

CFR 45 §46.111 **Criteria for IRB approval of research**

In order to approve research covered by this policy the Rocky Mountain College IRB makes a determination regarding whether all of the following requirements are satisfied:

1. **Risks to subjects are minimized:**
 - a. By using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and
 - b. 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 (e.g., 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. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, 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** or appropriately waived in accordance with §46.117.

6. **Protocols for protecting privacy and maintaining confidentiality are in place:** When appropriate, there are adequate provisions to protect the privacy of subjects and to monitor and/or maintain the confidentiality of data and the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.