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Purpose of the Conflict of Interest Policy

Effective interactions between research institutions, government, the private sector and industry are essential to bring about the rapid application of scientific discoveries to address the needs of the nation and to maintain the efficient translation of research findings. However, the resulting relationships, now encouraged in many forms, are increasingly complex, and may involve financial interests that give rise to a Financial Conflict of Interests (FCOI) through its potential to directly and significantly impact the design, conduct or reporting of an Investigator's research in return for a financial benefit to the Investigator or their immediate family.

A Financial Conflict of Interest may arise even though no improper conduct or unethical behavior has occurred. Rochal and its Investigators are responsible for identifying and then managing these Financial Conflict of Interests to strengthen accountability and transparency, promote research objectivity, and maintain the integrity of research findings and prudent stewardship of public funds.

Rochal's Conflict of Interest Policy was developed to comply with the specific 2011 federal requirements defined in the United States Department of Health and Human Services' Objectivity in Research Regulations 42 CFR Part 50 Subpart F (grants) and 45 CFR Part 94 (contracts). The U.S. Public Health Service (PHS) oversees and monitors Rochal's compliance with these regulations. PHS may inquire at any time, before, during, or after a sponsored research award about an Investigator's Significant Financial Interest and Rochal's review and response to such disclosure, regardless of whether the disclosure resulted in Rochal's finding a FCOI.

All Rochal Investigators are responsible for familiarizing themselves with the regulations so Rochal can effectively work with them to comply with these federal disclosure requirements. In turn, all Investigators will be notified about Rochal's conflict of interest requirements, as well as their disclosure responsibilities under this Conflict of Interest Policy.

Rochal's Dir. of Administration will administer this Policy and emphasize compliance with its requirements, including the review of Annual Disclosure Forms, the training and management of Investigators with regard to Financial Conflict of Interest requirements, and the timely identification, reporting and management of FCOIs. In those instances where a funding agency or sponsor has more stringent requirements and regulations relating to conflict of interest than those of Rochal's Conflict of Interest Policy, the requirements and regulations of that funding agency or sponsor will take precedence.

Who must comply with the Conflict of Interest Policy?

This Policy applies to all Rochal Investigators regardless of title or position who are responsible for the design, conduct or reporting of research. Collaborative and visiting

researchers and subrecipient Investigators who are receiving federally funded research through Rochal may also be required to comply with Rochal's Conflict of Interest Policy.

What should be disclosed in the Annual Disclosure Form?

Each of the following Significant Financial Interests should be disclosed on the Annual Disclosure Form and described to the extent they reasonably appear to be related to the Investigator's Institutional Responsibilities. In the interest of full transparency, Investigators should err on the side of disclosure.

1. With regard to any publicly traded entity, domestic or foreign, the value of any remuneration received from the entity in the 12 months preceding the disclosure plus the value of any equity interest held in the entity as of the date of disclosure that, when aggregated, exceeds \$5,000.
 - Remuneration includes salary and any payment for services not otherwise identified as salary, such as consulting fees, honoraria and paid authorship.
 - Equity interests include stocks, stock options, or other ownership interests, as determined through reference to public prices or other reasonable measures of fair market value.

Note: Disclosure is not required for income from investment vehicles, such as mutual funds, ETFs, and retirement accounts as long as the Investigator does not directly control the investment decisions made in these vehicles.

2. With regard to any non-publicly traded entity, domestic or foreign, (a) the value of any remuneration received from the entity in the 12 months preceding the disclosure that when aggregated exceeds \$5,000, and (b) any equity interests in the entity (regardless of value) that are held by the Investigator or their spouse or domestic partner or dependent children.
 - Equity interests include stocks, stock options, or other ownership interests.
 - If at the time of disclosure there is no reasonable basis for assessing the fair market value or percentage interest in the non-publicly traded entity, the Investigator must fully describe the nature of the equity interest, including the number of shares owned, voting rights, etc.
3. Financial interests received in connection with patents, copyrights, know-how, or other intellectual property rights (e.g., royalties, license fees, equity or other consideration) that when aggregated over the prior 12 months exceeds \$5,000, including consideration received pursuant to the agreement to share royalties related to such intellectual property rights.

