

PHELAN-MCDERMID SYNDROME FOUNDATION FINANCIAL CONFLICT OF INTEREST POLICY - RESEARCH GRANTS AND COOPERATIVE AGREEMENTS

I. Purpose.

This policy promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of Foundation research funded by third parties, including the Public Health Service (PHS), through grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.

II. Applicability.

This policy is applicable whenever the Foundation applies for, or receives, third party, including PHS, research funding by means of a grant or cooperative agreement and, through the implementation of this policy by the Foundation, to each Investigator who is planning to participate in, or is participating in, such research.

III. Definitions.

As used in this policy:

Affiliate means, with respect to any specified Person, (a) any other Person directly or indirectly controlling or controlled by or under direct or indirect common control with such specified Person or (b) any other Person that owns, directly or indirectly, Ten Percent (10%) or more of such specified Person's capital stock or other equity interests. For the purposes of this definition, (i) "control," when used with respect to any specified Person, means the power to direct the management and policies of such Person, directly or indirectly, whether through the ownership of voting securities, by contract or otherwise; and the terms "controlling" and "controlled" have meanings correlative to the foregoing; and (ii) HHS shall be deemed an "affiliate" of PHS and PHS an "affiliate" of HHS.

Disclosure of significant financial interests means an Investigator's disclosure of significant financial interests to the Foundation.

Financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of third party, including PHS, funded research.

FCOI report means the Foundation's report of a financial conflict of interest to a Third Party Awarding Entity.

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

HHS means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

Foundation means the Phelan-McDermid Syndrome Foundation.

Foundation responsibilities means an Investigator's professional responsibilities on behalf of the Foundation, including research, research consultation, teaching, professional practice, Foundation committee memberships, and service on panels such as Foundation review boards or Foundation data and safety monitoring boards.

Investigator means the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of existing or proposed Third Party-Funded Research, which may include, for example, collaborators or consultants.

Manage means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

PD/PI means a project director or principal Investigator of a Third Party-Funded Research project; the PD/PI is included in the definitions of senior/key personnel and Investigator under this policy.

Person means a natural person, partnership (whether general or limited and whether domestic or foreign), limited liability company, foreign limited liability company, trust, estate, association, corporation, custodian, nominee or any other individual or entity in its own or representative capacity.

PHS means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

Public Health Service Act or PHS Act means the statute codified at 42 U.S.C. 201 *et seq.*

Research means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). As used in this policy, the term includes any such activity for which research funding is available from a Third Party Awarding Entity through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, Foundation training grant, program project, or research resources award.

Senior/key personnel means the PD/PI and any other person identified as senior/key personnel by the Foundation in the grant application, progress report, or any other report submitted to the PHS by the Foundation under this policy.

Significant financial interest means:

(1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's responsibilities on behalf of the Foundation:

(i) 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;

(ii) 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); or

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (*i.e.*, that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their Foundation responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, the Foundation 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 the Foundation of higher education. Disclosure of such sponsored travel shall include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. Upon receipt, members of the Foundation's FCOI Monitoring Committee will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with respect to the Third Party-Funded Research.

(3) The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Foundation to the Investigator if the Investigator is currently employed or otherwise appointed by the Foundation, including intellectual property rights assigned to the Foundation and agreements to share in royalties related to such rights; 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; income from seminars, lectures, or teaching engagements 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; or income from service on advisory committees or review panels for 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.

Third Party Awarding Entity means the third party who funds the research that is subject to this policy, including any government or PHS funding source.

Third Party-Funded Research means any Research funded by a party other than the Foundation or using monies or resources other than Foundation monies or resources, including any government-funded or Third Party-Funded Research.

IV. Responsibilities of Foundation.

The Foundation shall:

(a) Maintain this policy up-to-date, actively enforce it and make this policy available via its Website at all times.

