

Financial Conflict of Interest in Sponsored Research Policy

February 12, 2015

I. Summary Policy

Research and Business Development Center (RBDC) is committed to preserving public trust in the objectivity of research. RBDC expects that all research be conducted with the highest scientific and ethical standards. Research programs should never be influenced by the existence of related opportunities for financial gain by principal investigators. The results of the funded research should never be biased by financial or other considerations available to the principal investigators.

Legal requirements arising from RBDC research sponsored by the Public Health Service (PHS) and the National Science Foundation (NSF) require institutions to have in place a research-specific policy to eliminate, reduce or manage conflicts of interest. While these legal requirements refer specifically to receipt of federal funding in the establishment of a policy governing financial or other conflicts of interest, compliance with the policy is expected of all RBDC personnel or independent contractors involved in sponsored research activities, regardless of funding source.

This document constitutes a general policy by specifically addressing Public Health Service (PHS) regulations, “Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought” and “Responsible Prospective Contractors.” These are also known as the Financial Conflict of Interest, or FCOI, regulations (42 CFR Part 50 Subpart F and 45 CFR Part 94).

The purpose of this policy is to provide guidance to RBDC personnel and independent contractors regarding the disclosure, management, reduction or elimination of financial conflicts of interest. Investigators are responsible for complying with the institution’s written FCOI policy and for disclosing their significant financial interest(s) (SFI’s) as defined in the procedures.

II. Managing Conflict of Interest in Sponsored Research

The effects of conflict of interest can be eliminated, or substantially reduced by early and full disclosure of relevant or substantial personal financial interest in the potential outcomes of sponsored research. A consistently applied process allows for development of an effective management plan and administrative review. This policy is designed to safeguard individual and institutional reputations by defining and delineating the range of opportunities appropriate for RBDC personnel and independent contractors under specified circumstances.

III. Application of this Policy

This policy is broadly applicable to all RBDC personnel or independent contractors. Contractors include full-time faculty members at partner universities who are engaged in scholarly activities funded in whole or in part by external entities. Other RBDC personnel or independent contractors who do not direct, but are involved in research activities may also encounter conflicts of interest. These may include administrative or staff personnel providing some level of research support, research associates, post-doctoral fellows, and part-time personnel such as student assistants.

As per federal regulations this policy is publically accessible on the RBDC website; www.rbdcenter.org and is in force as of February 12, 2015.

Standards in this policy are to be administered with discretion and judgment based upon the facts and circumstances of any given case.

IV. Definitions

Awarding Sponsor - Agency, foundation or institution that funds the research that is subject to this policy.

Public Health Service - The Public Health Service Act of 1944 structured the United States Public Health Service (PHS) as the primary division of the Department of Health, Education and Welfare (HEW), which later became the United States Department of Health and Human Services. The PHS comprises all Agency Divisions of Health and Human Services and the Commissioned Corps.

Agencies within the Public Health Service:

- Administration for Children and Families (ACF)
- Administration on Aging (AoA)
- Agency for Healthcare Research and Quality (AHRQ)
- Agency for Toxic Substances and Disease Registry (ATSDR)
- Centers for Disease Control and Prevention (CDC)
- Centers for Medicare & Medicaid Services (CMS)
- Federal Occupational Health (FOH)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS)
- National Institutes of Health (NIH)
- Substance Abuse and Mental Health Services Administration (SAMHSA)

Disclosure - Formal, written reporting of all involvement or situations which constitute, or might appear to constitute, conflicts of interest relative to the assigned responsibilities of principal investigators. Such reporting must occur prior to the submission of a proposal for externally sponsored research and at any time during the

conduct of the sponsored research in which a conflict arises. Federal law requires disclosure of the detailed financial aspects of the conflict if the amount of financial gain to the individual exceeds \$5,000.

Significant Financial Interest (SFI)

- an equity interest in, or payments for, services exceeding **\$5,000 in a 12 month period** from a business, non-profit entity, or another institution
- This includes any equity interest in non-publically traded entities
- Once the dollar threshold is met by an individual, **all** SFI related to the individual's research responsibility must be disclosed

SFI *excluded* from disclosure include the following:

- Income from Seminars, lectures or teaching engagements sponsored by and/or service on advisory or review panels for a federal, state or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or research institute that is affiliated with an institution of higher education.
- 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.

Financial Conflict of Interest (FCOI)

An SFI that could directly and significantly affect the design, conduct, or reporting of research.

V. Potential Conflicts of Interest in Sponsored Research Activities

Conflicts of interest in sponsored research activities are most likely to occur when principal investigators and other involved personnel or contractors are involved with commercial interests with outside entities. Such interests may include but are not limited to the following involvements which may present conflicts of interest:

Serving Outside Interests - Conducting research when any of the participants in the externally sponsored activity or their immediate families have an equity ownership, managerial, consulting, or other significant financial interest in the sponsoring outside entity whose product, process, or device is under study.

