Guide to Informed Consent

Introduction to the Guide

- The guide covers the information that must be provided to subjects during the consent process and provides sample language that you may adapt to your protocol. The samples are designed to prompt your thinking.

- Don't use the samples uncritically because they may not be right for your study. Consider your audience. The samples include a variety of reading levels and assume varying levels of familiarity with research terminology and methodology.

- When you write your scripts for oral consent procedures or write consent forms, remember that you are engaging in a conversation with your potential subjects. Refer to yourself as "I" and to the subjects as "you."

- Use everyday language at the appropriate reading level. To lower a reading level, keep sentences short and substitute multi-syllabic words with phrases made up of short words. For example, "participate" can be replaced with "be in."

- Use your knowledge about what is culturally appropriate in your research setting when you design your consent, child assent, and parental permission processes.

- Be aware that you may need to secure consent at multiple levels. For example you many need to secure permission from community leaders before you invite individuals to be in your study.

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1.

Introduce yourself and invite people to be in your research study. Be sure to use the word "research."

The following examples could be used in either oral or written consent processes. Remember not to use these examples verbatim, but use them to stimulate your thinking about how you want to interact with your subjects.

- *Hi, I am (your name), an undergraduate student at SMC in the United States, studying the rise of the female monastic movement in contemporary Japan. I am writing to ask if you would be willing to participate in my research.*
  or
- *Hello, my name is (name) and I am an undergraduate here at SMC. With the help of (advisor name), I am conducting a survey research study to understand how college students cope with pain. If you are interested, I would like to ask you some questions.*
  or
- *I am conducting research to write a paper for my college in America. I want to know how individuals who live in Jisha feel about Chinese and foreign tourists coming to the village. If you decide to answer my questions, this interview will take about 20 to 30 minutes.*

An introduction similar to the following example may be useful when you are presenting information to people who are not familiar with the research process, including children:

I am (name), an undergraduate student at SMC. I am asking you to take part in a research study. The purpose of this consent form (this conversation) is to give you the information that will help you decide to be in this study or not. Please feel free to ask any questions you have as you read this form (as I explain my research to you). Feel free to ask questions about the purpose of the study, what I will ask you to do, the possible risks or benefits, or anything else you would like to ask. When I have answered all your questions, you can decide if you want to be in the study or not. This process is called informed consent.

2. **The Purpose of the Research and the Research Activities**

Explain the purpose of the study, the activities that subjects will participate in, the

number of subjects, and the estimated duration of the study. Present activities in the order they will be experienced by the subjects. Remember to write in a conversational style. Provide sufficient information for a subject to make a decision, but aim for brevity. Weed out any repetition in your first drafts.

3. Benefits to Participation in the Research

Describe the benefits to the subjects, if any. If there are no direct benefits to the subjects, describe what you hope to learn. This may be a restatement from Section 8 of your Application for Protocol Approval.

4. **Potential Risks/Harm**

Describe the risks to the subjects, if any. If there are no risks, it is not necessary to say so. There are generally two types of risk in social and behavioral research: 1) a breach of confidentiality leading to the release of confidential, sensitive, or personal information, and 2) risks of harm associated with research questions.

5. **An Explanation of your Confidentiality Procedures**

Participants may disclose personal, sensitive, or even potentially damaging information to you, presumably within a relationship of trust. To ensure that such information is protected, you have developed the confidentiality procedures you listed in Section 10 of the Application for Protocol Approval. Explain these procedures in everyday language to your potential subjects.

For example.

> *I have a designed a way to protect the information you will share with me. (to make sure no one will know what you share with me.) I need to be able to connect your answers to the short questionnaire with the transcript from our interview. I will assign you a number and put the number on your questionnaire and your transcript, but not your name. On a separate piece of paper I will list your name and the number I have given you. When I have all the questionnaires and transcripts connected, I will destroy the list with your name on it.*

or

> *I will not ask you to put your name on the questionnaire. Signed consent forms will be kept separately from the surveys.*

6. Risks Associated with Research Questions

A potential risk associated with research question is probing for personal information that

subjects might experience as an invasion of privacy, or presentation of material that subjects might consider sensitive, offensive, threatening, or degrading. These risks can be managed by providing several examples of the kinds of questions you plan to ask and making it clear that subjects may skip questions they don't want to answer. The following text was part of a child assent process for children who had been abandoned by their parents.

