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

INVESTIGATORS RESPONSIBILITIES

Purpose:

To define the responsibilities of a research investigator within the UPR MSC.

Sources:

UPR Medical Sciences Campus Federal Wide Assurance;
45 CFR 46;
Investigational drugs - 21 CFR 312.60;
Investigator devices - 21 CFR 812.100;
Biologics - 21 CFR 600.10

Applicability:

Research Investigators

Policy:

The principal investigator is the ultimate protector of the research participant's rights and safety. He or she is responsible to:

(a) Submit a research project for IRB review

(b) Ensure that all human subjects' research receives IRB approval before the research is started

(c) Conduct study in accordance with the approved protocol and consent

(d) Personally conduct or supervise the study

(e) Maintain a protocol file for human research project documents

(f) Comply with Federal and Institutional time periods for record retention

(g) Recruit subjects in an ethical manner

(h) Ensure that the requirements for obtaining informed consent are met

(i) Respond to subjects who have an adverse event

(j) Keep subjects fully informed of any new information

(k) Provide reports as required by the sponsor and by the IRB

(l) Make records available for inspection

(m) Ensure accountability of investigational drugs, devices, or biologics

(n) Protect the privacy of subjects and maintain the confidentiality of data

Procedure:

To serve as the principal investigator on a human subject's research, an individual must be certified in Human Subjects' Protection. He or she must also meet one of the following criteria:

- A credentialed medical staff and/or faculty member of UPR MSC.

- A non-medical staff person with a UPR MSC appointment such as nurse, pharmacist, etc. The IRB may require a UPRMSC faculty or medical staff to serve as a co-investigator depending on the nature of the study.

If the principal investigator is not a UPRMSC attending physician and the protocol includes treatment at a UPRMSC affiliated facility, a responsible UPRMSC physician-investigator must be identified. The responsible physician investigator must be certified in Human Subjects' Protections.

Investigators may not initiate any research activity involving human subjects without prior IRB review and approval. Therefore, the investigator must have approval prior to publication or presentation of human subjects' research data (e.g., journal article, poster session, public speech or presentation, or project report).

The principal investigator must not institute any changes to the IRB-approved protocol and/or consent form document without first obtaining IRB approval for such changes. The sponsor (if applicable) must also be notified of an investigator's intent to modify the protocol or consent form. In rare instances, an investigator may deviate from the protocol without first notifying the IRB in order to eliminate immediate hazard to a study participant. Any such protocol deviations must be promptly reported to the IRB. Documentation surrounding the event should also be placed in the research record and the medical record, if applicable.

The principal investigator may delegate study-related activities, but he or she is ultimately responsible for the conduct of the study. It is the responsibility of each investigator to assure that all procedures in a study are performed with the appropriate level of supervision and only by individuals who are licensed or otherwise qualified to perform them. Every member of the research team is responsible for protecting participants in research. Co-investigators, study coordinators, nurses, research assistants, and all other research staff have a strict obligation to comply with all IRB determinations and procedures, to adhere rigorously to all protocol requirements, to inform investigators of all serious and unexpected adverse reactions or unanticipated problems involving risk to participants or others, to oversee the adequacy of the informed consent process, and to take whatever measures are necessary to protect the safety, rights and welfare of participants. Regardless of involvement in research, each member of the research community is responsible for notifying the IRB promptly of any serious or continuing noncompliance with applicable regulatory requirements or determinations of the designated IRB of which they become aware, whether or not they are directly involved in the research.

It is the responsibility of the principal investigator to inform all co-investigators about the protocol and consent form. It is also the responsibility of the principal investigator to be aware of any conflicts of interest for any members of the study team. The principal investigator must provide all co-investigators, research coordinators and other research staff with a copy of the current research protocol and consent form and fully inform them of:

- Study procedures (including modifications to the protocol).
- Informed consent requirements and process.
- Potential risks associated with study participation and the steps to be taken to prevent or minimize these potential risks.
- Adverse event reporting requirements.
- Data and record-keeping requirements.
- Current IRB approval status of the study.

Principal investigators must also ensure that if their protocol lists collaborating investigators at other institutions, that appropriate IRB approval for the study has been obtained at the other institution.

The recruitment of subjects must respect the research subjects' privacy and confidentiality. An investigator should not contact patients who are not in his or her practice unless the patient's physician or caregiver has previously notified the potential research subject (or the parent or legal representative of the potential research subject) and obtained his or her approval for such contact.