Note: Disclosure is not required for royalties, fees or other consideration paid to the Investigator by Rochal for intellectual property owned by Rochal.

4. Any advisory relationship, consulting, outside teaching, or scientific/academic appointment including adjunct, visiting or honorary, with any domestic entity (other than Rochal, both paid as volunteer, as well as any unpaid appointment that provides the Investigator with access to, or in-kind support for, laboratory space, research materials, supplies, equipment, staff participation or living expenses.

Note: Disclosure is not required for the following:

- Salary or other remuneration received from Rochal if the Investigator is currently employed or appointed by Rochal.
 - Income from seminars, lectures, or teaching engagements sponsored by a U.S. federal, state or local government agency, institution of higher education, academic teaching hospital, medical center or research institute that is affiliated with a U.S. institution of higher education as defined in 20 U.S.C 1001(a).
 - Income from service on advisory committees or review panels for U.S. federal, state or local government agency, institution of higher education, academic teaching hospital, medical center or research institute that is affiliated with a U.S. institution of higher education as defined in 20 U.S.C 1001(a).
5. Any relationship with a foreign entity or government including, but not limited to, any involvement with a government talent recruitment program or similar-type program, both paid as the volunteer, and any position or scientific appointment stemming from a foreign government, which includes local, provincial or equivalent governments, government agencies, institutions of higher education, academic teaching hospitals, medical centers, or research institutes that are affiliated with an institution of higher education.
 6. All reimbursed expenses, gifts, gratuities, favors, lodging, or entertainment offers that when aggregated over the prior 12 months exceeds \$1,000. As a reminder, Investigators may not solicit or accept reimbursed expenses, gifts, gratuities, favors, lodging, or excessive entertainment for themselves, their spouse or domestic partner or dependent children, alone or in combination, or for any person or organization that does business or has the potential of doing business with Rochal. Except from this prohibition are non-cash gifts of nominal value involving normal and ordinary social amenities or sales promotions.
 7. Sponsored/Reimbursed travel that meets the following criteria:
 - Travel within the United States received from a U.S. entity that when aggregated exceeds \$5,000.

Note: Disclosure is not required for Sponsored/Reimbursed Travel stemming from a U.S. federal, state, or local government agency, institution of higher education, academic teaching hospital, medical center, or a research institute that is affiliated with a U.S. institution of higher education as defined in 20 U.S.C. 1001(a).

- Travel outside the United States received from a U.S. or foreign entity regardless of dollar amount.

Information needed for the disclosure of Sponsored/Reimbursed Travel:

- Identity of the sponsor/organizer
- Month and year of the travel
- Financial value by range of the travel
- Value of any associated honorarium
- Purpose of the travel
- Destination of the travel
- Time duration of the travel

Who must submit an Annual Disclosure Form?

At time of appointment/employment, all Investigators, are required to enter an initial Annual Disclosure Form that describes all Significant Financial Interests related to their Institutional Responsibilities and then submit a new Annual Disclosure Form each subsequent year thereafter. Collaborative and visiting researchers and subrecipient Investigators who are subject to Rochal's Conflict of Interest Policy and participating in PHS-funded research are also required to submit an Annual Disclosure Form to Rochal's Dir. of Administration.

Updating the Annual Disclosure Form

All Investigator are required to simultaneously submit a current, accurate Annual Disclosure Form that identify and describe both existing and new Significant Financial Interests related to their Institutional Responsibilities to Rochal's Dir. of Administration. Subrecipient Investigators will complete an Annual Disclosure Form based on their particular finding cycle. Updated disclosures should also include any FCOIs identified on a project that was transferred from another institution.

Investigators are required to promptly disclose Significant Financial Interests to accurately reflect their external activities as follows:

- Disclose Significant Financial Interests no later than at the time of application for PHS-funded research.

- Within 30 days of acquiring and/or discovering a new Significant Financial Interest, including through purchase, marriage, or inheritance.
- Within 30 days of a material change to a previously disclosed Significant Financial Interest.

