

Control of Institutional Review Board for Research

All faculty and staff members are required to present to the Institutional Review Board for Research an appropriately detailed description of proposed investigations involving human subjects, including clinical research. Either the entire committee or, in cases of expedited review, those members with competence related to the specific proposal, review each proposal, and (1) approve, (2) require changes if necessary, or (3) disapprove the proposed investigation. The decisions of the committee give special attention to the “adequacy of provisions for protecting the rights and welfare of the subjects, the appropriateness of the methods used to secure the informed consent of the subjects, and the risks and potential ... benefits of the investigation.”

All proposed changes in investigative protocol must be brought to the attention of the committee prior to making the changes effective. Proposed changes referred to the committee are evaluated on the same basis as for initial review.

The advice of the committee is conveyed to the principal investigator in writing over the signatures of those members involved in the specific review. When modifications in protocol are required, effort is made to reach an agreement between the committee and the investigator prior to the formal notification of the investigator. Each investigator, with the advice of the committee, reports to the committee concerning appropriate procedures; these reports become part of the committee's permanent file.