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

IRB COMMUNICATION WITH INVESTIGATORS, INSTITUTIONAL OFFICIALS AND FEDERAL AGENCIES

Purpose:

To describe the process of IRB communication with investigators and reporting to the institutional officials and federal agencies.

The IRB must timely notify each investigator, in writing, of the outcome of the IRB's review specific to their study. The determination of the IRB, including any conditions of approval, should be clearly stated.

IRB is also responsible to report actions taken about reports of unanticipated problems, protocol suspension or termination, findings of non-compliance with human subject protection regulations, or other actions considered of pertinence to Institutional Officials, OHRP and FDA if applicable.

Sources:

21 CFR 56.109, 56.113
45 CFR 46.109, 46.113
Guidance on reporting incidents to OHRP/May 27, 2005

Applicability:

These policies and procedures apply to all research submitted to the IRB.

Policy:

The Institutional Review Board (IRB) at the University of Puerto Rico Medical Sciences Campus complies with federal regulations and notifies investigators of all decisions made by the IRB in writing. It is vital that open and frequent communication be maintained between the IRB, the investigator, and the investigator's research team.

IRB actions about reports of unanticipated problems, protocol suspension or termination, findings of non-compliance with regulations or other actions considered of interest to Institutional Officials, are promptly communicated in writing by the IRB office. These actions will also be notified if applicable to the federal agencies (OHRP and FDA).

Procedure:

Communication with investigators

The IRB office utilizes electronic software for the management of the protocols submitted. This software allows the investigators to monitor the status of their protocols, sends reminders for continuing reviews and allows exchange of information between the IRB members, IRB staff and investigators.

IRB decisions are communicated on real time to the investigators through software generated e-mails. These are followed by formal letters signed by the IRB Chairperson. The IRB letters should include the title and protocol number, the IRB decision, and if applicable the rational for the decision, a list of the issues to be addressed by investigators and the IRB recommendations for addressing these issues.

The IRB notifies the investigator regarding the review decision of all submissions related to new or on-going research projects. These decisions include:

- All recommendations for revisions, additions, or deletions to a research project.

- Notification of an impending continuing review and the outcome of the project once it has been reviewed.

- Actions to withdraw, suspend, or terminate approval for a research project and the reason such action is being taken.

- Status of all adverse events submitted for review.

The OPPHI fosters open communication from the investigator regarding questions, concerns and suggestions as they pertain to the IRB. Questions are answered as promptly as possible and triaged for appropriate responses.

Appeal of IRB Action

An investigator may appeal the revisions required by the IRB in the protocol and/or informed consent form. This appeal must be in writing and submitted to the IRB Chair. Investigators may also appeal an IRB decision to disapprove a study. Any such appeal may be in writing and must be reviewed by the full IRB at a convened meeting. If the appeal is denied and the study disapproved, the Investigator's institution cannot overrule the IRB's decision.

IRB Reports to Institutional authorities, funding agencies and to the Federal Government

Written reports of IRB actions regarding unanticipated problems, protocol suspension or terminations, findings of investigator's non-compliance with human subjects' protection regulations, or other actions considered pertinent to Institutional Officials are prepared by the IRB office staff within a week following the IRB meeting. These reports are forwarded to the investigator's supervisors and the Institutional Official.

The Chancellor of Medical Sciences Campus is the designated Institutional Official as per our Assurance with OHRP. Whenever reports are required to be sent to OHRP and/or FDA they are sent in writing following the guidelines offered by the agency and signed by the Chancellor.

Contact Information for Compliance Oversight:

OHRP

Kristina Borror
Director
Division of Compliance Oversight
Office for Human Research Protections
101 Wootton Parkway, Suite 200
Rockville, MD 20852

FDA

For Drug Products:
Division of Scientific Investigations (HFD-45) Office of Compliance
Center for Drug Evaluation and Research
White Oak Campus
10903 New Hampshire Ave. BLDG 51, Rm. 5341
Silver Spring, Maryland 20993

For Biologic Products:
Bioresearch Monitoring Branch (HFM-664) Division of Inspections and Surveillance
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research/FDA
1401 Rockville Pike, Room 400S Rockville, Maryland 20852-1448

For Medical Devices:
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard – HFZ 403
Rockville, MD 20850

Links to guidelines for reporting incidents:

OHRP
http://www.hhs.gov/ohrp/policy/incidreport_ohrp.html

FDA
http://www.fda.gov/oc/gcp/irbterm.html