Required Components of Informed Consent

Informed consent is not a single event or just a form to be signed; it is an **educational process** that takes place between the investigator and the prospective subject. The basic elements of the consent **process** include:

- full disclosure of the nature of the research and the participant's involvement,
- adequate comprehension on the part of the potential participant, and
- the participant's voluntary choice to participate.

The consent **form** documents that the informed consent process took place. It must contain all the required components of informed consent, as defined in *45 CFR 46.116*, and listed below. The consent form must be written in language that assures the potential participant's comprehension: avoid technical terms and complex sentences, even for the educated layperson. When the participant population is not homogeneous, different consent documents may be required for different populations. Guidelines for constructing a consent form:

- Replace technical terms with ordinary language
- Write in the second person "You" -- for example: "You are invited to participate in a research project..., " "You will be asked to..."
- However, do not make coercive statements such as "you understand that ...," "you have been told that..."
- Use active tense rather than passive tense verbs ("We did" rather than "It was done")
- Write shorter sentences
- Headings for paragraphs are helpful and make the form easier to read
- Use adequate white space so that the form is easy to read. Avoid find print.

Informed Consent Form

1. Provide a clear, concise explanation of the purposes of the research including the name of the study (the IRB can waive if the study is found to **require** deception).
2. Explain what will be happening to the participant during the study, and indicate participant's **time commitment** for each component.
3. Describe the frequent and/or important **risks, side effects or discomforts** of the study procedures. For instance, even though it is not considered a risky procedure, a needle stick to draw blood creates discomfort. If it appears that there are no real risks to participation, state, "We do not anticipate any risks to you participating other than those encountered in daily life." See our Sample Consent Form for an example of proper wording of a risk statement.
4. Describe any **benefit** from participating. ***Learning about how experiments are conducted, receiving a gift, or earning extra credit for being a research participant is NOT a benefit.*** Gifts and extra credit are considered ***compensation***.
5. State that the participant's involvement is **voluntary**, the participant may **refuse to participate** before the study begins, **discontinue at any time**, or **skip any questions** that may make him/her feel uncomfortable, with **no penalty** to him/her, and **no effect on the compensation earned** before withdrawing, **or academic standing** or record.
6. State that the participatant is allowed to **ask questions** concerning the study, both before agreeing to be involved and during the course of the study. *See required contact information in #11 below.*
7. Describe how participant's **confidentiality** will be protected.
8. Describe what will be done with the **data** once the study is completed.
9. Indicate that **recording devices**, audio or visual, are being used (when applicable).

- Describe what will be done with the any video or audio tapes upon the completion of the study (destroyed, erased, archived, etc.), and when (after transcription, 3 years, 5 years, etc.).
- Provide a separate signature line on the consent form for the participantt to agree to be video/audio taped or photographed. For example:

  Please sign below if you are willing to have this interview recorded on tape (specify audio or video). You may still participate in this study if you are not willing to have the interview recorded.

  I am willing to have this interview recorded on tape:

  Signed: _____
  Date:_____

10. Indicate that the participant shall receive a **copy** of the signed and dated consent form.
11. Provide the name(s) of the investigator(s) and contact information.
12. Indicate that the participant may contact the Institutional Review Board (IRB) with any concerns or complaints. Include our email address (uchs@cornell.edu), phone (607-255-5138), and website (http://www.irb.cornell.edu)
13. **At the bottom of the form: "This consent form will be kept by the researcher for at least three years beyond the end of the study and was approved by the IRB on [date]."**

REMEMBER - if the participant is under the age of 18, parental consent is required.
This includes college and university students under the age of 18 unless waiver request is approved.
If the participant is 7-17 years old, child assent is also required.

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