Annual Disclosure Form Review

Rochal's Dir. of Administration will review the Annual Disclosure Forms and any new or modified Significant Financial Interests disclosed throughout the year, and as such, may request further information or clarification from the Investigator. Rochal's Dir. of Administration will review each of the Investigator's disclosures and determine whether a Significant Financial Interest is related to PHS funded research.

If there are Significant Financial Interests related to the Investigator's funded research, these relationships must be examined and dealt with according to Rochal and the funding agency policies on conflict of interest. A personal financial interest with an entity would be reasonably considered related to an Investigator's research in circumstances such as the following:

- Entity sponsors research at Rochal in which the Investigator is directly involved
- Entity has financial interest that could reasonably be considered to have a potential influence on the design, conduct or reporting of the Investigator's research
- Entity has a reasonable possibility of being financially affected by Investigator's research
- Entity makes monetary or in-kind gifts or loans to Rochal that benefit the Investigator's research including a gift or loan of equipment
- Entity makes a product that is under study in research in which the Investigator is involved
- Entity licenses intellectual property from Rochal in which the Investigator has a financial interest
- Entity has a Material Transfer Agreement to provide materials used in the Investigator's research of for materials provided by the Investigator to the entity
- Entity sponsors or makes a product that is under study in human subjects in which the Investigator is directly or indirectly involved

A FCOI will be deemed to exist when Rochal's Dir. of Administration reasonably determines that a Significant Financial Interest could directly or significantly affect the design, conduct or reporting of the Investigator's research. Rochal's Dir. of Administration reviews and analyzes the specific circumstances of a Significant Financial Interest by taking into account such factors as the nature of the Investigator's relationship to an outside entity, the dollar value of that relationship, and the overlap between that relationship and the Investigator's research.

Rochal's Dir. of Administration may, if warranted, involve the Investigator in determining whether a Significant Financial Interest is related to the research in question.

Managing a Financial Conflict of Interest

If a Significant Financial Interest is identified as a FCOI, Rochal's Dir. of Administration will take action to manage the FCOI by robustly reducing or eliminating the conflict by designing a management plan or mechanism appropriate for the specific situation. Rochal's Dir. of Administration will forward a detailed letter to the Investigator describing the management plan and its implementation.

This written plan will require that the Investigator take certain steps according to guidelines approved by Rochal's Dir. of Administration. Conditions or restrictions that might be imposed to manage a FCOI include the following:

- Disclosure of the FCOI to lab personnel and collaborators
- Disclosure of the FCOI directly to human subject research participants
- Disclosure of the FCOI in publications, journals, and posters, etc.
- Disclosure of the FCOI to audiences at conferences and seminars
- Monitoring of research, proposals and data by independent peer reviewers
- Modification of research plan
- Removal of an affected Investigator from participation in all or the portion of the research funded by the entity affected by the Significant financial Interest by the affected Investigator
- Divestiture of a Significant Financial Interest by the affected Investigator
- Limiting the dollar value of fees received and/or stock ownership
- Severance of the relationships creating the conflict

The Investigator will be asked to review and sign the letter to acknowledge agreement with the management plan, or the Investigator may, at this point, appeal the findings of Rochal's Dir. of Administration within 30 days. Rochal's President will determine whether the FCOI exists and the appropriate plan for managing the FCOI. Rochal's President has the final review and authority regarding the management of all FCOIs.

Reporting a Financial Conflict of Interest to the Funding Agency

Rochal will promptly notify the appropriate funding agency about any corrective action taken or to be taken in a situation of noncompliance.

- a. With regard to a new NIH – sponsored research award, Rochal will report the identified FCOI to the NIH through the electronic Research Administration (eRA) Commons FCOI Module. Rochal will submit the FCOI report before dispensing or spending any funds. If the FCOI is eliminated prior to dispensing or spending any

funds, then no FCOI report is required. In addition, Rochal's required to submit a FCOI report for FOICs identified for subrecipient Investigators, if applicable.