> *You will be asked to answer some questions about your everyday thoughts and feelings and also about how you feel living apart from your parents. Some of the questions may be difficult to answer. Some of the questions may make you feel uncomfortable or sad. Of you want to skip a question just tell me and we will go on. You could say "next question' to let me know you want to skip to the next question.*

If it is reasonable to assume that subjects might become distressed by questions (even though they know the topic under study and have agreed to participate), the researcher should identify appropriate resources for supportive counseling. For example, an undergraduate student interviewing survivors of "rape camps" during the war in the former Yugoslavia identified a local group established to provide support for war rape victims and provided contact information for the group to the study participants.

7. **Confidentiality Procedures For Research Questions**

Either in the introduction to the confidentiality procedures or within the discussion of the procedures themselves, it is a good practice to acknowledge that the procedures were developed to protect subjects' privacy or to state your concern for their well-being. Samples of confidentiality language at different reading levels are provided below.

A. Not collecting identifiers:

- *Your privacy is important to me. Therefore, I will not collect your names or any identifying information.*
  or
- *I will not ask you for your name.*
  or
- *I would like to use direct quotations, but will do so in such a way that you cannot be identified.*
  or

- *I will write only your initials, not your name, on the notes from the interview. Neither your name nor your initials will not be used is the presentation of this research to others, so no one here in your community, or elsewhere, will know what you said.*
  or
- *We will ask you to tell us your name at first, but only to make sure that we don't mistakenly ask you to answer the questions more than once. After we have finished asking the questions, we will destroy the list of names so nobody will able to know which answers are yours.*

B. Using fictional names and misleading identifiers:

- *I will use pseudonyms and misleading information when preparing reports or articles about the research.*
  or
- *I will use false names when writing reports about this study. I will also make up some information about you so no one will be able to guess who you really are*.

C. Using unique identifiers:

- *You will be given a code number that will be used instead of your name on the questionnaire you fill in for this study. The key that shows which number goes with your name will be kept in a locked cabinet and destroyed when the study is completed.*
  or
- *I will assign you a unique identification number so that I can link study materials. They key will be kept in a password protected file accessible only to me and my advisor. Your signed consent form will be kept separate from the study data.*

D. Reporting results:

- *I will use aggregate data only when reporting on the results of the research.*
  or
- *We won't report what we learn about any one person. We will only write about the combined responses of groups of people. For example, we might say that 20% of our participants answered XYZ.*
  or
- *I intend to interview 30 people interested in this issue and will compile all the information into an advisory report which I will then give to the Center for XYZ.*

E. Using Names

There may be situations in which subjects do not object to their names being used, or even prefer that they be identified in your report. Nevertheless, you should ask if it is permissible.

- *With your permission I would like to use your name in my report and attribute quotations to you.*
  or
- *I will be using our interview to write a paper on this topic and I plan on using your name and what you tell me in our interview in this paper. It is not important to have your names, your story is much more important to me, so please don't feel that my research will be damaged in any way if prefer that I don't use your name. May I have your permission to use the information you give me in this interview in the paper I will write? May I also use your name in both the paper and discussions of my research? (After the interview: Is it still all right if I use your name?)*

F. Audio recording interviews:

Individuals

- *With your permission, I would like to tape this interview so that I can make an accurate transcript. The tape will be destroyed as soon as the transcript is completed.*
  or
- *If it is OK with you, I would like to tape this interview so that I can write down what you said without mistakes. Once I have made my notes, I will erase the tapes.*
  or
- *With your permission, I would like to tape this interview because I think that your story will be valuable for other researchers interested in this topic.*

Groups

If you are recording a group session, you must have permission from all members to record the session – or limit the group to those who agree to be audio taped. It may be appropriate to offer group participants the option of using pseudonyms during the session.

G. **Focus Groups**

Focus groups are unique in that there are significant limits upon the level of confidentiality that can be offered. It may be the case that focus group participants already know each other or that the topic is innocuous, and therefore confidentiality it not an issue; however, that may not always be true.

Sample language when confidentiality may be an issue

Every effort will be made to protect your identity as a participant in the study. You will not be identified in any report or publication of this study or its results. Even though we will emphasize to all participants in the study that comments made during the focus group sessions should be kept confidential, it is possible that participants may repeat comments outside the group at some point in the future. Therefore, we encourage you to be open as you can, but remain aware of our limits in protecting confidentiality.

