

Financial Conflict of Interest Policy

Purpose

Epigenome Technologies Inc. (ETI) develops biochemical technologies for use in biological research and performs experiments on behalf of clients that may relate to their own development activities. In some cases, ETI may perform research funded by the United States Government. The purpose of this policy is to establish guidelines and procedures to identify, manage, and mitigate financial conflicts of interest that may arise while ETI carries out grants and cooperative agreements that adopt the Public Health Services (PHS) policy for research, to ensure compliance with the Federal regulations governing Financial Conflict of Interest (FCOI) regulation, promoting objectivity in research. The policy aims to uphold transparency, integrity, and objectivity in research activities and to protect the interests of ETI, its stakeholders, and the public. In accordance with PHS regulations, this policy is publicly- accessible on ETI's website.

Scope

This policy applies to (1) any ETI employee listed as principal investigator or key personnel on grants and cooperative agreements that adopt the PHS policy for research, or (2) any employee with access to physical client samples, client sample metadata such as sample type or experimental design involved in these grants and cooperative agreements. The policy ensures that all covered individuals understand their responsibilities, obligations, and reporting requirements related to financial conflicts of interest in research. Compliance with this policy is essential to uphold the ethical standards and promote the integrity and objectivity of research conducted by ETI.

Definitions

1. **Financial Conflict of Interest (FCOI)** means a Significant Financial Interest (SFI) that could directly and significantly affect the design, conduct, or reporting of research and development.
2. **Investigator** means the project director or principal Investigator and any individual who is responsible for the design, conduct, or reporting of the results of work performed or to be performed under the PHS-sponsored project. This includes the Principal Investigator (PI), Project Director (PD), Co-Investigators, and any other individual who has responsibility for designing, conducting, or reporting of research funded by PHS or proposed for such funding.
3. **Key Personnel.** A PHS research Project Director, Principal Investigator and any other personnel considered essential to work performance and identified as Key Personnel in the contract proposal, grant, or contract.
4. **Principal Investigator.** An Investigator who has primary responsibility for the scientific and technical conduct, reporting, fiscal and programmatic administration of a sponsored project.

5. **Research.** As used in this Policy, any activity for which research funding is available from a PHS-awarding agency. Excluded from this Policy, consistent with the underlying federal regulations, are Phase I Small Business Innovative Research (SBIR) and Phase I Small Business Technology Transfer Research (STTR) awards.
6. **Subrecipients** means collaborators from other institutions who share responsibility for the design, conduct or reporting of research results, and who will be conducting research under a sub-grant or subcontract from ETI.
7. **Significant Financial Interest (SFI)** means a financial interest consisting of one or more of the following interests of the Investigator or the Investigator's spouse or registered domestic partner and dependent children for the following categories:
 - a. In case of a publicly traded entity (domestic or foreign), an SFI exists if the value of any remuneration (other than remuneration described in the exceptions below) 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. Included are salary (other than salary described in the exceptions below), consulting fees, honoraria, and the equity interest value at the date of disclosure as determined by public prices or other reasonable measure of fair market value;
 - b. In case of a non-publicly-traded entity (domestic or foreign), an SFI exists if the value of any remuneration (other than remuneration described in the exceptions below) 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, registered domestic partner, or dependent children) holds any equity interest;
 - c. Intellectual property rights and interests, upon receipt of income, exceeding \$5,000 during the twelve months preceding disclosure from such rights and interests (with the exceptions noted below)
 - d. **Travel expenses.** Travel related to the Investigator's Institutional Responsibilities must also be disclosed when the travel is reimbursed or sponsored by an individual or entity other than a U.S. government agency, a U.S. institution of higher education, or a research institute, academic medical center, or hospital affiliated with a U.S. institution of higher education, if the aggregated total of such reimbursed or sponsored travel exceeds \$5,000 per entity during the twelve months preceding disclosure.
 - e. **Exceptions:** The term "Significant Financial Interest" does not include the following types of financial interests:
 - i. Salary, royalties, or other payments made by ETI to the employee;
 - ii. Any ownership interests in ETI held by the employee;
 - iii. Income from investment vehicles, such as mutual funds and retirement funds, in which the Investigator does not directly control investment decisions.

