



BOARD OF TRUSTEES  
UNIVERSITY OF PUERTO RICO

CERTIFICATION NUMBER 8  
2012-2013

I, Aida Ávalo de Sánchez, Secretary of the Board of Trustees of the University of Puerto Rico, **DO HEREBY CERTIFY THAT:**

The Board of Trustees, in its regular meeting held on August 11, 2012, having considered the recommendation of the President of the University of Puerto Rico and the Vice President for Research and Technology, approved the following:

**POLICY AND GUIDELINES FOR FINANCIAL CONFLICTS OF INTERESTS AND COMMITMENTS IN RESEARCH AND SPONSORED PROGRAMS OF THE UNIVERSITY OF PUERTO RICO, that is attached as an integral part of this Certification.**

**IN WITNESS WHEREOF**, issued under the seal of the University of Puerto Rico, this fourteen day of August 2012.



*Aida Ávalo de Sánchez*  
Aida Ávalo de Sánchez  
Secretary

UNIVERSITY OF PUERTO RICO  
BOARD OF TRUSTEES

**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)

August 15, 2012

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## I. INTRODUCTION

In 2008, the Board of Trustees, through its Certification Number 63, 2007-08, approved its POLICY ON CONFLICTS OF INTERESTS AND DISCLOSURE OF FINANCIAL INTERESTS IN RESEARCH AND OTHER SPONSORED PROGRAMS OF THE UNIVERSITY OF PUERTO RICO. This policy at the University of Puerto Rico (U.P.R.) served well its purpose. Since then, the federal regulations related to programs that provide funds for forefront research in the University have undergone changes. It is therefore imperative for the University to modify its existing rules in order to adjust them to its current level of research development and to harmonize them with new federal policies and requirements.

In particular, on August 25, 2011, the U.S. Department of Health and Human Services (HHS) issued new rules that amend the Public Health Service (PHS) regulations on “Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought” (42 C.F.R. Part 50, Subpart F) and Responsible Prospective Contractors (45 C.F.R. Part 94). The new rules substantially modify the definitions, thresholds, and requirements for disclosing, reviewing, managing, and reporting financial relationships between research personnel and outside entities. The major changes resulting from the new rules on Financial Conflict of Interest (FCOI) (<http://grants.nih.gov/grants/policy/coi/>) for PHS-related research and investigators include:

- A requirement that **investigators complete FCOI training prior** to engaging in PHS-funded research and re-training every four years.
- A requirement that reduces the monetary threshold at which significant **financial interests (SFI) require disclosure from \$10,000 under the old rule to \$5,000 under** the new rule.
- **A requirement that investigators disclose to their institutions all of their significant financial interests (SFI) related to their institutional responsibilities.**
- Require institutions to **report to the PHS awarding component** additional information on identified financial conflicts of interest and how they are being managed.
- Require institutions to make certain **information accessible to the public** (generally on the institutional website or in writing upon request) concerning identified significant financial interests held by senior/key personnel.
- Require **compliance with the rule by subcontractors.**

The University of Puerto Rico in its firm commitment to uphold integrity, transparency and accountability in its conduct of research; and, to harmonize its existing conflict of interest (COI) policies and procedures with the new federal norms, and any applicable local and state laws and regulations, herein establishes this POLICY AND GUIDELINES FOR FINANCIAL CONFLICTS OF INTERESTS AND COMMITMENTS IN RESEARCH AND SPONSORED PROGRAMS OF THE UNIVERSITY OF PUERTO RICO (“Policy and Guidelines”). These new Policy and Guidelines shall be effective immediately upon their approval.

## **II. POLICY STATEMENT**

The University of Puerto Rico (“the University” or “U.P.R.”) is a public corporation of the Commonwealth of Puerto Rico with the main objectives of teaching, research and public services. Consistent with the U.P.R.’s mission, all faculty, employees and students are encouraged to participate in research activities and in those that promote interactions with industry, businesses, government and other academic institutions. The U.P.R. and its personnel (faculty, staff, students and employees) are committed to the fundamental principles of integrity, transparency and accountability during the conduct of their research activities, while fulfilling their university responsibilities, and assuring the public and sponsors trust. The U.P.R. establishes and enforces standards that to guarantee that the design, conduct, and reporting of all federal and non-federal research will be free from bias resulting from Investigator financial conflicts of interest and commitment. Accordingly, this policy further provides the mechanism(s) for ensuring the integrity of University research when such conflicts arise.

