

Financial Conflict of Interest Policy

Effective Date: 04.18.2023

Revision: 1417 D

Approval: Constantine Stoios, Senior Vice President & Chief Financial Officer

Overview

Coriell Institute for Medical Research Conflict of Interest Policy requires that PIs and all personnel working on research projects, regardless of source of funding, disclose significant financial interests that may reasonably be perceived to influence their work. This policy is intended to promote objectivity in research with the reasonable expectation that the design, conduct, and reporting of the research will be free from bias resulting from Investigator financial conflicts of interest. This policy and related administrative procedures will be administered, managed and enforced by the Coriell Research Office.

Investigators should make a reasonable, good-faith determination as to whether their research or other Institutional Responsibilities could affect the value of a financial interest or have a financial impact on the Entity in which they hold a financial interest. For example, do not disclose a spouse's salary with a company (Donkey's Place) whose business focus is not related to Investigator's Research (cancer research) or other Institutional Responsibilities. Additionally, you do not have to disclose stocks if the stock is unrelated to your work at Coriell (ex: GameStop).

Please note that having something to disclose does not imply any wrong-doing or inappropriate activities. The emphasis is on disclosure of financial interests so that Coriell can conform to federal financial disclosure rules and those of many granting entities.

A Significant Financial Interest (SFI) can be any of the following:

- a. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- b. Business Concerns
 - 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, 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. **You do not have to disclose income from investment vehicles such as mutual funds or retirement accounts, as long as you do not directly control the investment decisions made in these vehicles.**
 - 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).
- c. Employment, directorship, trusteeship, partnership, or affiliation with other organizations.
- d. The occurrence of certain reimbursed or sponsored travel.
 - a. Sponsored travel means travel that is paid on behalf of the Investigator and not reimbursed to the Investigator (so that the exact monetary amount may not be readily determined). Travel that is reimbursed or sponsored by the following types of entities is **excluded** from reporting:

U.S. federal, state or local government agencies; U.S. institutions of higher education or research institutes affiliated with them; U.S. academic teaching hospitals; or U.S. medical centers.

A Significant Financial Interest can be your own, that of your spouse, or that of your dependent children.

The term Significant Financial Interest **does not include** the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator; **income from seminars, lectures, teaching engagements, advisory committee service, or review panels and reimbursed or sponsored travel when such activities are sponsored by a U.S. governmental entity; an institution of higher education, academic teaching hospital, and medical center in the U.S.; and a research institute that is affiliated with an institute of higher education or a related entity in the U.S., do not require disclosure.**

When Do You Disclose

No later than at the time of application.

Annually: Disclosures must be updated at least annually. Investigators will only be notified to update their disclosure annually if no action has been taken within the last 12 months.

Within 30 days of a new Significant Financial Interest (SFI): A revised COI disclosure must be made within thirty days of discovering or acquiring a new significant financial interest (e.g., through a new agreement, purchase, marriage, or inheritance).

What You Need to Disclose

Although most governmental contracts and grants require the disclosure of a “significant financial interest”, Coriell Institute for Medical Research, in order to promote absolute transparency and research integrity, requires that all investigators should disclose any “financial interest” **whether or not a “significant financial interest,”** as well as any other personal involvement of the investigator, or his or her immediate family, that are related to the individual’s Institutional responsibilities or sponsored research.

Financial interest means anything of monetary value, whether or not the value is readily ascertainable. Interests include, but are not limited to: income; honoraria or other payment for services; equity such as stock, stock options or other ownership rights, employment; reimbursed travel or sponsored travel; and services, relationships or positions, even if uncompensated.

Who Needs to Disclose

All Coriell faculty, non-faculty employees, students and other individuals who, in the course of their association with Coriell:

1. Apply for or receive funds for any research or training purpose, by grant or sub-grant, or by contract or subcontract, or by cooperative agreement, or are engaged in research (i.e.: are responsible for the design, conduct, or reporting of research; or *(For example: an undergraduate student entering data must disclose because they are engaged in the conduct of the study, or administrative personnel must disclose, who have decision-making authority over the distribution of funds, whether research or discretionary).*

2. Conduct unsponsored/unfunded research.

Subrecipient Requirements

If Coriell carries out research funded by the PHS through sub-recipients, contractors, or collaborators, Coriell must take reasonable steps to ensure that Investigators working for such entities either (1) comply with this FCOI Policy or (2) the entity has its own policy that meets applicable federal requirements on financial conflicts of interest.

Other sponsors, federal or private, may also require that the sub-recipients, contractors, or collaborators be responsive to the sponsor's Conflict of Interest standards. Such provisions will flow down to the sub-recipients, contractors or collaborators through contracts.

Institutional Responsibilities

The Coriell Research Office will collect and perform an initial review of all disclosed SFIs to determine whether an Investigator's SFI is related to funded research and, if so related, whether the SFI is an FCOI. An SFI is related to funded research when the Coriell Research Office reasonably determines that the SFI:

- could be affected by the funded research; or
- is in an entity whose financial interest could be affected by the research.

