



Key Elements in Informed Consent

Informed consent should include all of the following that apply:

1. Explanation of research purpose and procedures;
2. Description of procedures;
3. Benefits to the participant and/or society;
4. Risks; even minor risks that would be significant to only a few;
5. Alternate procedures/treatments available for a condition;
6. Participation is voluntary and the participant can withdraw without penalty or loss of benefits;
7. Who to contact with pertinent questions (this typically should include where to address questions that come up at a later time);
8. The amount of time required of the subjects;
9. Confidentiality of data and final disposition of data;
10. If the research involves more than minimal risk, a description of compensation and treatment that is available for injury and who to contact in the event of a research related injury; and
11. A statement of acknowledgement of having read and understood the consent document, having the opportunity to have questions answered by the Principal Investigator (or appropriate individual) and consent to participate in the study followed by the signature of the participant.
12. If the project involves the use and/or disclosure of protected health information, the Authorization for Disclosure of Patient Medical/Health Information (HIPAA Procedure 1.050 and the associated form) can be integrated with the Informed Consent Form.

Sample consent forms are available from the OSRP.



Special Populations

The consent form must be signed by the parent, guardian, or other responsible party if the study involves minors or others who are unable to sign suitable consent. Special provisions are to be made for soliciting the assent of children, when in the judgment of the IRB the children are capable of providing assent. Factors in this judgment include age, maturity, and psychological state of the children. This judgment can be made for all children involved in the study or individual child, as the IRB deems appropriate (See additional requirements for obtaining assent in Section 46.408 of 45 CFR 46).

Special procedures are required if the project involves pregnant women, fetuses, human in vitro fertilization (45 CFR 46 Sub Part B), prisoners and wards of the state (45 CFR 46 Sub Part C), or minors (45 CFR 46 Sub Part D).

In studies which involve little or no risk, or when attributes of the study indicate oral presentation to be ethically advantageous, consent information may be presented orally. Oral presentation must include each of the above that apply. When consent information is read to a group, one witness must sign acknowledgement that the oral script was in fact presented to the group.

The IRB may waive or alter elements of the consent requirements outlined above in studies that:

- involve no more than minimal risk;
- if the waiver will not adversely affect subjects rights or welfare; and
- if the research could not practically be carried out without the waiver.

In cases where Informed Consent is waived, the participant should be provided with pertinent information after participation.