

### **Table 1: Required Elements of Informed Consent**

1. A statement that the study involves research
2. An explanation of the purposes of the research
3. The expected duration of the subject's participation
4. A description of the procedures to be followed, including invasive procedures
5. The identification of any procedures that are experimental
6. A description of any reasonably foreseeable risks or discomforts to the subject (some local laws may require that relative frequencies be given for risks and discomforts, such as common, uncommon, rare)
7. A description of any benefits to the subject or to others that reasonably may be expected from the research. The subject should be made aware when there is no intended clinical benefit to him or her.
8. A disclosure of appropriate alternative procedures or courses of treatment that might be advantageous to the subject and their important potential risks and benefits.
9. A statement describing the extent to which confidentiality of records identifying the subject will be maintained
10. For research involving more than minimal risk, an explanation as to whether any compensation and/or medical treatments are available should injury occur, and if so, what they consist of and where further information may be obtained.
11. An explanation of whom to contact in the event of a research-related injury to the subject.
12. An explanation of whom to contact for answers to pertinent questions about the research (e.g. investigator) and research participants' rights (e.g. IRB office).
13. A statement that participation is voluntary and refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.
14. A statement that the subject may discontinue participation in the research at any time without penalty or loss of benefits to which he or she is otherwise entitled.

(Available at: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116>)