- iv. income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency located in the United States, a United States 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 a United States Institution of higher education;
- v. income from service on advisory committees or review panels for a federal, state, or local government agency located in the United States, a United States 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 a United States Institution of higher education.”

Disclosure

- a. All individuals covered by this policy shall disclose all Significant Financial Interests defined above to ETI’s CEO or the person(s) /committee designated by the CEO using the Conflict of Interest Disclosure Form **no later than the earlier of: (i) Time of application for PHS-funded research (ii) within thirty (30) days** of discovering or acquiring (e.g., through purchase, marriage or inheritance) any new Significant Financial Interest (with the exception of travel disclosures, noted below); and at least annually throughout the period of the award.
- b. Before joining an ongoing PHS-funded research project new Investigators must submit a disclosure of Significant Financial Interests to ETI’s CEO or person/committee designated by the CEO. Principal Investigators must identify all Investigators on the award who (that is, all individuals who will have responsibility for designing, conducting, or reporting the research to be funded by PHS) are required to disclose Significant Financial Interests.
- c. **Sponsored or reimbursed travel** will be disclosed:
 - i. Prospectively listing all anticipated travel including information about the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration of the trip, for the twelve (12) month period following the filing of the Investigator’s annual disclosure form;
 - ii. Within thirty (30) days of the occurrence of travel that either was not listed on the prospective annual travel report pursuant to paragraph a) or that significantly varied in the threshold reporting details from what was listed in the prospective report.
- d. **Subrecipients** should comply with the policies and procedures for disclosure and review of a Significant Financial Interests at the institution at which they are employed or, if their institution does not have a conflict of interest policy that complies with the PHS regulations, they must comply with the ETI policies and procedures for disclosure and review of a Significant Financial Interests related to PHS sponsored awards. Subaward agreements issued by ETI will include terms that require the subrecipient institution to certify that its policy is in compliance with PHS conflict of interest regulations, and unless the subrecipient does not have a PHS-compliant policy, will indicate that the recipient organization is responsible for reviewing the disclosures submitted by its Investigators and, if a FCOI is identified, for sending ETI notification of the conflict and of the subrecipient institution’s plan to manage, reduce or eliminate the identified conflicts, in accordance with PHS reporting requirements detailed below.

Review and Assessment

a. With each PHS proposal, progress report, incremental funding or extension, Investigators' Significant Financial Interests disclosures will be reviewed by the Chief Executive Officer (CEO) of ETI or a person or committee designated by the CEO to determine whether there are any Significant Financial Interests that reasonably appear to be related to the PHS-funded research activity in which the Investigator is engaged. Investigators shall have an opportunity to indicate whether or not they believe the Significant Financial Interest(s) they reported are related to their PHS-funded research activities.

b. The review process should consider the nature, extent, and potential impact of the conflict on the design, conduct and reporting of the sponsored research.

c. The review process shall adhere to the following review guidelines:


1. A FCOI should be **related** to PHS-funded research in that: (i) the value of the interest itself (e.g., intellectual property) could be affected by the design, outcome, or reporting of the research project, or (ii) the value of the financial interest (e.g., stock price, honorarium continuations) could be affected by the design, outcome, or reporting of the project.
2. The individual involved is an **investigator** on the related PHS-funded research project.
3. The SFI meets the definition of a **reportable financial interest** as defined above.

d. Any SFI disclosure received from an Investigator on a PHS-funded research project will be reviewed by the CEO or a designated employee within 60 days.

e. Any time ETI discovers an undisclosed SFI, delinquent SFI disclosure, or non-reviewed SFI disclosure, the SFI will be reviewed by the CEO or a designated employee within 60 days.

