Protocol Preparation Guidelines

Preparation Checklist

1. Include all research materials including the surveys and questionnaires you plan to use. (Incomplete protocols will be returned to you without an IRB review.)
2. Your protocol should provide a detailed data management plan that clearly states how and when data will be gathered, stored and destroyed and who will have access to it at each stage of the study.
3. If you plan to collaborate with other organizations, complete and submit Appendix IRB01-Collaborative Research. Your protocol should also include a description of the training and supervision of any people who conduct research on behalf of the researchers to ensure that they conduct this work in a manner consistent with DKUs guidelines for research involving human subjects.
4. If you will conduct your research in China or other non-English speaking countries and regions, provide both English and local language versions of your recruitment and consent forms, as well as your research instruments.
5. Be sure that your protocol describes the complete experience of your research subjects from when you first contact them to the time their participation ends. Make sure the recruitment process is described in detail.

   If you have more than one study population, your protocol should clearly describe the experience of each group.
6. When you review your protocol before you submit it, make sure that it is consistent. If the protocol says that an interview will take 30 minutes, the consent form should also say 30 minutes.
7. Spend time on your consent forms and scripts. Make sure they are written in plain language and easy to understand.
8. Make your consent forms short and concise. People are unlikely to read long consent forms. If your study is complicated, you might want to use lists and bullet points.
9. Use the guides and samples to help you write consent forms.

   Don't use consent forms from other researchers' studies. They probably won't fit your study.
10. Be candid about risks. It is normal for studied to pose at least some minor risks to human subjects and it is best to acknowledge these (so that the IRB reviewers know you are aware of them) and then explain how you have taken reasonable steps to minimize these.
11. Be candid about confidentiality. It is generally not possible to ensure that the data generated in a study is 100% confidential, especially when interviews, focus groups and other face-to-face research methods are involved. It is better to acknowledge confidentiality problems and explain how you manage them rather than simply saying you will keep all data confidential.

Detailed Guidelines

IRB Protocols: An IRB protocol should meet the following requirements:

1. The protocol should describe the procedures for collecting data from the human subjects.
2. The protocol should describe:
    a. whether the data collected from the human subjects is identifiable;
    b. procedures that will be used to de-link identities from data;
    c. how information containing identity links will be securely kept.
3. Any compensation should be paid to participants up front.

Consent forms: A consent form should include, but not limited to, the following basic elements:[1]

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
2. A description of any reasonably foreseeable risks or discomforts to the subjects.
3. A description of any benefits to the subject or to others which may reasonably be expected from the research.
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
6. An explanation of who to contact for answers to pertinent questions about the research and research subjects' rights, and who to contact in the event of a research-related injury to the subject. There should be separate contact persons for the research and the research subjects' rights.
7. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. (Most researchers in the social and behavioral sciences are not in a position to impose penalties. However, specific study-related assurances that there will be no negative consequences associated with choosing not to take part might be appropriate.)
8. A translation of the consent form in the local language of the research conducted in the field should be provided with the protocol.

Additional elements may also be included in the consent form depending on the nature of the study as[1]:

1. A statement that the particular treatment or procedure may involve risks to the subject (or the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable.

[1] Hicks, L. ed. *Human subjects research (HSR) guide for social, behavioral, and educational research*. CITI Program at the University of Miami. 2014. Pp. 49-51

2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
3. Any additional costs to the subject that may result from participation in the research.
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject. Subjects need to know, for example, how their compensation will be affected if they choose not to complete an interview. Discussion of what happens to data already collected if they withdraw midway through the study also may be addressed in this section.
5. A statement that significantly new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.
6. The approximate number of subjects involved in the study.

Other notes on consent forms:

Consent forms should not include statements made on participants' behalf such as: "I have read the above consent form" "I understand the consent form" "I have received satisfying answers to my questions" and so forth.

Consent forms should explicitly state that participants have the rights to ask questions when they do not understand, and that they have the right to withdraw from the study whenever they do not feel comfortable or sense it is not in their best interests.

The language used in consent forms should be understandable to the subjects, and contain as few professional or academic terms as possible. In particular, for studies conducted in rural areas, the language should be as simple as possible and appropriate to the general literacy levels in these areas.

Consent forms for focus group interviews, stakeholder group interviews, and other data gathering that involves more than one individual present should clearly state that what is said in those events will not be private as other individuals may repeat what is said to others outside of the meetings. Assurances that in the research and publication of research that no personal information will be given are appropriate.

Glossary:

Informed Consent: Informed consent is a process that includes discussion with participants about the nature of the research, potential risks and benefits, and the extent to which privacy and confidentiality will be maintained. It is the responsibility of the researcher to ensure that subjects understand the research and their role in it and that the subjects have sufficient time to consider their decisions. Informed consent **is not** a contract or the form itself that someone signs, or a single event.

Documentation of informed consent: Evidence of informed consent may be through a signed document or, in some cases, through oral consent. Oral informed consent may be obtained among people who are not literate, people who may feel at risk if any record of their name were recorded and that confidentiality breached in any way, or if the research proposes no more than minimal risk to subjects and involves no procedures for which written consent is normally provided outside of the research context.

Privacy: the control a person participating as a subject of research has over the extent, timing, and circumstances of sharing information about oneself with others. This includes sharing feelings, thoughts, experiences, perceptions, and personal data.

Confidentiality: the obligation of researchers and institutions to appropriately protect the information disclosed to them. It includes the expectation that information will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without permission.

Identifiable data: any information that can be linked to a particular individual. This may be by means of either using names or other personal data on any form or questionnaire, by using a code-book which lists names and random numbers associated with those names to link to questionnaire or survey responses, or to the collection of information about a person (such as sex, age, occupation, ethnicity, neighborhood) that would allow personal identification even without knowing a name.

Research Instrument: Means of gathering data to conduct research. It includes standardized instruments such as surveys, questionnaires, inventories and assessments to be used in the proposed research, or an online questionnaire. Research instrument must be submitted as part of the IRB approval application or request for approval.