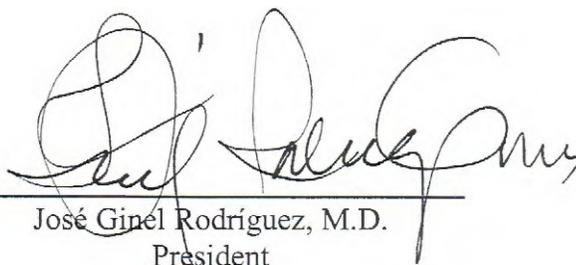


# Universidad Central del Caribe

## Research Conflict of Interest Policy



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José Giné Rodríguez, M.D.  
President

August 2012

## **RESEARCH CONFLICT OF INTEREST POLICY**

### **Universidad Central del Caribe (UCC)**

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.

#### **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.

#### **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 s/he 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 will be completed when the Notice of Award is received and turned in to the OADRGS. 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.

### **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.

# UNIVERSIDAD CENTRAL DEL CARIBE

## DISCLOSURE FORM

### Disclosure

The purpose of this document is to assist in the determination of whether restrictions, oversight, or other conditions might be advisable prior to the University's acceptance of a sponsored award or the completion of a technical transfer agreement. Disclosure forms are to be forwarded to the Office of the Associate Dean for Research and Graduate Studies (OADRGS).

### Section A

#### Significant Financial Interests in a Sponsored Project

##### A.1.

Do you personally have an **ownership interest in the sponsor** of any project consisting of (a) stock with a current market value of more than \$5,000. Include those cases in which a company is not listed on a stock exchange. (Do not report holdings in mutual funds or TIAA/CREF).

NO \_\_\_\_\_ YES (please describe) \_\_\_\_\_

##### A.2.

Do you, your spouse, and/or your dependents, in the aggregate, have ownership interests (stock, stock options, and/or any debt, securities or capital holding) that have a current market value of \$5,000 or more or hold any equity in any outside entity **related to** the proposed sponsored project? (Do not report holdings of mutual funds or TIAA/CREF). An entity **related to** the sponsored project would include any:

- supplier of equipment, materials or services related to the research;
- business commercializing a product that the research is intended to evaluate or further develop; or,
- party whose financial interests would seem to be directly and significantly affected by the research.

NO \_\_\_\_\_ YES (please describe) \_\_\_\_\_

##### A.3.

Are you an employee, officer or director to the sponsor of the project?

NO \_\_\_\_\_ YES (please describe) \_\_\_\_\_

**A.4.**

Do you, your spouse and/or your dependents, in the aggregate, receive salary or other remuneration or financial considerations equal to or more than \$5,000 per year as an employee, consultant, officer, or board member of any entity **related to** the project?

An entity **related to** the project includes any:

- supplier of equipment, materials or services related to the research;
- business commercializing a product that the research is intended to evaluate or further develop; or,
- party whose financial interests would seem to be directly and significantly affected by the research.

**NO** \_\_\_\_\_ **YES (please describe)** \_\_\_\_\_

**Section B**  
**Significant Financial Interests in a Technology Transfer Agreement**

**B.1.**

Do you personally have an ownership interest (equity share or stock in the entity with which the University is negotiating a technology transfer agreement consisting of (a) stock with a current market value of more than \$5,000 (Do not report holdings in mutual funds or TIAA/CREF).

**NO** \_\_\_\_\_ **YES (please describe)** \_\_\_\_\_

**B.2**

Are you an employee, officer or director to the entity with which the University is negotiating a technology transfer agreement?

**NO** \_\_\_\_\_ **YES (please describe)** \_\_\_\_\_

**B.3.**

Do you, your spouse, or your dependents have any other ownership, managerial relationships with the entity with which the University is negotiating a technology transfer agreement that you wish to volunteer and submit for review and evaluation in order to forestall future criticism of the objectivity of your research?

**NO** \_\_\_\_\_ **YES (please describe)** \_\_\_\_\_

# UNIVERSIDAD CENTRAL DEL CARIBE

## DISCLOSURE FORM Reimbursed or Sponsored Travel

### Disclosure

The Public Health Service requires that you disclose any reimbursed or sponsored travel related to institutional responsibilities (including purpose of trip, sponsor, destination and duration), except travel reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. UCC will determine if any travel requires further investigation, including determination or disclosure of the monetary value.

This document must be completed and please return to the Office of the Associate Dean for Research and Graduate Studies (OADRGS). If you require additional space to list your reimbursed or sponsored travel, please attach additional pages.

**Traveler's Name:** \_\_\_\_\_

**Position:** \_\_\_\_\_

**Department:** \_\_\_\_\_

Legal name of the entity that reimbursed or sponsored the travel:

Purpose of travel: \_\_\_\_\_

Destination: \_\_\_\_\_

Dates of travel: \_\_\_\_\_

Approximate monetary value: \_\_\_\_\_

Briefly describe the activity or activities of the entity: \_\_\_\_\_

\_\_\_\_\_

Describe the relationship of travel to institutional responsibilities: \_\_\_\_\_

\_\_\_\_\_

Nature of reimbursed or sponsored travel expenses (e.g. transportation, hotels, meals, entertainment):

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

## CERTIFICATION

I have read and understood the University's Research Conflicts of Interest Policy and to the best of my knowledge have made all required financial disclosures.

I will comply with any conditions or restrictions imposed by the University regarding conflicts of interest.

Should my outside financial or managerial interests, or those of my spouse and/or dependents, change during the next calendar year so as to change my response to any of the above questions, I agree to submit a revised DISCLOSURE and CERTIFICATION.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Printed Name: \_\_\_\_\_

This disclosure is related to sponsored project \_\_\_\_\_  
(Specify)

This disclosure is related to technology transfer agreement \_\_\_\_\_  
(Specify)

This disclosure is related to reimbursed or sponsored travel \_\_\_\_\_  
(Specify)

### **OADRGS**

Approved by:

\_\_\_\_\_  
Name

\_\_\_\_\_  
Signature

Date: \_\_\_\_\_

**RESEARCH CONFLICT OF INTEREST POLICY**  
**Universidad Central del Caribe (UCC)**

**Revision history**

<b>Revision Date</b>	<b>Changes</b>	<b>Page</b>
April 2011	Disclosure due date was included.	2
	Title of sections.	2-4
August 2012	Travel information included in Significant Financial Interest	2
	Conflict of Interest changes decreasing the dollar amount.	3
	Disclosure form changes decreasing the dollar amount.	5-6
	Disclosure form for reimbursed or sponsored travel add.	7
	Certification add the information about reimbursed or sponsored travel	8