

Criteria for IRB Approval of Research

The Federal Regulations set out the specific criteria that should be considered by the IRB in determining whether or not to approve research involving human subjects. The following is excerpted directly from the regulations (45 CFR 46.111):

1. **Risks to subjects are minimized** (by using procedures which do not cause unnecessary risk and by, when possible, using procedures already being performed on subjects for diagnosis and treatment)
2. **Risks to subjects are reasonable in relation to anticipated benefits.** 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.
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.
5. **Informed consent will be appropriately documented,** in accordance with, and to the extent required by 46.117.
6. **Adequate provision is made for monitoring data** collected to ensure the safety of subjects.
7. **Adequate provision is made to protect the privacy of subjects and to maintain the confidentiality of data.**
8. **Additional safeguards have been included in the study to protect the rights and welfare of subjects** when some or all 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.)