



Puerto Rico Clinical and Translational Research Consortium

Conflict of Interest in Research

I. Procedure Title: Financial Conflict of Interest in Research at The University of Puerto Rico- Medical Sciences Campus

II. Overview/Procedure Description:

This Standard Operating Procedure is based on the University of Puerto Rico (U.P.R.) Board of Trustees Policy and Guidelines for Financial Conflicts of Interests and Commitments in Research and Sponsored Programs of the University of Puerto Rico. The U.P.R. establishes and enforces standards to guarantee that the design, conduct, and reporting of all federal and non-federal research will be free from bias resulting from Investigator financial conflict of interest and commitment. It is intended to provide effective and transparent processes for the disclosure, review, management and reporting of the potential conflict of interest within the University community.

The Puerto Rico Clinical and Translational Research Consortium (PRCTRC) has an obligation to ensure that any investigator, co & sub-investigator planning to participate, or is participating in research, and any other person, regardless of title or position, who is responsible and has the authority to make independent decisions related to the design, conduct, reporting or direct administration of University research independently of its source of funding, comply with this policy.

A. Purpose:

Establishes procedures to identify eliminate and manage institutional conflict of interest of the research and sponsored programs conducted at the U.P.R. pertaining to all research projects, independently of their source of funding.

III. Area(s) of Responsibility:

Apply to all U.P.R. investigators, and to all funded U.P.R. research, as well as to all unfunded human subjects' research. Investigators means the project director or principal investigator and any other person, regardless of title or position, who is responsible and has the authority to make independent decisions related to the design, conduct, reporting or direct administration of University research funded by the federal sponsor, or proposed for such funding, which may include, for example, sub grantees, contractors, collaborators or consultants.

IV. Procedure Details:

1. Education and Training

Prior to engaging in any research protocol project, all investigators must complete training on the investigator obligations under this policy. This training must be repeated at least every four (4) years and must be completed immediately if this policy is revised so as to affect the investigator obligations, if an investigator is new to the University, or if the University finds an investigator to have violated this policy or any applicable management plan.

All U.P.R. investigators and research personnel are required to complete prior to August 24, 2012, the web-based NIH tutorial of Financial Conflict of Interest <http://proctrc.rcm.upr.edu/researchers/regulatory-knowledge-and-support>, or a valid alternative resource.

2. Prior to submission/initiation of research

Prior to the investigator's submission of a grant application or the University's execution of a cooperative agreement or sponsored research contract, or prior to initiation of any human subjects research, whether funded or not, each investigator is required to submit a disclosure form describing any financial interest held by the investigator, the investigator's spouse or any depend child of the investigator determines to be reasonably related to the investigator's institutional responsibilities. This disclosure form will be endorsed by the research personnel's unit head (department chair, institute director, division head, among others) and submitted to the campus Chancellor-designated Conflict of Interest Officer (COIO) who will then review any financial interest disclosed.

When an investigator not covered above reasonably concludes or reasonably should conclude that his/her research presents or appears to present financial conflict of interest, the investigator must disclose that fact to its corresponding campus COIO. In those cases where the University has determined that a financial conflict of interest exists, no research funds may be expended and no research may begin until the investigator has agreed in writing to any management plan required by the University for this research.

3. Annual Updated to Disclosure

Each investigator who submits a financial interest disclosure for to the University is required to update that disclosure annually during the period of the award or, for non-sponsored research, annually during the conduct of the project. Annual updates must be submitted by September 1st of each calendar year.

It is the responsibility of the principal investigator or project director of a research project to ensure that each Investigator working on/who will work on the project submits a timely annual

update to a previously submitted disclosure form. The annual update will be submitted to the campus' COIO, who will then review any updated financial interest disclosed.

4. Updating or Submitting a New Disclosure in an Ongoing Project

When changes occur related to a financial interest in an ongoing research project, the Investigator is required to update the disclosure describing that interest. This may occur, for example, where the investigator acquires a new financial interest or has changes to a previously disclosed financial interest. A disclosure is also required when a new investigator is added to an existing project. Such disclosures must be submitted to the COIO for revaluation within 30 days of the event requiring the disclosure.

5. NONCOMPLIANCE

Failure to file a complete and truthful disclosure as required by this policy or to comply with the conditions or restrictions imposed in the resolution, management, or elimination of the financial conflicts of interest constitutes a violation of University policy and may violate state and/or federal law. In such cases, the investigator will be subject to appropriate sanctions consistent with University policies relating to faculty, staff, or other applicable disciplinary policies. In addition, the University may suspend an ongoing research project, halt the expenditure of funds, or suspend technology transfer activity to prevent continued violation of this policy. In any case in which the investigator does not comply with any applicable conditions or restrictions imposed pursuant to this policy, the University will withdraw any affected applications for funding if the project cannot otherwise be completed without the services of the investigator.

In the event the University discovers that a failure to comply with this policy has biased the design, conduct, or reporting of the research in accordance with the process outlined, the U.P.R. will promptly notify the sponsor of the research as required by applicable law and describe the corrective action(s) taken or to be taken.

VI. References:

Manual of Policy and Guidelines for Financial Conflicts of Interests and Commitments in Research and Sponsored Programs of the University of Puerto Rico, Certification No. 8 (2012-2013) of August 15, 2012.