(b) Inform each Investigator of the Foundation's policy on financial conflicts of interest, the Investigator's responsibilities regarding disclosure of significant financial interests, and of these regulations, and require each Investigator to complete training regarding the same prior to engaging in research related to any Third Party-Funded Research grant and at least every four years, and immediately when any of the following circumstances apply:

(1) The Foundation revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;

(2) An Investigator is new to the Foundation; or

(3) The Foundation finds that an Investigator is not in compliance with the Foundation's financial conflict of interest policy or management plan.

(c) If the Foundation carries out Third Party Funded Research through a sub-recipient (e.g., subcontractors or consortium members), the Foundation must take reasonable steps to ensure that any sub-recipient Investigator complies with this policy by:

(1) Incorporating as part of a written agreement with the sub-recipient terms that establish whether the financial conflicts of interest policy of the Foundation or that of the sub-recipient will apply to the sub-recipient's Investigators.

(i) If the sub-recipient's Investigators must comply with the sub-recipient's financial conflicts of interest policy, the sub-recipient shall certify as part of the agreement referenced above that its policy complies with this policy. If the sub-recipient cannot provide such certification, the agreement shall state that sub-recipient Investigators are subject to the financial conflicts of interest policy of the Foundation for disclosing significant financial interests that are directly related to the sub-recipient's work for the Foundation;

(ii) Additionally, if the sub-recipient's Investigators must comply with the sub-recipient's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the sub-recipient to report all identified financial conflicts of interest to the Foundation. Such time period(s) shall be sufficient to enable the Foundation to provide timely FCOI reports, as necessary, to the Third Party Awarding Entity;

(iii) Alternatively, if the sub-recipient's Investigators must comply with the Foundation's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the sub-recipient to submit all Investigator disclosures of significant financial interests to the Foundation. Such time period(s) shall be sufficient to enable the Foundation to comply timely with its review, management, and reporting obligations under this policy.

(2) Providing FCOI reports to the Third Party Awarding Entity regarding all financial conflicts of interest of all sub-recipient Investigators consistent with this policy, *i.e.*, prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

(d)(1) Establish a committee reporting to the Foundation's Board of Directors named the "FCOI Monitoring Committee" whose charter shall be to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the Third Party-Funded Research on behalf of the Foundation.

(2) Designate the Foundation official(s) to serve as members of FCOI Monitoring Committee, set out the duties of such members and provide for the period of time members are to serve.

(e)(1) Require that each Investigator who is planning to participate in the Third Party-Funded Research disclose to the Foundation's designated official(s) the Investigator's significant financial interests (and those of the Investigator's spouse and dependent children) no later than the time of application for Third-Party-Funded Research.

(2) Require each Investigator who is participating in the Third Party-Funded Research to submit an updated disclosure of significant financial interests *at least annually*, in accordance with the specific time period prescribed by the Foundation, during the period of the award. Such disclosure shall include any information that was not disclosed initially to the Foundation pursuant to paragraph (e)(1) of this section, or in a subsequent disclosure of significant financial interests (e.g., any financial conflict of interest identified on a Third Party-Funded Research project that was transferred from another Foundation), and shall include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest).

(3) Require each Investigator who is participating in the Third Party-Funded Research to submit an updated disclosure of significant financial interests *within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.*

(f) Provide guidelines consistent with this policy for the FCOI Monitoring Committee Members to determine whether an Investigator's significant financial interest is related to Third Party-Funded Research and, if so related, whether the significant financial interest is a financial conflict of interest. An Investigator's significant financial interest is related to Third Party-Funded Research when the Foundation, through the FCOI Monitoring Committee, reasonably determines that the significant financial interest could be affected by the Third Party-Funded Research; or is in an entity whose financial interest could be affected by the Research. The Foundation may involve the Investigator in the FCOI Monitoring Committee's determination of whether a significant financial interest is related to the Third Party Funded Research. A financial conflict of interest exists when the Foundation, through the FCOI Monitoring Committee, reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the Third Party-Funded Research.

