

**Comprehensive Cancer Center University of Puerto Rico (CCCUPR)
Disclosure of Financial Interests and Management of Conflict of Interests Related to
Sponsored Projects for Objectivity in Research**

A. PURPOSE

This Policy is designed to promote compliance with Federal regulations regarding objectivity in research and apply its principles and standards to all externally sponsored research at the Comprehensive Cancer Center University of Puerto Rico (CCCUPR).

This policy is created to ensure that the public trust and sponsor financial support are not compromised to advantage the personal gain of Investigators. This policy establishes a process of disclosure and independent review to identify potentially harmful conflicts of interest between an Investigator's obligations related to the sponsored project and their financial interests or obligations, and a process to reduce, manage or eliminate such conflicts to preserve objectivity in the design, conduct, or reporting of research.

This policy implements the Public Health Service (PHS) regulations on the Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is sought (42 CFR Part 50, Subpart F and 45 CFR Part 94). These regulations are designed to promote objectivity by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of PHS-funded research will be free from bias resulting from any Investigator's financial conflicts of interest. Moreover, this policy intends to comply with FDA requirements for applicants to certify the absence of and/or disclose the existence of certain financial arrangements, under various regulations (21 CFR Parts 54, 312, 314, 320, 330, 601, 807, 812, 814, and 860).

This Policy also complies with Grantee Standards and applicable regulations established by the National Science Foundation (NSF).

B. LEGAL BASIS

The CCCUPR Enabling Act, Act No. 230 of August 26, 2004, as amended, establishes the CCCUPR as the government entity principally responsible for the implementation of public policy regarding the prevention, orientation, research, and provision of clinical services and treatment related to cancer. Pursuant to these objectives, Act 230-2004 authorizes the CCCUPR to develop and foster a research agenda focused on cancer and to establish its own administrative structure with its own operational regulations towards this end. Act 230-2004, Art. 5(b), (c), and (j). To that effect, the CCCUPR General Regulations authorize the Executive Director to adopt all policies, procedures, and regulations necessary to achieve the objectives of Act 230-2004, except the General, Human Resources, and Bid and Purchase Regulations, which shall be approved by the CCCUPR Board of Directors. General Regulations, Art. III, Sec. 3.

C. SCOPE

This policy applies to all research funded by the PHS, NSF, and other sponsors that adopt the PHS or NSF regulations. This policy applies to the Principal Investigator(s) and all individuals responsible for designing, conducting, or reporting PHS and NSF-funded research and research supported by entities adopting PHS or NSF regulations.

D. APPLICABILITY

This policy applies to all individuals (faculty, staff, students, intramural, and extramural collaborators, etc.) applying for or participating in a project subject to PHS or NSF conflict of interest policies and meeting the definition of Investigator set by the aforementioned Agencies.

E. DEFINITIONS

Annual Disclosure: The annual financial disclosure forms all CCCUPR Investigators on externally sponsored proposals and awards are required to complete before proposal submission and maintained updated throughout the awards.

Conflict of Interest Addendum: Form used to collect additional information about the significant financial interest, financial entity, and research Project for evaluation by the Institutional Official, their designee, or the Conflict-of-Interest Committee.

Conflict of Interest Committee (COIC): CCCUPR Committee is appointed by the Executive Director to review disclosures of financial interests related to externally funded research and determine if they constitute a financial conflict of interest.

Federal Drug Administration (FDA): The Food and Drug Administration (FDA) is an agency within the U.S. Department of Health and Human Services. FDA is responsible for protecting public health by assuring the safety, effectiveness, quality, and security of human and veterinary drugs, vaccines and other biological products, and medical devices. The FDA also requires FCOI disclosures in order to participate in Clinical Trials.

Financial Conflict of Interest (FCOI): a Significant Financial Interest (SFI) related to the research could directly and significantly affect the design, conduct, or reporting for the funded research.

Institutional Official: The Director of the Research and Education Support Division or their designee.

Institutional Responsibilities: administrative, research, clinical service, teaching/education, outreach, consultative and advisory activities, and institutional and public service on behalf of the CCCUPR within the scope and course of the Investigator's appointment or employment with the CCCUPR.

Investigator: Any individual responsible for the design, conduct, reporting, and/or authorship of sponsored research, regardless of the compensation received. Investigator includes, but is not limited to, Principal Investigator (PI), Project Director (PD), Co-Investigators, collaborators or consultants or and any other person regardless of title, position or institutional affiliation. The term will also include the investigator's spouse, domestic partner, and dependent children.

