

IT BIO, LLC

Policies and Procedures for Financial
Disclosures and Conflicts of Interest in
Extramurally Sponsored Activities

Office of Director IT BIO

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**Policies and Procedures for
Financial Disclosures and Conflicts of Interest
(COI) in Extramurally Sponsored Activities**

Declaration of Policy

IT BIO, LLC is fully committed in complying, preserving, and strengthening conduct in research, which is ethical, maintains company integrity, and builds public trust. IT BIO, LLC personnel engaged in extramurally funded research, therefore, shall act in best interest of research development and public interest in a manner which is consistent with their public responsibilities and to the IT BIO and shall exercise great care that no detriment to the IT BIO is resulted from conflicts between their personal financial interests and the interests of the IT BIO. Such interests can compromise the integrity of research program, and the appropriate use of public resources for public good. Accordingly, investigators shall be obliged to disclose all significant financial interests they may have in extramurally funded research and shall comply with restrictions imposed by the IT BIO to manage, remedy, and eliminate conflicts relating to those interests.

This policy at the outset outlines the obligations of IT BIO staff to disclose significant financial interests and the responsibility of the IT BIO to review such information and take appropriate steps to manage, reduce, or eliminate related conflicts. Certain financial interests are inherent in the incentive structure of the for-profit enterprise. It is not the intent of this policy to prohibit all extramurally sponsored activities in which investigators hold a more easily defined significant financial interest, however, it is required that these interests be disclosed and that the project be conducted in such a way that such interests do not compromise, or appear to compromise, an investigator's professional judgment in conducting projects or reporting results.

This policy implements NIH requirements of 2011 FCOI regulation at [42 CFR Part 50 Subpart F](#). "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought." Our policy is guided per NIH policy: https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1.10_financial_conflict_of_interest.htm.

Applicability

This subpart of policy applies to all IT BIO employees and collaborators that is applying for, or that receives PHS research funding by means of a grant or cooperative agreement and, through the implementation of this subpart by the IT BIO, to each Investigator who is planning to participate in, or is participating in, such research; provided, however, that this subpart does not apply to SBIR Program Phase I applications.

IT BIO staff and collaborators at publicly funded or privately owned Universities and Research Institutions, and who serve as investigators in proposals submitted to external sponsors. Sub-awardees and their personnel must either comply with this policy or document that their institutions or organizations implement in compliance with requirements of 42 CFR Part 50, Subpart F, certifying that:

1. There is in effect at respective collaborating (sub-awardee) institutions an up-to-date, written and enforced administrative process to identify and manage Financial Conflicts of Interest (FCOI) with respect to all research projects for which NIH funding is sought or received;
2. The IT BIO shall promote and enforce Investigator compliance with the regulation's requirements including those pertaining to disclosure of Significant Financial Interests;
3. The IT BIO shall identify and manage FCOIs and provide initial and ongoing FCOI reports to the NIH consistent with this subpart;
4. When requested, the IT BIO will promptly make information available to the NIH/HHS relating to any Investigator disclosure of financial interests and the company's review of, and response to, such disclosure, whether or not the disclosure resulted in the IT BIO's determination of an FCOI;
5. The IT BIO shall fully comply with the requirements of the regulation.
6. The collaborating Institutions will be subject to the IT BIO's FCOI policy.

Definitions

Small Business Innovation Research (SBIR) Program means the extramural research program for small businesses that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as amended. For purposes of this subpart, the term SBIR Program also includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102-564.

Conflict of Interest is a divergence between an individual's private interests and his or her professional obligations to the IT BIO such that an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal gain, financial or otherwise.

Investigator refers to the Project Director/Principal Investigator, any other person identified by IT BIO as Senior/Key personnel in a grant application, progress report, or other report submitted to an external sponsor, and others who direct or can materially influence the research, or who are responsible for the design, conduct, and reporting of such research.

