



Financial Conflict of Interest Policy for Promoting Objectivity in Research

Last Revised: September 21, 2022

1. PURPOSE

RenBio, Inc. (“RenBio”) seeks through its research and development efforts to advance first-in-class and best-in-class antibody and therapeutic protein technologies to humans, and to modernize and transform the antibody and therapeutic protein fields to significantly reduce the impact of diseases worldwide. All individuals engaged in Research at RenBio must discharge their duties in a manner that promotes and preserves public trust, proper stewardship, and confidence in the integrity of RenBio. This Financial Conflict of Interest Policy for Promoting Objectivity in Research (“Policy”) is intended to assure the objectivity with which Research projects are designed by identifying and managing, through a process of disclosure and review, conflicts of interest between an Investigator’s Research responsibilities and their personal financial interests.

This Policy sets forth the requirements for disclosure of Financial Interests. Unless otherwise specified within this Policy or in a specific funding agreement, this Policy applies to all Research performed at, or on behalf of, RenBio, regardless of Research funding source.

2. APPLICABILITY

This Policy applies to all Investigators participating in or planning to participate in Research for or on behalf of RenBio, and includes all full, part-time, temporary, and contract employees, graduate students, visiting scientists, and researchers. This Policy also extends to any subcontractors, sub-grantees, or sub-awardees (collectively, “Subrecipients”) at other institutions conducting Research for or on behalf of RenBio, as further described below.

3. DEFINITIONS

Disclosure means an Investigator’s disclosure of significant financial interests to RenBio, whether on an SFI Disclosure Form or otherwise.

Financial Conflict of Interest (FCOI) means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of Research.

Financial Conflict of Interest Management Plan (FCOI Management Plan) means a plan developed in accordance with this Policy for the management, reduction, or elimination of an identified Significant Financial Interest.

Financial Conflict of Interest Report (FCOI Report) means RenBio’s report of a Financial Conflict of Interest to the awarding agency of PHS.

Financial Interest means anything of monetary value, whether or not the value is readily ascertainable.

Institutional Responsibilities means an Investigator’s professional activities on behalf of RenBio (e.g., teaching, administration, research, clinical care, or service on Institutional Review Board (“IRB”) panels, editorial boards, or peer review panels).

Investigator means the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of Research, including collaborators or consultants.

Institutional Official means the individual within RenBio designated as responsible for management of this Policy, including the solicitation and review of disclosures of Significant Financial Interests, training of Investigators, record retention, and reporting to funding agencies, sponsors, and the public as detailed herein. Annelyn O'Rourke has been designated as the Institutional Official for RenBio.

PD/PI means project director or principal Investigator of a research project.

Research means a systematic investigation, study, or experiment designed to contribute to generalizable knowledge relating broadly to public health, including behavioral and social sciences research. The term encompasses basic and applied research (e.g., a published article, book, or book chapter) and product development (e.g., a diagnostic test or drug).

Senior/Key Personnel means the PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution under this subpart.

Significant Financial Interest ("SFI") is defined by the regulations to mean:

1. A financial interest consisting of one or more of the following interests of the Investigator (aggregated together with those of the Investigator's spouse, same-sex or domestic partner, and dependent children) that reasonably appear to be related to the Investigator's Institutional Responsibilities:
 - 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 the 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), and 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; or
 - 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, same-sex domestic partner, or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

- c. With regard to any **intellectual property rights and interests** (e.g., patents, copyrights), a *significant financial interest* exists upon receipt of income related to such rights and interests.
2. Investigators must disclose the occurrence of **any reimbursed or sponsored travel** (i.e., that which is paid on behalf of the Investigator and/or the Investigator's spouse, same-sex domestic partner, and dependent children) that is related to the Investigator's Institutional Responsibilities.
 - a. This disclosure requirement does not apply to travel paid for by RenBio or travel that is reimbursed or sponsored by any U.S. Federal, state, or local government agency, an Institution of higher education as defined as 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
 - b. This disclosure must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The Institutional Official may determine that further information is need, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI.
3. The term *significant financial interest* does not include the following:
 - a. Salary, royalties, or other remuneration paid by RenBio to the Investigator if the Investigator is currently employed or otherwise appointed by RenBio, including intellectual property rights assigned to RenBio 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 U.S. federal, state, or local government agency, an Institution of Higher Education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of Higher Education.

4. OVERVIEW

All Investigators covered by this Policy are required to disclose SFI that could affect or be affected by Research on which they are working or proposing to work for or on behalf of RenBio. Every Investigator has an obligation to become familiar with, and abide by, the provisions of this Policy and must undergo regular training as described herein. Any Investigator with questions regarding FCOI or this Policy should contact the Institutional Official for assistance.