(g) Take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a sub-recipient Investigator pursuant to paragraph (c) of this section. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and mitigation report.

(h) Provide initial and ongoing FCOI reports to the Third Party Awarding Entity as required by such Third Party Awarding Entity.

(i) Maintain records relating to all Investigator disclosures of financial interests and the Foundation's review of, and response to, such disclosures (whether or not a disclosure resulted in the Foundation's determination of a financial conflict of interest) and all actions under the Foundation's policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to Third Party Awarding Entity.

(j) Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.

(k) Certify, in each application for funding to which this policy applies, that the Foundation:

(1) Has in effect an up-to-date, written, and enforced administrative process to identify and manage financial conflicts of interest with respect to all research projects for which funding is sought or received by a third party;

(2) Shall promote and enforce Investigator compliance with this policy's requirements including those pertaining to disclosure of significant financial interests;

(3) Shall manage financial conflicts of interest and provide initial and ongoing FCOI reports to the Third Party Awarding Entity consistent with this policy;

(4) Agrees to make information available, promptly upon request, to the Third Party Awarding Entity or related parties designated by such Third Party Awarding Entity relating to any Investigator disclosure of financial interests and the Foundation's review of, and response to, such disclosure, whether or not the disclosure resulted in the Foundation's determination of a financial conflict of interest; and

(5) Shall fully comply with the requirements of this policy.

V. Management and reporting of financial conflicts of interest.

(a) Management of financial conflicts of interest.

(1) Prior to the Foundation's expenditure of any funds under a Third Party-Funded Research project, the designated official(s) of the Foundation shall review all Investigator disclosures of significant financial interests; determine whether any significant financial interests relate to Third Party-Funded Research; determine whether a financial conflict of interest exists; and, if so, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such financial conflict of interest. Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:

(i) Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);

(ii) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;

(iii) 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;

(iv) Modification of the research plan;

(v) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;

(vi) Reduction or elimination of the financial interest (e.g., sale of an equity interest); or

(vii) Severance of relationships that create financial conflicts.

(2) Whenever, in the course of an ongoing Third Party-Funded Research project, an Investigator who is new to participating in the research project discloses a significant financial interest or an existing Investigator discloses a new significant financial interest to the Foundation, the designated official(s) of the Foundation shall, within sixty days: review the disclosure of the significant financial interest; determine whether it is related to Third Party-Funded Research; determine whether a financial conflict of interest exists; and, if so, implement,

on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest. Depending on the nature of the significant financial interest, the Foundation may determine that additional interim measures are necessary with regard to the Investigator's participation in the Third Party-Funded Research project between the date of disclosure and the completion of the Foundation's review.

(3) Whenever the Foundation identifies a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the Foundation during an ongoing Third Party-Funded Research project (e.g., was not timely reviewed or reported by a sub-recipient), the designated official(s) shall, within sixty days: review the significant financial interest; determine whether it is related to Third Party-Funded Research; determine whether a financial conflict of interest exists; and, if so:

(i) Implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward;

(ii)(A) In addition, whenever a financial conflict of interest is not identified or managed in a timely manner including failure by the Investigator to disclose a significant financial interest that is determined by the Foundation to constitute a financial conflict of interest; failure by the Foundation to review or manage such a financial conflict of interest; or failure by the Investigator to comply with a financial conflict of interest management plan, the Foundation shall, within 120 days of the Foundation's determination of noncompliance, complete a retrospective review of the Investigator's activities and the Third Party-Funded Research project to determine whether any Third Party-Funded Research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

(B) The Foundation is required to document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements:

(1) Project number;

(2) Project title;

(3) PD/PI or contact PD/PI if a multiple PD/PI model is used;

(4) Name of the Investigator with the FCOI;

(5) Name of the entity with which the Investigator has a financial conflict of interest;

(6) Reason(s) for the retrospective review;

(7) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);

(8) Findings of the review; and

(9) Conclusions of the review.