Significant Financial Interest means 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 to IT BIO or collaborating institution (sub-awardee):

(i) IT BIO regard a *significant financial interest* exists if the value of any remuneration received from the **publicly traded 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**, IT BIO considers 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) IT BIO require Investigators 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 responsibilities to IT BIO; 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 IT BIO's FCOI policy require specifying the details of this disclosure, which include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the IT BIO's FCOI policy, the IT BIO Director office 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 the PHS-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 IT BIO to the Investigator if the Investigator is currently employed or otherwise appointed by the IT BIO, including intellectual property rights assigned to the IT BIO and agreements to share in royalties related to such rights; any ownership interest in the IT BIO held by the Investigator, for commercial or for-profit organization; 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.

Responsibilities of IT BIO regarding investigator financial conflict of interests

IT BIO shall:

(a) Maintain an up-to-date, written, enforced policy on financial conflicts of interest that complies with this subpart, and make such policy available via a publicly accessible IT BIO Web site <http://www.itbiollc.com>. IT BIO shall make its written policy available to any requestor within five business days of a request.

(b) Inform each Investigator of the IT BIO'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 PHS-funded grant and at least every four years, and immediately when any of the following circumstances apply:

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

(2) An Investigator is new to an Institution; or

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

(c) If the IT BIO carries out the PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), the Institution (awardee Institution) must take reasonable steps to ensure that any subrecipient Investigator complies with this subpart by:

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

(i) If the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with this subpart. If the subrecipient cannot provide such certification, the

agreement shall state that subrecipient Investigators are subject to the financial conflicts of interest policy of the awardee Institution (IT BIO) for disclosing significant financial interests that are directly related to the subrecipient's work for the awardee Institution (IT BIO);

(ii) Additionally, if the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to the awardee Institution (IT BIO). Such time period(s) shall be sufficient to enable the awardee Institution (IT BIO) to provide timely FCOI reports, as necessary, to the PHS as required by this subpart;

(iii) Alternatively, if the subrecipient's Investigators must comply with the awardee Institution's (IT BIO's) financial conflicts of interest policy, the agreement referenced above specifies time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests to the awardee Institution. Such time period(s) is sufficient to enable the awardee Institution to comply timely with its review, management, and reporting obligations under this subpart.

(2) Providing FCOI reports to the PHS Awarding Component regarding all financial conflicts of interest of all subrecipient Investigators consistent with this subpart, *i.e.*, prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

(d) IT BIO designated Director to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the PHS-funded research.

(e)

(1) IT BIO require that each Investigator who is planning to participate in the PHS-funded research disclose to the IT BIO's designated official (Director) the Investigator's significant financial interests (and those of the Investigator's spouse and dependent children) no later than the time of application for PHS-funded research.

(2) IT BIO require each Investigator who is participating in the PHS-funded research to submit an updated disclosure of significant financial interests at least annually, in accordance with the specific time period prescribed by the IT BIO, during the period of the award. Such disclosure shall include any information that was not disclosed initially to the Institution 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 PHS-funded project that was transferred from another Institution), and shall include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest).

(3) IT BIO require each Investigator who is participating in the PHS-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 subpart for the designated institutional official(s) to determine whether an Investigator's significant financial interest is related to PHS-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 PHS-funded research when the Institution, through its designated official(s), reasonably determines that the significant financial interest: could be affected by the PHS-funded research; or is in an entity whose financial interest could be affected by the research. The Institution may involve the Investigator in the designated official(s)'s determination of whether a significant financial interest is related to the PHS-funded research. A financial conflict of interest exists when the Institution, through its designated official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

(g) IT BIO shall take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subrecipient 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 a mitigation report pursuant to [§ 50.605\(a\)](#).

(h) IT BIO provide initial and ongoing FCOI reports to the PHS as required pursuant to [§ 50.605\(b\)](#).

(i) IT BIO maintain records relating to all Investigator disclosures of financial interests and the IT BIO's review of, and response to, such disclosures (whether or not a disclosure resulted in the IT BIO's determination of a financial conflict of interest) and all actions under the IT BIO's policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in [45 CFR 75.361](#) for different situations.

(j) IT BIO 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 subpart applies, that the IT BIO:

(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 from the PHS;

(2) Shall promote and enforce Investigator compliance with this subpart'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 PHS Awarding Component consistent with this subpart;

(4) Agrees to make information available, promptly upon request, to the HHS relating to any Investigator disclosure of financial interests and the Institution's review of, and response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of a financial conflict of interest; and

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

Management and reporting of financial conflicts of interest

(a) Management and reporting of financial conflicts of interest.

