

Financial Conflicts of Interest in Research Policy

Preamble

Effective August 24, 2012, the Department of Health and Human Services has amended existing Public Health Service (“PHS”) regulations for promoting objectivity in research. These regulations are designed to encourage research integrity by requiring disclosure and management of any conflicts of interest of investigators who receive research funding from the National Institutes of Health (“NIH”). To comply with the amended regulations, the Hepatitis B Foundation (Foundation) has revised its written policy on financial conflicts of interest in research. This policy is accessible to the public on the Hepatitis B Foundation’s external web site at www.hepb.org.

- a) informs all investigators of the federal conflict of interest rules and their responsibilities under those rules;
- b) mandates conflict of interest training for investigators before they engage in research under a federally funded grant and at prescribed intervals thereafter;
- c) requires investigators applying for, or receiving, federal research funding to disclose any significant financial interests;
- d) designates institutional officials who will review disclosure statements, identify any financial interests that could directly and significantly affect the design, conduct or reporting of the funded research, and determine appropriate measures to manage or eliminate the conflicts of interest;
- e) establishes mechanisms for ensuring compliance with the policy and any stipulated remedial measures, and imposes sanctions, as appropriate, for an investigator’s failure to comply; and
- f) requires institutional reporting to the funding agency of any conflict of interest, if mandated, and maintenance of related records for three years from the date of submission of final grant expense reports.

This policy is intended to supplement, not replace, the Foundation’s general policy on conflicts of interest. Members of the scientific staff, as well as other employees, will continue to be subject to the Foundation’s existing conflicts of interest policy, which requires annual disclosure of personal financial interests and external commitments, irrespective of the receipt of grant funding from federal sources.

As noted, this policy affects only research funded by agencies of the PHS.

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The Foundation considers compliance with these rules fundamental to maintaining continued public trust in the integrity of research conducted at the Foundation. Members of the scientific staff are encouraged to direct any questions concerning the rules to the Foundation's President.

Policy

I. Definitions

- A. "Family" means an Investigator's spouse, domestic partner or dependent children.
- B. "Equity Interest(s)" means stock, stock options, warrants, and other existing or contingent ownership interests in a commercial entity.
- C. "Financial Conflict of Interest" or "FCOI" means a Significant Financial Interest (as defined in Section I.G below) that could directly and significantly affect the design, conduct, or reporting of PHS or NSF-funded research.
- D. "Institutional Responsibilities" means an Investigator's professional responsibilities on behalf of the Foundation, including but not limited to, activities such as research, research consultation, teaching, administration, institutional committee memberships, and service on panels such as Institutional Review Boards.
- E. "Investigator" means a principal investigator and any other person who is responsible for the design, conduct or reporting of research, including key personnel, for which PHS or NSF funding is sought or obtained.
- F. "Research" means a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health. The term encompasses basic and applied research and product development.
- G. "Significant Financial Interest" or "SFI" means any of the following items of monetary value received by an Investigator, alone or in combination with his or her Family (and not excluded below) that appear reasonably related to the Investigator's Institutional Responsibilities.
1. payments or anything of monetary value in or from a *publicly traded entity* where the aggregate value of the payments received during the 12 month period preceding the disclosure, or expected over the next 12 months, exceeds \$5,000; or the aggregate value as of the date of disclosure of any Equity Interest in the entity exceeds \$5,000, as determined through reference to public prices or other reasonable measures of fair

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market value;

2. payments or anything of monetary value from a *non-publicly* traded entity where the aggregate value of the payments received during the 12-month period preceding disclosure, or expected over the next 12 months, exceeds \$5,000;
3. Equity Interests of any value in a non-publicly traded entity;
4. payments received from an organization other than the Foundation relating to intellectual property rights and interests (for example, patents and copyrights) when such income exceeds \$5,000; and
5. travel that is reimbursed or sponsored by an organization *other than* a federal, state, or local government agency located in the United States, a domestic institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a domestic institution of higher education when such income exceeds \$5,000.

The term does not include the following types of financial interests received by an Investigator:

1. salary, royalty payments arising from intellectual property rights assigned to the Foundation and agreements to share in royalties related to such rights, or other remuneration paid by the Foundation to the Investigator if the Investigator is currently employed;
2. 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 those vehicles;
3. income from seminars, lectures, or teaching engagements sponsored by, and service on advisory or review panels for, a federal, state, or local government agency located in the United States, a domestic institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a domestic institution of higher education.

II. Procedures

A. Disclosure

Investigator(s) (including any person responsible for the design, conduct or reporting of the funded research) must disclose any SFI at the following time(s):

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1. prior to submitting a funding proposal to any PHS agency;
2. annually during the period of the award;
 - a. within thirty (30) days of discovering or acquiring any new SFI during the term of a grant; and
 - b. within thirty (30) days following reimbursement of travel expenses by a third party; or, if travel costs are paid directly by the third party, within thirty (30) days of the completion of the trip (see Section I.G.5 for a description of travel costs that do not have to be disclosed). When disclosing an SFI that is reimbursed or sponsored travel, the Investigator must detail, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination and duration, and the monetary value.

