

12.0 IRB Actions following review by the convened IRB

Last Revised on 12 December 2003

12.1 Approval of research

In the case of an approval with no changes, the research may proceed once the PI receives written documentation of IRB approval.

Unless otherwise specified, the approval period for research approved without changes is one year from the date of the meeting at which approval was granted.

12.2 Stipulated minor changes or clarifications required prior to approval

The IRB may determine that a study may be approved with stipulated minor changes or clarifications. Minor changes are those changes that do not involve potential for increased risk or decreased benefit to the human subjects. Some examples of minor changes are: changes in contact information or identity of non-key research personnel, changes in the study title, and changes in the consent form that reflect the minor changes listed earlier.

For minor changes, the IRB Chair or a voting IRB member(s) designated by the Chair must ensure that the PI makes the appropriate changes to the research protocol. Such changes must be clearly delineated at the convened meeting so that subsequent review requires simple verification of concurrence. The research may proceed after the required changes are verified and the designated reviewer approves the protocol.

The chair, the primary reviewers, or a subcommittee may be assigned responsibility for reviewing the changes to ensure that the stipulated changes are appropriately addressed. The application receives final approval when all required changes have been submitted and approved.

Unless otherwise specified, the approval period for research for which minor changes were stipulated is one year from the date of the last convened meeting at which the protocol was reviewed.

12.3 Deferral

The term “deferral” is used to describe the situation in which an IRB determines that substantive changes must be made before approval may be granted. The PI’s response, including any amended materials, must be reviewed by the convened IRB.

Subject to IRB discretion, a proposal may be withdrawn if the PI does not respond to a deferral within a reasonable amount of time. If the investigator wishes to conduct a study that has been withdrawn, he/she must submit a new application, incorporating comments from the prior IRB review.