Financial Conflict of Interest Policy

I. Introduction

The federal Public Health Service (PHS) has adopted regulations (42 CFR Part 50 Subpart F and 45 CFR Part 94) on Promoting Objectivity in Research. These regulations describe the actions an individual and an organization must take in order to promote objectivity in PHS-funded 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. The regulations apply to all PHS-funded grants, cooperative agreements, research contracts (but not Phase 1 Small Business Innovation Research or Small Business Technology Transfer program grants), and subawards where the originating sponsor is PHS.

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 PHS-funded research (e.g., National Institutes of Health (NIH)) studies conducted by Investigators. FCOIs 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 FCOIs as they may affect research performed at or under the auspices of the Rose Research Center, LLC (herein referred to as "RRC").

II. Definitions

Financial Conflict of Interest (FCOI): a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

HHS: the Department of Health and Human Services

Institutional responsibilities: an Investigator's professional activities on behalf of RRC (e.g., administration, research or consulting).

Investigator: the Principal Investigator (PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by award, or proposed for such funding, which may include, for example, collaborators or consultants. RRC's PI, upon consideration of the individual's role and degree of independence in carrying out the work, will determine who is responsible for the design, conduct, or reporting of the research.

PHS: the Public Health Service of the US Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

NIH: the biomedical research agency of the PHS

Significant Financial Interest (SFI):

1. A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appear to be related to the Investigator's institutional responsibilities on behalf of RRC.
   a) With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated for the investigator, investigator's spouse and dependent children, exceeds $5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
   b) With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
   c) With regard to intellectual property rights and interests (e.g., patents, copyrights), a significant financial interest exists upon receipt of income of greater than $5,000 related to such rights and interests.
2. The term significant financial interest does not include the following types of financial interests:
   a) Salary, royalties, or other remuneration paid by RRC to the Investigator if the Investigator is currently employed or otherwise appointed by RRC, including intellectual property rights assigned to RRC and agreements to share in royalties related to such rights;
   b) 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;
   c) Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency located in the United States (US), a US Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a US Institution of higher education; or
   d) Income from service on advisory committees or review panels for a federal, state, or local government agency located in the US, a US Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a US Institution of higher education.
3. Investigators must disclose the occurrence of any foreign or domestic reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available) related to the Investigator's institutional responsibilities. The details of this disclosure will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The disclosure requirement does not apply to travel that is reimbursed or sponsored by the following:
   - a federal, state, or local government agency located in the US,
   - a US Institution of higher education,
   - an academic teaching hospital,
   - a medical center, or
   - a research institute that is affiliated with a US Institution of higher education.

   Foreign Financial Interests -- Investigators must disclose all foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity,

including foreign Institutions of higher education or a foreign government (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of $5,000).

III. Disclosure

Prior to the submission of an application to the NIH Grantee for funding, the PI and all other Investigators at RRC must have disclosed to RRC's designated official an up-to-date listing of their Significant Financial Interests [SFIs] (and those of their spouse and dependent children), as defined above. Any new Investigator, who, subsequent to the submission of an application to NIH for funding from NIH, or during the course of the research project, plans to participate in the project, must similarly disclose their SFI to the designated official promptly and prior to participation in the project.

Each Investigator who is participating in research under an award from NIH must submit an updated disclosure of SFI at least annually, during the period of the award. Such disclosure must include any information that was not disclosed initially to RRC pursuant to this Policy, or in a subsequent disclosure of SFI (e.g., any financial conflict of interest identified on a NIH-funded project directly as a NIH Grantee and/or indirectly through a subaward) that was transferred from another Institution, and must include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).

Each Investigator who is participating in research under an award from NIH must submit an updated disclosure of SFI (including reimbursed travel) within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.

IV. Review by RRC's Designated Official

The designated official will conduct reviews of disclosures. The designated official will review any SFI that has been identified in a disclosure; these interests will be compared to each research award on which the Investigator is identified as responsible for the design, conduct, or reporting of the research to determine if the SFI is related to the award and, if so, whether the SFI creates a Financial Conflict of Interest (FCOI) related to that research award. The designated official has been initially designated as RRC Executive Vice President David Botts.