- b. With regard to an ongoing NIH – sponsored research award, Rochal will report to the NIH through the eRA Commons FCOI Module information about the identified FCOI within 60 days of the FCOI's identification. For any Significant Financial Interest that is identified as a FCOI subsequent to Rochal's initial FCOI report during an ongoing NIH funded research project, Rochal shall within 60 days, review the Significant Financial Interest disclosure, determine whether it is related to the research, 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 the FCOI.
- c. Annual FCOI follow-up reports will be provided to the NIH for any FCOI previously reported by Rochal. The annual FCOI report will specify whether the FCOI is still being managed, describe any changes to the management plan or explain why the FCOI no longer exists. Rochal will provide annual FCOI reports for the duration of the project period, including extensions with or without funds, as prompted by the eRA Commons generated email that requests that the follow-up report be submitted.
- d. Rochal will meet the reporting requirements pertaining to FCOIs for other federally funded agencies, including DOD, DOE, NSF and USDA as instructed by the particular agency.
- e. With regard to a new, non-federally funded award, Rochal may, if warranted, disclose through written notification, information about the identified FCOI to any corporation, educational institution, non-profit entity, private foundation, trust and individual donor before dispensing or spending any funds.
- f. With regard to an ongoing, non-federally funded award, Rochal may, if warranted, disclose through written notification, information about the identified FCOI to any corporation, educational institution, non-profit entity, private foundation, trust and individual donor during the award's duration.

What information is submitted to the NIH about a Financial Conflict of Interest?

Information submitted to the NIH about an identified FCOI includes the following:

- Project number/contract number
- Name of the Principal Investigator
- Name of the Investigator with the FCOI
- Name of the entity with which the Investigator has the FCOI
- Statement about how the FCOI was managed

- The nature of the FCOI (e.g., equity interest, consulting fees, intellectual property rights and interests, travel reimbursement, and honoraria).
- The value of the financial interest; \$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 a value cannot be readily determined through reference to public prices or reasonable measures of fair market value.

A description of the key elements of Rochal's management plan must also be submitted to the NIH including the following information:

- Role and principal duties of the conflicted Investigator in the research project
- Conditions of the management plan
- How the management plan is designed to safeguard objectivity in the research project
- Confirmation of the Investigator's agreement to the management plan
- How the management plan will be monitored to facilitate Investigator compliance
- Other information as needed

Other funding agencies outside the NIH may require that different information be submitted, and Rochal will meet their requirements as instructed.

Public Accessibility of Rochal's Conflict of Interest Policy

Rochal's Conflict of Interest Policy is publicly accessible on its website (www.rochaltech.com).

What happens after FCOI is reported to the NIH?

The NIH evaluates the FCOI information received through the eRA Commons FCOI Module to determine if Rochal's actions are sufficient to management of the identified FCOI. The NIH may request and review additional information before implementing, if needed, further corrective actions to ensure research objectivity. If the NIH decides that the particular FCOI will bias the objectivity of the funded research to such an extent that further corrective action is needed or that Rochal has not managed the FCOI in accordance with the regulation, it may impose special award conditions, suspend funding or enforce other actions until the matter is sufficiently resolved.

Other funding agencies outside the NIH may have a different process, and Rochal will meet their requirements as instructed.

Non-Compliance and Enforcement

Rochal will establish enforcement mechanisms, provide for employee sanctions and take other administrative action, where appropriate, in the event an Investigator is non-compliant with the Conflict of Interest Policy or management plan. Violations of this Policy may be grounds for progressive disciplinary action including:

- Placing a hold on the processing of new sponsored research applications from a non-compliant Investigator.
- Withholding disbursement or distribution of project-specific funding to the Investigator's laboratory
- Termination of employment

An Investigator is non-compliant and in violation of the Policy if an Investigator fails to:

- Submit an Annual Disclosure Form or provide an update to an Annual Disclosure Form by the deadline established for such submissions by Rochal's Dir. of Administration
- Provide Rochal's Dir. of Administration with written acknowledgement of a management plan
- Provide Rochal's Dir. of Administration with requested documentation regarding compliance with a management plan

If an Investigator fails to comply with Rochal's Conflict of Interest Policy or management plan, within 120 days Rochal will:

- Complete a retrospective review of the key elements (see below) of the Investigator's activities and the NIH funded research project to determine and bias in the design, conduct or reporting of research.
- Document the retrospective review
- Document Rochal's determination as to whether any NIH funded research, or portion thereof, conducted during the period of time the Investigator's non-compliance with the Conflict of Interest Policy of management plan, with biased in the design, conduct or reporting of such research.