Manage: means taking action to address a FCOI (which can include reducing or eliminating the conflict of interest) to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

National Science Foundation (NSF): refers to an independent federal agency dedicated to promoting the advancement of science, and any non-NSF organization adopting NSF regulations for Assurance of Objectivity in Research and/or grantee standards.

National Cancer Institute (NCI): is part of the National Institutes of Health and is the Federal Government's principal agency for cancer research, training, dissemination, and other cancer-related programs. NCI Manages the Cancer Therapy Evaluation Program (CTEP) and the Clinical Trials Support Unit (CTSU) which require investigators participating in NCI Clinical Trials to complete the NCI and FDA FCOI annually with their registrations and updates.

Public Health Service (PHS): any unit, agency or entity of U.S. Department of Health and Human Services (DHHS) responsible for the public health of the US Population; any units to which the authority involved may designate as PHS, and any non-PHS organization adopting PHS regulations on the Responsibility of Applicants Promoting Objectivity in Research.

Principal Investigator: An Investigator employed by the CCCUPR with the primary responsibility for the scientific, technical, programmatic, reporting and administrative management of a sponsored research project.

Program Director: An Investigator employed by the CCCUPR with the primary responsibility for the scientific, technical, programmatic, reporting and administrative management of a sponsored research project.

Research: As used in this policy, the term includes any such activity for which research funding is available from PHS through a grant, cooperative agreement, career development awards, center grants, individual fellowships, infrastructure awards, institutional training grants, program projects or research resources awards, conference grants and Phase II Small Business Innovative Research (SBIR) and Phase II Small Business Technology Transfer Research (STTR) awards, whether authorized under the PHS Act or other statutory authority. Consistent with the underlying PHS regulations, excluding this policy are Phase I SBIR awards and Phase I STTR awards issued or proposed to PHS.

The term also includes any research or educational activities funded or proposed for funding by NSF or sponsors following NSF regulations.

Remuneration: includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); 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.

Research Related Disclosure: Investigators will certify that there are no significant financial interests to disclose related to the research proposal to be submitted in the Internal Transmittal Form, as well as, at the time of acceptance of awards in the Award Participation Acceptance Form. Using the Conflict-of-Interest Addendum, investigators who reported significant financial interest(s) must identify how they relate to each proposal or awarded project.

Related Financial Interest: Interests of the Investigator, their spouse, domestic partner or dependent children, or interests of the company in which these individuals have an interest, that would reasonably appear to be affected by the research to be done or currently ongoing in the associated grant or contract. Related financial interests include but are not limited to the following:

- (1) The research results could be relevant to the development, manufacturing, or improvement of the products or services of the entity in which the Investigator, their spouse, domestic partner or dependent children have a financial interest.
- (2) The Investigator, their spouse, domestic partner or dependent children have a financial interest in an entity that might manufacture or commercialize a drug, device, procedure, or any other product used in the project or that will predictably result from the project.
- (3) The Investigator, their spouse, domestic partner, or dependent children have cumulative consulting income exceeding \$10,000 during the prior twelve months from a single entity, which would reasonably appear to be affected by the research.
 - Note: Disclosure of consulting income is encouraged so that the COIC members can make an independent assessment of the relatedness. Consulting based on an individual's academic expertise is considered related.
- (4) The Investigator, their spouse, domestic partner, or dependent children have a financial interest in an entity, and the sponsored project proposes to subcontract a portion of the work, or lease property, or make referral of participants to, or make purchases from the entity; or
- (5) The Investigator, their spouse, domestic partner or dependent children have a financial interest in an entity that is part of a consortium, or that will otherwise participate in the sponsored project.

Significant Financial Interest (SFI) for PHS funded Research: A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse, domestic partner and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

- (1) Concerning any **publicly traded entity**, a SFI exists if the value of any 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. For purposes of this policy, remuneration includes salary and any payment for

services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); 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.

- (2) Concerning any **non-publicly traded entity**, a SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse, domestic partner, or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
- (3) **Intellectual property** rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- (4) **Travel Reimbursements** — Any amount received during the prior twelve months made to, or on behalf of, the Investigator, regardless of amount, by a for-profit or non-profit entity, except travel that is reimbursed or sponsored by a federal, state, or local government agency, U.S. Institution of higher education (as defined at 20 U.S.C. 1001), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. Investigators should also exclude their spouses' travel reimbursements or sponsorships, registered domestic partners, and dependent children.
- (5) Holding any **position of influence** (e.g., director, officer, trustee, dean, or faculty) at an institution outside of the CCCUPR.

