perspective. The IREC's role is to find a balance between the benefits of the research and the risk to the subjects in the study. The following guidance is intended to help investigators create a comprehensive protocol and facilitate timely review by the IREC.

Purpose of the Study

Provide a brief lay summary of the purpose of the study. This should be a clear statement of what question(s) you're asking or hypothesis(es) you're testing and the supporting rationale.
Along with your study purpose you'll be prompted to address what you hope to learn from the study.

Study Procedures

In this section, please detail all study procedures that involve human subjects. This is often where protocols get held up – if not enough detail is provided in this section about study procedures, then the IREC cannot safely assess what risks the participants might be exposed to. Providing as much detail as possible in terms of how the participants will be involved in the study will help to expedite the review process. Avoid using jargon or acronyms whenever possible. If using jargon or acronyms is necessary, please define them the first time they are used.

Here are some additional points to consider regarding this section:

1. Provide a sequential, step-by-step description of everything participants will be asked to do in your study.

2. Describe the physical setting and location in which the data collection will take place. For example, are you interviewing participants in a public place? Their home? Your office?
Is the study being conducted online? This information should be clearly stated in the study procedures.

3. Describe any tools you will use such as questionnaires, surveys, or any other data collection devices.

4. Indicate whether you will be using audio or video taping. Describe the procedures associated with the audio and/or video and provide rationale for why you are audio/video taping. Be sure to indicate whether being audio or video tape is a requirement for participation in the study.

5. The study procedures section also asks about deception. If your study involves deception or incomplete disclosure, justify it here. Explain why the deception or incomplete disclosure is necessary to achieve the goals of the study. Also explain the debriefing process. When will participants be debriefed? Who will debrief them, and how will they be debriefed?

Background

Describe past findings leading to the formulation of the study. A complete literature review is not necessary. However, a clear explanation of why this research is needed and how it fits into what is already known about the topic should be discussed.

Explain why more research is needed, the potential benefits of the research, and include a description of what gap you hope to fill in the research.

Subject Population

Information in this section is crucial to understanding how participants will be identified, recruited, compensated, etc. Providing as much information and detail as possible in this section can help to expedite the review process. Two very important components of this section are recruitment and compensation.

Recruitment

All aspects of recruitment should be described. Be sure that your description includes the following:

1. Describe where you will recruit. Are you recruiting on campus? In a public place? From a particular course during class time? Be clear about where you will seek potential participants

2. Describe in detail how participants will be recruited. Will there be flyers advertising your study? If so, where will they be posted? Will participants be recruited by email? Will you approach potential participants in person? Give a clear description of how potential participants will be made aware of the study.

3. The IREC needs to see all materials that will be seen by potential participants. So if you're using a flyer, text, or email to recruit, a copy should be attached in the attachments section of the protocol form. If you are speaking with people in person about the study, you'll need to attach an oral script, outlining exactly what you will say to potential participants about the study.

Compensation

Please detail what compensation, if any, will be provided to participants. Explain the amount and type of compensation (payment, experimental credit, gift card, etc.) and include a schedule for compensation as well as provisions for prorating, if applicable.

Risks

The IREC is required to ensure that the potential risks to participants (however minimal) are clearly justified by the potential benefits of the research. This section of the protocol form asks that you delineate any potential risks to subjects. These questions should not be answered "N/A". Below are some tips for filling out this section of the protocol form.

1. A statement such as "There are no foreseeable risks" or "There are no known risks" may be acceptable and is likely to be the case for some risk categories for some research studies. This may be the case when risks encountered in the research are no greater than those normally encountered in everyday life.

2. There is almost always a minimal risk of breach of confidentiality which should be addressed in this section of the protocol form. If you have outlined in the protocol and consent document the steps you will take to ensure the confidentiality of the data, then this section should contain a description of that particular risk.

3. Think carefully about any discomfort a participant might experience during the course of your study. For example, the discomfort of having their views challenged by others in a focus group, the stress one may encounter when completing an exam-like instrument, the anxiety one might experience when discussing or answering questions about sensitive topics, or the discomfort or physical fatigue associated with exercise. These should be addressed as risks in the protocol form.

Benefits

It is possible that participants will benefit directly from their participation in research by gaining knowledge or skills. However, if the participants will not DIRECTLY benefit, this should be stated plainly. Indirect benefits can also be mentioned in this section (for example, benefits to the discipline as a result of what is learned from the research project.

