

	Universidad Central del Caribe	Policy#	ADR 006
		Implementation Date	April 2011
		Contact	Associate Dean for Research and Graduate Studies
	Research Conflict of Interest Policy	Last Reviewed/Update	February 2020 August 2012
		Approval by	President

Rationale

In response to federal regulations codified at 42 CFR, Parts 50 and 93 by the U.S. Department of Health and Human Services regarding Public Health Service Policies on Research Misconduct; Final Rule, effective June 16, 2005, and all amendments thereafter (see *Federal Register*, 2005, Vol. 70, No. 94, pp. 28370-38400), the UCC has established standards and procedures to be followed by investigators applying for federal funding to ensure that the design, conduct, or reporting of research, educational activities, cooperative agreements or contracts will not be biased by any conflicting financial interest of those investigators responsible for the proposed activity. The UCC also adheres to existing policies and procedures governing professional ethics and conduct established by the Commonwealth of Puerto Rico.

A potential conflict of interest occurs when there is a divergence between an investigator's private interests and his/her professional obligations such that an independent observer might reasonably question whether the investigator's professional actions or decisions are determined by considerations of personal gain, financial or otherwise. An actual conflict of interest depends on the situation and not on the character or actions of the investigator. This policy seeks to maintain a reasonable balance between competing interests, give UCC the ability to identify and manage financial interests that may bias the activity, and minimize reporting and other burdens on investigators.

Significant financial interest

"Significant financial interest" means anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); intellectual property rights (e.g., patents, copyrights and royalties from such rights); and travel reimbursement and sponsored travel (see 42 CFR 50.603 and 45 CFR 94.3).

"Significant financial interest" does not include:

1. Salary, royalties, or other remuneration from UCC including fee-for-service;
2. Any ownership interest in the institution, if the institution is an applicant under the Small Business Innovation Research program or the Small Business Technology Transfer program;
3. Income from seminars, lectures or teaching engagements sponsored by public or nonprofit entities.

Conflict of Interest

A conflict of interest may occur when an investigator's affiliation with an external organization meets any one of the following criteria:

1. The principal investigator is an officer, director, partner, trustee, employee, advisory board member, or agent of an external organization or corporation providing goods or services under a sponsored project on which she/he is participating in any capacity;
2. The principal investigator, his/her spouse and dependent children hold an aggregate equity interest that both exceeds \$5,000 in value as determined through reference to public prices or other reasonable measures of fair market value or hold ownership interest in any single entity;
3. The principal investigator, his/her spouse and dependent children earn salary, royalties or other payments from an external organization that, when aggregated, are expected to exceed \$5,000 over the next twelve months.

Disclosure

Each investigator must certify on the "Conflict of Interest Disclosure Form" that he/she has read and understands the UCC conflict of interest policy; that to the best of his/her knowledge, there are no actual or potential conflicts of interest, or if such conflicts exist, they have been or will be managed in a manner satisfactory to the institution or disclosed to the sponsor prior to the award. Investigators also must certify that they will comply with any conditions or restrictions UCC imposes to manage actual or potential conflicts of interest.

If UCC carries out federally-funded research or educational activities through subgrantees, contractors, or collaborators, UCC will take reasonable steps to ensure that investigators working for such entities comply with financial disclosure regulations either by requiring those entities to comply with the UCC policy or by requiring the entities to provide written evidence of compliance from their institution.

Disclosure forms are available at the OADRGS and should be completed when the Notice of Award is received. The Associate Dean will review any potential conflicts and determine which disclosed interests could directly and significantly affect the design, conduct or reporting of the research or educational activity. If it is determined that a potential conflict exists, any or all of the following actions may be recommended:

1. Public disclosure of significant financial interests;
2. Reformulation of the workplan to eliminate the conflict(s);
3. Monitoring of research or educational activity by independent reviewers;
4. Divestiture of relevant personal interests;
5. Disqualification from participation in the portion of the project that would be affected by the significant financial interests;
6. Severance of outside relationships posing a conflict of interest;
7. Other appropriate disclosures or activities.

If the Dean of Medicine determines that imposing the above or other conditions or restrictions would be inequitable, or that the potential negative impact that may arise from a significant financial interest is outweighed by interests of scientific progress, technology transfer, or the public health and welfare, then the Dean may recommend that, to the extent permitted by federal regulations, the research go forward without imposing such conditions or restrictions.

If the investigator is dissatisfied with the decision, s/he may appeal to the President who will consult with the investigator and other appropriate person(s) or entities as s/he deems necessary and appropriate to the particular circumstances. In the event that the investigator and the President cannot satisfactorily manage, reduce or eliminate the conflict, UCC shall inform the federal sponsor of the conflict and provide the disclosure information relevant to the proposal.

The disclosure records will be maintained by the OADRGS in strict confidence. Access to such records will be limited to the federal sponsor, the investigator in question, and those parties determined by the Dean of Medicine to have a valid reason for access to the records, except in the case of an appeal, in which case the Dean of Medicine shall disclose to the investigator the other persons or entities with which it intends to consult. The UCC will maintain records of financial disclosures and records relating to the management of actual and potential conflicts of interest until three years after the termination of the grant to which they relate or the resolution of any government action involving such records.

Disclosure due date

Complete the disclosure form and certification annually and submit to the Office of the Associate Dean for Research and Graduate Studies (OADRGS) by September 15. If a conflict of interest arises at any point throughout the year a new disclosure form and certification must be completed.

When a Notice of Award is received, each investigator involved in the project is required to disclose to the OADRGS a listing of significant financial interests that would reasonably appear to be affected by the activity proposed for funding. Financial disclosures must be updated during the period of the award, either on an annual basis, or as new reportable significant financial interests are obtained.

Penalties

Violations of this policy, such as willful concealment of financial interests, may result in disciplinary measures according to the impact that non-compliance has in institutional operations.

Any allegations of violations will be reviewed by the Associate Dean for Research and Graduate Studies who will present the evidence to the Research Advisory Committee. The Committee will make recommendations regarding the imposition of sanctions to the Dean of Medicine. An investigator may appeal the imposition of sanctions to the President of UCC. The decision of the President with regard to sanctions will be final.

Disciplinary measures can include a freeze of grant or contract expenditures, suspension of salary and employment until the situation is rectified or separation from institutional service.

Approved by:

Waleska Crespo
Waleska Crespo, DrPH
President

February 12, 2020
Date