

## **INLIGHTA BIOSCIENCES POLICY ON FINANCIAL DISCLOSURES IN SPONSORED PROJECTS**

Responsible Officer: Director of Research Development

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Section I:	Introduction
Section II:	Definitions
Section III:	Application
Section IV:	Research Financial Conflict of Interest Disclosure, Review and Management
Section V:	Monitoring of Management Plans
Section VI:	Audit
Section VII:	IRB Review of Research Financial Conflicts of Interest
Section VIII:	Investigation and Resolution of Policy Violations
Section IX:	Appeals
Section X:	Sanctions for Policy Violations
Section XI:	Additional Reporting Requirements
Section XII:	Records Management
Section XIII:	Publication of Policy

### **Section I: Introduction**

#### **A. Purpose:**

The purpose of this policy is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, or reporting of funded research, grants or cooperative agreements will be free from bias resulting from an Investigator's financial conflicts of interest (and/or of the Investigator's spouse and/or dependent children). This policy complies with the following federal regulations:

- Title 42 Code of Federal Regulations (CFR), Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought ([Code of Federal Regulations \(govinfo.gov\)](https://www.govinfo.gov))

#### **B. Scope:**

This policy applies to Investigators participating in, or planning to participate in the design, conduct, reporting or proposing research funded by National Institute of Health (NIH) or Public Health Service (PHS).

If a research project involves subcontractors, subgrantees, or sub awardees (collectively subrecipients), the subrecipient institution must provide written assurance that a financial conflict of interest in research policy is in effect at that institution and compliant with all applicable federal regulations. Should National Institute of Health (NIH) or Public Health Service (PHS) funds be subcontracted by InLighta to a subrecipient institution without a

conflict of interest in research policy, a written agreement must state that this policy shall apply to the subrecipient.

## Section II: Definitions

- A. **Financial Interest** means anything of monetary value or potential monetary value held by the Investigator, the Investigator's spouse and/or dependent children, regardless of whether or not the value is readily ascertainable.
- B. **Financial Conflict of Interest** means a Significant Financial Interest (see below) related to a research program or project that could directly and significantly affect the design, conduct or reporting of research.
- C. Significant Financial Interest (SFI) **means a** financial interest consisting of one or more of the following interests of the Investigator (and/or of the Investigator's spouse and/or dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:
1. 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 the 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 interests includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
  2. Regarding 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 (and/or the Investigator's spouse and/or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
  3. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
  4. For PHS-funded investigators, any reimbursed or sponsored travel related to an Investigator's institutional responsibilities, including that which is paid on behalf of the investigator so that the exact monetary value may not be readily available.
  5. The term *significant financial interest* **does not include** the following types of financial interests:
    - a. Salary or consulting fees paid by InLighta to the Investigator if the Investigator is currently employed or otherwise appointed by InLighta.
    - b. Income from seminars, lectures, or teaching engagements sponsored by a federal, state or local agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education..

- c. Income from service on advisory committees or review panels for a federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
- d. Travel by a PHS-funded Investigator that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

### **Section III: Application**

In order to address potential Research Financial Conflicts of Interest, Investigators must make full disclosure of relevant information related to any Significant Financial Interest so that the appropriate parties may evaluate such information as set forth below.

### **Section IV. Research Financial Conflict of Interest Disclosure, Review and Management**

#### **A. Training**

Each Investigator is responsible for understanding this Policy and all applicable laws and regulations relating to Research Financial Conflicts of Interest. Each Investigator must complete training specific to Research Financial Conflicts of Interest (hereinafter referred to as the "Training"). Each Investigator must complete the Training prior to engaging in activities pursuant to the Sponsored Project and at least every four (4) years thereafter at the discretion of the Conflict of Interest Officer.

If an Investigator is added to a Sponsored Project after the commencement of the Sponsored Project activities, such Investigator must complete the Training prior to engaging in activities pursuant to the Sponsored Project.

For projects funded by PHS agencies, if the Sponsored Project involves a subcontract or consulting agreement for individuals outside InLighta to conduct a portion of the Sponsored Project, such individuals may have to complete the Training if they are responsible for the design, conduct, performance or reporting of the Sponsored Project. For more information on the applicability of this Policy to sub-recipients and consultants, see Section IV.I below.

#### **B. Disclosure of Significant Financial Interests**

In addition to the training described above, all Investigators must disclose their Significant Financial Interests so that InLighta can determine if those interests are related to a Sponsored Project in which such Investigator is involved.

1. Annual Disclosure. Each year any investigator who conducts research on any InLighta project must disclose via the electronic system all significant financial interests (SFIs) that are relevant to an investigator's institutional research responsibilities or within 30 days after he/she becomes aware of new SFI or after a financial conflict of interest has been eliminated.

Where required by the external sponsor, InLighta shall not submit a Sponsored Project proposal to an external sponsor unless each Investigator has completed the Disclosure of Significant Financial Interest Form and the PI/PD has provided the certification that all Significant Financial Interests have been disclosed. For clarification, InLighta may proceed with proposal submission once all Disclosure of Significant Financial Interest Forms for all Investigators have been received and the PI/PD has certified that all Investigators involved in the PI/PD's Sponsored Project have completed a Disclosure of Significant Financial Interest Form.

