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

IRB ADMINISTRATIVE OFFICE (OPPHI)

Purpose:

To define the scope of authority and duties of the Human Research Subjects Protection Office of the UPR MSC (Oficina para la Protección de Humanos en Investigación, in Spanish).

Source:

Federal Wide Assurance signed with the DHHS (FWA #00005561).

45CFR 46.115
21 CFR 56.115

Applicability:

This policy applies to all human subjects' research activities conducted by any UPR MSC faculty, staff, students, other affiliated investigators, or otherwise conducted at or sponsored by the University of Puerto Rico Medical Sciences Campus, irrespective of the scope, funding, or location of the research.

Background:

The Office of Human Research Protection (OHRP) is the key federal office responsible for implementation of the Common Rule (45 CFR 46) and other federal regulations concerning human research protections. The University

of Puerto Rico Medical Sciences Campus filed Institutional Assurance (FWA #00005561), committing to comply with federal regulations for human research subjects' protection irrespective of the source of funding.

The Human Research Subjects Protection Office, (Spanish acronym OPPHI), of the UPR Medical Sciences Campus, was created in October 2006 as the administrative support office for the IRB. For the purpose of this document, OPPHI and IRB office will be used interchangeably.

Policy:

The Human Research Subjects Protection Office of the UPR MSC (OPPHI by Spanish acronym) or IRB Office, while performing administrative functions for the IRB, supports IRB responsibility to promote and enhance the ethical conduct of research; provide oversight for ongoing human subjects research; promote education for investigators, institutional officials and IRB members; and evaluate research that does not comply with the requirements of the institution.

Procedure:

The IRB office is the central point of contact for investigators, research subjects, and regulatory agencies. It is responsible for organizing and documenting the IRB review process, monitoring research regulations, producing educational programs and materials for faculty and staff, and providing assurance that the MSC is in compliance with federal, state, and campus policies. The IRB Office responds to the Chancellor's Office who is the federally authorized institutional officer charged with overseeing human subjects' research and IRB functions at the UPR MSC.

Responsibilities of the OPPHI office include:

(1) Establish and administer institutional policies regarding responsible conduct of research.

(2) Ensure respect, beneficence, and justice for all research participants as a result of oversight by the Institutional Review Boards (IRB) through:
   (a) Initial review of all human subjects research for approval when appropriate,
   (b) Periodic continuing review of all ongoing human subject research protocols,
   (c) Evaluation of adverse and serious event reports,
   (d) Investigation of allegations of research improprieties and non-compliance regarding IRB policies, federal regulations applicable to human subjects research and the institutions' FWA with OHRP.

(3) Serve as a resource for investigators regarding policies and regulatory requirements.

(4) Serve as the liaison with the Office for Human Research Protections and the Food and Drug Administration in the Department of Health and Human Services, as well as with other federal departments and agencies with similar responsibilities.

(5) Participate in the education and training of investigators, signatory officials and IRB members.

(6) Collaborate with other area IRBs and research review committees.

(7) Maintain communication with the appropriate committees dealing with research involving animals, biosafety and radiation.

Other activities of the OPPHI Office are:

(1) Receive all research protocols and reports from the investigators.

(2) Verify that all required documents have been received. If any are missing, contact the Principal Investigator. Verify the completeness of the documents.

(3) Serve as a link between the IRB members and the investigators.

(4) The IRB office will create the IRBWISE accounts and maintain a register of all the investigators.

(5) Assign a protocol number in the IRBWISE System for each protocol.

(6) Complete a preliminary review process within 1-2 weeks of time of receipt of protocol.

(7) Provide administrative assistance to the IRB.

(8) The Office will collaborate with the IRB Chair for the assignment of primary reviewers for every protocol to be reviewed and collaborate in the preparation of the meeting's agenda.

(9) Distribute meetings' materials to the IRB members one week prior to the meeting.

(10) Insert approval date into database upon approval by IRB.

(11) Maintain all IRB records and research files in a confidential manner and according to 45 CFR 46.115, including copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects; records of continuing review activities; copies of all correspondence between the IRB and the investigators.

(12) Maintain minutes of IRB meetings in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote of these actions including the number of members voting for, against and abstaining; the basis for requiring changes or disapproving research; and a summary of the discussion of issues related to the research presented and their resolution.

(13) Maintain a list of IRB members identified by name and representative capacity together with their credentials.