

IRB Policy #:	210
Policy Title:	<i>IRB Responsibilities in Review</i>
Date Approved:	
Date Reviewed:	

Purpose: To establish the responsibilities of the IRB during the protocol review process.

Policy:

The IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy. (45 CFR 46.109(a))

Except when an expedited review procedure is applicable, the IRB shall review proposed research at convened meetings at which a majority of the members are present, including at least one member whose primary concern is in a non-scientific area. To be approved, research shall receive the approval of a majority of those members present at the meeting. If the required number of members is lost during a meeting or a non-scientist is not present, any IRB action or vote taken at this time shall be considered invalid. (45 CFR §46.108(b))

The IRB shall require that information given to subjects as part of the informed consent process is in accordance with 45 CFR §46.116. The IRB may require that information, in addition to those required elements specified in 45 CFR §46.116(a), be given to subjects when in the IRB’s judgment the information would meaningfully add to the protection of the rights and welfare of the subject.

The IRB shall require documentation of informed consent or may waive documentation in accordance with 45 CFR 46.117.

The IRB shall notify investigators in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of research activity. If the IRB disapproves or requests modifications to the research activity, it shall include in its written notification a statement of the reasons for its decision and shall give the investigator an opportunity to respond in writing. (45 CFR §46.109(d))

The IRB may request that the administrative office conduct targeted audits to assess compliance with local, state and federal regulations, subject safety, and IRB policies and procedures when it determines the need for additional supervision or participation by the IRB during the initial and continuing review or as new information is presented by the PI. When the audit report is received, the IRB may accept it with or without revisions, impose additional measures for subject’s safety (e.g., request status reports after each subject intervention), decrease the continuing review cycle, conduct a follow-

up audit, require oversight/signatures by superior on all research, replace the PI by a qualified investigator who is not subordinate to the investigator being replaced, or limit the PI's ability to submit new research studies to the IRB.

Certification of IRB review and approval for all Federally-sponsored research involving human subjects shall be submitted to the ORC for forwarding to the appropriate Federal department or agency, as required. Compliance will occur within the time and manner prescribed for forwarding certifications or IRB review to DHHS or other Federal department or agency. (45 CFR 46.103(f))