(1) Prior to the IT BIO's expenditure of any funds under a PHS-funded research project, the Director IT BIO shall, consistent with [§ 50.604\(f\)](#): review all Investigator disclosures of significant financial interests; determine whether any significant financial interests relate to PHS-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 PHS-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 IT BIO, the Director of the Institution shall, within sixty days: review the disclosure of the significant financial interest; determine whether it is related to PHS-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, IT BIO 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 the Institution's review.

(3) Whenever IT BIO identifies a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the IT BIO during an ongoing PHS-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the Director IT BIO shall, within sixty days: review the significant financial interest; determine whether it is related to PHS-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 IT BIO to constitute a financial conflict of interest; failure by the IT BIO 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 IT BIO shall, within 120 days of the determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-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 IT BIO shall 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 IT BIO 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 IT BIO shall notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report will include, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the IT BIO'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 IT BIO will submit FCOI reports annually, as specified elsewhere in this subpart. Depending on the nature of the financial conflict of interest, an Institution may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date that the

financial conflict of interest or the Investigator's noncompliance is determined and the completion of the Institution's retrospective review.

(4) IT BIO shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

(5)

(i) Prior to the IT BIO's expenditure of any funds under a PHS-funded research project, the IT BIO 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 Institution 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 subpart;

(B) The IT BIO determines that the significant financial interest is related to the PHS-funded research; and

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

(ii) The information that the IT BIO 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) IT BIO shall post on its publicly available www.itbiollc.com database an updated at least annually. In addition, the IT BIO shall update the Web site within sixty days of the receipt or identification of information concerning any additional significant financial interest of the senior/key personnel for the PHS-funded research project that was not previously disclosed, or upon the disclosure of a significant financial interest of senior/key personnel new to the PHS-funded research project, if IT BIO determines that the significant financial interest is related to the PHS-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 IT BIO's identification of a new financial conflict of interest. If the IT BIO responds to written requests for the purposes of this subsection, the IT BIO 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 IT BIO'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 IT BIO'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 subpart that must be managed pursuant to this section, IT BIO shall place mechanism in place of managing other financial conflicts of interest in its policy on financial conflicts of interest, as IT BIO deems appropriate.

(b) Reporting of financial conflicts of interest.

(1) Prior to the IT BIO's expenditure of any funds under a PHS-funded research project, the Institution shall provide to the PHS Awarding Component an FCOI report regarding any Investigator's significant financial interest found by the Institution to be conflicting and ensure that the Institution has implemented a management plan in accordance with this subpart. In cases in which the Institution identifies a financial conflict of interest and eliminates it prior to the expenditure of PHS-awarded funds, the Institution shall not submit an FCOI report to the PHS Awarding Component.

(2) For any significant financial interest that the Institution identifies as conflicting subsequent to the Institution's initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator who is new to the research project), the Institution shall provide to the PHS Awarding Component, within sixty days, an FCOI report regarding the financial conflict of interest and ensure that the Institution has implemented a management plan in accordance with this subpart. 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 Institution (e.g., was not timely reviewed or reported by a subrecipient), the Institution also is required to complete a retrospective review to determine whether any PHS-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 Institution is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.

(3) Any FCOI report required under [paragraphs \(b\)\(1\)](#) or [\(b\)\(2\)](#) of this section shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of the Institution'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 PHS-funded research and the basis for the IT BIO's determination that the financial interest conflicts with such research; and

(viii) A description of the key elements of the IT BIO'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 IT BIO with regard to an ongoing PHS-funded research project, the IT BIO shall provide to the PHS Awarding Component 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 PHS-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 IT BIO shall provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

(5) In addition to the types of financial conflicts of interest as defined in this subpart that must be reported pursuant to this section, IT BIO require the reporting of other financial conflicts of interest in its policy on financial conflicts of interest, as the Institution deems appropriate.

Remedies

(a) If the failure of an Investigator to comply with an Institution'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 PHS-funded research, the IT BIO shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken.

(Action-A). The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the PHS-funded research project. PHS may, for example, require Institutions employing such an Investigator to enforce any applicable corrective actions prior to a PHS award or when the transfer of a PHS grant(s) involves such an Investigator.