f. Whenever an SFI is identified as a FCOI by the CEO or designated employee, ETI will establish plan to manage and monitor the FCOI for the duration of the project (see "Management and Mitigation")

g. **Retrospective Review.** Any time ETI discovers a delinquent, non-disclosed, non-reviewed SFI, an SFI not managed in a manner in compliance of the FCOI policy, or an investigator in non-compliance of the management plan, a retrospective review of the Investigator's activities in the PHS/NIH-funded research project, or portions thereof, will be conducted to determine whether bias exists in the design, conduct, or reporting of the project. This retrospective review will be completed within 120 days and document at a minimum:

- Project Number
 - Project Title
 - Contact PD/PI
 - Name of the Investigator with FCOI
 - Name of the entity with which the Investigator has a FSI
 - Reason(s) for the retrospective review
 - Detailed methodology used for the review
 - Review findings of the review, including biases and harm
 - Conclusions of the review
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The results of this review may be reported to the NIH (see “Reporting to PHS”).

In the case the retrospective review determines that a bias can be reasonably expected, ETI will report to NIH and submit a mitigation report within 120 days of such finding. Such mitigation report is submitted as a “Revised FCOI Report” if the FCOI had been previously reported to the NIH. The mitigation report includes the key elements documented in the retrospective review above, a description of the impact of the bias on the research project, and plan of action or actions taken to eliminate or mitigate the effect of the bias.

Management and Mitigation

- a. Upon identification of a financial conflict of interest, the designated person or committee shall develop and implement a plan to manage or mitigate the conflict.
- b. ETI will follow the guideline below in specifying the management plan:
 - Public disclosure of financial conflicts of interests when presenting or publishing the research; to staff members working on the project; to the Institution’s Institutional Review Board(s), Institutional Animal Care and Use Committee(s);
 - For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
 - 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;
 - Modification of the research plan;
 - Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research;
 - Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
 - Severance of relationships that create financial conflicts.
- c. In the event that the review process shows that an Investigator’s Significant Financial Interest reasonably appears to directly and significantly affect the design, conduct or reporting of the PHS-funded research; or is in an entity whose financial interest could be affected by the research, the Disclosure and appropriate documentation shall be forwarded to ETI for consideration and restrictions should be placed on the project to eliminate or manage the Financial Conflict of Interest before the support can be accepted.
- d. The management plan is to be implemented prior to the expenditure of PHS funds awarded for the research project, and shall specify the actions that are required to manage the Financial Conflict of Interest, and shall include:
 - The role and principal duties of the conflicted Investigator;
 - Conditions of the management plan;
 - How the plan will safeguard objectivity in the research activity;
 - Confirmation of the Investigator’s agreement to the plan; and
 - How the plan will be monitored.

The same review process takes place when an Investigator reports a new Significant Financial Interest.

C. REPORTING TO PHS

- a. Prior to the expenditure of any funds provided under a PHS award, the ETI must provide to the PHS funding agency an initial report regarding Investigator Financial Conflict of Interest, if a significant Financial Conflicts of Interest is determined to exist.
- b. During the period of the award, ETI shall, within 60 days of receipt of disclosure of a new or newly discovered Significant Financial Interest, review the disclosure, determine whether it is related to PHS-funded research, determine whether it constitutes a Financial Conflict of Interest, and if so, implement a management plan and report the Financial Conflict of Interest to the PHS funding agency.
- c. For any Significant Financial Conflict of Interest that the ETI reports to a PHS awarding agency, the ETI shall provide to the PHS awarding agency an annual Financial Conflict of Interest report that addresses the status of the conflict and any changes to the management plan, for the duration of the project. The annual report shall specify whether the Financial Conflict of Interest is still being managed or explain why it no longer exists. EIT must provide annual reports to the PHS awarding agency for the duration of the project period (including extensions with or without funds).
- d. Within 60 days of determining that a Significant Financial Conflict of Interest exists for a new Investigator who joins an ongoing PHS-funded research activity, ETI must implement a management plan and submit a report to the PHS funding agency.
- e. In any case in which the Department of Health and Human Services (DHHS) determines that a PHS-sponsored project of clinical research 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 a significant Financial Conflict of Interest that was not managed or reported by EIT as required by this policy and Federal regulation, ETI shall require the Investigator to disclose the Financial Conflict of Interest in each public presentation of the results of the research and to request an addendum to previously published presentations.
- f. If, upon review, bias is identified in the design, conduct, or reporting of PHS/NIH-funded research, the CEO or a designated employee will:
 - i. Develop a mitigation plan to remediate the effects of bias.
 - ii. Submit a Mitigation Report to the NIH documenting the FCOI including entity name, name of the Investigator with the FCOI, the nature of the SFI(s), value of the SFI(s), the nature of the bias, and the actions specified in the mitigation plan.
- g. If ETI identifies an Investigator out of compliance with this Policy, ETI will take corrective action immediately, including a review of any non-disclosed FSI, and promptly notify the NIH of the instance of non-compliance.

