Roswell Park Cancer Institute Policy and Procedure	Date Issued: 11/1/1995	Number: 1102.1
Title: Managing Conflicts of Interest in Research	Revision: 11	Effective Date: 3/23/13
Prepared by: VP for Corporate Ethics	Approved by: Michael B. Sexton, General Counsel	Page: 1 of 7

A. GENERAL STATEMENT OF POLICY

Roswell Park Cancer Institute (RPCI) and Health Research, Inc., Roswell Park Cancer Institute Division (HRI) promote objectivity in research by establishing policies and procedures to ensure that the design, conduct or reporting of research funded under the Public Health Service (PHS), or any other funding source, is not biased by any conflicting financial interest of an investigator, research team member, or officer of RPCI or HRI.

B. SCOPE

This policy is applicable to key personnel and administrators of RPCI and HRI who are directly working on research projects, applications for grant funding (including the PHS), as well as contracts or cooperative agreements for research. Personnel are informed of the need to provide disclosures by the RPCI Institutional Conflict of Interest Committee.

C. ADMINISTRATION

This Policy and Procedure will be administered by the Vice President for Corporate Ethics and the RPCI Institutional Conflict of Interest Committee.

D. POLICY / PROCEDURE

1. **Definitions**

   a. **Conflict of Interest** means a Reportable Interest that could directly and significantly affect the design, conduct or reporting of research.

   b. **Institutional Responsibilities** means all professional research responsibilities performed in the course of employment.

   c. **Management Plan** means a plan for eliminating or managing an Investigator's Conflict of Interest as determined by the Conflict of Interest Committee.

   d. **Reportable Interest** means an interest (financial or non-financial) that the Investigator must disclose annually on Conflict of Interest Form and if related, on per study disclosure form, Supplemental Disclosure Form: B as described below.

1. Reportable Financial Interest means anything of monetary value, whether or not the value is readily ascertainable, held by the Investigator (as well as the Investigator's spouse, parents, and dependent children) that reasonably appears to be related to the Investigator's professional research responsibilities. Reportable Financial Interests include the following.

    a. Remuneration received from an entity or its affiliate whose product or process is utilized in the Investigator's research or competes with such a product or process, during the 12 months preceding disclosure; or any equity interest in entity or affiliate in excess of $5,000. Remuneration includes salary and any payment for services, including honoraria and consulting or speaking fees. An equity interest includes any stock, stock option or other ownership interest.
    b. Intellectual property rights and interests (e.g., patents, copyrights) upon receipt of income related to such rights; and,
    c. Payment of the Investigator's travel-related or other expenses that are related to his/her Institutional Responsibilities by such an entity or affiliate.

2. Reportable Financial Interest does **not** include the following interests of the Investigator.
    a. salary, royalties, or other remuneration paid by RPCI or HRI;
    b. income from publicly traded investments, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these accounts; or
    c. income from seminars, lectures, teaching and service on advisory panels when the activity is sponsored or paid for entirely by: a governmental agency, an institution of higher education, an academic teaching hospital, or a medical center.

3. Reportable Non-Financial Interest means any other interest that might reasonably be expected to bias the design, conduct or reporting of research. For example, when the Investigator or Investigator's spouse is an uncompensated board member or officer of an organization that advocates for treatment involved in the research. Another example includes Investigator participation in the development, production or marketing of a product or process involved in the research without a financial interest in connection with the product or process.

2. **Obligations of all Personnel Covered by this Policy**

Each person covered by this policy shall disclose all Reportable Interests held by the Investigator, and Investigator's spouse, parents and dependent children. In addition, when new Reportable Interests are acquired, an updated report must be filed disclosing all relevant information. Covered Personnel must provide notice of Reportable Interests as follows.

1. Conflict of Interest Form is sent to the RPCI Designated Official no later than April 15th of each year (April 1 - March 31st)
2. Supplemental Disclosure Form is submitted through CRS with the research packet before applying for human subject research.
3. Form DOH-3995 is submitted to HRI Director prior to submitting an application for research funding.
4. Updates of these forms are submitted within 15 calendar days of discovering or acquiring a previously undisclosed Reportable Interest.

An Investigator shall comply with a request for additional information about a Reportable Interest made by the relevant Conflict of Interest Committee, Institutional Review Board, HRI or funding agency.

An Investigator who fails to disclose a Reportable Interest as provided above may be required to receive additional training, suspend research, and/or be disciplined. If the non-disclosing Investigator is not a RPCI/HRI employee, RPCI/HRI may take appropriate remedial action, including, when considered necessary to protect the objectivity of the research, requiring the Investigator to withdraw from the research.

