“(a) In order to approve research covered by this policy [the regulations] the IRB shall determine that all of the following requirements are satisfied.

(1) Risks to studies 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, [handicapped or] 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 [part 50].

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117 [§50.27].

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

(7) When [Where] 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, [handicapped, or] 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.’’ 45 CFR 46.111, 21 CFR 56.111 [FDA]
“(c) In order to approve research in which some or all of the subjects are children, an IRB must determine that all research is in compliance with part 50, subpart D of this chapter.” 21 CFR 56.111

The Institutional Review Board's (IRB) primary duty is the protection of the rights and welfare of human subjects involved in research. The IRB must determine that the approval criteria have been satisfied to approve research.

To assist IRB members in determining whether approval criteria have been satisfied, evaluation criteria and IRB considerations have been developed and provided in Human Research Protection Program (HRPP) Manual 6 “IRB Evaluation Criteria.” Checklists are also available the HRPP web site.

Additional Considerations
If the research study involves special categories of research subjects, such as pregnant women, human fetuses, neonates, prisoners, children, individuals with diminished capacity, and HIV and AIDS, see HRPP Manual 6-8 “Special Categories of Research Subjects” for additional IRB evaluation considerations and approval criteria.

If the research study involves investigational drugs or devices, see HRPP Manual 7 “Investigational Drugs and Devices.”