Compensation **is not** considered a benefit of participation and as such should not be referred to in this section of the protocol form.

Procedures to Maintain Confidentiality

The following should be included in this section:

1. An explanation of where the data will be stored (in a locked filling cabinet in a locked office? On a password-protected computer?)

2. A list of individuals who will have access to the data. If the data will be stored in a locked office, who has a key to the office?

3. A description of how the identity of participants will be protected. Will data be recorded by geographical area or group rather than by individuals? Will numeric identifiers or pseudonyms be used?

4. A statement indicating how long data will be kept before it is destroyed.

The terms "anonymous", and "confidential", often present problems in this section of the protocol form. See below for an explanation of each.

1. A study is **anonymous** if there is no way of tracing the data back to the participant from whom it was obtained. No study that involves the creation of a code can be considered anonymous as the identity of the research subject could be linked to the data.
Generally, online surveys can be considered anonymous if no participant names, email addresses, or IP addresses are collected.

2. A study is **confidential** if data can be linked back to participants. Thus, **any** data collected face-to-face (consumer survey, focus groups, standing in front of a classroom, etc.) is automatically considered in the category of being "confidential" as opposed to
"anonymous". This is true even when the researcher assigns a coding number to the subject – and this number cannot be traced back to the subject – because the researcher him-/herself knows who provided the data.

Be sure that the description of procedures to maintain confidentiality uses "confidential" or "anonymous" appropriately. These two terms are independent of each other.

Please remember that it is almost always impossible to guarantee confidentiality. Information submitted electronically or in a group setting cannot be considered secure.

Confidentiality can also not be guaranteed when there is suspected mistreatment of children and serious threats against self or others. It is also possible that a court might order the release of data or a list of subjects. Because of this, it is important to focus on the steps you will take to maximize confidentiality rather than guaranteeing that confidentiality will be maintained.

Conflict of Interest

The department of Health and Human Services recommends that investigators conducting human subject research consider the potential effects that a financial relationship of any kind might have on the research or on interactions with research subjects. This section of the protocol form asks questions about any financial connections an investigator may have that could potentially influence the research.

Informed Consent

The protocol form has questions regarding the consent process that each investigator should answer. When uploading a consent document in e-protocol, the questions will be presented below the attached document. A template for informed consent can be found at the end of this section.

Below are some points to consider when drafting your consent document.

1. The consent document is written for the participants in the research. Make sure it is written in the second person throughout (i.e. “You will be asked to…)

2. Try to avoid phrases like “You will be required to” or “You will be expected to”. Participation is voluntary and participants have the right to withdraw from the study at any time. This should be clear in the consent document.

3. Be sure to outline all exclusion/inclusion criteria for the study. If criteria for participation were outlined in the protocol form, the same criteria should be found in the consent document.

4. if you are using audio or video recording be clear about whether or not this is a requirement for participation in the study. In other words, can people who don't agree to be video or audio taped still participate in the study?

5. When describing what participants will be asked to do during the study, be sure to describe everything participants will do. Often the protocol form contains information that is not included in the consent document. If a research activity is mentioned in the protocol form, it should also be included in the consent document. Also, if a research activity is mentioned in the consent document, it should also be described in the e-protocol form.

6. In the section of the consent document that discusses benefits of participation, do not mention compensation. Compensation is not considered a benefit.

7. If your study involves multiple activities describe each activity clearly in the consent document AND provide an estimation of the amount of time it will take to complete each activity.

Assent

One of the most important things is that assent be written at an appropriate reading level for the age group being targeted. You can check reading level using Microsoft Word or by entering text at https://readability-score.com/.

If you are recruiting participants under the age of 18, you will need to obtain parental permission as well as the assent of the minor. If your study is recruiting people both above and below the age of 18, please note that you will still need a separate parental permission document along with the consent document you will use for participants 18 years of age and older. A general template for an assent form is provided in Appendix E.

Attachments

All study related materials should be included with the protocol form. Any document referenced within the protocol form should be attached in this section.

Below is a list of commonly attached documents.

1. Recruitment materials (flyers, email, oral scripts)
2. Letters of support or approval from outside organizations
3. Surveys/questionnaires
4. Visual stimuli that will be presented to participants
5. Debriefing Documents
6. Grant Proposals