3. **Contractual Obligations imposed on Other Researchers and Personnel Involved in Funded Research**

Every agreement for work that is subcontracted to institutions, investigators, or personnel outside RPCI and HRI will explicitly require that subcontractor and subcontractor's personnel comply with their own policies that are consistent with this Policy (and, by reference 42 CFR 50 and 45 CFR Part 94). Key personnel, such as the principal investigator, will acknowledge these obligations in the contract process, or will not be permitted to participate in the research in any way.

4. **Training**

a. Basic Information

Personnel covered by this Policy shall receive copies of: this Policy, 42 CFR 50 Subpart F, and 45 CFR 94.

Personnel will be informed that RPCI may maintain a publicly available web site on which it will promptly post the following information on disclosed Conflicts of Interest: the Investigator's name, title and role in connection with the research; the name of the entity in which the Conflict of Interest is held; and the nature of the Conflict of Interest.

b. Required Online Training

Each Investigator is required to complete either the National Institute of Health (NIH) Financial Conflict of Interest (FCOI) training tutorial or the Responsible Conduct in Research training through the City course prior to conducting research, and every following three years.

a. Online training from the NIH website is accessible through: http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm
b. Online training from the Citi Training site is accessible through http://cititraining.org follow the instructions.
c. Personnel completing the online course must print the certificate of completion and forward to the Grants Office. When subsequent training is completed every three years, updated certificates must be likewise printed and forwarded.

5. **The Conflict of Interest Committee Structure and Functions**

a. Structure

The President/CEO shall appoint an Institutional Conflict of Interest Committee (Committee) to oversee and administer this Policy and to support adherence to ethical principles in the conduct, funding and reporting of research activities at RPCI/HRI. The Committee shall be composed of not less than ten (10) individuals. At least four (4) Committee members shall be faculty members chosen from the Ph.D. faculty at RPCI/HRI, one (1) of whom shall be from the Department of Prevention and Population Sciences, and at least (3) Committee members shall be physician members of the faculty. One (1) committee member shall be an attorney licensed to practice law in the State of New York. A Chairman shall be appointed by and shall serve at the pleasure of, the President/CEO.

Each Committee member shall serve a two (2) year term, which can be renewed. The initial membership terms shall be staggered so that in any year not more than three (3) committee seats will become vacant. For meetings, a quorum of not less than six (6) members is required, and actions may be taken by vote of a majority of those present at a meeting at which a quorum is present. At least one member of the Office of Research Subject Protection (ORSP) staff will be present at each committee meeting, where practicable, to record the actions of the committee, and to facilitate communications between the Committee and the IRB.

b. Committee Review of Disclosures

Disclosures presenting a potential conflict as identified by the Designated Official will be reviewed and evaluated by the Committee. Ad hoc reviewers may be consulted on a case-by-case basis. The Committee shall have access to all relevant facts, details, documents, and will analyze the disclosures to assess whether an actual or potential conflict of interest exists or is a risk. If a member of the Committee has any role in a program or conflict being reviewed by the Committee, that member shall disclose that to the Committee and excuse himself or herself from any review or deliberations by the Committee relating to that program.

1. *Determining if a Reportable Interest is related to the Research*

The Committee or designee will review each completed disclosure form to determine whether any Reportable Interests is related to the Investigator's research. If the Committee determines that the Investigator has no Reportable Interest related to a research activity, it shall so inform the Investigator.

The Committee will consider the following factors.

a. Whether the Reportable Interest could be affected by the research;
b. Whether the research could affect the entity in which the Investigator has Reportable Interest.

2. *Determining whether a Related Reportable Interest Creates a Conflict of Interest*

When the Committee or designee determines that a Reportable Interest is related to the Investigator's research, then the Committee shall determine whether the related Reportable Interest constitutes a Conflict of Interest. The

Committee shall make such a determination before any funds are expended on the involved research (other than funds expended to prepare an application for approval of the research or to obtain funding for the research), and prior to the enrollment of human subjects. If the Committee determines that the related Reportable Interest is not a Conflict of Interest, it shall so inform the Investigator.

The Committee shall determine that an Investigator has a Conflict of Interest when a related Reportable Interest could reasonably be expected to directly and significantly affect the design, conduct or reporting of the research. Such determination shall be made based on objective factors, not on the Investigator's character, reputation or past conduct. The Committee may consider any information it deems relevant to its inquiry, and the Research. Specific procedures are provided in "Institutional Responsibilities" appended to this Policy.