## **III. OBJECTIVE**

The University of Puerto Rico reaffirms through this document its commitment to uphold integrity, transparency and accountability in its conduct of research; while, harmonizing its existing COI policies and procedures with new federal norms, and any applicable local and state laws and regulations. The objective of the present Policy and Guidelines is to identify, eliminate, or manage any possible threat to the integrity of the research and sponsored programs conducted at the University of Puerto Rico. These Policy and Guidelines set forth policy and procedures that are to be followed by the University in resolving or managing actual and potential faculty conflicts of interest and commitment pertaining to all research projects, independently of their source of funding.

#### **IV. SCOPE OF POLICY**

The present guidelines and policy apply to any INVESTIGATOR planning to participate, or participating in the RESEARCH, independently of its source of funding. *Provided, however,* that several provisions of these Policy and Guidelines apply only to investigators applying for or conducting research funded by the Public Health Service (including the National Institutes of Health), as indicated below.

The terms “Investigator” and “Research” are defined below in section VI. J and N, respectively.

In addition to the conflict of interests Policy and Guidelines established in this document, the University of Puerto Rico shall comply with all local and federal laws concerning intellectual property such as, but not limited to, the Small Business Patent Procedures Act, the Bayh-Dole Act, Cooperative Research and Technology Enhancement Act (known as the CREATE ACT), the American Investors Act (known as AIA Act) and any other applicable to these issues.

#### **V. OVERSIGHT OF POLICY**

The Vice President for Research and Technology (VPRT) shall oversee these Policy and Guidelines. The Chancellor of each academic unit shall designate a Conflict of Interest Officer(s) (COIO), as the University’s institutional official responsible for the implementation of these Policy and Guidelines to review and recommend to the investigator, unit head (departmental chair, center/institute director, division head, others), deans, and chancellor the management plans for disclosed financial conflicts of interest.

The COIO will be assisted by an ad hoc Conflict of Interest Committee (COIC) to be appointed by the Chancellor on a need basis. Each campus will therefore be responsible for the implementation of this policy, consistent with the previous U.P.R. policy for the disclosure of financial conflicts of interest. No member of the COIC who holds a significant financial interest in a project may participate in the review of interest or the development of a management plan for that project. COIC meetings shall be closed to the public.

#### **VI. DEFINITIONS**

The following definitions apply to terms as they are used in this policy, unless the context clearly indicates otherwise:

### **A. Conflict Management Plan**

The designed actions or plan of measures delineated and strategically to address the risk of real or apparent financial conflict of interest to protect research subjects, and maintain public trust in the University's research and its personnel.

### **B. Conflict of Commitment**

When an employee of the university engages in an outside activity that burdens or interferes with their fulfillment of primary responsibilities, commitments and obligations to the university, even if the outside activity is valuable to the university or contributes to their professional development and competence.

### **C. Design, Conduct, or Reporting of Research**

Oversight, decision-making, or participation in research that includes, but not limited to, creating the structure, roles, and/or protocol of a research project; the execution of the research roles and protocol; and/or the publishing, presentation, or discussion of the research results.

### **D. Direct Administration of Research**

Oversight or decision-making impacting research that includes, selection of vendors, determining the allocation of funds, sponsor negotiations for the research project, protocol review and approval, or managing resulting intellectual property and licensing opportunities.

### **E. Entity/External Entity**

An entity or organization other than the University, whether public or private, such as, a company, partnership, professional associations, and voluntary health organizations, among others.

### **F. External Commitment**

An obligation or activity (e.g., management, employment, advisory, or consulting role) that is not related to primary responsibilities, commitments or obligations to the University.

### **G. Financial Conflict of Interest (FCOI) – Real, Apparent**

A Real Financial Conflict of Interest arises when a financial interest, or other opportunity for personal financial gain, is likely to compromise or influence the objective design, conduct, reporting, or direct administration of research.

An Apparent Conflict of Interest arises when there is a reasonable apprehension, which reasonably well-informed persons are likely to have, that an individual's opportunity for personal financial gain could compromise or influence the design, conduct, reporting, or direct administration of research.

#### **H. Financial Interest**

Financial Interests means anything of monetary value, whether or not the value is readily ascertainable, in any one of the following categories: compensation, compensation for management, advisory, or consulting roles; gifts, services, loans; payments or in-kind gifts for services; licensing, patent, royalty, and other intellectual property agreements; equity interests in a public or private company (e.g., stocks, stock options, bonds, property interests, dividends, convertible securities, or other ownership interest); a position in an external entity giving rise to a fiduciary duty such as director, officer, partner, trustee, employee or any position of management; or, for researchers with funding from the Public Health Service, any reimbursed or sponsored travel.