Accepting Gifts and Gratuities - Accepting gratuities, gifts of more than nominal value, or special favors from outside entities supporting sponsored research.

Consulting - Entering into paid consulting agreements with outside entities whose influence may affect in a material way (direction, focus, timing, reporting, etc.) research

at RBDC sponsored either by the outside entity, or any other sponsor, institutional or external, of related work.

Use of RBDC or Partner University Employees - Using RBDC or partner university employees (e.g., students, or secretarial, clerical, or technical staff) to perform services for an outside entity in which the principal investigator or his/her immediate family has an equity ownership, managerial, consulting, or other significant financial interest.

Use of RBDC or Partner University Resources - Using non-reimbursed or otherwise unauthorized substantial or continuing use or purchase of institutional resources such as equipment, supplies, facilities, or space to support the interests/activities of an outside entity in which a principal investigator, or his or her immediate family, has an equity ownership, managerial, consulting, or other significant financial interest.

Access to Research Information - Providing privileged access to research information or other intellectual property, developed with support from one outside entity, to another outside entity in which the principal investigator, or his or her immediate family, has an equity ownership, managerial, consulting, or other significant financial interest.

VI. Disclosure

Disclosure forms are available from RBDC.

Investigators must disclose the occurrence of any reimbursed travel or sponsored travel related to his/her research responsibilities (including purpose of trip, sponsor/organizer, destination, and duration). Individuals are *NOT* required to disclose travel that is reimbursed or sponsored by a federal, state, or local government agency, another institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

Investigators must report any SFI to RBDC's Grant Administrator by the time a research application is submitted to an external Sponsor. Investigators must submit to the Grant Administrator an updated disclosure statement at least annually, AND within 30 days of "discovering or acquiring" a new SFI.

Disclosures should include the following:

- Grant/Contract number
- Project Director/Principal Investigator (PD/PI) or Contact PD/PI
- Name of investigator with FCOI
- Whether FCOI was managed, reduced, or eliminated
- Name of the entity with which the investigator has a FCOI
- Nature of FCOI, e.g., equity, consulting fees, travel reimbursement, honoraria

- Value of the financial interest \$0-4,999; \$5K-9,999; \$10K-19,999; amounts between \$20K-\$100K by increments of \$20K; amounts above \$100K by increments of \$50K or statement that a value cannot be readily determined.
- A description how the financial interest relates to outside funded research and the basis for the Institution's determination that the financial interest conflicts with such research
- Key elements of the Institution's management plan
- Status of the FCOI
- Changes to the management plan

Management Plan - Before spending any funds, the Grant Administrator of RBDC must review all investigator SFI disclosures with the investigator and develop a formal, written Financial Conflict of Interest Management Plan. Conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- (i) Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- (ii) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- (iii) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
- (iv) Modification of the research plan;
- (v) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- (vi) Reduction or elimination of the financial interest (e.g., sale of an equity interest);
- (vii) Severance of relationships that create financial conflicts.

Whenever, in the course of an ongoing research project, an investigator who is new to participating in the research project discloses a significant financial interest or an existing investigator discloses a new SFI, RBDC's Grant Administrator shall, within sixty days:

- Review the disclosure of the SFI
- Determine whether it is related to the proposed or existing funded 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 financial conflict of interest.

Depending on the nature of the significant financial interest, RBDC's Grant Administrator may determine that additional interim measures are necessary with regard to the investigator's participation in the funded research project between the date of disclosure and the completion of RBDC's review.

Whenever an SFI is identified that was not disclosed in a timely fashion by an investigator or, for whatever reason, was not previously reviewed by the Grant

Administrator of RBDC during an ongoing research project (e.g., was not timely reviewed or reported by a subrecipient), the Grant Administrator shall, within sixty days:

- Review the significant financial interest with the investigator and the Administrative Director of RBDC
- Determine whether it is related to the funded research
- Determine whether a financial conflict of interest exists; and, if so:

(i) 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 financial conflict of interest going forward;

(ii) In addition, whenever:

- an FCOI is not identified or managed in a timely manner, including failure by the investigator to disclose an SFI that is determined by the Grant Administrator of RBDC to constitute an FCOI
- failure by the RBDC Grant Administrator to review or manage such an FCOI
- the investigator fails to comply with a FCOI management plan,

then RBDC's Administrative Director shall, within 120 days of the institution's determination of noncompliance, complete a retrospective review of the investigator's activities and the research project to determine whether any research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

