What Should an Informed Consent Include? (under Pre-2018 Common Rule)

Elements of Informed Consent

1. Study Title

2. Names and affiliations of the investigator(s)

3. Purpose of the Research: Describe the purpose of your research study.

Invitation to Participate and Introduction: Invite participants to volunteer for the research study and explain why they have been invited.

4. Study procedures: In this section you should describe what participation in the research study entails including an explanation of what they will be asked to do, how long the activity will take and how often the activity will occur. If the sessions will be audiotaped or videotaped, an explanation of what will take place and whether or not one can opt out should be provided here.

5. Potential risks and discomforts: Describe any potential for risks or harms to the subject (psychological, social, legal, or financial) and their probability of occurring, as a result of participation in the research and/or from a breach of confidentiality.

6. Potential benefits: Describe any anticipated benefits to the subjects. If there are no direct benefits to the participant, be sure to clearly state this. You should also describe any potential immediate or future benefits beyond the participant (ie. potential contributions to science or community wellbeing).

7. Cost and Compensation: Describe any cost to the participant, including time spent, and any compensation offered to for participation in the research.

8. Confidentiality: In this section you would describe how subject information will be kept confidential, including where it will be kept, who will have access to it, and at what point it will be destroyed. It should also be noted that data will only be kept confidential to the extent permitted by law (i.e. mandated reporters must report suspected abuse).

9. Participation and Withdrawal: You must state clearly that participation in the research study is voluntary and they may refuse to answer or skip any questions or withdraw from the study at any time without penalty. You should provide examples to participants of what would be considered a penalty.

10. Contact Information: Provide the contact information (email address and/or telephone number) for the investigator and advisor, when the investigator is a student, for questions about the research. In addition, you will need to provide the contact information of the Simmons University's Human Protections Administrator for questions about the subject's rights as a human subject or concerns about the research (irbprotocols@simmons.edu).

11. Consent Statement

Sample Statement:
I have read this consent form and have had an opportunity to discuss this with the investigator and all of my questions have been answered. The purpose and procedures of this research project and the predictable discomfort, risks, and benefits that might result have been explained to me. I understand that my participation is voluntary and that I may withdraw my participation at any time without penalty.

I voluntarily agree to participate in this research study. I have been given a copy of this consent form.

Signatures of subject and investigator

I _____ agree to allow you to audio/video record my interview.

I _____ do not agree to you to audio/video record my interview.

Signatures of subject and investigator

General notes:

It is important to use lay language that will be easily understood by the subject population you are asking to sign the informed consent. Avoid the use of jargon.

Be aware of the difference in meaning between anonymous and confidential. The data cannot be described as both anonymous and confidential.

- A research study is considered anonymous when the data is recorded in such a way that the information provided cannot be linked to the subject who provided the data.
- In research studies involving data that is being kept confidential the researcher can identify the subjects either directly (in the case of interviews) or through the information being collected.

Informed Consent for Biomedical/Clinical Research: If your study is biomedical in nature, rather than being a social, behavioral or educational research study, and involves a clinical trial your informed consent document will need to include additional elements such as alternative procedures, possibility of unforeseeable risks, compensation or treatment in case of injury, potential termination without regard to consent, additional costs, consequences of withdrawal, provision of significant new findings, and number of subjects.