Significant Financial Interest (SFI) for NSF funded Research: Significant financial interests are anything of monetary value, including but not limited to the following:

- (1) Income exceeding \$10,000 from a single public or nonprofit entity including salary, consultant payments, honoraria, royalty payments, dividends, loans from the entity, or any other payments or consideration with value during the prior twelve months when aggregated for an Investigator, their spouse, domestic partner and dependent children.
- (2) Equity interest, in the form of stock, stock options, real estate, or any other investment or ownership interest that when aggregated for an Investigator and the Investigator's spouse, domestic partner and dependent children, either exceeds \$10,000 in value (market value if publicly traded; reasonable internal estimate of value if not publicly traded) for any single entity or exceeds a 5% ownership interest in any single entity.
- (3) Intellectual property interest held by the Investigator, their spouse, domestic partner or dependent children in a patent, patent application, or a copyright of software assigned to or assigned to a party other than UPR-CCC.

New Significant Financial Interest: A new significant financial interest is a new different type of SFI (e.g., royalty payment versus income) than what had previously been disclosed for the

same source/entity or the same type or nature of SFI (e.g. royalty payment) from a different source/entity (e.g., company A versus company B).

Travel Disclosure for PHS: disclosure of travel reimbursements defined in the SFI description.

F. Responsibilities

Institutional Official: or their designee is responsible for implementing this policy, for the final decisions regarding the acceptability of disclosures, and approval of any required management plan.

Investigators: Are responsible for disclosing their financial interest as defined by this Policy. Investigators participating in NCI's CTEP research and clinical trials and registered in CTSU must maintain and disclose their financial interests as required by NCI. Collaborators from institutions that participate as subrecipients in sponsored research must submit their disclosure before proposal submission and before award acceptance. Investigators who are not UPR-CCC employees and not collaborators from a subrecipient institution(s) are subject to this Policy.

Conflict of Interest Committee: is responsible for reviewing financial disclosures to determine if a Financial Conflict of Interest (FCOI) does exist, making recommendations and proposing management plans to the Institutional Official.

Office of Sponsored Programs (OSP): is responsible for obtaining, documenting, and filing disclosures and additional information as defined in this Policy; conducting administrative reviews of disclosures and make referrals to the COIC; providing administrative support to the COIC; providing training, information and advice to UPR-CCC investigators, employees and collaborators regarding this policy; reporting information about FCOIs and their management to the sponsoring agencies.

G. Policy

- Investigators must disclose **Significant Financial Interests** related to their Institutional Responsibilities annually by submitting and updating their Annual Disclosure Forms every fiscal year.
- Investigators participating in NCI's CTEP research and clinical trials and registered in CTSU must disclose Significant Financial Interests related to their Institutional Responsibilities annually by submitting and updating their **Financial Disclosure Forms** every fiscal year as required by NCI.
- Investigators must disclose **new Significant Financial Interest** related to research, as defined in this policy, within 30 days of acquiring or discovering the new SFI.
- Investigators must certify the accuracy of their Annual Disclosure and that no new Significant Financial Interest or Related Financial Interest was acquired or discovered before proposal submission to sponsoring agency by completing the appropriate section of the Internal Transmittal Form.

- Investigators must certify the accuracy of their Annual Disclosure and that no new Significant Financial Interest or Related Financial Interest was acquired or discovered before award acceptance by completing the appropriate section of the Award Acceptance Form.
- Investigators must disclose Travel related Significant Financial Interest by completing the Travel Disclosure for PHS form.
- Investigators must complete training on financial conflicts of interest before engaging in research at UPR-CCC and every four (4) years. Investigators failing to comply with the policy or mitigation and management plans must retake Financial Conflicts of Interest training.
- Investigators from other institutions who share the responsibility for the design, conduct and reporting of the research, and conducting research under a subaward or subcontract must comply with their organization's Conflict of Interest policy. If their organization does not have a Policy, the investigator must comply with UPR-CCC's Policy. The Investigator's home Institutions shall provide the UPR-CCC with a written assurance, before receiving any funding, that the institution has a written FCOI policy and that the institution is compliant with the financial conflict of interest requirements of 42 CFR Part 50, Subpart F. The written assurance must be updated and submitted to the UPR-CCC on an annual basis. However, this does not relieve institutions from the responsibilities of reporting to the UPR-CCC any identified financial conflicts of interest within thirty (30) days so that the UPR-CCC may comply with its reporting obligation to the sponsoring agency.
- Individuals performing under an independent consulting agreement must comply with UPR- CCC's FCOI Policy when the description of duties under the agreement meets the definition of an investigator.
- Investigators agree to abide by the conflict of interest mitigation and/or management plan as established by the COIC. Failure to comply with the mitigation and/or management plan will result in sanctions.
- Investigators do not have to disclose the following types of financial interests: salary, royalties, or other remuneration paid by the UPR-CCC to the Investigator if the Investigator is currently employed or otherwise appointed by the UPR-CCC, including intellectual property rights assigned to the UPR-CCC and agreements to share in royalties related to such rights; 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; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, U.S. institution of higher education (as defined at 20 U.S.C. 1001), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; or income from service on advisory committees or review panels for a federal, state, or local government agency, an institution of higher education (as defined at 20 U.S.C. 1001), an

academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

- Violation of any of the provisions of this policy could result in sanctions, including termination. Any person seeking guidance or who becomes aware of any potential, known or suspected violation of any provision in this policy shall report such matters to the UPR-CCC Director of Sponsored Programs. No person will be subjected to retaliation, retribution, or reprisal for making a good faith report or seeking guidance regarding or participating in the investigation or resolution of a potential, known, or suspected violation of any provision of this policy.
- This policy establishes procedures for disclosure, training and independent review to identify potentially harmful conflicts of interest between investigator's obligations related to the sponsored project and their personal financial interests or obligations, and a process to reduce, manage or eliminate such conflicts to preserve objectivity in the design, conduct, and reporting of research.

H. PROCEDURES

I. Training:

Investigators will receive training on the FCOI Policy, the Federal Regulation 42 CFR Part 50, Subpart F, and other Federal Regulations pertaining to Conflict of Interests:

- Before engaging in research related to any grant;
- Every four years, and
- Immediately, if:
 - (1) The UPR-CCC revises its FCOI policy in such a way that affects the requirements of the Investigators,
 - (2) An Investigator is new to the institution, or,
 - (3) An Investigator is not in compliance with the FCOI policy or management plan.Training will be provided in person or online modalities. Acceptable forms of training are: NIH FCOI Tutorial and Certificate (<https://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>); Citi Programs COI Basic and/or Refresher Training, and training provided by OSP.

II. Disclosure

A. Annual Disclosure

Investigators must complete and submit their Annual Disclosure in the following instances:

- Every fiscal year, within 30 days of solicitation from OSP;
- Whenever the UPR-CCC revises its FCOI policy affecting the requirements for Investigators;
- Within 30 days of appointment or affiliation with the UPR-CCC;
- As it relates to engaging in new externally sponsored research conducted on behalf of the

UPR-CCC, before applying for funding to the external sponsor or before initiating that research, whichever is earlier.

- When participating in NCI's CTEP research and clinical trials and registering in CTSU by completing Financial Disclosure Forms every year as required by NCI. Investigators must forward a copy of the submitted Financial Disclosure Form to OSP.

B. Significant Financial Interests or Research Related Interest

1. General Disclosure:

Investigators must disclose Significant Financial Interests within 30 days of acquiring the SFI or discovering that the SFI exists by completing the Conflict of Interest Addendum.

2. Before Proposal Submission:

Investigators must certify that no new SFI or Research Related Interests exist for the proposed research, by completing the Internal Transmittal Form before proposal submission. If there is a new SFI or Research Related Interest, investigators will submit a Conflict-of-Interest Addendum form detailing the SFI.

3. Before Award Acceptance:

Investigators must certify that no new SFI or Research Related Interests exist for the sponsored research by completing the Award Acceptance Form upon receiving the notice of award for the sponsored project. If there is a new SFI or Research Related Interest, investigators will submit a Conflict-of-Interest Addendum form detailing the SFI.

4. Special Considerations for IRB

Investigators may have to disclose SFI or Research Related Interest in Subject Consent Forms, if recommended by the IRB and/or the COIC.

C. Travel Related Significant Financial Interests

Investigators must complete the Travel Disclosure for PHS Form within 30 days of travel reimbursement by third party.