RBDC is required to document the retrospective review; such documentation 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 a financial conflict of interest
- (6) Reason(s) for the retrospective review
- (7) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed)
- (8) Findings of the review; and
- (9) Conclusions of the review

(iii) Based on the results of the retrospective review, if appropriate, the Grant Administrator of RBDC shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If bias is found in a Public Health Service (PHS) funded project, RBDC is required

to notify that PHS Awarding Sponsor promptly and submit a mitigation report to the PHS Awarding Sponsor. 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 Institution'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). Thereafter, RBDC will submit FCOI reports annually, as specified elsewhere in this subpart. Depending on the nature of the financial conflict of interest, RBDC may determine that additional interim measures are necessary with regard to the investigator's participation in the externally funded research project between the date that the financial conflict of interest or the investigator's noncompliance is determined and the completion of the Institution's retrospective review.

Whenever RBDC implements a management plan pursuant to this subpart, the RBDC Administrative Director shall monitor investigator compliance with the management plan on an ongoing basis until the completion of the research project.

Disagreement on Resolution of Conflict of Interest - In the event that the principal investigator (and other involved personnel) and direct line staff are unable to agree on resolution of conflict of interest either prior to proposal submission (during the approval request stage) or during the execution of a research contract, the Executive Director of RBDC shall render a decision regarding strategy for managing the conflict. The Executive Director's decision and plan shall be binding. Steps will be taken to safeguard the affected research, and to protect RBDC and its personnel. In the event that individuals have been found to be out of compliance with this policy, the Executive Director may also impose appropriate sanctions. Recommended sanctions for failure to comply with this policy may include, but are not limited to, rescinding contracts involving the funds, freezing funds or accounts, prohibiting participation in future sponsored activities, suspension, probation or termination.

VII. Subrecipients

RBDC must take reasonable steps to ensure that colleagues working for subrecipients comply with the federal regulations by requiring those investigators to comply with the Institution's policy or by requiring the subrecipient entities to provide assurances to RBDC that will enable RBDC to comply with the federal rules:

- Incorporate as part of a written agreement terms that establish whether the FCOI policy of the awardee Institution or that of the subrecipient will apply to subrecipient investigators and include time periods to meet disclosure and/or FCOI reporting requirements.

- Subrecipient Institutions who rely on their FCOI policy must report identified FCOIs to RBDC's Grant Administrator in sufficient time to allow RBDC to report the FCOI to the PHS or other Awarding Sponsor (e.g., NIH through the eRA Commons FCOI Module) to meet reporting obligations if the project is funded by the PHS or other agency.

VIII. Reporting to the PHS

Before spending any PHS funds, RBDC must report any FCOI to the agency awarding the PHS funds. RBDC must also submit an annual update report until the conflict no longer exists. In addition, RBDC must provide a report within 60 days of learning of any new SFI on an existing PHS-funded contract or grant.

Any FCOI report required under paragraphs of this section shall include sufficient information to enable RBDC, and if federally funded, the PHS Awarding Sponsor to understand the nature and extent of the financial conflict, and to assess the appropriateness of the RBDC's management plan. Elements of the FCOI report shall include, but are not necessarily limited to the following:

- (i) Project number
- (ii) PD/PI or Contact PD/PI if a multiple PD/PI model is used
- (iii) Name of the investigator with the financial conflict of interest
- (iv) Name of the entity with which the investigator has a financial conflict of interest
- (v) Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium)
- (vi) 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
- (vii) A description of how the financial interest relates to the PHS funded research and the basis for the Institution's determination that the financial interest conflicts with such research
- (viii) 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
 - (F) Other information as needed.

For any FCOI previously reported by RBDC with regard to an ongoing PHS-funded research project, RBDC shall provide to the PHS Awarding Sponsor an annual FCOI report that addresses the status of the FCOI and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists. RBDC shall provide annual FCOI reports to the PHS Awarding Sponsor for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Sponsor.

IX. Disclosure to the Public

The federal rules require *either* an institution disclose all SFIs held by senior/key personnel on a publicly accessible website *or* provide a written disclosure in response to a request within 5 business days. RBDC shall provide a written disclosure upon request. This information will include the investigator's name, title and role with respect to the research project, the name of the entity in which the SFI is held; the nature of the SFI, and the approximate dollar value of the SFI.

X. Investigator Training

RBDC has a responsibility to train each investigator doing externally sponsored research on the RBDC's Financial Conflict of Interest Policy and the federal regulations before that investigator may do any research. The training must be done at least once every four years or "immediately" when:

- (1) The institution changes its policy
- (2) An investigator is new to an institution, or
- (3) An investigator is found to be out of compliance with the rules.