(iii) Based on the results of the retrospective review, if appropriate, the Foundation shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, the Foundation is required to notify the Third Party Awarding Entity promptly and submit a mitigation report to the Third Party Awarding Entity. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the Foundation's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, the Foundation will submit FCOI reports annually, as specified elsewhere in this policy. Depending on the nature of the financial conflict of interest, the Foundation may determine that additional interim measures are necessary with regard to the Investigator's participation in the Third Party-Funded Research project between the date that the financial conflict of interest or the Investigator's noncompliance is determined and the completion of the Foundation's retrospective review.

(4) Whenever the Foundation implements a management plan pursuant to this policy, the Foundation shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the Third Party-Funded Research project.

(5)(i) Prior to the Foundation's expenditure of any funds under a Third Party-Funded Research project, the Foundation shall ensure public accessibility, via a publicly accessible Web site or written response to any requestor within five business days of a request, of information concerning any significant financial interest disclosed to the Foundation that meets the following three criteria:

(A) The significant financial interest was disclosed and is still held by the senior/key personnel as defined by this policy;

(B) The Foundation determines that the significant financial interest is related to the Third Party-Funded Research; and

(C) The Foundation determines that the significant financial interest is a financial conflict of interest.

(ii) The information that the Foundation makes available via a publicly accessible Web site or written response to any requestor within five business days of a request, 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 significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant financial interest (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; 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.

(iii) If the Foundation uses a publicly accessible Web site for the purposes of this subsection, the information that the Foundation posts shall be updated at least annually. In addition, the Foundation shall update the Web site within sixty days of the Foundation's receipt or identification of information concerning any additional significant financial interest of the senior/key personnel for the Third Party-Funded Research project that was not previously disclosed, or upon the disclosure of a significant financial interest of senior/key personnel new to the Third Party-Funded Research project, if the Foundation determines that the significant financial interest is related to the Third Party-Funded Research and is a financial conflict of interest. The Web site shall note that the information provided is current as of the date listed and is subject to updates, on at least an annual basis and within 60 days of the Foundation's identification of a new financial conflict of interest. If the Foundation responds to written requests for the purposes of this subsection, the Foundation will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the Foundation's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

(iv) Information concerning the significant financial interests of an individual subject to paragraph (a)(5) of this section shall remain available, for responses to written requests or for posting via the Foundation's publicly accessible Web site for at least three years from the date that the information was most recently updated.

(6) In addition to the types of financial conflicts of interest as defined in this policy that must be managed pursuant to this section, the Foundation may require the management of other financial conflicts of interest in its policy on financial conflicts of interest, as the Foundation deems appropriate.

(b) Reporting of financial conflicts of interest.

(1) Prior to the Foundation's expenditure of any funds under a Third Party-Funded Research project, the Foundation shall provide to the Third Party Awarding Entity an FCOI report regarding any Investigator's significant financial interest found by the Foundation to be conflicting and ensure that the Foundation has implemented a management plan in accordance with this policy. In cases in which the Foundation identifies a financial conflict of interest and eliminates it prior to the expenditure of the Third Party-Funded Research awarded funds, the Foundation is not required to submit an FCOI report to the Third Party Awarding Entity.

(2) For any significant financial interest that the Foundation identifies as conflicting subsequent to the Foundation's initial FCOI report during an ongoing Third Party-Funded Research project (e.g., upon the participation of an Investigator who is new to the research project), the Foundation shall provide to the Third Party Awarding Entity, within sixty days, an FCOI report regarding the financial conflict of interest and ensure that the Foundation has implemented a management plan in accordance with this policy. Pursuant to paragraph (a)(3)(ii) of this section, where such FCOI report involves a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed or managed by the Foundation (e.g., was not timely reviewed or reported by a subrecipient), the Foundation also is required to complete a retrospective review to determine whether any Third

Party-Funded Research, or portion thereof, conducted prior to the identification and management of the financial conflict of interest was biased in the design, conduct, or reporting of such research. Additionally, pursuant to paragraph (a)(3)(iii) of this section, if bias is found, the Foundation is required to notify the Third Party Awarding Entity promptly and submit a mitigation report to the Third Party Awarding Entity.

