

# Criteria for IRB Approval

## (45 CFR 46.111 and 21 CFR 56.111)

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IRB review is necessary for all human subjects research that does not qualify as exempt research or for expedited review.

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* by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes (Beneficence).
  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 will 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 (Beneficence).
  3. *Selection of subjects is equitable*. In making this assessment the IRB will 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 considerations of research involving vulnerable populations, such as children, prisoners, pregnant women, handicapped, mentally disabled persons, or economically or educationally disadvantaged persons (Justice).
  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 the Federal regulations (Respect for Persons).
  5. Informed consent will be appropriately *documented* in accordance with, and to the extent required by the Federal regulations (Respect for Persons).
  6. When appropriate, the research plan makes adequate provision for *monitoring* the data collected to assure the safety of subjects (Beneficence).
  7. When appropriate, there are adequate provisions to protect the *privacy* of subjects and to maintain the *confidentiality* of data (Respect for Persons and Beneficence).
- 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 (Respect for Persons and Beneficence).