III. Disclosure Review

- (1) All financial Disclosure Forms filed by Investigators will undergo an administrative review by the UPR-CCC Director of Sponsored Programs to determine if SFI or Research Related Interest exists.
- (2) The Director of Sponsored Programs may request updated or additional information from the Investigator.
- (3) The Director of Sponsored programs will forward the files to the COIC for further review.
- (4) The COIC will determine if the SFI appears to affect the design, conduct or reporting of the research and it constitutes a FCOI that needs to be managed, reduced, or eliminated.

IV. Management, Mitigation, and Elimination Plans

The COIC, IRB, or Institutional Official may recommend conditions or restrictions to manage, mitigate or eliminate the FCOI and/or its effects on the design, conduct or reporting of research. The Management Plans will specify roles and duties of the conflicted investigator; conditions of the management plan; how plan will safeguard objectivity in research; confirmation of the investigator's agreement with the plan, and how the management plan will be monitored to ensure compliance.

The Conditions in the Management, Mitigation and Elimination Plans may include:

- Modification of the research or program plan
- Review by an oversight committee or panel
- Public disclosure of SFI
- Monitoring of research project by an independent reviewer
- Limitations of involved party in the project's design, conduct or reporting
- Severing relationships that create actual or potential conflicts
- Divestiture of SFI
- Any other action which reduces or eliminates the potential FCOI.

The Investigator must agree to abide by the Plan as recommended by the Institutional Official, COIC, or IRB before spending funds. The UPR-CCC Director of Sponsored Programs shall monitor Investigator's compliance with the management plan on an ongoing basis until the completion of the funded research project.

V. Dispute Resolution and Appeals

If the Investigator disagrees with the COIC's decision and/or the FCOI Management Plan, the matter will be referred to the UPR-CCC Executive Director or their designee. The Executive Director will review in writing the FCOI and discuss the management plan with the PI, the Investigator, and the UPR-CCC Director of Sponsored Programs, as deemed necessary. The Executive Director will then recommend the related parties regarding the final determination for the FCOI Management Plan.

If the Investigator disagrees with the recommendation of the Executive Director, the COIC may determine that the FCOI is unmanageable and may recommend that the Project does not proceed.

VI. External Reporting

A. Reporting to Sponsoring Agency

Before the expenditure of any funds, the UPR-CCC Institutional Official shall provide an FCOI report regarding any Investigator's SFI found to be conflicting, including implementing a management plan, to the Sponsoring Agency.

In cases in which the FCOI is eliminated before the expenditure of funds, the Institutional Official shall not submit an FCOI report to the Sponsoring Agency

The FCOI report to the sponsors shall include sufficient information to enable the sponsoring agency to understand the nature and extent of the financial conflict and assess the management plan's appropriateness. Elements of the report shall include, but are not necessarily limited to the following:

- (1) Project number
- (2) PD/PI or Contact PD/PI if a multiple PD/PI model is used
- (3) Name of the Investigator with the FCOI
- (4) Name of the entity with which the Investigator has a FCOI
- (5) Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium)
- (6) Value of the financial interest (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value
- (7) A description of how the financial interest relates to the sponsored research and the basis for the Institution's determination that the financial interest conflicts with such research; and
- (8) A description of the key elements of the Institution's management plan, including:
 - a) Role and principal duties of the conflicted Investigator in the research project;
 - b) Conditions of the management plan;
 - c) How the management plan is designed to safeguard objectivity in the research project;
 - d) Confirmation of the Investigator's agreement to the management plan;
 - e) How the management plan will be monitored to ensure Investigator compliance; and
 - f) Other information as needed.

Additional FCOI reports must be submitted to the Sponsoring Agency under the following circumstances:

- Throughout the lifetime of an award when progress reports are submitted, or at the time that an award is extended. When a FCOI ceases to exist during an ongoing sponsored research, updated information about the status of that FCOI should be provided with the subsequent progress report.
- Within sixty (60) days of determining that a FCOI exists based on the disclosure of a newly acquired SFI by an Investigator during an ongoing sponsored research project.
- Within sixty (60) days of determining that a FCOI exists for an Investigator who joins an ongoing sponsored research project.

B. Public Reporting

To comply with federal regulations, the Institution will make available to the public within 5 days of a request the following information concerning financial conflicts of interest:

- (1) Investigator's name
- (2) Investigator's title and role concerning the research project
- (3) Name of entity in which a significant financial interest is held
- (4) Nature of the significant financial interest
- (5) Approximate dollar value of the significant financial interest within ranges (e.g., \$0 - 4,999; \$5,000-9,999; \$10,000-19,999; \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 in increments of \$50,000), or a statement that the value of the interest cannot be readily determined through reference to public prices or other reasonable measures of fair market value

The UPR-CCC shall ensure public accessibility of information concerning any SFI disclosed to the UPR-CCC that meets the following three criteria:

- (1) The SFI was disclosed and is still held by the senior/key personnel;
- (2) The UPR-CCC determines that the SFI is related to the sponsored research; and
- (3) The UPR-CCC determines that the SFI is a FCOI.

