

Financial Conflict of Interest Policy

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Approval: Constantine Stoios, 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.

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.
 - 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.
 - a. Travel
 - a. Travel which is paid on the behalf on the Investigator and not reimbursed to the Investigator (so that the exact monetary value may not be readily available).
 - b. Reimbursed travel that is not 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.

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, or teaching engagements sponsored by a federal, state, or local government agency, an Institution of higher education, a medical center, or a research institute that is affiliated with an Institution of higher education; or 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.

When Do You Disclose

At Award Set-up: For a new award, a Conflict of Interest Disclosure and Attestation must be completed once the award is received. The award will not be processed for set-up until all study team members' Disclosure have been reviewed and approved by the Research Office.

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.

Conflicts of Interest Training

Online training will be completed every 4 years via the NIH's online tutorial, or through an equivalent training provided by a recognized organization such as the FCOI training provided by CITI.

Institutional Responsibilities

The Coriell Research Office will collect and perform an initial review of all disclosed SFIs to determine if a FCOI exists. 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 a FCOI and is working on research involving human subjects the IRB must be notified of any management plan.

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 or within 60 calendar days for any interest that Coriell identifies as conflicting subsequent to Coriell's initial report under a Public Health Service (PHS)-funded research project, Coriell must provide the PHS Awarding Component with a FCOI report 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

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.