

## Informed Consent Checklist

This checklist was adapted from the Human Participant Protections Education for Research Teams website (<http://cme.nci.gov/ic-pop1.htm>).

1. Is there a statement that the study involves research?
2. Is there an explanation of the purpose of the research?
3. Is the participant.
  - a. Given an invitation to participate
  - b. Told why he/she was selected.
  - c. Told the expected duration of the participation.
  - d. Informed that participation is voluntary?
  - e. Informed that all records are confidential?
  - f. Told that he/she may withdraw from the research at any time without penalty or loss of benefits?
4. Procedures.
  - a. Are the procedures identified and explained?
  - b. Are the procedures that are being investigated clearly identified?
  - c. Are treatment conditions identified?
5. Risks and discomforts.
  - a. Are foreseeable risks or discomforts identified?
  - b. Is the likelihood of any risks or discomforts identified?
  - c. Is there a description of the steps that will be taken to minimize any risks or discomforts?
  - d. Is there an acknowledgement of potentially unforeseeable risks?
  - e. Is the person informed about what treatment or follow up courses of action are available should there be some physical, emotional, or psychological harm?
6. Is there a description of the benefits, if any, to the participants or to others that may be reasonably expected from the research and an estimate of the likelihood of these benefits?
7. Is there a disclosure of any appropriate alternative procedures or courses of treatment that might be advantageous to the participant?
8. Records and documentation.
  - a. Is there a statement describing how records will be kept confidential?
  - b. Is there a statement as to who will have access to the records?
9. For research involving more than minimal risk,
  - a. Is there an explanation and description of any compensation and other medical or counseling treatments that are available if the participants are injured through participation?
  - b. Is there a statement where further information can be obtained regarding the treatments?
  - c. Is there information regarding who to contact in the event of research-related injury?
10. Contacts.
  - a. Is the person given a list of contacts for answers to questions about the research and the participant's rights?
  - b. Is the principal researcher identified with name and phone number?
11. Is there a statement indicating that the participant is making a decision whether or not to participate, and that his/her signature indicates that he/she has decided to participate having read and discussed the information in the informed consent?
12. Are all technical terms fully explained to the participant?
13. Is the informed consent written at a level that the participant can understand?

Other Considerations.

1. If the participant is or may become pregnant is there a statement that the particular treatment or procedure may involve risks, foreseeable or currently unforeseeable, to the participant or to the embryo or fetus?
2. Is there a statement specifying the circumstances in which the participation may be terminated by the investigator without the participant's consent?
3. Are any costs to the participant clearly spelled out?
4. If the participant desires to withdraw from the research, are procedures for orderly termination spelled out?

Is there a statement that the Principal Investigator will inform the participant or any significant new findings developed during the research that may affect them and influence their willingness to continue participation?