

## Eight Criteria Required to Approve Research

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 **45CFR46.116/21CFR50**.
5. **Informed consent will be appropriately documented**, in accordance with, and to the extent required by **45CFR46.117/21CFR50.27**.
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**.
8. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, **handicapped**, 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**. (NOTE: FDA has additional criteria for children. OHRP has additional legal criteria for Protections for Pregnant Women, Human Fetuses, Neonates, Prisoners and Children. An OHRP governed study is essentially either 1) research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency or 2) if you have a Federal-Wide Assurance and you chose the option to apply your FWA to all studies, regardless of funding source. Federal and State regulations are the minimum protections for vulnerable populations and the IRB may desire additional protections for these populations or determine other populations as requiring additional protections as well.)

Source: 45CFR46.111, 21CFR56.111 (Note, items in red are 45CFR46 (OHRP) only and items in blue are 21CFR56 (FDA) only)