Special Types of Approval for Research Involving Humans

Note: The types of approval discussed below apply only to specific, funded projects. Both overall and concept approvals are issued via the expedited review procedure.

Overall Approval

Overall approval is limited to an IRB application for a training grant, center grant, or program project grant that involves human participants. This type of approval allows the Principal Investigator (PI) and the Office of Sponsored Programs Administration (OSPA) to provide a single IRB approval date to the funding agency for the overall award itself. Overall approval is, therefore, an administrative tool; it does not indicate approval for any of the specific projects described in the grant.

To obtain approval for the individual projects described in the training grant, center grant, or program project grant, the PI of each individual project should submit an Application for Approval of Research Involving Humans to the IRB for any project that involves human participants. The completed review form should include the funding source of the overall award.

Concept Approval

Concept approval is limited to an IRB application for a funded project where the funding agency has approved an initial period of time for development of the final protocol, questionnaires, data forms, or similar activities. Since the IRB cannot approve “draft” protocols or informed consent documents, concept approval shows that the IRB has approved the study in concept only, so that OSPA can award the funds for the preliminary work. Concept approval is, therefore, an administrative tool; it does not indicate approval for the enrollment of human participants.

Human participants cannot be enrolled in a project that has only concept approval. To obtain approval to enroll human participants, the PI must submit an Application for Approval of Research Involving Humans or an Exempt Study Review Form to the IRB for the study that received concept approval.