INTRODUCTION

The University of Puerto Rico Medical Sciences Campus acknowledges that it bears full responsibility for the performance of all research involving human subjects done at the campus, its associate institutions or by its faculty and or students, residents/fellows, including complying with Federal and local laws as they may relate to such research.

The Institution will ensure that, unless specifically exempted, **all** research will be reviewed and approved by the IRB. The involvement of human subjects in research as covered by this policy will not be permitted until the IRB has reviewed and approved the research protocol ensuring that an informed consent is required and obtained in accordance with and to the extent required by the Code of Federal Regulations (CFR). When applicable, certification of the IRB's review and approval for all federally funded research involving human subjects will be submitted to the awarding agency with the application of proposal for funding or as soon as approved by the IRB. Furthermore, the IRB's review of research on a continuing basis will be conducted at appropriate intervals but not less than once per year. Federally funded research involving human subjects will be handled in the same manner.

It is the policy of this Institution, that unless informed consent has been specifically waived by the IRB, no research investigator shall involve any human being as a subject in research unless the research investigator has obtained the legally effective informed consent from the subject or the subject's legally authorized representative.

The Institution will require appropriate additional safeguards in research that involves: (1) fetuses, pregnant women, or human ova in vitro fertilization, (2) prisoners, (3) children, (4) the cognitively impaired, and/or (5) other potentially vulnerable groups. In doing so, this Institution acknowledges and accepts its responsibilities for protecting the rights and welfare of human subjects in research.

This Institution is responsible for ensuring that no performance site cooperating in the conduct of research does so without the Federal

department or agency approval of an appropriate assurance of compliance and satisfaction of IRB certification requirements.

The Institution maintains IRB panels in accordance with all applicable regulations. These IRBs will have the responsibility and authority in the Institution, its components and affiliates to review, approve, disapprove or require changes in appropriate research activities for the protection of human subjects.

This Institution encourages and promotes constructive communication among the IRB, investigators, research administrators, department heads, clinical care staff, other Institutional officials, and human subjects as a means of maintaining a high level of awareness regarding the safeguarding of the rights and welfare of the subjects.

As such, the institution will exercise the appropriate administrative overview to ensure that its practices and procedures designed for the protection of the rights and welfare of human subjects are being effectively applied and are in compliance with the established requirements.