
This guideline provides actions that must be taken by the IRB office before the conduct of research:

- The IRB shall review and have authority to approve, require modifications to (to secure approval), or reject all research activities covered by this policy.

- The IRB shall require that information given to subjects as part of the informed consent process is in accordance with IRB Policy V. The IRB may require that information, in addition to that specifically mentioned in IRB Policies (II, III, and IV), be given to the subjects when in its judgment this information may meaningfully add to subjects’ rights and welfare.

- The IRB shall require documentation of informed consent or may waive documentation in accordance with University policy.

- The IRB shall notify Principal Researchers and the VPAA in writing of a decision to approve or not approve a proposed research activity, or require modifications that must be completed to secure IRB approval of a research activity. If the IRB decides not to approve a research activity, it shall state in its written notification the reasons for its decision and offer the PI an opportunity to respond in person or in writing.

- The IRB shall conduct continuing reviews of research covered by IRB policies at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and research.