	University of Puerto Rico Medical Sciences Campus Human Research Subjects Protection Office	Effective: 9/1/2008
		Rev. 07/01/2014

DESIGNATION OF THE INSTITUTIONAL REVIEW BOARD

Purpose:

To define the composition, membership, appointment and responsibilities of the Institutional Review Board.

Source:

45 CFR 46.107, 109 and 113
21 CFR 50.50
21 CFR 56.107, 109 and 113

Applicability:

University of Puerto Rico Medical Sciences Campus

Background:

As per federal regulations, each IRB shall have at least five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience, expertise, and diversity of its members, including considerations of race, gender and cultural backgrounds. In addition to possessing the professional competence necessary to review the specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations applicable law, and standards of professional

conduct and practice. The IRB shall therefore include persons knowledgeable in these areas.

Policy:

The IRB shall at all times be sufficiently qualified through the professional competence, expertise and diversity of its membership to ensure that a thorough and competent review is undertaken.

Procedure:

Composition of the IRB

There are currently three IRB panels at UPR MSC. They are comprised of members with varying backgrounds of expertise, experience, and diversity to provide a complete review of research activities commonly conducted by the institution and to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.

Diversity of Membership

The IRB membership is monitored to assure diversity of its members, including representation of varying professions and backgrounds; both genders; and individuals knowledgeable about community research and qualitative research; individuals knowledgeable about and experienced working with vulnerable subjects and special populations (as defined in the Subparts B, C and D).

Each IRB membership will be drawn from the following groups:

- Faculty members and administrative staff employed by the MSC
- Representatives from the different Schools of the UPR MSC
- Representatives of the community at large (non-scientists and scientists)
- Behavioral scientist(s)
- Prisoner's advocate

Voting members may have an alternate. The voting and alternate status of IRB members must be appropriate to their representative capacity and qualifications. Alternates will be nominated and appointed in the same manner as voting members, and provided the same educational materials and training as regular members. Alternates serve the same appointment period as their full Board member partner. Alternate members, and their primaries, are listed on the IRB's membership roster. The Director of the Office for the Protection of Human Research Participants and the IRB Administrator are ex-officio members (non-voting) of each IRB.

Selection and appointment

The UPR MSC Chancellor appoints all the members of the IRB. The Director of the Human Research Subject's Protection Office, in consultation with the IRB Chairs and IRB members, recommends candidates.

The Chairpersons and Vice Chairpersons are chosen within Board members that have served for at least one year on a Board. The chairpersons are designated by the Chancellor while the Vice Chairpersons are selected among the members. The IRB members are appointed for a period of three years and Chairpersons are appointed for five years.

Faculty members designated to the IRB need to have a professional degree; be knowledgeable in the area they represent; have the appropriate credentials and be familiar with research using human subjects.

Non-affiliated members are selected by nomination from the community. They are interviewed by the IRB staff to inform them about the obligations of being a Board member and to determine suitability for Board membership.

Prior to appointment as a voting member or alternate, candidates must attend an individual orientation and at least one meeting where an experienced IRB member is assigned as a mentor to familiarize them with the meeting process. A letter of appointment from the Chancellor will be sent to the appointee accordingly.

Authority, Duties and Responsibilities

The UPR MSC IRB has the authority to review, approve, disapprove or require changes in research or related activities involving human subjects. The IRB has the authority to:

- Review and approve, require modifications (to secure approval), or disapprove all research activities covered by this policy.(45 CFR 46.109, and 21 CFR 56. 109)
- Require that information given to subjects as part of informed consent is in accordance with 45 CFR 46.116 and 21 CFR 50.25.
- Require documentation of informed consent or waive documentation in accordance with 45 CFR 46.117 and 21 CFR 56.109(c).
- Notify investigators in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it will include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in writing, or in special circumstances, in person.
- Conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year.
- Have authority to observe or have a third-party observe the consent process and to review the research documentation.
- Review research (45 CFR 46.403) or clinical investigations (21 CFR 50.50) involving children as subjects and approve only those clinical investigations that satisfy the criteria and conditions as described in subparts D of the federal regulations cited.
- The IRB also has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with serious harm to subjects (45 CFR 46.113) (21 CFR 56.113). Any suspension or termination of approval will include a statement of the reasons for the IRB's action and will be reported promptly to the investigator, appropriate institutional officials, and the Department or agency head.

The IRB does not have the authority to grant retroactive approval should a research study be initiated without prior IRB review.

Member's responsibilities include serving as primary reviewer for assigned protocols, reviewing assigned materials in advance of scheduled meetings, and, presenting their review at the IRB Meeting for which the project was assigned including assessment of risk level, recommended action and recommended period of approval. Members who do not adequately fulfill their responsibilities, as determined by the IRB Chair, may be asked to step down from IRB membership by the UPR MSC Chancellor.

Attendance Requirement

IRB Members are expected to attend all scheduled meetings of their IRB panel and participate in the discussion and review of all protocols. Members of the IRB who are not able to attend a scheduled meeting should provide sufficient advance notice (at least five working days) to the OPPHI. If a member is absent for three times with or without the required advance notice and justification, he or she may be asked to leave the position and a replacement will be appointed.

Removal of IRB Members

IRB members, including the Chair of an IRB, are subject to removal before the completion of their approved term for cause, at the discretion of the appropriate Institutional Officer. They are subject to removal based on any of the following:

(a) Scientific misconduct: fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting or reporting research;

(b) Any breach of confidentiality;

(c) Failure to protect the rights of human research participants;

(d) Failure to comply with attendance requirements;

(e) Failure to report or disclose a major conflict of Interest;

(f) Failure to comply with federal regulations, institutional policies, or IRB requirements for their own ongoing research activities;

(g) Inability to fulfill his/her role as member or Chair effectively and efficiently.

Removal of the IRB member shall be recommended by the IRB chairperson with approval of the Chancellor. Removal of the Chairperson shall be recommended by the Director of the IRB Office with approval of the Chancellor.

IRB Members Roster

OPPHI Staff is responsible for preparing, registering and updating a list of IRB members identified by name, earned degrees and representative capacity. They will also keep a file with credential documentation, sufficient to describe each member's chief anticipated contributions to IRB deliberations.

OPPHI posts the current rosters of all three IRBs on its website.

IRB Fees

The MSC IRB charges a $1,850.00 fee for the initial review and processing of industry sponsored protocols and a $900.00 fee for each Continuing Review submitted for review. **(Only for Industry "Pharmaceutical" Sponsored Clinical Trials)**