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

CONFLICTS OF INTEREST

Purpose:

This policy is intended to protect subjects of human research. It is not intended to eliminate all situations of conflict of interest, but rather to enable individuals to recognize situations that may be subject to question and resolve them so as to avoid conflicts of interest. Thus an integral part of the policy is disclosure whereby individuals regularly review their professional activities.

Sources:

DHHS 2004 Final Guidance: Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subjects Protection.

Applicability:

Investigators, IRB Members, IRB Staff

Background:

Public trust in the research enterprise and the legitimacy of its powerful role in society require a constant amenability to public scrutiny. Consequently, it is necessary at all times to assure the continued confidence of the public in the judgment of scholars and clinicians and in the dedication of academic research institutions to the integrity of the

research enterprise. The strength of this assurance is based on the assumption that scholars are honest and conduct their research with the highest standards and integrity.

Policy:

(1) Researchers submitting protocols using human subjects must disclose all interests that may be perceived as a conflict with the best interest of the subject in order for the research to be considered for approval.

(2) IRB's are also responsible for ensuring that members who review research have no conflicting interest.

Procedure:

Investigators Conflict of Interest

Individuals directly involved in the conduct, design or reporting of research involving human subjects should not have more than a minimal personal financial interest in a company that sponsors the research or owns the technology being studied. A conflict of interest arises when a researcher is or may be in a position to put his or her own interest before the best interests of research subjects. Conflicts involving the IRB itself or conflicts involving the institution must be managed. In order to manage such conflicts, the IRB must be informed of potential conflicts of interest.

Researchers who have completed Financial Disclosure forms required by the FDA to be submitted to a sponsor of the research may submit a copy of that form to the IRB.

Researchers must complete the IRBWISE Conflict of Interest questions in the IRBWISE application. Based on the information submitted by the researcher for review, the IRB may determine that:

(a) no conflict exists, or

(b) a conflict exists and must be disclosed to the subjects in the informed consent statement, or

(c) a conflict exists and the researcher must resolve the conflict before the research can be approved.

Examples of Reportable and Non Reportable Activities

(1) Non-Reportable Activities

The following activities and relationships do not need to be reported and do not represent a conflict of interest because they have been generally accepted practices and do not violate fundamental ethical principles:

(a) Receiving royalties for published scholarly works and other writings.

(b) Accepting honoraria for commissioned papers and occasional lectures.

(c) Receiving payment for reasonable travel and lodging expenses related to presentations of scholarly work or to a person's academic endeavor.

(d) Investing in mutual funds.

(e) Participating in a University approved corporation.

(f) Payments for clinical research to an approved practice corporation or to a department fund for salary or other expenses of conducting clinical trials.

(2) Reportable Activities

(a) Conducting research in applied and/or clinical research on a technology developed by the investigator or a member of his/her immediate family (spouse, children, parent, in-laws, and siblings).

(b) The financial relationship of an investigator or his/her immediate family member with the sponsor of his/her research (acting as scientific advisor or consultant, or

receiving honoraria exceeding $5,000 annually, or acting as director or other executive).

(c) Conducting applied and/or clinical research on a technology owned by a business in which the investigator or a member of his/her immediate family holds 5% or more of the outstanding stock or stock options.

(d) Receiving royalties under institutional royalty-sharing policies from marketing the drug, device or procedures that is the subject of the research.

(e) Receiving payments directly from the sponsor, rather than through the University or an approved UPR MSC entity, for recruiting subjects.

Conflict of Interests among IRB Members

IRB members may not participate in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested. IRB Board Members are responsible for making known any potential or perceived conflict of interest concerning protocols reviewed by the IRB. This would include the IRB member's service in any of the following categories with respect to the study in question:

- Principal Investigator,
- Co-Principal Investigator,
- Investigator receiving funding from the study, as listed in the study budget,
- In a supervisory role over the PI of the study, or
- Family member of investigators.

Board members should make known any conflict of interest prior to the beginning of the Board's discussion of the protocol under review. They must leave the meeting room prior to the Board's deliberation and vote.

If the Conflict of Interest status of an individual changes during the course of a study, the individual is required to declare this to their IRB Chairperson and the Director of the HRSPO.