The Baruch S. Blumberg Grants Manager will maintain disclosure forms, to be completed by each Investigator, which will require the Investigator to disclose reportable SFIs, or certify that he or she has no such interests. Upon submission of a grant application, the Foundation must certify that it has received the Investigators' disclosure forms. For all grant submissions subsequent to the initial application, or at least annually, Investigators must submit an updated statement of any changes that have occurred since submitting their most recent disclosure statement, or certify that no changes have occurred. Additionally, at any time during the term of the grant, Investigators must submit an updated disclosure statement within thirty (30) days of discovering or acquiring a new SFI.

B. Review and Implementation

The Foundation's President will review any SFI reported by an Investigator to determine if it is related to the Investigator's PHS-funded research (this determination may involve discussions with the Investigator). If it is determined that the SFI is related to the Investigator's PHS-funded research, the Foundation's Chief Executive Officer will appoint an *ad hoc* committee (the "COI Committee", which generally will include the Foundation's President, Director of Accounting/HR and the Baruch S. Blumberg Grants Manager) to determine if such interest could constitute a potential FCOI by directly and significantly affecting the design, conduct or reporting of the funded research, and whether such SFI can be managed. The COI Committee will submit its recommendations to the Chief Executive Officer, who will determine if the FCOI can be managed or eliminated. If s/he concludes that the FCOI can be managed, the President, in consultation with the COI Committee and the Investigator, will develop a FCOI management plan for the Chief Executive Officer's approval. Examples of conditions or restrictions that might be imposed to manage FCOIs include, but are not limited to:

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1. public disclosure of SFIs;
2. monitoring of research by independent reviewers;
3. modification of the research plan;
4. disqualification from participation in all or a portion of the research funded by the granting agency;
5. divestiture of SFIs; or
6. severance of relationships that create actual or potential FCOIs.

The aim of a management plan is to ensure open and timely dissemination of research results, protect trainees, and preserve the integrity of the research. The Investigator will be asked to acknowledge in writing that he or she understands and will comply with any conditions imposed by the President for managing or eliminating a FCOI. Should he or she decline or fail to agree to these conditions, the Foundation will take appropriate disciplinary action, including without limitation suspending the Investigator's research and, with requisite approval of NIH, designating a substitute Investigator.

If the President reports an SFI, the chair of the Board of Directors will be responsible for assembling the COI Committee, in consultation with the Chief Executive Officer, and determining if the financial interest constitutes a potential FCOI. With concurrence of the Executive Committee of the Board of Directors, the chair will implement measures to manage or eliminate any FCOI of the President.

If the Chief Executive Officer reports an SFI, the chair of the Board of Directors will be responsible for assembling the COI Committee and determining if the financial interest constitutes a potential FCOI. With concurrence of the Executive Committee of the Board of Directors, the chair will implement measures to manage or eliminate any FCOI of the Chief Executive Officer.

The Foundation will monitor, on an ongoing basis until the completion of the research project, the compliance with the conditions mandated in an established management plan.

C. Subrecipients (Applicable to PHS-funded research only)

The PHS rules require the Institute to take reasonable steps to ensure that subcontractors or subrecipients comply with the federal rules. Therefore, when the Foundation carries out the PHS-funded research through a subrecipient, the Foundation will incorporate, as part of a written agreement with the subrecipient, terms that 1) require the subrecipient to maintain a FCOI policy that complies with federal requirements and 2) establishes whether the Foundation's or subrecipient's FCOI policy will apply to the subrecipient Investigators.

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If the subrecipient's policy will apply, the subrecipient must report any FCOIs to the Foundation within forty-five (45) days of identification so that the Foundation can report them to the PHS in a timely manner (see Section II.E below for additional information on reporting).

Alternatively, if the Foundation's FCOI policy will apply, the agreement shall specify time period(s) for the subrecipient to submit all subrecipient Investigator disclosures of SFIs to the Foundation. Such time periods shall be sufficient to enable the Foundation to comply with timely review, management, and reporting obligations under the federal rules as described in Section II.E.

If the Foundation is a subrecipient of PHS funds, this policy will apply to the required FCOI review, rather than the policy of the sub-awarding organization.

D. Public Access of Disclosed SFIs (Applicable to PHS-funded research only)

The Foundation will make available to the public upon request information concerning any SFI disclosed to the Foundation that meets the following three criteria:

1. The disclosed SFI is still held by an Investigator of an active PHS-funded project;
2. The Foundation determines that the SFI is related to the PHS-funded research; and
3. The Foundation determines that the SFI is a FCOI.