#### **I. Human Subjects/Participants Research**

A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge, involving a living individual about whom an investigator (whether professional or student) conducting the research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

#### **J. Investigator**

Investigator 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. The latter includes SBIR (Small Business Innovative Research) and/or STTR (Small Business Technology Transfer), Phase II applicants/awardees, while Phase I SBIR/STTRs are exempt.

#### **K. Institutional/University's Responsibilities**

Encompasses an investigator's professional responsibilities, commitments and obligations on behalf of the University, including, but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.



### **L. Manage**

Affirmative action taken to address a financial conflict of interest, which includes reducing or eliminating the financial conflict of interest, to ensure that the design, conduct, and reporting of research are free from bias or the appearance of bias.

### **M. Non-Sponsored University/Institutional Research**

The pursuit of professional interests through research that is supported by University funds including, but not limited to, internal allocations, gifts, endowment income, fellowships, licensing income, and cost sharing.

### **N. Research**

A systematic investigation designed to develop or contribute to generalizable knowledge and encompasses basic, clinical, applied, and translational research. Research, for the purpose of this policy, includes all sponsored and all non-sponsored University research projects.

### **O. Research Personnel**

Any individual responsible for the design, conduct, or reporting of research, including senior/key personnel, as well as those responsible for the direct administration of research.

### **P. Research-Related Financial Interest or Commitment**

An external commitment or financial interest that is likely to bias the outcome of research.

### **Q. Senior/Key Personnel**

Refers to the research project director or principal investigator and any other individual who contributes to the scientific development or execution of a project in a substantive, measurable way, and who is included in the grant application, progress report, or any other report submitted by the institution, whether or not they receive salaries or compensation under the grant, including the following:

- *For sponsored research:* (1) Principal investigators, co-principal investigators, co-investigators, and any other individual named in a sponsored project budget, narrative, key personnel list, by CV attachment, or noted anywhere else by name in a proposal or award, and (2) Anyone who during the course of a sponsored project assumes a role synonymous with the roles above.

- *For non-sponsored research:* Those whose role on the research project is synonymous with the roles described above.
- *For Institutional Review Board protocols:* Principal investigators and co-investigators consistent with the procedures of each campus.

#### **R. Significant Equity Interest**

For a publicly held business, an equity interest that when aggregated for you and your family exceeds the Public Health Service (PHS) threshold, currently: (i) \$5,000 in value as determined through reference to public prices or other reasonable measures of fair market value, or (ii) representing five percent ownership in such business. For a privately held business, any equity interest in such business, regardless of the amount.

#### **S. Significant Financial Income**

Payments or anything of monetary value (including the value of an equity interest) from a single entity that when aggregated for you and your family for the past 12 months or expected over the next 12 months, exceeds the PHS threshold, currently \$5,000.

#### **T. Significant Financial Interest**

A financial interest (see definition of Financial Interest) that includes a significant equity interest or significant financial income. Encompasses remuneration, as defined in the provision below, and anything of monetary value or potential monetary value held by an investigator (and by the investigator's spouse and dependent children), and that reasonably appears to be related to the investigator's institutional responsibilities, as follows:

1. With regard to any publicly traded entity, remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000.
2. With regard to any non-publicly traded entity, the value of any remuneration received from the entity in the calendar year preceding the disclosure, when aggregated, exceeds \$5,000, or any equity interest (e.g., stock, stock option, or other ownership interest);
3. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests; or
4. A position giving rise to a fiduciary duty, such as director, officer, partner, trustee, employee, or any position of management.

5. For Investigators applying for or conducting research funded by the PHS, any reimbursed or sponsored travel related to the investigator's institutional responsibilities (i.e., travel is paid on behalf of the investigator and not reimbursed to the investigator so that the exact monetary value may not be readily available). Disclosure of this interest will include the purpose and duration of the trip, the identity of the sponsor/organizer, and the travel destination.

***Provided also, that for purposes of the definition of significant financial interest:***

1. Remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship), and
2. Equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

***And provided, further, that the term significant financial interest does not include:***

1. Salary or other remuneration paid by the University to the investigator if the investigator is currently employed or otherwise appointed by the University;
2. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the investigator does not directly control the investment decisions made in these vehicles;
3. Income from seminars, lectures, teaching engagements, or travel reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, medical center, or research institute affiliated with an institution of higher education; or,
4. Income from service on advisory committees or review panels for a federal, state, or local government agency or institution of higher education.