(Action-B). The PHS Awarding Component and/or HHS may inquire at any time before, during, or after award into any Investigator disclosure of financial interests and the Institution's review (including any retrospective review) of, and response to, such disclosure, regardless of whether the disclosure resulted in the Institution's determination of a financial conflict of interest. An Institution is required to submit, or permit on site review of, all records pertinent to compliance with this subpart. To the extent permitted by law, HHS 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 PHS Awarding Component may decide that a particular financial conflict of interest will bias the objectivity of the PHS-funded research to such an extent that further corrective action is needed or that the Institution has not managed the financial conflict of interest in accordance with this subpart. The PHS Awarding Component may determine that imposition of specific award conditions under [45 CFR 75.207](#), or suspension of funding or other enforcement action under [45 CFR 75.371](#), is necessary until the matter is resolved.

(Action-C) In any case in which the HHS determines that a PHS-funded 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 financial conflict of interest that was not managed or reported by the Institution as required by this subpart, the Institution 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 .

Obligation to Disclose Financial Interests

By submitting a Significant Financial Interest Disclosure Form (attached below), each IT BIO staff who serves as an investigator on proposals submitted to external sponsors must disclose for himself or herself, and for his or her spouse and dependent children –

1. all significant financial interests that would reasonably appear to be affected by the activities funded or proposed for funding, and
2. all significant financial interests in entities whose financial position would reasonably appear to be affected by activities funded or proposed for funding.

Regardless of the above minimum requirement, an investigator in his or her best interest may choose to disclose other financial or related interests that could present, or be perceived to present, a conflict of interest. Also, it is not possible to specify all the possible personal relationships or business arrangements which might result in significant financial interests for IT BIO staff engaged in extramurally sponsored activities. In completing a Financial Disclosure Statement, however, IT BIO staff are expected to follow the spirit of this Policy and disclose other financial interests that might be anticipated to threaten the same harm. For example, the financial interests of a parent, sibling, independent child, unmarried domestic partner, or a close associate may be perceived as grounds for the same kind of conflict of interest, and should be reported, if known. Similarly, the promise of future gifts, or the offer of a loan on

advantageous terms not available to the general public, might represent a disclosable significant financial interest.

Review of Disclosures

A standing Financial Disclosure Review Committee (FDRC) comprised of Director IT BIO, administrative specialist, and a senior scientific staff at IT BIO shall be responsible for (a) reviewing financial disclosures, (b) developing or approving plans to manage or eliminate conflicts of interest, and (c) advising the campus community about this policy.

Conflict Resolution Plans

Final responsibility for the review of financial disclosures and approval of a Conflict Resolution Plan is vested with Director IT Bio. In the event that the resolution plan specified by the Director in consultation with senior scientific staff is deemed unacceptable to the investigator whose interests have been disclosed, he or she may request reconsideration, and may meet with the committee to explain why the plan is unacceptable and to propose changes.

Certification of Compliance

Each person judged to have a conflict of interest must sign an agreement certifying that he or she will adhere to all conditions or restrictions imposed by the Director IT Bio and senior research staff and will cooperate fully with any individual(s) assigned responsibility for monitoring compliance. IT BIO will not accept an award until the Director has received signed Certifications of Compliance for all project personnel judged to have a conflict of interest.

Updating Financial Disclosures

All investigators are responsible for updating information on new reportable significant financial interests, such that accurate and current information is on file with the IT BIO at all times.

Reporting

All investigators at IT BIO must submit a Financial Conflict of Interest (COI) Resolution Reporting Form for the project at least annually or more frequently if so required.

Record Keeping

The Office of Director IT BIO shall be responsible for maintaining records related to all disclosures, associated reviews and actions (whether or not a disclosure resulted in a determination of a financial conflict of interest), reporting/updating information, etc. The records shall be maintained for a minimum of three (3) years after the date of the termination or completion of the corresponding funded project, or the resolution of any audit or legal action involving the records.

Enforcement

Whenever an investigator has violated this policy or the terms of an approved Conflict Resolution Plan, the Director shall recommend sanctions which may include disciplinary action ranging from a letter of reprimand to termination of employment.