

Federal Criteria for the Approval of Human Subjects Research

The KUMC Institutional Review Board (IRB) follows federal requirements for approving research. In order to approve human subjects research, the IRB must determine that the research meets all eight federal criteria that are listed in 45 CFR 46.111. The criteria are summarized as follows:

1. **Risks to subjects are minimized.** Note that all risks should be considered, including the potential for economic, legal, physical, psychological and social harm.
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.
3. **Selection of subjects is equitable.**
4. **Informed consent will be sought** from each prospective subject or the subject's legally authorized representative, except for cases in which the requirement is waived.
5. **Informed consent will be appropriately documented** as required.
6. When appropriate, the research plan makes adequate provision for **monitoring the data 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, 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.