V. Guidelines for Determining "Relatedness" and Financial Conflict of Interest

The designated official will determine whether an Investigator's SFI is related to the research under a NIH award and, if so, whether the SFI is a financial conflict of interest. An Investigator's SFI is related to the research under the award when the designated official reasonably determines that the SFI could be affected by the research conducted under the award, or is in an entity whose financial interest could be affected by the research. The designated official may involve the Investigator in the determination of whether a SFI is related to the research supported by the award.

A financial conflict of interest exists when the designated official reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the NIH-funded research.

In determining if an Investigator's SFI is related to the research under a NIH award, and if so, whether the relationship creates a FCOI, the designated official considers the role of the Investigator and the

opportunity (if any), to bias the results, the nature of the research being proposed, and the value of the SFI in relation to the size and value of the entity. In addition, the designated official may also consider the following factors:

1. Whether the research is of a basic or fundamental nature directed at understanding basic scientific processes; or
2. Whether the degree of replication and verification of research results is such that immediate commercialization or clinical application is not likely; or
3. Whether the goal of the research is to evaluate an invention linked to the SFI (such as where the SFI is a patent, or an interest in a company that has licensed the invention); or
4. Where the research involves human subjects, whether there are double blind conditions or the involvement of a data and safety monitoring board; or
5. Where the SFI is in a privately held company, whether the researcher's SFI could result in the researcher having influence over company decisions, or whether the research could have a significant impact on the company's business or financial outlook (excluding Phase I SBIRs and STTRs); or
6. The magnitude of the SFIs (e.g., the amount of consulting, or the percentage or value of equity); or
7. Where the SFI is in the sponsor of the research, and the sponsor is a licensee of the Discloser's technology, the amount of commercialization payments received by the Investigator from that technology, both currently or in the future; or
8. The number and nature of relationships an Investigator has with an entity (multiple entanglements can create a relationship with an outside entity that is stronger than the sum of the parts); or
9. Whether the goal of the research is to validate or invalidate a particular approach or methodology that could affect the value of the SFI; or
10. Whether other scientific groups are independently pursuing similar questions; or
11. Whether sufficient external review of the research conducted and the reporting of research results exist to mitigate undue bias; or
12. Whether the goal of the project is a comparative evaluation of a technology in which an Investigator has a SFI; or
13. Whether the project involves a subaward to an entity in which the Investigator has a SFI

VI. Management of Significant Financial Interests that Pose Financial Conflict(s) of Interest

If a conflict of interest exists, the designated official will determine by what means – such as the individual's recusal from decisions affecting the conflicting entity, abstention from the external activity, modification of the activity, and/or monitoring of the activity by a subcommittee – the conflict should be avoided or managed in order to mitigate undue bias. In making those determinations, the designated official will be guided by the principles discussed in this Policy the designated official will also take into consideration whether the Investigator's ongoing role is necessary to continue advancing the research, based upon the factors such as the uniqueness of his or her expertise and qualifications. Examples of conditions that might be imposed to manage a financial conflict of interest include, but are not limited to:

1. Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
2. For research projects involving human subjects research, disclosure of financial conflicts of interest directly to human participants;

3. 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;
4. Modification of the research plan;
5. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
6. Reduction or elimination of the financial interest (e.g., sale of an equity interest);
7. Severance of relationships that create financial conflicts;
8. For research projects involving human subjects research, use of a data and safety monitoring board;
9. Double-blind conditions;
10. Provisions to conduct the work simultaneously at multiple sites;
11. Written disclosure of the conflict to all individuals working on the research project;
12. Annual reports on the research progress to the designated official.
13. Disclosure at any presentation of information related to the FCOI.

If the designated official determines that a conflict exists, they will communicate their determination and the means they have identified for eliminating or managing the conflict, in writing, to the individual, to the relevant PI, and the appropriate direct supervisor. The designated official will keep a record of the disclosure and other relevant information for at least three years. If the designated official prescribes monitoring of the activity, it will describe what monitoring shall be performed and what records are to be kept.

