**Criteria for IRB approval of research. -- CFR 46.111**

 (a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

 (1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

 (2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

 (3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

 (4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by [§46.116](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116).

 (5) Informed consent will be appropriately documented, in accordance with, and to the extent required by [§46.117](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.117).

 (6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

 (7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

 (b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

**Basic elements of informed consent** **-- CFR 46.116**

 (1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

 (2) A description of any reasonably foreseeable risks or discomforts to the subject;

 (3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

 (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

 (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

 (6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

 (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

 (8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.