Monitoring and Enforcement



- a. The CEO of ETI or a designated person or committee shall monitor compliance with this policy, review any changes in circumstances, and reassess the effectiveness of implemented management or mitigation strategies.
- b. Non-compliance with this policy may result in disciplinary action, including but not limited to warnings, reprimands, loss of privileges, suspension, or termination.

Maintenance of Records

All records related to FCOI, including FSI disclosures, institutional review of SFI disclosures, management plans, mitigation plans, NIH filings or communications, including documentation of actions taken relating to management or mitigation plans, shall be retained for at least three years after the date the final expenditures report is submitted to the NIH or, where applicable, from other dates specified in 45 CFR 75.361.

Annual Declarations

- a. All individuals covered by this policy shall be required to make an annual declaration confirming their compliance with this policy and disclosing any new or ongoing conflicts of interest.
- b. The CEO of ETI, or a designated officer, shall solicit disclosures and provide training reminders for all covered employees (i) whenever a new application for PHS is submitted **and** (ii) each new year.

Confidentiality and Protection

- a. The company will handle all significant financial conflict of interest disclosures and related information with utmost confidentiality, ensuring the privacy and protection of individuals involved.
- b. The company will maintain appropriate records and documentation related to conflicts of interest, their disclosure, and the actions taken to manage or mitigate them.

Training and Education

- a. The company will provide regular training (at least once every 4 years) and education programs to inform all employees of federal FCOI regulations and to raise awareness of financial conflicts of interest, the policy, and the responsibilities of individuals covered by the policy.
- b. New employees covered by the policy should will receive a copy of this policy and training on this policy and policy materials as part of their orientation process.
- c. FCOI training materials and a copy of this policy will be made available on the company intranet or file storage provider. A recommendation of FCOI training materials can be found at <https://grants.nih.gov/grants/policy/coi/fcoi-training.htm>.
- d. Employees will be provided with instructions of his or her responsibility to disclose all foreign and domestic SFI in a timely manner. A FCOI disclosure form is available on the company intranet or storage provider, and employees will be made aware of this form for easy disclosure.
- e. Any employee found not to be in compliance with this policy, or any management plans arising from the policy, is required to re-complete FCOI training.



Review and Amendment

This policy is reviewed yearly to ensure its effectiveness and relevance to the company's operations. Any necessary amendments or updates shall be made with the approval of the CEO. Any changes to this policy impacting investigator requirements will be reflected in company training materials, and all employees will be required to complete the revised training materials.

Accessibility

- a. A copy of this Policy will be made publicly available on the ETI website.
- b. ETI will maintain on its public website a list of all identified FCOIs held by key personnel related to PHS-funded projects. FCOIs will remain listed for at least three years after the date the final expenditures report is submitted for the relevant project. This list will include the project number, title, contact PD/PI, name of the Investigator with the FCOI, and name of the relevant FCOI entity.