No expenditures on a NIH award will be permitted until the Investigator has complied with the Disclosure requirements of this Policy and has agreed, in writing, to comply with any plans determined by the designated official necessary to manage the FCOI. The designated official will communicate, in writing, with the NIH Grantee to notify it of the existence and the nature of a FCOI and whether the conflict has been managed, reduced, or eliminated. No expenditures can be incurred until the NIH Grantee has reported the FCOI to NIH. The NIH Grantee will notify RRC when it may incur expenditures.

The designated official will keep a record of Investigator disclosures of financial interests and the designated official's review of, and response to, such disclosure and all actions under this policy. Such records will be maintained and kept for at least three years from the date the final expenditures report is submitted and in accordance with the terms and conditions of the award and relevant NIH Regulations.

VII. Public Accessibility to Information Related to Financial Conflicts of Interest

Prior to the expenditure of any funds under a NIH award, RRC will ensure public accessibility, via a publicly accessible Web site or by written response to any requestor within five business days of a request, of information concerning any SFI disclosed that meets the following three criteria:

1. The SFI was disclosed and is still held by the senior/key personnel. Senior/key personnel are the PI and any other person identified as senior key personnel by RRC in the award application, progress report or any other report submitted to the NIH Grantee;
2. RRC has determined that the SFI is related to the research funded through an award; and
3. RRC has determined that the SFI is a financial conflict of interest.

The information that RRC will make available via a publicly accessible Web site or in a written response to any requestor within five days of request will include, at a minimum, the following:

1. The Investigator's name;
2. The Investigator's title and role with respect to the research project;
3. The name of the entity in which the SFI is held;
4. The nature of the SFI; and
5. The approximate dollar value of the SFI in the following ranges: $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.

If RRC uses a publicly accessible Web site to comply with the public disclosure requirements of the NIH regulations, the information posted will be updated at least annually, and within sixty days of receipt or identification of information concerning any additional SFI of the senior/key personnel for the NIH-funded research project that had not been previously disclosed, or upon the disclosure of a SFI of senior/key personnel new to the NIH-funded research project, if it is determined by the designated official that the SFI is related to the research and is a financial conflict of interest.

If RRC responds to written requests for the purposes of public accessibility, it will ascertain from the Investigator that the information provided is current as of the date of the correspondence, and will note in its written response that the information is subject to updates, on at least an annual basis and within 60 days of RRC's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

Information concerning the SFIs of an individual, as limited by this Policy, will remain available, for responses to written requests or for posting via RRC's publicly accessible Web site for at least three years from the date that the information was most recently updated.

VIII. Reporting of Financial Conflicts of Interest

Prior to the expenditure of any funds under an award funded by NIH, RRC will provide to NIH a FCOI report compliant with NIH regulations regarding any Investigator's Significant Financial Interest found to be conflicting and will ensure that the Investigator has agreed to and implemented the corresponding management plan. While the award is ongoing (including any extensions with or without funds), RRC will provide to NIH an annual FCOI report that addresses the status of the FCOI and any changes in the management plan. For any SFI that is identified as conflicting subsequent to an initial FCOI report during an ongoing NIH-funded research project (e.g., upon the participation of an Investigator who is new to the research project), RRC will provide to NIH, within forty five days, an FCOI report regarding the financial conflict of interest and ensure that RRC has implemented a management plan and the Investigator has agreed to the relevant management plan.

IX. Training Requirements

Each Investigator must complete training on RRC's Financial Conflict of Interest Policy prior to engaging in research related to any NIH-funded award and at least every four years, and immediately (as defined below) when any of the following circumstances apply:

1. RRC revises this Policy, or procedures related to this Policy, in any manner that affects the requirements of Investigators (training is to be completed within the timeframe specified in communications announcing such changes);
2. An Investigator is new to RRC research under a NIH award (training is to be completed prior to his/her participation in the research); or
3. RRC finds that an Investigator is not in compliance with this Policy or a management plan issued under this Policy (training is to be completed within 30 days in the manner specified by the designated official).

In fulfillment of the training requirement, RRC requires its investigators to complete the National Institutes of Health's Financial Conflict of Interest tutorial (http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm). All investigators must print a certification of completion at the end of training and retain it for audit purposes; training will also be documented in RRC Talent Learning Management System (LMS).