RenBio will review SFI and manage, minimize, or eliminate FCOI to ensure that Research will be free from bias resulting from Investigator financial interests. In determining an appropriate FCOI Management Plan, RenBio will work to achieve the following goals:

- Safeguard the integrity of RenBio Research programs.
- Ensure that the Research project is objective and without bias in the design, conduct, or reporting of the Research.
- Ensure that the Research sponsors' access to RenBio equipment, supplies, and intellectual property rights is appropriate and consistent with applicable law, RenBio policy, and RenBio financial and reputational interests.
- Address unique circumstances and conditions that may be presented by individual cases.

RenBio will also take reasonable steps to ensure that any Investigators for Subrecipients of Research comply with this Policy and any applicable Federal regulations regarding FCOI as required by Federal research sponsors.

5. DISCLOSURE

A. Requirements

An Investigator shall disclose any situation in which the Investigator has, or may have, a real or potential SFI under this Policy using RenBio's SFI Disclosure Form.

Investigators shall keep their supervisors informed of the Investigator's SFI. If a supervisor becomes aware of an SFI that an Investigator has not disclosed, the supervisor shall discuss the situation with the Investigator, require that a written disclosure be made as provided in this Policy, and inform the Institutional Official to anticipate the receipt of a new Disclosure.

B. Frequency

Annually, all Investigators must submit an SFI Disclosure Form to the Institutional Official reporting any SFI that reasonably appears related to the Investigator's Institutional Responsibilities. If no SFI is present, the Investigator must submit an SFI Disclosure Form that states "none." The date such annual Disclosure is due shall be set by RenBio and distributed company-wide.

In addition to the annual disclosure, Investigators have an ongoing obligation to update Disclosures within thirty (30) days after a new SFI is acquired or discovered (e.g., through purchase, marriage, or inheritance). Newly hired Investigators should make a Disclosure as part of their new hire employment process.

6. REVIEW, MANAGEMENT, AND REPORTING

A. Institutional Official Review and Responsibilities

The Institutional Official will ensure compliance with all parts of this policy, and will review all Disclosures and investigate SFI to determine whether an SFI could directly and significantly affect the design, conduct, or reporting of Research such that it would constitute an FCOI. The Institutional Official is responsible for the following implementation, review, and management tasks:

1. Training, Reporting and General Compliance

- a. Implement and manage the training of Investigators in accordance with this Policy;
- b. maintain an up-to-date version of this Policy on RenBio's publicly available website;
- c. oversee initial and ongoing reporting to sponsors, as required;
- d. determine all requirements related to Financial Conflicts of Interest contained in the funding agreement, including sponsor reporting and Subrecipient monitoring;
- e. implement and monitor compliance with FCOI Management Plans;
- f. coordinate discipline of an Investigator for violations of this Policy and any FCOI Management Plan;
- g. oversee the retrospective review and related procedures if an FCOI is not identified or managed in a timely manner; and
- h. maintain records in accordance with this Policy.

2. Identification of FCOIs and Implementation of Management Plans

- a. Review all SFIs as well as any additional materials needed to fully evaluate the relationship of the SFI to the Research;
- b. determine whether the SFI requires an FCOI Management Plan to manage, reduce, or eliminate the FCOI and develop such a plan;
- c. determine whether the SFI is an FCOI that must be reported to the Research sponsor;
- d. with respect to Research involving human subjects, evaluate SFI and recommend appropriate management measures and reporting to IRB panels; and

- e. investigate allegations of noncompliance with this Policy or any FCOI Management Plan and determine corrective actions, disciplinary sanctions, and sponsor reporting, as appropriate.

Investigators cannot decide whether an SFI must be managed or whether it is an FCOI; this determination is made through the review process. The Institutional Official will decide on the appropriate action to manage, reduce, or eliminate any FCOI, and will develop any needed FCOI Management Plan.

B. FCOI Management Plans

As appropriate, the Institutional Official will develop plans for the management, reduction, or elimination of identified FCOI (each a “FCOI Management Plan”). A FCOI Management Plan will focus on the steps by which the objectivity of the Research can be ensured which may include, but are not limited to:

1. Public disclosure of an Investigator’s FCOI (e.g., when presenting or publishing the research);
2. For Research involving human subjects, disclosure of Investigator FCOI directly to participants;
3. Appointment of an independent reviewer capable of taking measures to protect the design, conduct, and reporting of the Research against bias resulting from the FCOI;
4. Modification of any Research proposal or plan;
5. Change in personnel or personnel responsibilities, or disqualification of an Investigator from participating in all or any portion of any Research;
6. Reduction or elimination by an Investigator of the FCOI.

