

Effective Date: August 24, 2012

[To Be Completed by Policy Review Committee]

Investigator Financial Conflict of Interest Policy

PURPOSE

It is our policy to ensure that employees avoid situations in which their personal interests influence, or appear to influence, their professional or scientific objectivity. United States Federal regulations, including 45 CFR Part 94, require institutions to have policies in place to ensure that Investigators do not have significant financial interests that could bias research funded by the Public Health Service (PHS), which includes the National Institutes of Health (NIH). In order to identify and mitigate any such conflicts of interest, Investigators are required to disclose all significant financial interests that reasonably appear to be related to the Investigator's institutional responsibilities, and institutions are required to develop specific mechanisms by which conflicts of interest will be satisfactorily managed, reduced, or eliminated. The purpose of this policy is to set forth the procedures that Charles River will follow to manage these potential conflicts of interest and ensure compliance with these regulations.

DEFINITIONS

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

Financial Conflict of Interest (FCOI) means a Significant Financial Interest (SFI) that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

Institutional Responsibilities means an Investigator's professional responsibilities on behalf of Charles River, which may include activities such as research, research consultation, Charles River committee memberships such as the Institutional Animal Care and Use Committee, etc.

Investigator means the project director, principal investigator, Study Director, or any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS or proposed for such funding.

Key Personnel includes the project director, principal investigator and any other personnel considered to be essential to work performance in accordance with the U.S. Department of Health & Human Services Acquisition Regulation (HHSAR) subpart 352.242–70 and identified as key personnel in the contract proposal and contract.

Significant Financial Interest (SFI) means one or more of the following interests of an Investigator (and those of the Investigator’s spouse and dependent children) that reasonably appears to be related to the Investigator’s Institutional Responsibilities.

- Publicly traded entities: a SFI exists if (a) the value of any remuneration received from the entity in the twelve months preceding the disclosure, and (b) the value of any equity interest held 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); 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.
- Non-publicly traded entities: a SFI exists when (a) there are holdings of *any* equity interest (e.g., stock, stock option, or other ownership interest) regardless of value, or (b) if the value of any remuneration received from the entity in the twelve months preceding the disclosure exceeds \$5,000.
- Intellectual property rights and interests (e.g., patents, copyrights): a SFI exists upon receipt of any income related to such rights and interests.
- Sponsored Travel: a SFI exists when the Investigator has any reimbursed travel or travel which is paid on behalf of the Investigator; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a 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.

The following are **not** Significant Financial Interests:

- salary, royalties, or other remuneration paid to Investigator by Charles River as an employee;
- any ownership interest in Charles River;
- 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; or
- income from seminars, lectures, or teaching engagements or service on advisory committees or review panels 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.

POLICY

INVESTIGATOR DISCLOSURE PROCEDURES

Each Investigator who is planning to participate in any PHS-funded research must complete a Significant Financial Interest Disclosure form and submit it to the Office of Legal Compliance prior to the submission of a proposal for any PHS funded contract, grant, or cooperative agreement. The disclosure form will identify all Significant Financial Interests (as defined above), including those of the Investigator's spouse and dependent children. If the Investigator has no Significant Financial Interests, this should be noted on the form.

Any new Investigator performing work on an ongoing PHS-funded contract shall complete a Significant Financial Interest Disclosure form, as described above, prior to the initiation of any work on the applicable contract.

Disclosures of SFIs must be updated by all Investigators on an annual basis during the period of any affected contract. Disclosures must also be updated within 30 days of discovering or acquiring any new SFI (e.g., through purchase, marriage, or inheritance).

Type of Disclosure	Timing of Disclosure
Initial Disclosure Related to New PHS Contract	No later than time of submission of proposal by Charles River to a PHS agency or prime contractor
Addition of Investigator to Ongoing PHS Contract	Before commencing activities on contract
Update to an Existing Disclosure	Within 30 days of acquiring or discovering a new SFI
Annual Update to an Existing Disclosure	Once annually during contract period

Disclosures of any SFIs involving reimbursed or sponsored travel will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. Further information may be required by the Office of Legal Compliance during the review process in order to determine whether the travel constitutes a FCOI, including a determination or disclosure of monetary value.

CHARLES RIVER OFFICE OF LEGAL COMPLIANCE REVIEW PROCESS

The Corporate VP of Legal Compliance will designate a staff member to conduct an initial review of all SFI disclosures made by Investigators to determine whether the SFI is related to the PHS-funded research and, if so, whether the SFI may represent a Financial Conflict of Interest. If the initial determination is made that there may be a potential for a FCOI covered by this policy, the Office of Legal Compliance will review the information and conduct an appropriate inquiry to make a final determination of whether the SFI represents a FCOI as defined by this policy. Employees are expected to fully cooperate with such inquiry. The Office of Legal Compliance will coordinate any such inquiry with the senior management of the facility where the Investigator is employed. If it is determined that a FCOI exists, the Office of Legal Compliance will request that the Investigator withdraw from the project or develop a FCOI Management Plan. The FCOI Management Plan will outline appropriate remedies to manage, reduce, or eliminate the FCOI in order to ensure that the design, conduct, and reporting of the research will be free from bias. The FCOI Management Plan will be approved by the Office of Legal Compliance and implemented prior to the expenditure of any funds under a PHS award. The Office of Legal Compliance will monitor Investigator compliance with all FCOI Management Plans.

