
The following criteria must be met to obtain approval of research:

- To obtain approval, all of the following requirements should be satisfied:
  - Risks to subjects are minimized:
    - by using procedures consistent with sound research design and that do not unnecessarily expose subjects to risk, and
    - whenever appropriate, by using procedures already being performed on subjects for research purposes.
  - Risks are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of knowledge that may reasonably be expected to result from the study. In evaluating risks and benefits, the IRB should consider only those possible from the research (as opposed to those stemming from therapies received by subjects even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in research (e.g., possible effects on public policy) as among those research risks that fall within the purview of its responsibility.
  - Selection of subjects occurs in an equitable manner. As it makes this assessment the IRB should include the purposes of and settings of the research study, and be particularly cognizant of special problems in involving vulnerable populations in research (e.g., children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons).
  - 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.
  - Informed consent will be appropriately documented in accordance with and to the extent required.
  - When appropriate, the research plan will make adequate provision for data monitoring to ensure subjects’ safety.
  - When appropriate, adequate provisions will be made to protect subjects’ privacy and to maintain data confidentiality.

- If any of the potential population groups may be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards will be included in the study to protect their rights and welfare.