**U. Sponsor**

An external entity that funds or supports research. Sponsors include federal, state, and local governments and private entities, both non-profit and for profit.

**V. Sponsored Research**

Research funded by a sponsor or external entity through a grant, contract, or agreement.

## **VII. GUIDELINES AND PROCEDURES**

### **A. Scope of Section and General Requirements.**

#### *1. Scope.*

Subsections A through D.4 of this Section VII apply to all U.P.R. investigators and to all funded U.P.R. research, as well as to all unfunded human subjects' research. Additional requirements found in Section VII.E apply only to human subject's research, while additional requirements found in Section VII.D apply only to PHS-funded research.

#### *2. Current Disclosure Required.*

Failure to have a current disclosure on file or to provide additional information requested by the COI Officer or Committee may result in a delay of study approval and/or release of research funds.

#### *3. Responsibility to Review Report.*

The COIO and COIC are responsible for reviewing reports, collecting additional required information, identifying financial conflicts of interest, and determining required management plans.

### **B. Disclosure of Financial Interests.**

#### *1. 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 dependent child of the investigator that the investigator determines to be reasonably related to the investigator's institutional responsibilities. The 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 COIO who will then review any financial interest disclosed as provided in VII.C below.

When an investigator not covered above reasonably concludes or reasonably should conclude that his/her research presents or appears to present a 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.

*2. Annual Update to Disclosure.*

Each investigator who submits a financial interest disclosure form 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 as provided in VII.B below.

*3. 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 evaluation within 30 days of the event requiring the disclosure.

**C. Review by Conflict of Interest Officer (COIO).**

Three principles are accounted for in the process of University review of reports of external commitments and financial interests: (1) respecting the confidentiality of reported information, (2) managing rigorously both real and apparent financial conflicts of interest, and (3) achieving consistency across the University in the way that financial conflicts of interest are identified and managed. Initial review of the investigator's disclosure and significant financial interest (if any) will be done by the campus' COIO. The COIO will in turn present the cases to the campus' Conflict of Interest Committee designated by the Chancellor for expedited or regular review.

*1. Determination of Significant Financial Interest.*

Prior to the investigator's expenditure of any funds, or prior to the initiation of the research in the case of research with no external funding, the COIO will review the disclosed financial interest to determine whether it constitutes a significant financial interest.

*2. Determination of Financial Conflict of Interest.*

Upon concluding that the disclosed financial interest constitutes a research related significant financial interest, the COIO will review the disclosed significant financial interest to determine whether a financial conflict of interest exists and thus whether further review and management is required.

In this review, the COIO will notify the relevant unit head (departmental chair, center/institute director, division head, others) of the existence of the financial conflict of interest. This notification will alert the unit head to the existence of the financial conflict of interest in the event he/she does not support the conduct of the research project in the University facilities with center/institute/departmental resources.

**D. Review by Conflict of Interest Committee (COIC) and Management Plan.**

**REQUIREMENT OF MANAGEMENT PLAN.** Where the Conflict of Interest Officer has determined that a financial conflict of interest exists, the campus' Conflict of Interest Committee will develop and recommend for implementation to the investigator, unit head, dean and chancellor a management plan that specifies the actions that have been and/or will be taken to manage the financial conflict of interest.

1. In so doing, the COIC will consider the nature of the research, the nature and size of the interest, the degree to which the conflict is related to the research, the extent to which the interest could be affected by the research, and any management strategies that would mitigate or eliminate the conflict.
2. Management strategies may include, but are not limited to:
  - a) Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
  - b) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;

- c) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias, or the appearance of bias, resulting from the financial conflict of interest;
- d) Modification of the research plan;
- e) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- f) Reduction or elimination of the financial interest (e.g., sale of an equity interest);  
and
- g) Severance of relationships that create actual or potential financial conflicts.

**MANAGEMENT PLAN DEVELOPMENT AND MONITORING.** Management Plan Development: Under the expedited and full committee review processes, the COIO will review the COIO's preliminary determinations of real or apparent financial conflicts of interest and oversee development of proposed management plans. Where full committee review is advised, the COIC votes on whether a real or apparent financial conflict of interest exists, and, if so, whether to approve the recommended management plan as presented by the subcommittee or with modifications. Based on the COIC decisions, the COIO will finalize the management plan. Management measures may, as appropriate, include, but are not limited to:

1. Disclosure of the external commitment or financial interest to human participants, fellow researchers, students involved in the research activity, journal publishers, and/or others;
2. Research personnel's abstention from certain project segments or decisions;
3. Modification of the external commitment or financial interest;
4. Modification of the research plan (including the assignment of responsibilities);
5. Monitoring of the potentially affected research activity by an independent individual or subcommittee;
6. Divestiture or severance of a external commitment or financial interest;
7. Independent review of student research progress;
8. Discontinuation of advisee's or subordinates employee's participation in External Entity.