If bias is found, Rochal will submit a mitigation report with the key element (see below) addressing the impact of the bias on the research project, including the extent of the harm done, and any qualitative and quantitative data to support any actual or future harm, analysis of whether the project is salvageable and the actions Rochal has taken, or will take, to eliminate or mitigate the effect of the bias. Depending on the nature of the FCOI, Rochal may determine that additional interim measures are necessary with regard to the Investigator's participation in the research project between the date the FCOI is identified and the completion of Rochal's retrospective review. Thereafter, Rochal will submit FCOI reports as prescribed by the regulation.

Furthermore, if the NIH 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 an FCOI that was not managed or reported by Rochal, Rochal 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.

The following key elements apply to both the retrospective review and mitigation report:

- Project number
- Project title
- Principal Investigator name
- Name of the Investigator with the FCOI
- Name of the entity with which the Investigator has the FCOI
- Reason(s) for the retrospective review
- Detailed methodology used for the retrospective review including the methodology of the process, composition of the review panel, documents reviewed etc.
- Findings of the review
- Conclusions of the review

Subrecipient Conflict of Interest Compliance:

A subrecipient relationship is established when federal funds flow down or through Rochal to another individual or entity and the subrecipient will be conducting a substantive portion of a PHS-funded research project and is accountable to Rochal 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 Rochal's terms and conditions, and as such, Rochal will take reasonable steps to ensure that any subrecipient Investigator is in compliance with the federal FCOI regulation.

If the subrecipient's conflict of interest policy applies to the subrecipient Investigator, the subrecipient institution will certify as part of the agreement with Rochal 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 Rochal's Conflict of Interest Policy for disclosing Significant Financial Interests that are directly related to the subrecipient's work for Rochal. Rochal 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

Rochal. Such time period must be sufficient to enable Rochal to provide timely FCOI reports to the NIH as necessary, through the eRA Commons FCOI Module.

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

Other funding agencies outside the PHS may have a different process as it pertains to subrecipients, and Rochal will meet their requirements as instructed.

Record Retention:

Records relating to conflict of interest matters covered under this Conflict of Interest Policy for PHY-funded research must be maintained for a minimum period 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.

Key Definitions

1. Disclosure – refers to the Investigator's disclosure of Significant Financial Interests.
2. Financial Conflict of Interest (FCOI) – will be deemed to exist when Rochal reasonably determines that a Significant Financial Interest disclosed by an Investigator could directly and significantly affect the design, conduct or reporting of the Investigator's research.
3. Foreign entities – include, but are not limited to, those stemming from a foreign company or government, including local, provincial or equivalent governments, government agencies, institutions of higher education, academic teaching hospitals, medical centers, or research institutes that are affiliated with an institution of higher education.
4. Investigator – refers to any person regardless of title or position who is responsible for the design, conduct or reporting of research.
5. Manage – means taking action to address, reduce or eliminate a Financial Conflict of Interest to the extent possible, so that those responsible for the design, conduct and reporting of research will be free from bias.
6. Regulation or FCOI regulation – refers to 42 CFR Part 50 Subpart F, Promoting Objectivity in Research (grants) and 45 CFR Part 94 (contracts).
7. Report – refers to Rochal's report of identified Financial Conflicts of Interest to the applicable funding agency affected by the FCOI. In the case of NIH funding, a report about the identified FCOI will be entered into the eRA Commons FCOI Module. Other

funding agencies may have separate reporting requirements, and these will be met as required.

8. Significant Financial Interests – means a financial interest of the Investigator and/or the Investigator’s spouse or domestic partner and dependent children, alone or in combination, that reasonably appears to be related to the Investigator’s institutional responsibilities for Rochal. Types of financial interests include remuneration, equity interests in a publicly and non-publicly traded entity, intellectual property rights and interests, and reimbursed or sponsored travel.
9. Sponsored/Reimbursed Travel – is any travel expense related to an Investigator’s institutional responsibilities that are either paid directly by a third party on behalf of Investigator so that the exact monetary value may not be readily available or for which the Investigator is reimbursed by a third party.