You could lower the reading level of a focus group consent form with phrases such as:

I won't use your name in any of my notes or reports that I write. I will ask everyone not to repeat what they hear in this group. However, you should think about what you decide to share with the group if there is something you want to be private.

If the members of the group do not know each other and the nature of the topic warrants, you might need to give participants the option of using a pseudonym during the group discussion.

8. **The Voluntary Nature of Participation**

Make it clear to potential subjects that their participation is voluntary.

- *I want to hear your story and your experience but if at any time you don't want to answer one of my questions, or continue talking about something, please tell me and we will move on and not go back to it. We can also stop at any time if you wish.*
  or
- *Your participation in this research is completely voluntary. You may choose only to answer certain questions and may end the interview at any time.*
  or
- *It is perfectly OK if you don't want to try this. No one will be mad at you and we will still care for you just like we always do.* (Text from an assent process for children.)

9. Compensation

In most cases, you will probably not have a budget for compensation subjects. If you do, describe any compensation or incentives you will offer. If you plan to compensate subjects, tell them what will happen if they withdraw from the study. Will they receive partial or full compensation? For example:

You will receive $10.00 if you complete the questionnaire. If you decide not to complete it, you will still receive the $10.00.

Please note that compensation cannot be so high as to unduly influence people to participate in your study. How high is too high will depend upon the setting and the population from which you are recruiting subjects.

10. **Providing the Opportunity to Ask Questions**

Give potential participants an opportunity to ask questions before they decide to be in the research. For example:

- *Do you have any questions about me, my research, or our interview before we begin?*
  or
- *If you have any questions about this research, please ask me now. If you have questions at a later time, you can contact me at (phone, email, local address, in person - whatever is most appropriate for the setting and circumstance). See the next section for information about other required contacts.*

11. Providing Contact Information

For information about the study:

- You: your phone number, email address, or dwelling – whatever is most appropriate. If you will only be in-country for a short period of time, list the dates that you will be available there.
- Your faculty advisor, assuming that the potential subjects have access to email or phone
- Your in-country contact, if you are abroad

For information about subjects' rights as research participants:

- The Institutional Review Board in the US if the research requires written consent, again assuming that your subjects would have the resources to contact the United States

If the subjects do not have the resources to make contact with the US, you can provide an in-country contact, e.g., a contact in your hosting organization or a public service or research organization familiar with your study population and your topic. If review by an ethics committee in the country where the research is taking place is required, that committee should be the contact for questions about subjects' rights.

Here are ways to present the SMC IRB or in-country ethics committee contact:

- *All research with human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, you may contact the committee, anonymously if you wish, at (phone or email.)*
  or
- *If you would like to speak with someone besides me about the research or if you have any questions or concerns about your rights as a research subject, you may contact (in country contact).*

Note: If you are using an oral consent process, consider providing subjects with cards that include the appropriate contact information.

12. **Documenting Consent**

A. Obtaining Signatures

When using written form, create the appropriate signature section. In this part of the form, you switch from second person when addressing the potential subject to first person for the subject to provide his or her agreement to participate. It may be useful to insert a line before the signature section of the form to indicate a shift in the process.
For example:

Participant's Agreement:
I agree to participate in the research described above.
*Signature of Research Participant:*_____ *Date:* ___

Layered Consent

You may need to ask subjects to tell you which parts of the study they wish to participate in and which parts they do not. For example:

Please initial the boxes that apply-:
___*I agree to be interviewed.*
___*I agree to be observed while I conduct shamanic ritual healing ceremonies*.

B. **Copying Subjects**

Subjects who sign consent forms must be given a copy of the form. The subjects should be told in the consent form that they will receive a copy. (Their copy does not

need to be signed.) Insert this information before the signature section:

You will be given a copy of this form for your records.

C. **Mailed Surveys**
When mailing surveys for participants to complete and return by mail, a cover letter should provide all the information that one would include in an informed consent form. If subjects complete and return the survey, they have agreed to be in the study. It is not necessary to send an informed consent document for them to sign and return along with the completed survey.

D. **Recording Oral Consent**
Although it is not the norm, there may be circumstances in which it would be appropriate to record an oral consent process.

- Your potential subjects do not read or write.
- You are conducting interviews over the phone.
- It is culturally inappropriate to ask people to sign documents

When you prepare an oral consent script, you need to write as if you were speaking. This can be a challenge. One technique is to tell a friend what you imagine you would tell a subject. If you record your conversation, you can convert the recording into a script.