It is the principal investigator's responsibility to oversee the informed consent process, making sure that each potential subject fully understands the purpose of the research, the research procedures, the potential risks of study participation, and his or her rights as a research study volunteer. Informed consent must be obtained prior to the initiation of any study procedure. It is also the principal investigator's responsibility to be sure that anyone obtaining consent from subjects is certified in Human Subjects' Protection and appropriately knowledgeable about the study. The principal investigator is also required to include appropriate additional safeguards in the study to protect research subjects who are likely to be vulnerable to coercion or undue influence. It is the principal investigator's responsibility to assure that potential subjects have the cognitive ability to give consent. To attest to the appropriateness of the subject for the study and the adequacy of the consent process, all consent forms must be signed by the principal investigator or consent designee within 30 days of the subject signing the consent form.

The principal investigator must maintain a file of human subject's research project documents. The file must include the following items:

- A copy of the human subject's research application submitted to the IRB along with all IRB approvals, amendments, continuing reviews, protocol deviations, and adverse events.

- A copy of the sponsor's protocol (if applicable).

- A copy of the Federal grant application (if applicable).

- A copy of the investigator's brochure for an investigational new drug (if applicable).

- A copy of the investigational device exemption information (if applicable).

- A copy of an investigator-initiated IND or IDE application (if applicable).

- A copy of the consent form with the IRB stamp and expiration date.

- The original of each consent form signed by each participant enrolled in the research. For studies involving inpatients, the investigator is responsible for ensuring that a copy of the consent form is in the patient's medical record.

- A copy of all correspondence with the IRB, sponsor, funding source, FDA, or others.

- A copy of all data derived from the study (case report forms, computer data, adverse event reports, drug/device accountability records etc.)

The principal investigator is required to retain records associated with a human subject's research project. The record-keeping requirements vary depending on whether Federal funding was provided for the project or the protocol was conducted under FDA regulations. The data stored must be kept in a secure, protected manner.

Records for projects that involve FDA regulated articles (drugs, devices, biologics, assays, etc.) must be kept for periods required by FDA regulations based on whether the principal investigator is a sponsor or an investigator.

FDA Regulated Research Investigators

An investigator is required to maintain adequate records of the disposition of the drug, including dates, quantity, and use by subjects. If the investigation is terminated, suspended, discontinued, or completed, the investigator shall return the unused supplies of the drug to the sponsor, or otherwise provide for disposition of the unused supplies of the drug under 21 CFR 312.59.

An investigator is required to prepare and to maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual subject administered the investigational drug or employed as a control in the investigation. Case histories include the case report forms and supporting data including: signed and dated consent forms and medical records, progress notes of the physician, the subjects' hospital charts, and the nurses' notes. The case history for each individual must document that informed consent was obtained prior to participation in the study.

Records are required to be maintained for a period of two years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until two years after the investigation is discontinued and FDA is notified.

Investigators must ensure that investigational products are used only for the specific protocol for which they were provided, that each study participant is given specific instructions for their use, and that each subject is following the directions. Investigational products must be adequately and appropriately secured, especially in the case of drugs subject to the Controlled Substances Act. The material should be kept in a locked cabinet or enclosure with limited access.

Confidentiality of Data

It is the responsibility of the investigator to provide a data privacy and confidentiality plan with justification in the protocol on what steps are taken to maintain confidentiality of subject data. The plan must describe how confidential information will be protected from improper use and disclosure. Discussion of maintenance of subject identifiers or a plan to destroy

identifiers at the earliest opportunity consistent with the appropriate conduct of the research must be included. Assurances must be provided that confidential (private) information is necessary for the conduct of the research and that this information will not be re-used or disclosed to any other person or entity without written authorization by the subject.

Consent Designees

The principal investigator does not have to obtain consent personally. The study team may include consent designees who are authorized to obtain consent. Consent designees listed on the protocol Checklist (or added to the study by amendment) may obtain consent only after the approval of the IRB for each designee. Each individual who interacts with potential research participants as part of the consent process must have completed Human Subjects' Protections Certification. The principal investigator must ensure that each of these individuals is knowledgeable about the study and capable of answering study- related questions posed by the potential participant.

Participant Complaints/Concerns

The principal investigator is responsible for providing contact information in the consent form to allow participants an opportunity to express complaints or concerns about study procedures or participation. Contact information must be included in the consent form. Complaints received by the IRB will be investigated and reported to convened IRB and institutional official (if, applicable).

The principal investigator is required to retain documentation in the protocol file of any complaints or concerns and their resolution. Serious complaints should be brought to the attention of the IRB when they occur, and all complaints should be reported at the time of continuing review.

Data and Safety Monitoring Plan

For studies that do not have a data safety monitoring board (DSMB), it is the responsibility of the investigator to provide a Data and Safety and Monitoring Plan (DSMP) for the IRB to review as part of the protocol.