In the course of an ongoing PHS-funded research project, an Investigator who is added to the project may disclose a SFI, or an existing Investigator may disclose a new SFI, as required by the **Investigator Disclosure Procedures** section above. Within 60 days of such disclosure or the identification of any other SFI that was not previously disclosed or reviewed, the Office of Legal Compliance will review the SFI; determine whether it is related to the PHS-funded research; determine whether a FCOI exists; and, if so, implement, on at least an interim basis, a FCOI Management Plan that shall specify the actions that have been and will be taken to manage such FCOI. Depending on the nature of the SFI, the Office of Legal Compliance may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date of disclosure and the completion of its review.

An investigator's SFI is related to the PHS-funded research when Charles River, through the Office of Legal Compliance, reasonably determines that the SFI could be affected by the PHS-funded research, or is in an entity whose financial interest could be affected by the research. Charles River may involve the Investigator in its determination of whether a SFI is related to PHS-funded research. Charles River may request additional clarifying information from the Investigator if necessary to make this determination.

A FCOI exists when Charles River, through the Office of Legal Compliance, reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

If it is discovered that a FCOI is not identified or managed in a timely manner, the Office of Legal Compliance will complete a retrospective review of the Investigator's activities and the research project to determine whether any PHS-funded research conducted prior to the identification and management of the FCOI was biased in its design, conduct, or reporting. This review will be completed within 120 days of the determination of noncompliance. The Office of Legal Compliance will document the retrospective review in accordance with PHS regulations. If bias is found during the review, Charles River will notify the PHS awarding agency promptly and submit a mitigation report to the PHS awarding agency.

REPORTING TO PHS BY THE CHARLES RIVER OFFICE OF LEGAL COMPLIANCE

Should any reported SFI or non-compliance require reporting to PHS, the Office of Legal Compliance will provide reports in accordance with PHS regulations. If the research is conducted under a subcontract from a prime PHS-awardee or contractor, such reporting shall be made available to the prime such that they may fulfill their reporting obligations to the PHS.

INVESTIGATOR TRAINING

Each Investigator must complete training regarding FCOI, Investigator's responsibilities regarding required disclosures, and compliance with applicable regulations prior to engaging in research under an applicable contract. Each Investigator must also complete refresher training at least once every four years and within 30 days of the occurrence of the following:

- Charles River makes changes to this policy in any manner that affects the requirements of Investigators
- Charles River finds that an Investigator is not in compliance with this policy or a FCOI Management Plan

SUBCONTRACTS

Subcontractors performing any work as an Investigator under applicable contracts must certify that they are in compliance with pertinent FCOI regulations. Applicable subcontracts must be coordinated with the Charles River Corporate Legal Department / Office of Legal Compliance to ensure that all requirements under 45 CFR Part 94 are satisfied, including the filing of appropriate FCOI reports to the PHS awarding agency.

RECORD RETENTION

Records of Investigator SFI Disclosure forms, review and response to such Disclosure forms, FCOI Management Plans, and actions taken to manage each FCOI will be retained in accordance with PHS regulations.

PUBLIC ACCESSIBILITY

We will ensure public accessibility by providing a written response within 5 business days of receipt of any written request for information concerning any SFI that meets all of the following criteria:

- The SFI was disclosed and is still held by Key Personnel as defined by this policy;
- Charles River determines that the SFI is related to PHS-funded research; and
- Charles River determines that the SFI is a Financial Conflict of Interest.

POLICY ENFORCEMENT AND REMEDIES FOR NON-COMPLIANCE

Failure to comply with this Policy and associated procedures may result in disciplinary action, up to and including termination of employment with Charles River. Breaches of policy include, but are not limited to: failure to file the necessary disclosure forms; knowingly filing incomplete, erroneous or misleading disclosure forms; or failure to comply with a FCOI Management Plan or other procedures prescribed by Charles River.

The Office of Legal Compliance shall investigate alleged violations of this policy. Whenever it is determined that an Investigator has violated this policy or the conditions or restrictions imposed by a FCOI Management Plan, the Office of Legal Compliance will convey its conclusions to the local Human Resources department, who will recommend sanctions, which may include disciplinary action ranging from a letter of reprimand to termination of employment.

GENERAL

The Company reserves the right to amend or terminate this Policy at any time as the Company deems necessary.

SCOPE

This policy applies to any Investigator who is responsible for the design, conduct, or reporting of research activities in projects: (1) funded by PHS where the solicitation or contract includes a requirement for management of Investigator Financial Conflicts of Interest, with an award date on or after the effective date; or (2) to be included in such proposals submitted to PHS on or after the effective date. The policy also applies to the Investigator's spouse and dependent children.

RESPONSIBILITIES

Any questions related to the interpretation of this Policy and/or a subject matter included in this Policy shall be directed to the Corporate Vice President of Legal Compliance.

RELATED DOCUMENTS

Significant Financial Interest Disclosure Form