3. D*eterminations for Disclosures that Follow Initiation of Research*

When an Investigator discloses a Reportable Interest after the initiation of the research or the Committee is otherwise informed of a potential Conflict of Interest not previously addressed, the Committee will undertake review of the Reportable Interest as described above within sixty (60) days of such disclosure or discovery.

6. **Managing Conflicts of Interest**

Whenever the Committee finds that an Investigator or other personnel has a Conflict of Interest, it shall manage the Conflict of Interest by developing, implementing, monitoring and enforcing a Management Plan.

The Committee may consult with the IRB and IACUC Committee, as well as the Investigator or other affected personnel when development a Management Plan. Each Management Plan must state the specific actions to be taken and the person or organization responsible for each such action. The Committee shall require implementation of all the actions which, in its judgment, will eliminate or mitigate the bias that the identified Conflict of Interest has had or is likely to have on the design, conduct or reporting of the research. The following are examples of actions that Conflict of Interest Committee may consider in preparing a Management Plan.

a. Require public disclosure of Conflicts of Interest (e.g., when publishing or presenting the research or disclosure of Conflicts of Interest directly to human subjects involved in the research)
b. Appoint an independent monitor empowered to take measures to prevent bias in the design, conduct or reporting of the research
c. Modify the plan for conducting or reporting the research
d. Replace the Investigator, change his/her responsibilities for designing, conducting or reporting the research, or disqualify the Investigator from participating in all or part of the research
e. Reduce or eliminate the Reportable Interest
f. Require the Investigator to sever the relationship causing the Conflict of Interest

A Management Plan covering federally-funded research will require the Investigator to disclose each Conflict of Interest in each publication and presentation of the research. Where the publication of research conducted to evaluate the human safety or effectiveness of a drug, medical device or treatment, is released prior Committee

Management of the Conflict of Interest, the Investigator will be required to request an addendum from the publication.

Each Management Plan will provide for monitoring Investigator compliance by HRI or RPCI. The Investigator is given the opportunity to review and sign the Management Plan approved by the Committee. By signing the Management Plan, the Investigator agrees to comply with all of its terms. A Management Plan concerning federally-funded research will be modified if required by the federal government.

Should an Investigator or other personnel decline to comply with a Management Plan, the Committee and the applicable supervisor will impose restrictions up to and including disciplinary action in accordance with the collective bargaining agreement. For example, refusal to sign the Management Plan may result in a withdrawal of the Investigator from all or part of the research. For subcontracted entities, it may result in the removal of the research from that entity. Any significant change in research must be approved by the IRB or IACUC Committee.

7. **Record Retention and Reporting Requirements**

a. Retention

The disclosure form and all records of further actions related to such disclosure will be maintained by the Committee for three years; related records may be maintained with study files for the life of the study or longer. Disclosures and related information will be kept confidential, except for required disclosures made public as described in this Policy.

b. Public Disclosure Requirements

Prior to expenditure of any funds under a NIH-funded research project, RPCI/HRI shall ensure public access, through a web site, or by written response within 5 business days of a request, to information concerning Conflicts of Interests. The information that is made available via a publicly accessible web site or written response consists of the following

1. Investigator's name;
2. Investigator's title and role with respect to the research project;
3. Name of the entity in which the Reportable Interest is held; Nature of the Reportable Interest; and
4. Approximate dollar value of the Reportable 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.

c. Reporting to Funding Sources

In compliance with federal regulations, RPCI and/or HRI will report the existence of a conflict of interest and the Committee's management to the federal granting authority or the private or public sponsor, as applicable. Unresolved conflicts will be reported by the Committee or the IRB to the RPCI General Counsel, the Senior Vice President for Clinical Research and the Senior Vice President for Basic Research.

E. LINKS TO RELATED INFORMATION

1. Institutional Responsibilities (Link to "Institutional Responsibilities to Implement and Enforce Objectivity in Research Standards"_

2. Disclosure Form (Link to Disclosure of Reportable Interest in a Research Project)

3. Regulatory links: 42 CFR 50 Subpart F; 45 CFR 94) (Link to .pdf files of 42 CFR 50 Subpart F, and 45 CFR 94)

F. DISTRIBUTION

This Policy and Procedure will be distributed to all Managers via the RPCI internal web page and to holders of backup hard copies of the manual. Managers are responsible for communicating policy content to pertinent staff.