E. **Witnessed Oral Consent**

Witnessed oral consent is required if subjects do not read and the research involves greater than minimal risk. The purpose of the witness is to confirm that subjects were informed of the risks and had the opportunity to ask questions and that they agreed to participate. Please contact the IRB staff if you believe that you need to develop a witnessed consent process.

13. **Parental Permission and Child Assent**

When research subjects are minors, parents provide permission for their children to become research subjects and children provide their assent to participate. The absence of dissent does not constitute assent. If a parent provides permission, but a child does not want to be in the research, the child's wishes prevail unless the health of the child is at stake.

In Western culture it is generally assumed that children have some autonomy, based on their age and maturity, to decide what will happen to them. On one end of the age continuum are infants and toddlers who are not capable of making decisions about whether to participate, although they may show dissent if they become distressed. On the other end of the continuum are older adolescents who are both capable of making a decision and actively assenting or dissenting to research participation. It is even possible

that seeking parental permission to talk with an adolescent could violate the adolescent's right to privacy or put the child at risk (research bout STDs, incest, pregnancy, or child abuse). Check with the IRB if you are concerned that securing parental permission would violate an adolescent's rights.

Voluntary Nature of Participation

When securing parental permission and child assent, the voluntary nature of both the permission and assent processes must be stressed.
For the parents:

> *You are being asked to allow your child to be in a research study. To join the study is voluntary. You may refuse to give permission, or you may withdraw your permission for child to be in the study for any reason. Even if you give permission, your child can decide not to be in the study or to leave the study at any time.*

For the children:

> *Your Mom [or Dad or guardian] needs to give me permission [to say it's OK] for you to be in the study. You do not have to be in this study even if your Mom [or Dad or guardian] has already given permission [said it's OK]. No one will be angry or upset with you if you decide not to be in the study.*

Note that in some countries children would find it incomprehensible that they would not do what their parents wanted or encouraged them to do. We assume greater degrees of childhood autonomy in the West than is the norm in other cultures. If the cultural norm is that children of a certain age do not make independent decisions, then although the children must be fully informed, it may not be appropriate to encourage them to make in independent decision. Of course, it they are distressed by the research experience, it is up to the researcher to stop.

Parental Permission Form or Script
Parental permission forms/scripts are similar to adult forms/scripts, except that they describe what the child will be asked to do. For example:

If you decide that your child can be in the study, we would like to interview your child for about 15 minutes.

Parental permission forms must include the name of the child. Both parental permission forms and child assent processes or forms must be clear about what parents or teachers will be told about the results of interaction with the children. This is particularly important if the study is about illegal activity.

Sometimes a researcher wants both the parents and their children to be in the study. It is possible to combine adult consent and parental permission in one process/form, although if a study is complex, it may be more straightforward to devise two forms/processes: one

for the parents to consent to their own participation and one to provide permission for a child to participate.

Child Assent Form or Script

The federal regulations do not describe the assent process. Thus, it is up to researchers to design assent processes that are consistent with the decision-making skills of their prospective subjects. Assent must be tailored to the emotional and cognitive maturity of the children. The ethnic background, nationality, educational level, and socioeconomic status of the families and children must also be taken into account when designing the parental permission and child assent processes.

As a general guideline, if the children are older adolescents (14 through 17 in the United States) you may be able to use the same language that you would use for adults; however, you would need to make it clear that parents or legal guardians still have to provide permission.

Common sense dictates that there is no sense using a written assent form if children haven't yet learned to read well. However, if culturally appropriate, children still need to be invited to participate in the research activities planned for them and they must assent. Even after children have assented, they may indicate by their behavior that they do not want to continue participation, for example, by becoming agitated by the research experience. If this should occur, their participation should be discontinued or put off until a better time, if appropriate.

The following set of questions can guide you in developing an oral assent process or written form for child assent for children and younger adolescents.

1. Why is this research study being done?
2. Why are you being asked to participate?
3. How many people will be in the study?
4. What will happen in this study?
5. Do you have to be in the study?
6. Who will be told the things we learn in this study?
7. What are the good things that might happen?
8. What are the bad things that might happen?
9. What if you don't want to be in this study?
10. Will you get any money or gifts for being in this study?
11. Who should you ask if you have any questions about the study?