The Foundation will respond within five (5) business days of receipt of a request for public disclosure. The response shall include, at a minimum, the following: the Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity in which the SFI is held; the nature of the SFI; and the approximate dollar value of the SFI (dollar ranges, as set forth in the PHS rules, may be used), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value. The Foundation will note in its written response that the information provided is current as of the date of correspondence and is subject to updates on an annual basis, or within sixty (60) days of the identification of new FCOI. The requester must ask for any such updates if s/he desires them. FCOI information will remain available for three (3) years from the date the information was most recently updated.

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E. Reporting

Prior to the Foundation's expenditure of grant funds from the PHS, it will report to the PHS any FCOIs found by the Foundation that have not been eliminated, and, along with certain other details required by the PHS, will provide assurance that the FCOI has been managed.

When FCOIs are identified during the term of the grant for an Investigator newly participating in the project, or the Foundation identifies a new FCOI for an existing Investigator, the Foundation will report such FCOIs to the PHS within sixty (60) days of identification.

Upon submission of annual progress reports, multi-year progress reports, if applicable, or at the time of extension, the Foundation shall provide the PHS with the status of a reported FCOI and any changes to the management plan, if applicable, until the completion of the project.

Each report to the PHS must include sufficient information to enable the agency to understand the nature and extent of the FCOI and to assess the appropriateness of the management plan. The required information includes:

1. project number;
2. name of Principal Investigator of the funded research;
3. name of Investigator with FCOI;
4. name of the entity in which the Investigator has a FCOI;
5. nature of the FCOI (e.g., equity, consulting fee, travel reimbursement, honorarium);
6. value of the SFI (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,000; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
7. a description of relationship of the SFI to the PHS-funded research and the basis for the Foundation's determination that the SFI conflicts with the research; and
8. a description of key elements of the Foundation's FCOI management

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plan, including;

- a) role and principal duties of the conflicted Investigator in the research;
- b) conditions of the management plan;
- c) how the management plan is designed to safeguard objectivity in the research project;
- d) how the management plan will be monitored to ensure Investigator compliance; and
- e) other information as needed.

F. Retrospective Review

Whenever the Foundation identifies a SFI that was not disclosed in a timely manner by the Investigator, or for whatever reason was not timely reviewed by the Foundation, the Foundation will determine whether the SFI constitutes a FCOI within sixty (60) days thereafter and implement an appropriate management plan.

If the FCOI was not identified or managed in timely manner, as when 1) the Investigator failed to disclose a SFI that subsequently was found by the Foundation to constitute a FCOI, 2) the Foundation failed to review or manage such FCOI, or 3) the Investigator failed to comply with the FCOI management plan, the Foundation shall complete a retrospective review of the Investigator's activities and the PHS-funded research project. The purpose of the retrospective review, which must occur within 120 days of the Foundation's determination of noncompliance, is to determine whether any PHS-funded research conducted during the period of the noncompliance was biased in the design, conduct, or reporting of such research.

The Foundation will document the retrospective review, which documentation must include, but not necessarily be limited to, all of the following key elements: project number and title; name of principal investigator, name of the Investigator with the FCOI; the name of the entity with which the Investigator has a FCOI; reasons for the retrospective review; detailed methodology used for the retrospective review, review findings and conclusions.

As appropriate, the Foundation will update any previously submitted FCOI report with information describing how the FCOI will be managed going forward.

If bias is found after a retrospective review, the Foundation will promptly notify the PHS and follow up with a mitigation report. The mitigation report must include, at a minimum, the key elements documented in the retrospective review and a description of the

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impact of the bias on the research project and the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias.

G. Enforcement and Sanctions for Noncompliance

If an Investigator fails to comply with the provisions of this policy, or with any conditions for managing or eliminating a FCOI mandated by the President, the President will discuss the violation with the Investigator and attempt to remedy it informally. If the President is unable to reach a resolution, he or she shall impose appropriate sanctions up to and including suspension or termination of the Investigator.

H. Training

Prior to engaging in any research project, all Investigators must complete training on the Investigator's obligations under this policy and repeat the training at least every four years. Training must be completed immediately (i) if this policy is revised to the extent that it affects Investigators' obligations; (ii) when an Investigator is new to the Foundation; or (iii) when the Foundation finds an Investigator to have violated this policy or any applicable management plan.

I. Record Keeping

The Foundation will maintain records relating to (i) all Investigator disclosures of SFI; (ii) measures implemented to manage or eliminate FCOIs; and (iii) all actions related to a retrospective review, if applicable, for at least three (3) years from the date of submission of the final grant expenditure report, or longer where applicable, unless any litigation, claim, audit or other action involving the records is commenced before the end of the three-year period, in which case, records will be retained until completion of the action and resolution of all issues.