**RESPONSIBILITY FOR OVERSEEING.** The management plan will state who is responsible for overseeing the implementation of the plan, and for reporting on compliance at stated intervals to the COIC. If the management plan prescribes monitoring of the activity, it will describe specifically how the monitoring shall be performed, who shall perform it, what records are to be kept, and what reports are made to the COIC.

**ADDITIONAL INPUT ON MANAGEMENT PLANS:** In making review and management decisions, the COIC and COIO may consult with others on an as-needed basis only, including campus administrative offices, the central Office for research Compliance and Integrity (ORCI), and the Office of the Vice President for Research and Technology, as well as the Research Personnel (and/or spouses/same-sex partners or dependent children, if applicable) and unit heads, particularly when the management plan will likely require unit-level implementation and/or monitoring.

**MANAGEMENT PLAN NOTIFICATION:** The COIC communicates this determination to the investigator, who must accept the requirements of the management plan in writing before beginning work on the project. Copies of the signed management plan will also be provided to the research personnel, unit head, those responsible for implementation of the management plan, and in the case of research involving human participants, to the Institutional Review Board. In addition, sponsors will be notified of the existence of a managed conflict if the regulations of that agency or award so require.

**SANCTIONS.** Any failure by research personnel to adhere to an approved management plan will be cause for one or more of the sanctions noted in Sanctions for Noncompliance. In addition, where such failure is not remedied, the non-compliance may be reported to the pertinent sponsor, if applicable, and disciplinary action may be commenced, including academic misconduct proceedings, and, in severe cases, termination. Any academic misconduct or termination proceedings will be conducted in accordance with the applicable University policies and codes.

#### **E. Specific Provisions Applicable to Human Subjects Research**

*As a general policy*, the University will not allow an investigator with a financial conflict of interest to conduct a clinical research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment. This prohibition applies, not only to the principal investigator of a clinical research project, but also to any investigator involved in the design, conduct, or reporting of the research. A principal investigator would thus be prohibited not only from serving in that role, but in any investigator role on the study.



## **F. Specific Provisions Applicable to PHS-funded Research**

In addition to the requirements of this policy outlined above, the University will apply the following specific provisions to research funded by PHS:

### *1. Monitoring.*

For PHS-funded research, the investigator's management plan will be monitored on an ongoing basis until the completion of the research project.

### *2. Sub-recipients.*

If the University carries out the PHS-funded research through a sub-recipient, the University will incorporate as part of a written agreement with the sub-recipient terms that establish whether the University's or the sub-recipient's policy on conflict of interest in research will apply to the sub-recipient Investigators.

If the sub-recipient's policy will apply, the sub-recipient will certify as part of the agreement that its policy complies with the PHS regulations on Objectivity in Research. Additionally, the agreement shall specify time period(s) for the sub-recipient to report all identified financial conflicts of interest to the University to enable the University to provide timely reports to PHS.

Alternatively, if the University's policy on conflict of interest will apply, the agreement shall specify time period(s) for the sub-recipient to submit all sub-recipient Investigator disclosures of significant financial interests to the University. Such time periods shall be sufficient to enable the University to comply with timely review, management, and reporting obligations under the PHS regulations.

### *3. Retrospective Review.*

In the event the University identifies a significant financial interest that was not disclosed in a timely manner by an investigator or, for whatever reason, was not previously reviewed by the University during an ongoing research project, and where the COIO has determined that the undisclosed significant financial interest constitutes a financial conflict of interest related to a PHS funded research project, the COIC will review the financial conflict of interest and the University will implement a management plan for the project within 60 days of identification of that interest. In addition, the COIC will, within 120 days of its determination of noncompliance, complete a retrospective review of the investigator's research activities associated with the project to determine whether the research conducted during the period of the noncompliance was biased in the design, conduct, or reporting of such research.

#### *4. Mitigation Plan.*

If the COIC determines in the conduct of its retrospective review of PHS funded research that the research or any part of it was biased, the COIC will recommend a mitigation plan to address any such issues. The University will notify the PHS Awarding Component of its determination and subsequently follow up with the mitigation report for the project.

