

### **Financial Conflict of Interest**

Rochal shall maintain and enforce an up-to-date, written policy on financial conflict of interest (FCOI). Rochal shall make its written policy available to any requestor within five business days of a request.

Rochal shall inform each partner, employee, intern and contractor of the company's policy on FCOI, his/her responsibilities regarding disclosure of significant financial interests, and of federal and industry guidelines.

Rochal shall require each employee or intern to complete training regarding financial conflict of interest prior to engaging in research related to any federally funded contract at least every four years and immediately when any of the following circumstances apply:

- an employee or intern is new to Rochal;
- Rochal finds that a partner, employee, intern or contractor is not in compliance with the company's FCOI policy or management plan; or
- Rochal revises its FCOI policies or procedures in a manner that affects the requirements of scientists.

Rochal's policy requires that all conflicts of interest shall be managed, reduced or eliminated prior to the expenditure of relevant funds.

According to National Science Foundation (NSF) guidelines, which Rochal shall apply to any federally funded project unless the federal agency has different guidelines, if Rochal carries out agency-funded research through subawardees, contractors or collaborators, then Rochal must take reasonable steps to ensure that:

- investigators working for such entities follow Rochal policies; or
- the entity has its own policies in place that meet the requirements of Rochal policies.

Rochal's policies shall include adequate enforcement mechanisms and provide for sanctions where appropriate.

Rochal shall maintain records of all financial disclosures and all actions taken to resolve conflicts of interest for at least three years beyond the conclusion of the action, or if federal funding was involved, for at least three years beyond the termination or completion of the award to which they relate, or until the resolution of any federal funder's action involving those records, whichever is longer.

### **Disclosure of Financial Conflict of Interest**

Rochal's Business Manager shall solicit and review financial disclosure statements, when needed, from each partner, employee, intern or contractor who is planning to participate in Rochal research; provide the President with guidelines consistent with standards to identify conflicting interests; and take actions necessary to ensure that such conflicting interests are managed, reduced or eliminated in conjunction with the President.

Rochal's Business Manager shall review all financial disclosures and determine whether a financial conflict of interest (FCOI) exists, and, if so, determine with the President what actions should be taken by Rochal to manage, reduce or eliminate such conflict of interest.

A financial conflict of interest exists when the Business Manager reasonably determines that a significant financial interest could directly and significantly affect the design, conduct or reporting of the research.

At the beginning of Rochal involvement and annually thereafter, each partner, employee, intern or contractor planning to participate in Rochal research must have submitted to Rochal's Business Manager a listing of his/her known significant financial interests (and those of his/her spouse and dependent children) that would reasonably appear to be affected by the research and in entities whose financial interests would reasonably appear to be affected by the research.

If at any time a Rochal partner, employee, intern or contractor determines he/she has a conflicting significant financial interest in Rochal research, then this interest must be reported within 30 days of such determination to Rochal's Business Manager.

If the affected Rochal research is funded by any external source, then the existence of the conflicting significant financial interest is to be reported to the external funder within 60 days of notification with assurance that the interest has been managed, reduced or eliminated in accordance with Rochal policies and procedures. Rochal is not required to report to external funders the nature or other details of a reported FCOI; however, Rochal is required to make information available, upon request, to the external funder regarding FCOIs identified by the company and how those interests have been managed, reduced or eliminated to protect the research from bias.

Rochal's FCOI report shall include the following information:

- contract number, if externally funded;
- distinguished method used to protect the involved research from bias (i.e., managed, reduced or eliminated); and
- name of the partner, employee, intern or contractor with the FCOI.

If Rochal is carrying out federally funded research through subrecipients (e.g. subawardees, subgrantees, contractors or collaborators) or subcontractors, then Rochal must take reasonable steps to ensure that scientists working for such entities comply with Rochal policies and procedures, either by requiring those scientists to comply with Rochal's policy or by requiring the entities to provide assurances to Rochal that will enable Rochal to comply with the regulations.

In addition, Rochal is responsible for reporting to external funders, including for federally funded grants, any conflicting interests it has identified, including those of subrecipients or subcontractors, and assuring that the interest has been managed, reduced or eliminated.

Rochal is required to keep all records of all financial disclosures and all actions taken by Rochal with respect to each conflicting interest as follows:

- for grants or cooperative agreements, at least three years from the date of submission of the final expenditures report, or, where applicable, from other dates specified in the grant or cooperative agreement for different situations; or
- for contracts, three years after final payment, or, where applicable, for the other time periods specified in the contract.