X. Failure to Comply with RRC's Financial Conflict of Interest

When a FCOI is not identified or managed in a timely manner, including, for example, because the underlying SFI is not disclosed timely by an Investigator or, because a FCOI was not timely reviewed or reported by RRC; or because an investigator failed to comply with a management plan; then RRC will within 90 days:

1. Complete a retrospective review of the Investigator's activities and the research project to determine any bias in the design, conduct or reporting of research;
2. Document the retrospective review consistent with the regulation;
3. Document RRC's determination as to whether any research, or portion thereof, conducted during the period of time of the Investigator's non-compliance with this Policy, was biased in the design, conduct, or reporting of such research.

If bias is found, RRC shall notify NIH promptly and submit a mitigation report to NIH that shall address the following:

- Impact of the bias on the research project and
- RRC's plan of action or actions taken to eliminate or mitigate the effect of the bias.

Thereafter, RRC shall submit FCOI reports annually to NIH, in accordance with the regulation and terms and conditions of the award agreement. Depending on the nature of the FCOI, RRC may determine that additional interim measures are necessary with regard to the Investigator's participation in the research project between the date that the FCOI is identified and the completion of RRC's independent retrospective review.

XI. Clinical Research

If RRC determines that one of its funded clinical research projects whose purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment has been designed, conducted or reported by an Investigator with a FCOI that was not managed or reported by RRC any, shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

XII. Clinical Research

A subrecipient relationship is established when federal funds flow down from or through RRC to another individual or entity and the subrecipient will be conducting a substantive portion of a PHS-funded research project and is accountable to RRC for programmatic outcomes and compliance matters. Subrecipients, who include but are not limited to collaborators, consortium members, consultants, contractors, subcontractors and subawardees, are subject to RRC's terms and conditions, and as such, RRC will take reasonable steps to ensure that any subrecipient Investigator is in compliance with the federal FCOI regulation. RRC will incorporate, as part of a written agreement with the subrecipient, terms that establish whether RRC's Investigator FCOI Policy or that of the subrecipient's institution will apply to the subrecipient Investigator.

If the subrecipient's conflict of interest policy applies to the subrecipient Investigator, the subrecipient institution will certify as part of the agreement with RRC that it is in compliance with the federal FCOI regulation and that the institution's portion of the project is in compliance with the federal conflict of interest policy. If the subrecipient cannot provide the certification, the agreement shall state that the subrecipient Investigator is subject to RRC's Investigator FCOI Policy for disclosing SFIs that are directly related to the subrecipient's work for RRC. RRC will, if applicable, submit a FCOI report to the NIH through the eRA Commons FCOI Module for any FCOIs identified for a subrecipient Investigator.

If the subrecipient's conflict of interest policy applies to the subrecipient Investigator, the agreement shall specify the time period for the subrecipient to report all identified FCOIs to RRC. Such time period must be sufficient to enable RRC to provide timely FCOI reports to the NIH as necessary, through the eRA Commons FCOI Module.

If the subrecipient Investigator is subject to RRC's Investigator FCOI Policy, the agreement shall specify the time period for the subrecipient to submit all Investigator disclosures of SFIs to RRC. Such time period shall be sufficient to enable RRC to comply with its review, management, and reporting obligations under the regulation. RRC will submit any NIH FCOI reports for a subrecipient Investigator through the eRA Commons FCOI Module.

XIII. Maintenance of Records

Records relating to conflict of interest matters covered under this Investigator FCOI Policy for PHS-funded research must be maintained for a minimum of three years after any applicable research project's final financial report is submitted to the funding agency, or until three years after the final action has been taken on any audit, litigation or claim, whichever is longer. Records for conflict of interest matters relating to other funded research will be maintained in accordance with RRC's Record Retention Policy.

XIV. Failure to Comply with This Policy

No expenditures of funds on an award supported by NIH will be permitted unless the Investigator has complied with the Disclosure requirements of this Policy and has agreed, in writing, to comply with any designated official-approved FCOI management plan.