#### *5. Public Access of Disclosed Significant Financial Interest.*

The U.P.R. will make available to the public upon request information concerning any significant financial interest disclosed to the University that meets the following three criteria:

- a) The disclosed significant financial interest is still held by the senior/key personnel of the active PHS project;
- b) The University determines that the significant financial interest is related to the PHS funded research; and
- c) The University determines that the significant financial interest is a financial Conflict of Interest.

The information request must be addressed to the corresponding campus Conflict of Interest Officer who will respond within five (5) business days of receipt of the request. Disclosed information will be provided to the extent required by applicable PHS regulations and state law. Written requests must be submitted to each campus' COIO and COIC, who will in turn inform the ORCI of such request and document the campus response within the required timeline.

### **G. Ongoing Research**

#### *1. Required Procedure.*

When in the course of an ongoing research project an investigator new to the project discloses a significant financial interest or an existing investigator discloses a new or changed significant financial interest, and where the COIO has determined that the disclosed significant financial interest constitutes a financial conflict of interest subject to management under this policy, the COIC will review the disclosure and the University will implement a management plan for the project within 60 days of the submission of the disclosure to the University.

2. *Special cases.*

In the case of either VII.A. or VII.F above, and depending on the nature of the financial conflict of interest, the University may determine that additional interim measures are necessary with regard to the investigator's participation in the research project between the date of disclosure and the implementation of the University's management plan. Particular consideration will be given to any additional interim measures that the University's Institutional Review Board views as necessary for the protection of human participants in any ongoing research.

**VIII. APPEAL**

Any investigator adversely affected by the decision of the COIC regarding management of a financial conflict of interest may appeal in writing, first, to the Vice President for Research and Technology, subsequently to the President of the University, and thereafter to the Board of Trustees of the University of Puerto Rico.

**IX. 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 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 in section VII.C., 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.

## **X. EDUCATION AND TRAINING**

Prior to engaging in any research project, all investigators must complete training on the investigator obligations under this policy. This training must be repeated at least every four 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 on financial Conflicts of Interest, or a valid alternative resource.

## **XI. REPORTING**

The University will provide initial and ongoing reports of its management of financial conflicts of interest to external sponsors of University research as required by law and in accordance with this policy. Each campus Office of Sponsored Programs or its equivalent will also provide additional guidance with respect to the electronic COI reporting system to be available through eRA Commons.

## **XII. RECORDS**

Records relating to all investigator disclosures of significant financial interests and the University's review and management of such disclosures, will be maintained by the University in the case of externally funded research for three years from the date of submission of the final expenditures report (in the case of grants and cooperative agreements) or three years from the final payment (in the case of research contracts), or as otherwise required by law. Such records in the case of research with no external funding will be maintained for three years from the close of the study.

## **XIII. SIGNIFICANT FINANCIAL INTERESTS OF INSTITUTIONAL OFFICIALS**

University officials who have a significant financial interest in an externally-sponsored research project may not participate in the solicitation, negotiation of contract terms and conditions, oversight of the research (unless named as a member of the research team), or management of any financial conflict of interest held by members of the research team.

#### **XIV. IMPLEMENTATION**

Chancellors shall implement these policies and guidelines forthwith. They must provide the reviewers (Conflict of Interest Officers and Committee) with appropriate administrative support to assure that technical advice on conflict of interest matters is provided, and assure that appropriate documents related to this policy are available to the public as required by law.

The Vice President for Research and Technology for the University of Puerto Rico (VPRT) has responsibility for assuring compliance with these Policy and Guidelines, related University regulations, and applicable State law. The VPRT is responsible for developing, issuing and notifying the necessary procedures to implement these Policy and Guidelines. Also, the VPRT will serve as the liaison on these matters with the University's academic units. Such procedures may be modified from time to time.

#### **XV. INTERPRETATION**

The President of the University of Puerto Rico shall settle any controversy, question, or clarification regarding the interpretation of these Policy and Guidelines and/or situations not foreseen by them.

#### **XVI. AMENDMENTS**

These Policy and Guidelines may be amended by the Board of Trustees, *motu proprio*, or upon the recommendation of the President of the University of Puerto Rico.

#### **XVII. EFFECTIVENESS**

These Policy and Guidelines shall become effective immediately after their approval. From that date on, Certification Number 63 (2007-2008), shall be considered without effect. Any policy, regulation, rule or procedure inconsistent or contrary to this Policy and Guidelines or its purposes shall be without effect.