For any FCOI Management Plan, the affected Investigator must agree in writing to the FCOI Management Plan and the proposed management strategies contained therein before the Investigator may resume participation in such Research, unless otherwise authorized by the Research sponsor and funding agency.

C. Retrospective Review

If an SFI is not identified or managed in a timely manner, or if an Investigator fails to comply with an FCOI Management Plan, the Institutional Official will review the Investigator’s SFI, determine if it is related to sponsored research and, if so:

1. Implement, on at least an interim basis, an FCOI Management Plan that specifies the actions that have been, and will be, taken to manage such FCOI going forward.
2. Complete a retrospective review of the Investigator’s activities and the affected sponsored Research within 120 days of the Institutional Official’s finding of noncompliance to determine whether any sponsored Research, or portion thereof,

conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such Research.

3. Document the retrospective review and include, at minimum, the following information:
 - i. project number;
 - ii. project title
 - iii. PD/PI or Contact PD/PI if multiple PD/PI model is used;
 - iv. name of the Investigator with the FCOI;
 - v. name of the entity with which the Investigator has a FCOI;
 - vi. reason(s) for the retrospective review;
 - vii. detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
 - viii. findings of the review; and
 - ix. conclusions of the review.
4. Based on the results of the retrospective review, if appropriate, RenBio shall update any previously submitted FCOI Report, specifying the actions that will be taken to manage the FCOI going forward.

D. FCOI Reporting to Sponsors

With respect to Research funded by a sponsor, the Institutional Official shall review the funding agreement and determine all required reporting to sponsor. The Institutional Official will implement procedures to ensure compliance with all reporting and other FCOI requirements contained in the funding agreement.

1. Contents of Report

Any FCOI Report provided to a sponsor must contain the following information:

- project number;
- PD/PI or Contact PD/PI if multiple PD/PI model is used;
- name of the Investigator with the FCOI;
- name of the entity with which the Investigator has a Financial Conflict of Interest;
- nature of the FCOI (e.g., equity, consulting fee, travel reimbursement, honorarium);
- value of the FCOI (dollar ranges are permissible), or a statement that the interest is one for which value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
- a description of how the FCOI relates to sponsored Research and the basis for RenBio's determination that the FCOI conflicts with such Research; and
- a description of the key elements of the Institution's FCOI Management Plan, including:
 - role and principal duties of the conflicted Investigator in the Research project;

- conditions of the FCOI Management Plan;
- how the FCOI Management Plan is designed to safeguard objectivity in the Research project;
- confirmation of the Investigator's agreement to the FCOI Management Plan;
- how the FCOI Management Plan will be monitored to ensure Investigator compliance; and

other information as needed or requested by the funding agency

7. SUBRECIPIENT MONITORING

For Research funded by a sponsor, the Institutional Official shall be responsible for determining and ensuring compliance with any additional Subrecipient monitoring, disclosure, or other requirements contained in the funding agreement.

8. TRAINING

Each Investigator must complete training prior to engaging in Research, at least every four years, and immediately when:

1. RenBio revises this Policy in any manner that affects Investigator requirements;
2. an Investigator is new to RenBio; or
3. an Investigator is not in compliance with this Policy or a FCOI Management Plan.

Each Investigator is ultimately responsible for making any necessary disclosures to RenBio as required by this Policy and following any prescribed FOCI Management Plan. Failure to do so shall be deemed a violation of this Policy and may result in sanctions on the Investigator, as detailed in Section 9(A).

9. GENERAL PRINCIPLES

A. Enforcement

Failure on the part of an Investigator to comply with this Policy will result in disciplinary action and/or sanctions, which may include formal reprimands or other appropriate measures, up to and including termination of the Investigator or suspension of the Research.

B. Confidentiality

To the extent permitted by law, all SFI Disclosure Forms, FCOI Management Plans, and related documentation will be treated as privileged and confidential. However, RenBio may be required to make such information available to sponsors to the extent required by the applicable funding agreement. If RenBio is requested to provide SFI Disclosure Forms, FCOI Management Plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

The Institutional Official and any other parties involved in reviews or investigations under this Policy will follow directions from outside counsel regarding appropriate procedures to afford the maximum confidentiality and privilege protection for any such reviews or investigations.

C. Recordkeeping

The Institutional Official shall be responsible for maintaining records relating to all Investigator Disclosure of SFI and RenBio's review of, and response to, such Disclosures (regardless of whether the Disclosure resulted in a determination of a FCOI) and all actions taken under this Policy, for at least three (3) years from:

1. the date of submission of the final expenditures report, for federally funded grants;
2. from the date of termination or completion of the award;
3. from the date of the resolution of any action by any governmental agency involving the records; or
4. as applicable, from any other date specified in 45 CFR Section 74.53(b) for different situations, as appropriate.