



## Financial Conflict of Interest Policy

### I. Introduction

The purpose of the Rose Research Center Financial Conflict of Interest (FCOI) Policy is to comply with Federal regulation 42 CFR Part 50 Subpart F and to protect Rose Research Center, its employees, its clients, and its research participants from potential or actual risks associated with any financial conflicts of interest related to Public Health Service (PHS) funded research (e.g., National Institutes of Health (NIH)) studies conducted by Investigators. The purpose of Federal Regulation 42 CFR Part 50 Subpart F is to promote objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under PHS grants and cooperative agreements will be biased by any conflicting financial interest of an Investigator.

A financial conflict of interest (COI) describes a situation in which the financial interests of an organization or an organization's official, acting within his or her authority on behalf of the organization, may affect or appear to affect the research, business transactions, or other activities of the organization. Financial COIs are of significant concern when financial interests create the potential for inappropriate influence over the organization's activities. This policy is intended to protect against exposure from risks related to COIs as they may affect research performed at or under the auspices of the Rose Research Center, LLC (herein referred to as "RRC").

An organization like RRC, including its officials, must balance many competing pressures. It engages in relationships with a variety of sponsors that may lead to financial benefit for the organization in many forms, including gifts, business ventures, royalty payments and equity from licensing intellectual property, as well as sponsored educational and research agreements. In addition, RRC-industry relationships are essential for advancing scientific frontiers and enabling the commercial development of discoveries to the benefit of the public. Nonetheless, while generally part of legitimate research and business activities, relationships with external entities or individuals cannot be allowed to compromise, or appear to compromise, the integrity of RRC's primary missions, including the safety and integrity of its research.

### II. Definitions

Financial Conflict of Interest in Research: A Financial COI in Research may occur whenever the financial interests of the organization, or of an official of the organization who has authority to act on behalf of the organization, might affect – or reasonably appear to affect – processes for the design, conduct, reporting, review, or oversight of research.

Covered Individuals: This Financial COI Policy applies to Investigators involved in PHS funded research or individuals named as senior/key personnel for the NIH-funded research project identified by the Institution pursuant to 42 CFR 50.605 (a) (5) (i)-(iv) FAQ G.2.

Significant Financial Interest (individual): For covered individuals, "significant financial interest" is defined as being consistent with RRC conflict of interest policy and procedures. Areas of consideration

include payments, honoraria, royalties (even through the organization), equity, options and warrants, management positions, and gifts.

Significant Financial Interest (institutional):

1. Royalties: Financial COI may be present when the organization has agreements to receive milestone payments and/or royalties from the sales of an investigational product that is the subject of the research;
2. Non-publicly traded equity: When, through its technology licensing activities or investments related to such activities, the organization has obtained an equity interest or an entitlement to equity of any value (including options or warrants) in a non-publicly traded company that is: i) the sponsor of research at the organization, or ii) the manufacturer of a product to be studied or tested at or under the auspices of the organization;
3. Publicly traded equity: When, through technology licensing activities or investments related to such activities, the organization has obtained an ownership interest or an entitlement to equity (including options or warrants) exceeding \$100,000 in value (when valued in reference to current public prices, or, where applicable, using accepted valuation methods), in a publicly-traded company that is i) the sponsor of research at the organization, or ii) the manufacturer of a product to be studied or tested at or under the auspices of the organization.
4. Gifts from sponsors: When the organization has received substantial gifts (including gifts in kind) from a potential commercial sponsor of research or a company that owns or controls products being studied or tested, or an individual affiliated with these companies.

The following circumstances should be evaluated:

- a) Whether a gift is of sufficient magnitude that even when held in the general endowment for the benefit of the entire organization, it might affect, or reasonably appear to affect, oversight of research at the organization;
- b) Whether a gift is held for the express benefit of the college, school, department, institute or other unit where the research is to be conducted; or
- c) Whether any official of the organization who has the authority, by virtue of their position, to affect or appear to affect the conduct, review or oversight of the proposed research has been involved in solicitation of the gift.

### **III. Identification of Potential Financial Conflicts of Interest**

The following significant financial and fiduciary interests of the organization warrant disclosure for potential Financial COI with respect to research:

- Significant financial interests for the organization.
- Significant financial interests on the part of covered individuals responsible for the oversight of research.
- Situations when an investigator or other RRC official with research oversight authority participates materially in a procurement or purchasing decision involving major purchases from, or non-routine supply contracts with, a company that sponsors research at the organization, or whose product is being studied or tested in human subjects research at the organization.

In addition to those circumstances indicated above, other financial relationships with research sponsors may warrant disclosure and documentation, depending on the circumstances. In general, the organization

should assess the potential for conflict of interest and weigh the magnitude of any risk to the research's integrity.

Although the listed circumstances are potential areas of concern, the goal of this policy is not to preclude RRC from accepting philanthropy from companies that sponsor research, or that own or control products that are being studied or tested. Rather, the policy is intended to require the organization to develop means of identifying and examining such circumstances, and of managing, through disclosure, separation of responsibilities, and as otherwise appropriate, mitigation of any actual or apparent conflicts of interest that may result. All gifts should be accepted in conformance with these policies. All RRC staff members are accountable for adhering to the organization's gift policy.

#### **IV. Management of Potential Financial Conflicts of Interest**

The reasons to manage Financial COIs include: 1) To maintain the highest possible standards in research; 2) To adhere to all applicable federal and state regulations; 3) To protect the reputation and credibility of RRC and its staff. Based on those needs, the following basic principles will be applied in the management of potential Financial COI:

1. When RRC itself has a significant financial interest, there is a presumption that human subjects research should not be carried out at RRC. In those situations where RRC investigators have unique capabilities, or where there are unique resources at the organization, the research may be performed at RRC after the establishment of a formal management plan.
2. When an individual in a supervisory role has a conflict of interest, there is not the same presumption made that the work cannot be performed, since in most cases alternative supervision can be arranged. The supervisor's role in relation to the research and to the researchers, along with the nature of the supervisor's conflict of interest, should be reviewed and a plan formulated so that an appropriately objective supervisor can oversee the research for the organization.

#### **V. Training and Documentation Requirements**

Investigators and other individuals engaged in human subject research at RRC are required to complete Financial COI training through the Collaborative Institutional Training Initiative (CITI) Program and documented in RRC Talent Learning Management System (LMS). Training must occur:

1. Prior to engaging in research related to any PHS-funded grant,
2. At least every 4 years, and
3. Immediately, if a) RRC revises its Financial COI policy and procedures in any manner that affects Investigator and staff requirements; b) an Investigator or other staff member is new to RRC; and/or c) an Investigator or other staff member is not in compliance with the policy or management plan.

Investigators and other individuals engaged in human subject research at RRC are required to complete RRC's Conflict of Interest Affirmation of Compliance:

1. An Investigator or other staff member is new to RRC,
  2. At least every 2 years, and
- Any changes occur resulting in potential COIs not previously reported.