In the event unmanaged conflicting financial interest exists that results in a bias in the design, conduct or reporting of Rochal research, then Rochal must promptly notify external funders, if applicable, of the corrective action taken or to be taken.

Rochal is required to establish adequate enforcement mechanisms and provide for sanctions where appropriate; however, Rochal may determine the nature of the enforcement mechanisms and sanctions.

Under Rochal policies and procedures, Rochal partners, employees, interns and contractors are required to disclose to Rochal's Business Manager a listing of significant financial interests (and those of his/her spouse and dependent children) that would reasonably appear to be affected by Rochal research and in entities whose financial interests would reasonably appear to be affected by Rochal research.

An interest in a pooled fund such as a diversified mutual fund may be sufficiently remote that it would not reasonably be expected to create a conflict of interest. Consult with Rochal's Business Manager.

Stock-option assets are to be reported annually or as new stocks are obtained, in the same manner as all other assets. The documentation needed to determine the value of a stock option is defined by each institution. Consult with Rochal's Business Manager.

Rochal may determine that the research will not be affected by qualified blind-trust assets not known to the partner, employee, intern or contractor that are managed by an independent fiduciary. Because such assets would not be known, they could not directly and significantly affect the design, conduct or reporting of the research.

Of course, if the partner, employee, intern or contractor is aware of the assets originally placed in the trust at the time of its formation, then he/she would be required to disclose any such assets that would reasonably appear to be affected by research. Only new assets purchased with the proceeds from the original assets would be unknown. Consult with Rochal's Business Manager.

Royalties related to patents owned by Rochal are considered remuneration from Rochal and would not be considered a significant financial interest.

Income from royalties from other sources could be considered a significant financial interest if the income fits the definition of a significant financial interest.

## **Disclosure of Significant Financial Interests**

Rochal's financial conflict of interest policy requires that each Rochal partner, employee, intern or contractor (Rochal person) disclose to a responsible representative of Rochal all "significant financial interests" of the Rochal person (including those of the spouse and dependent children) that would reasonably appear to be affected by the research or in entities whose financial interests would reasonably appear to be affected by such activities.

Rochal shall disclose to any impacted parties all significant financial interests that would reasonably appear to be affected by the research.

A significant financial interest is defined as anything of monetary value, including but not limited to:

- equity interests (e.g., stocks, stock options or other ownership interests);
- intellectual property rights (e.g., patents, copyrights and royalties from such rights); or
- salary or other payments for services (e.g., consulting fees or honoraria).

A significant financial interest consists of one or more of the following interests of the Rochal person (and those of his/her spouse and dependent children) that reasonably appears to be related to the scientist's responsibilities to Rochal:

- with regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. 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;
- 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 12 months preceding the disclosure, when aggregated, exceeds \$5,000, or when the scientist (or the scientist's spouse or dependent children) holds any equity interest (e.g., stock, stock option or other ownership interest); or
- intellectual property rights and interests (e.g., patents, copyrights) upon receipt of income related to such rights and interests.

The term does not include:

- an equity interest that when aggregated for the Rochal employee, partner or contractor and his/her spouse and dependent children does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a 5-percent ownership interest in any single entity;
- any ownership interests in Rochal if Rochal is an applicant under the SBIR program;
- income from investment vehicles, such as mutual funds and retirement accounts, as long as the scientist does not directly control the investment decisions made in these vehicles;

- income from seminars, lectures or teaching engagements 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;
- income from service on advisory committees or review panels for 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; or
- salary, royalties or other payments that when aggregated for the Rochal employee, partner or contractor and his/her spouse and dependent children over the next 12 months are not expected to exceed \$10,000; or
- salary, royalties or other remuneration from Rochal.

Rochal partners, employees, interns and contractors (Rochal persons) are required to disclose to an official designated by Rochal a listing of significant financial interests (and those of his/her spouse and dependent children) that would reasonably appear to be affected by Rochal research and in entities whose financial interests would reasonably appear to be affected by the research.

Rochal persons also must disclose the occurrence of any reimbursed or sponsored travel ( i.e., that which is paid on behalf of the scientist and not reimbursed to the scientist so that the exact monetary value may not be readily available), related to their responsibilities to Rochal, provided, however, that this disclosure requirement does not apply to travel that is 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.

Rochal's policy requires the details of this disclosure, which include at a minimum the purpose of the trip, the identity of the sponsor/organizer, the destination and the duration. Rochal's President shall determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a financial conflict of interest.