(3) Any FCOI report required under paragraphs (b)(1) or (b)(2) of this section shall include sufficient information to enable the Third Party Awarding Entity to understand the nature and extent of the financial conflict, and to assess the appropriateness of the Foundation's management plan. Elements of the FCOI report shall include, but are not necessarily limited to the following:

- (i) Project number;
- (ii) PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- (iii) Name of the Investigator with the financial conflict of interest;
- (iv) Name of the entity with which the Investigator has a financial conflict of interest;
- (v) Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- (vi) Value of the financial interest (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; 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;
- (vii) A description of how the financial interest relates to the Third Party-Funded Research and the basis for the Foundation's determination that the financial interest conflicts with such research; and
- (viii) A description of the key elements of the Foundation's management plan, including:
 - (A) Role and principal duties of the conflicted Investigator in the research project;
 - (B) Conditions of the management plan;
 - (C) How the management plan is designed to safeguard objectivity in the research project;
 - (D) Confirmation of the Investigator's agreement to the management plan;
 - (E) How the management plan will be monitored to ensure Investigator compliance; and
 - (F) Other information as needed.

(4) For any financial conflict of interest previously reported by the Foundation with regard to an ongoing Third Party-Funded Research project, the Foundation shall provide to the Third Party Awarding Entity an annual FCOI report that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the Third Party-Funded Research project. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists. The Foundation shall provide annual FCOI reports to the Third Party Awarding Entity for the duration of the project period (including extensions with or without funds) in the time and manner specified by the Third Party Awarding Entity.

(5) In addition to the types of financial conflicts of interest as defined in this policy that must be reported pursuant to this section, the Foundation may require the reporting of other financial conflicts of interest, as the Foundation deems appropriate.

Remedies.

(a) If the failure of an Investigator to comply with the Foundation's financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the Third Party-Funded Research, the Foundation shall promptly notify the Third Party Awarding Entity of the corrective action taken or to be taken. The Third Party Awarding Entity will consider the situation and, as necessary, take appropriate action, or refer the matter to the Foundation for further action, which may include directions to the Foundation on how to maintain appropriate objectivity in the Third Party-Funded Research project. The Third Party Awarding Entity may, for example, require the Foundation to enforce any applicable corrective actions prior to award or prior to transfer when the transfer of such Third Party-Funded Research involves such an Investigator.

(b) The Third Party Awarding Entity and/or its affiliates may inquire at any time before, during, or after award into any Investigator disclosure of financial interests and the Foundation's review (including any retrospective review) of, and response to, such disclosure, regardless of whether the disclosure resulted in the Foundation's determination of a financial conflict of interest. The Foundation is required to submit, or permit on site review of, all records pertinent to compliance with this policy. To the extent permitted by law, the Third Party Awarding Entity and its affiliates will maintain the confidentiality of all records of financial interests. On the basis of its review of records or other information that may be available, the Third Party Awarding Entity may decide that a particular financial conflict of interest will bias the objectivity of the Third Party-Funded Research to such an extent that further corrective action is needed or that the Foundation has not managed the financial conflict of interest in accordance with this policy. In those cases, the Foundation understands, where appropriate, the Third Party Awarding Entity may be entitled to impose special award conditions, suspend funding or take other lawful enforcement action, as necessary until the matter is resolved.

(c) In any case in which the Third Party Awarding Entity or its affiliates determines that a Third Party-Funded Research project 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 financial conflict of interest that was not managed or reported by the Foundation as required by

this policy, the Foundation shall require the Investigator involved 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.