	University of Puerto Rico Medical Sciences Campus Human Research Subjects Protection Office **OPERATING PROCEDURES**	Effective: 9/1/2008 Rev. 07/01/2014
SCOPE OF AUTHORITY		

Purpose:

To describe the authority of the IRB as defined by the Code of Federal Regulations and designated by the Chancellor of the Medical Sciences Campus.

Sources:

45 CFR 46; 21 CFR 50; 21 CFR 56

Applicability:

UPR MSC faculty, staff, students and all other affiliated investigators.

Background:

As per Institutional Assurance, the IRB shall review all new and continuing research that fall within the University of Puerto Rico Medical Sciences Campus. The IRB reviews research in accordance with current Department of Health and Human Services (DHHS) and Food and Drug Administration (FDA) regulations. The main purpose of the IRB is to protect the rights and welfare of Human subjects who participate in research.

Policies:

No research involving human participants may begin until the UPR MSC IRB has granted its approval or accepted a waiver of IRB review.
All human subjects' clinical or behavioral research conducted by UPR MSC investigators, regardless of its source of financial support, must be approved by the IRB unless the IRB determines it to be exempt from their review, and must comply with IRB policies and principles.

Except for research in which the only involvement of humans is in one or more of the categories exempted or waived, all research involving human subjects, and all other activities which involve such research, regardless of sponsorship, must be submitted to the IRB. This applies if one or more of the following occurs:

(1) The research is sponsored by this Institution, or

(2) The research is conducted by or under the direction of any employee or agent of this Institution (including trainees and students), in connection with his or her Institutional responsibilities, or

(3) The research is conducted by or under the direction of any employee or agent of this Institution using any property or facility of this Institution, or

(4) The research involves the use of this Institution's non-public information to identify or contact human research subjects or prospective subjects.

Procedure:

UPR MSC Faculty, Staff and Students

IRB review is required for all human subjects' research conducted on or off-campus by faculty, staff, students or any other affiliated investigator. An

investigator is an individual who assumes responsibility for part or all of the actual conduct of a research study and/or the reporting of results. When a faculty or staff member serves as a consultant that is, as expert advisor only, on a non- otherwise MSC- affiliated project, MSC IRB review of the research is not required.

Students proposing to engage in human subject research must have an internal or external faculty member as an advisor under whose supervision the research will be conducted. The student cannot be the principal investigator for the purpose of the IRB. In such cases the faculty advisor or other faculty member associated with the study will act as PI, while the student can be listed as co-investigator or sub-investigator.

Please note that when an employee of any type (faculty or staff, full time or part time, permanent or temporary), or a student conducts research at an institution that has its own IRB, approval is necessary from ***both*** the IRB at the site of the study and from the UPR MSC IRB.

UPR MSC Clinical Staff

Research conducted by clinical faculty (including *ad-honorem*) is subject to review by the UPR MSC IRB if the research is within the course and scope of their duties with the institution or is conducted at any of the UPR MSC-affiliated institutions, or conducted with UPR MSC databases, trainees or students.

Private physicians, who have clinical or adjunct faculty appointments, often perform important ancillary roles in research sponsored by the UPR MSC, such as: recruitment and preliminary screening of patients, follow-up of patients, adjustment of medications, performance of tests, and collection of blood/urine samples. In cases where a UPR MSC faculty member serves as the principal or a co- investigator in the conduct of the research, UPR MSC IRB will review the protocol in the standard manner. In the case when the primary responsibility is to be assumed by the clinical or adjunct faculty member for the conduct of a study at his or her private office, or at a non-affiliated hospital or facility, the

research **may** be reviewed by the UPR MSC IRB if all of the following conditions are met:

(1) The department chair certifies that:
   (a) the clinical faculty member is an active participant in the University's programs;
   (b) the clinical faculty member has agreed to conform to all department and university policies governing research including review and approval by the IRB of the proposed research; and
   (c) the standards of the private office or other facility where the research is to be conducted are sufficient to assure that adequate facilities and expert professional care is available for a subject in the event of difficulties;

(2) Approval of the IRB (or administration if there is no IRB) of the institution where the research is to be conducted is documented,

(3) The investigator understands his or her responsibilities relating to the conduct of human research and agrees in writing to abide by all requirements imposed by the UPR MSC IRB.

Non Employees

Individuals who are not employees of the institutions regularly covered by the UPR MSC IRBs, but who wish to conduct research involving patients, staff, students or facilities of any of the institutions regularly covered by the MSC IRBs, must have their proposed research reviewed by the appropriate MSC IRB, must obtain MSC IRB approval before beginning the study and must submit a "Non-affiliated Investigator's Agreement together with a copy of his/her Curriculum Vitae. The same instructions apply to individuals who are not employees of the institution and wish to conduct research in other facilities not regulated or administered by the MSC IRB.

These two documents are also required for those individuals who are not employees of the institutions regularly covered by the MSC IRBs and wish to serve in the capacity of a co-investigator on a research study for which the principal investigator is affiliated.