

§ 46.108 IRB functions and operations.

(a) In order to fulfill the requirements of this policy each IRB shall:

- (1) Have access to meeting space and sufficient staff to support the IRB's review and recordkeeping duties;
- (2) Prepare and maintain a current list of the IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications or licenses sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution, for example, full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant;
- (3) Establish and follow written procedures for:
 - (i) Conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution;
 - (ii) Determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and
 - (iii) Ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that investigators will conduct the research activity in accordance with the terms of the IRB approval until any proposed changes have been reviewed and approved by the IRB, except when necessary to eliminate apparent immediate hazards to the subject.
- (4) Establish and follow written procedures for ensuring prompt reporting to the IRB; appropriate institutional officials; the department or agency head; and the Office for Human Research Protections, HHS, or any successor office, or the equivalent office within the appropriate Federal department or agency of
 - (i) Any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and
 - (ii) Any suspension or termination of IRB approval.
- (b) Except when an expedited review procedure is used (as described in § 46.110), an IRB must review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

(Approved by the Office of Management and Budget under Control Number 0990-0260)