The UPR-CCC will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the UPR-CCC's identification of a new FCOI, which should be requested subsequently by the petitioner.

All financial disclosure forms, reports or records of any actions taken by the UPR-CCC to resolve conflicting financial interests will be recorded and kept on file in accordance with 42 CFR Part 50, Subpart F, Sec. 50.604 (e) and the Record Maintenance section of this policy.

VII. Compliance

As part of the Financial Disclosure Form, each Investigator will certify that if the UPR-CCC Sponsored Programs Manager and/or the COIC determine a FCOI exists, the investigator will adhere to all conditions or restrictions imposed upon the project and cooperate with the parties assigned to monitor compliance with said conditions.

VIII. Enforcement

Failure to disclose relevant financial interests or adhere to the restrictions outlined by the UPR- CCC manager office of Sponsored Programs will be considered a deviation from the established standards of conduct for conducting research at the UPR-CCC. In this case, the UPR-CCC Sponsored Programs Manager shall, within 60 days review the SFI, determine whether it is related to sponsored research, determine whether an FCOI exists, and, if so

implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such FCOI going forward.

Alleged violations will be reviewed by the Executive Director, who will recommend the COIC for action. Breaches include knowingly filing incomplete, erroneous, or misleading disclosure forms or failure to comply with the actions recommended by the CCCUPR Director of Sponsored Programs, the Executive Director, and/or the COIC. Suppose the Executive Director determines that there has been a breach of the policy. In that case, sanctions may be imposed including notification to the sponsor, termination of award, formal admonition letter or a letter to the investigator's personnel file.

IX. Retrospective Review

In addition, whenever an FCOI is not identified or managed promptly, including failure by the Investigator to disclose an SFI that the UPR-CCC determines to constitute an FCOI or failure by the Investigator to comply with an FCOI management plan, the UPR-CCC Director of Sponsored Programs shall, within 120 days of the UPR-CCC's determination of noncompliance, complete a retrospective review of the Investigator's activities and the sponsored research project to determine whether any funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

The UPR-CCC shall document the review which shall include, but not necessarily be limited to, all of the following key elements:

- (1) Project number;
- (2) Project title;
- (3) PD/PI or contact PD/PI if a multiple PD/PI model is used;
- (4) Name of the Investigator with the FCOI;
- (5) Name of the entity with which the Investigator has an FCOI;
- (6) Reason(s) for the retrospective review;
- (7) Detailed methodology used for the retrospective review (e.g., methodology of the review process, the composition of the review panel, documents reviewed);
- (8) Findings of the review; and
- (9) Conclusions of the review.
- (10)

Based on the results of the retrospective review, if appropriate, the UPR-CCC Director of Sponsored Programs shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, the UPR-CCC Director of Sponsored Programs must promptly notify the PHS Awarding Component and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the CCCUPR's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable).

X. Record Maintenance

The CCCUPR Director of Sponsored Programs will maintain records of all disclosures and related activities securely and confidentially in a password-protected database. The records will be kept for three (3) years following project termination or project completion, resolution of any government action involving the records, or until the end of any litigation, financial management review or audit started within the three (3) year period described above.

The disclosure statements and all related information will not be released to sponsors or any other party without written requests and approval by the CCCUPR Director of Sponsored Programs. The information will not be released without prior notification to the Investigator.

This policy is recommended by the Division of Research and Education Support on:

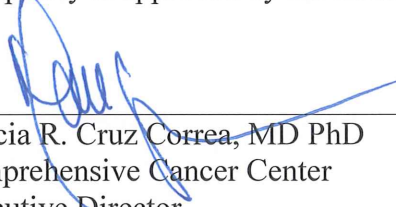


Elba V. Caraballo Rivera PhD, MS
Division of Research & Education Support
Director

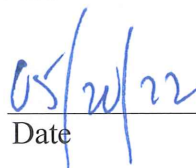


Date

This policy is approved by the Institution's Executive Director on:



Marcia R. Cruz Correa, MD PhD
Comprehensive Cancer Center
Executive Director



Date