The Investigator may be involved in making the determination of whether the SFI is related to the PHS/NIH-funded research. An FCOI exists when the Coriell Research Office reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of funded research.

If the Research Office believes a conflict exists, a Research Conflict Review Committee (RCRC) may be assembled to advise in regards to actual conflicts as well as the approval of management plans (see below).

Within 30 days of the disclosure of a SFI which is determined to be a FCOI, the Research Office and the investigator will develop a management plan to address the FCOI. These plans will be developed collaboratively and examples of conditions or restrictions that may be employed to manage conflicts include:

- Public disclosure of significant financial interests (e.g., when presenting or publishing the research), if appropriate to the discipline;
- Disclosure of significant financial interests directly to participants involved in human research;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of research;
- Modification of research plan;
- Change of personnel or personnel responsibilities or disqualification from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest);
- Severance of relationships that create the actual or potential conflict of interest; or
- If it proves impossible to reach an acceptable Management Plan, funds will be returned to the sponsor.

The determination of an FCOI as well as any management plan must be approved by the Chief Executive of the Research Office. If an investigator has an FCOI and is working on research involving human subjects or animal models, the IRB and IACUC must be notified of any management plans.

Additionally, if a Coriell President and/or CEO requires a management plan, this will be overseen by the Chair of the Coriell Board of Trustees.

Reporting

Prior to expenditure of any funds, within sixty (60) days of identification for an Investigator who is newly participating in the project, or within sixty (60) days for new, or newly identified FCOIs for existing Investigators, Coriell must submit initial, annual and revised FCOI reports to the PHS Awarding Component regarding the related FCOI and implemented Management Plan. This report must include the following information:

- Grant/Contract Number
- Project Director/Principal Investigator (PD/PI) or contact PD/PI
- Name of investigator with FCOI
- Nature of the FCOI (e.g., equity, consulting fees, or honoraria)
- Whether the financial interest was managed, reduced or eliminated
- Value of the financial interest
- Description of how FCOI relates to PHS-funded research and the basis for Coriell's determination that the financial interest conflicts with such research
- Key elements of the Management Plan

Annual updates are also required for the duration of the research project and must include:

- Status of the FCOI
- Changes to the management plan

Non-Compliance

The Coriell Research Office will complete a retrospective review within 120 days of the determination of noncompliance when an SFI is not disclosed timely or previously reviewed or whenever an FCOI is not identified or managed in a timely manner, including:

- Failure by the Investigator to disclose a significant financial interest that is determined by Coriell to constitute a financial conflict of interest;
- Failure by Coriell to review or manage such a financial conflict of interest; or
- Failure by the Investigator to comply with the financial conflict of interest management plan

The Research Office will document the retrospective review which shall include at a minimum the following key elements:

- Project Number
- Project Title
- 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 an FCOI;
- Reasons for the retrospective review;
- Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documentation reviewed);
- Findings of the review; and
- Conclusions of the review

When an investigator is found to have violated this policy or the terms of the management plan, the Coriell Research Office may impose sanctions consistent with Coriell policy. Disciplinary action may vary from a warning to termination of employment. In cases of violation, the Chief Executive of the Research Office (or designee) will notify the appropriate funding agency.

Conflicts of Interest Training

Training is required prior to involvement in any project and at least every four years thereafter. Anyone new to Coriell involved in a research project must complete the COI training module via the NIH's online tutorial, or through an equivalent training provided by a recognized organization such as the FCOI training provided by CITI. Investigators are also subject to re-training when either of the following circumstances occurs: (1) Coriell determines that an Investigator is not in compliance with the Institute's Policy or their specific management plan; or (2) Coriell revises its Policy in a manner that affects the requirements of Investigators' responsibilities.

Funding for any project may not proceed until all involved in these activities have completed the COI training.

Public Accessibility

In accordance with the federal regulations, Coriell will make certain information available to the public regarding FCOIs for those Senior/Key Personnel in conjunction with a specific PHS-funded research project. Requests must be submitted in writing to the Coriell Research Office, 403 Haddon Avenue, Camden, New Jersey 08103, Attention: Compliance Officer or via phone to the Coriell Ethics Hotline at 1-888-239-9180. Requests will be answered within five business days from the date of receipt by the Research Office. The request must identify the specific PHS project number and name for which the information is being requested and must include a named recipient. If the request is in writing, a return address with a physical street address must be included.

Records Retention

All FCOI-related records relating to all Investigator disclosures of financial interests, the reporting of potential conflicts of interest and commitment, and Coriell's review of, and response to disclosures and all actions and responses taken under this policy or retrospective review shall be maintained for three years from the date the final expenditures report is submitted to the PHS, or as required by applicable government regulations, whichever is greater.