### **Management of FCOI**

Rochal's policy on managing financial conflicts of interest (FCOI) shall include arrangements for keeping external and federal funders appropriately informed should the company find that it is unable to satisfactorily manage a conflict of interest that involves external or federally funded research.

Rochal's policy on managing FCOI shall designate one or more persons to review financial disclosures, determine whether a conflict of interest exists, and determine what conditions or restrictions, if any, should be imposed by Rochal to manage, reduce or eliminate such conflict of interest.

Prior to Rochal's expenditure of any external or federally funded research project, the President or Business Manager of Rochal shall:

- review all Rochal persons' disclosures of significant financial interests;

- determine whether any significant financial interests relate to external or federally funded research; and
- determine whether a financial conflict of interest exists, and, if so, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such financial conflict of interest.

A conflict of interest exists when Rochal's Board of Directors, or Business Manager and President, reasonably determines that a significant financial interest could directly and significantly affect the design, conduct or reporting of research activities. For federally funded activities, the Business Manager and President are responsible for determining any FCOI. For business contracts/agreements, the President and Board will determine any FCOI.

Examples of conditions or restrictions that might be imposed to manage, reduce or eliminate conflicts of interest include but are not limited to the following:

- 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;
- change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- disqualification from participation in the portion of the research that would be affected by significant financial interests;
- divestiture of significant financial interests;
- modification of the research study plan;
- monitoring of research by independent reviewers;
- public disclosure of significant financial interests (e.g., when presenting or publishing the research);
- reduction or elimination of the financial interest (e.g., sale of an equity interest); and
- severance of relationships that create financial conflicts.

If Rochal's Board determines that imposing conditions or restrictions would be either ineffective or inequitable, and that the potential negative impacts that may arise from a significant financial interest are outweighed by interests of scientific progress, technology transfer or the public health and welfare, then the Board may allow the research to go forward without imposing such conditions or restrictions.

Whenever Rochal identifies a significant financial interest that was not disclosed in a timely manner by a Rochal person, or for whatever reason was not previously reviewed by Rochal during an ongoing external or federally funded research project (e.g., was not reviewed or reported by a subrecipient in a timely manner), the designated official(s) shall, within 60 days:

- review the significant financial interest;
- determine whether it is related to the external or federally funded research; and

- determine whether a financial conflict of interest 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 FCOI going forward.

In addition, whenever a financial conflict of interest is not identified or managed in a timely manner including failure by the scientist to disclose a significant financial interest that is determined by Rochal to constitute an FCOI; failure by Rochal to review or manage such an FCOI; or failure by the Rochal person to comply with an FCOI management plan, Rochal shall within 120 days of the company's determination of noncompliance complete a retrospective review of the scientist's activities and the federally funded research project to determine whether any federally funded research, or portion thereof, conducted during the time period of the noncompliance was biased in the design, conduct or reporting of such research.

Rochal's President shall document the retrospective review, which shall include but not necessarily be limited to all of the following key elements:

- project number;
- project title;
- name of the Rochal person with the FCOI;
- name of the entity with which the scientist has an FCOI;
- reason(s) for the retrospective review;
- detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- findings of the review; and
- conclusions of the review.

Based on the results of the retrospective review, if appropriate, Rochal shall update the previously submitted financial conflict of interest report, specifying the actions that will be taken to manage the FCOI going forward.

If bias is found, then Rochal must notify and submit a mitigation report to the awarding component promptly. The mitigation report must include, at a minimum:

- a description of the impact of the bias on the research project;
- key elements documented in the retrospective review; and
- Rochal'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, or analysis of whether the research project is salvageable).

Thereafter, Rochal shall submit financial conflict of interest reports annually. Depending on the nature of the FCOI, Rochal may determine that additional interim measures are necessary with regard to the

scientist's participation in the federally funded research project between the date that the FCOI or the scientist's noncompliance is determined and the completion of Rochal's retrospective review.

Whenever Rochal implements a management plan, Rochal shall monitor scientist compliance with the management plan on an ongoing basis until the completion of the research project.

### **Remedies for FCOI**

If the failure of an employee, intern, contractor or partner to comply with Rochal's financial conflict of interest policy or an FCOI management plan appears to have biased the design, conduct or reporting of the research, then the company shall take corrective action to maintain appropriate objectivity in the research project.

In any case in which Rochal determines that research has been designed, conducted or reported by an employee, intern, contractor or partner with a financial conflict of interest that was not managed appropriately, the employee, intern, contractor or partner involved shall be required to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations of the research.