University of Puerto Rico
Medical Sciences Campus

USE OF HUMAN SUBJECT IN INVESTIGATION
INVESTIGATOR'S RESPONSIBILITIES

1. In designing the study, the investigators should consider the three underlying ethical principles for conducting research with human subjects: respect for persons, beneficence, and justice.

2. Research investigators should acknowledge and accept their responsibility for protecting the rights and welfare of human research subjects and for complying with all applicable provisions of the University policies dealing with protection of human subjects. Investigators must review the University's approved Assurance Document.

3. Investigators are responsible for insuring that research involving human subjects is submitted to and approved by the appropriate Institutional Review Board (IRB) before initiation of the research.

4. Research investigators who intend to involve human research subjects, will not decide the exemption from applicable Federal regulations or provisions. The investigators must submit a request for exemption that will be reviewed by designated representatives of the IRB.

5. Investigators are responsible for complying with all IRB policies, decisions, conditions, and requirements. Investigators are responsible for insuring that the research is carried out as specified in the approved IRB protocol.

6. Unless otherwise authorized by the IRB, investigators are responsible for obtaining and documenting informed consent in accord with Federal regulations (45 CFR 46 and 21 CFR 50)

7. Research investigators are responsible for providing a copy of the IRB approved informed consent document to each subject, unless the IRB has specifically waived this requirement.

8. Unless otherwise authorized by the IRB, investigators are responsible for insuring that assent from research subjects who are minors is obtained and documented in accord with IRB policies and requirements.

9. Research investigators are responsible for reporting progress of approved research to the IRB, as often as and in the manner prescribed by the approving IRB based on the risks to subjects, but no less than once a year.

10. Investigators are responsible for promptly submitting to the IRB a modification to a previously approved protocol when:

    a. It is proposed to involve human subjects, and the activity previously had only indefinite plans for involvement of human subjects;

    b. It is proposed to change the previously approved human subject research activities. The changes cannot be initiated without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subjects.

11. Research investigators must promptly report to the IRB and to the sponsoring Federal departments any injuries, adverse events or other unanticipated problems involving risks to subjects and others, in accord with IRB policies and requirements.