2. Proposal Development. Transactional disclosure by the PI is also required at the time a research proposal is submitted to InLighta's Grants Director in order to ensure compliance with Federal disclosure and management requirements. Whenever an Investigator discovers or acquires a new Significant Financial Interest, he or she must complete a Disclosure of Significant Financial Interest Form within thirty (30) days of discovering or acquiring the new Significant Financial Interest.
3. New Investigators Added to an Ongoing Sponsored Project. When an Investigator is added to an ongoing Sponsored Project, he or she must complete a Disclosure of Significant Financial Interest Form.

#### **C. Review of Significant Financial Interests by Conflict of Interest Officer**

The Conflict of Interest Officer shall review all disclosed Significant Financial Interests to determine whether or not a Significant Financial Interest relates to a proposed Sponsored Project and whether or not it would be considered a Research Financial Conflict of Interest. The Conflict of Interest Officer may contact the Investigator to request additional information he or she deems necessary to evaluate the Significant Financial Interest, and any failure by the Investigator to respond to such requests will delay the activation and expenditures of the Sponsored Project funds.

When the Conflict of Interest Officer has made a determination as to whether or not a Significant Financial Interest creates a Research Financial Conflict of Interest with regard to the Sponsored Project, he or she shall notify OSP.

When required by the sponsor, OSP shall certify in each application for funding for Sponsored Projects, in a manner specified by the sponsor, that InLighta:

1. has in effect an up-to-date, written, and enforced administrative process to identify and manage Research Financial Conflicts of Interest;
2. shall promote and enforce Investigator compliance with all applicable laws and regulations regarding Significant Financial Interests;
3. shall manage Research Financial Conflicts of Interest and provide initial and ongoing reports to the sponsor regarding such; and
4. agrees to make information available to the sponsor, upon the sponsor's request, relating to any Investigator disclosure of Significant Financial Interests and InLighta's review of, or response to, such disclosure, whether or not the disclosure resulted in a determination of a Research Financial Conflict of Interest.

If the Conflict of Interest Officer determines that a Significant Financial Interest creates a Research Financial Conflict of Interest, InLighta shall not allow expenditures of Sponsored Project funds from a sponsor until a Management Plan is implemented. In addition, for PHS funded projects, OSP must provide the PHS sponsor with a COI Report (defined below).

#### **D. Development of Management Plan**

If the Conflict of Interest Officer determines that the Significant Financial Interest relates to the proposed Sponsored Project, and creates a Research Financial Conflict of Interest, he or she shall, in consultation with the Investigator and InLighta Attorney (or his/her designee), develop a Management Plan.

At a minimum, a Management Plan shall contain:

1. a description of the Significant Financial Interest and how it creates a Research Financial Conflict of Interest;
2. the role and function of the conflicted Investigator in the Sponsored Project;
3. the rationale for including the conflicted Investigator in the Sponsored Project;
4. the conditions of the Management Plan;
5. how the Management Plan will safeguard objectivity in the Sponsored Project;  
and
6. confirmation of the Investigator's agreement to the Management Plan.

#### **E. Review by Conflict of Interest Committee and Approval of Management Plan**

The Conflict of Interest Officer shall submit each proposed Management Plan to the Conflict of Interest Committee for its review and approval in a timely manner. The Conflict of Interest Committee may contact the Investigator to request additional information it deems necessary to evaluate the Management Plan, and any failure by the Investigator to comply with such requests within three (3) business days will be considered a violation of this Policy.

In certain cases, a potential Research Financial Conflict of Interest may require correction or management before the Conflict of Interest Committee will have an opportunity to convene and evaluate the Management Plan. In those cases, the Conflict of Interest Officer may provide provisional approval of a Management Plan until such time as the Conflict of Interest Committee can complete its review. Any Management Plan approved by the Conflict of Interest Committee or provisionally approved by the Conflict of Interest Officer will be considered an "approved" Management Plan for the purposes of this Policy.

While the Conflict of Interest Officer and Conflict of Interest Committee will seek comments to a proposed Management Plan from the Investigator and will strive to create Management Plans that are acceptable to all interested parties, the Conflict of Interest Officer and Conflict of Interest Committee will have final discretion to determine the restrictions and conditions required to ensure InLighta's compliance with this Policy and its obligations to sponsors and other stakeholders.

After a Management Plan has been approved, the Conflict of Interest Officer shall provide a copy of the Management Plan to the Investigator, the Responsible Representative, OSP, and if

human participants are involved, the Institutional Review Board (IRB). Each Investigator is required to comply with any approved Management Plan relating to his or her activities, and the Management Plan shall provide that the relevant Investigators must agree in writing to abide by the Management Plan before the affected Sponsored Project may proceed.

InLighta shall not execute award documents or allow expenditures of research or service funds from external sponsors unless the PI/PD and each Investigator to be involved in the design, conduct or reporting of the Sponsored Project have agreed to abide by any and all conditions or restrictions imposed by the Management Plan (or alternatively, to be removed from the Sponsored Project) and the Research Financial Conflict of Interest has been disclosed to the sponsor if required by the sponsor.

#### **F. Public Disclosure of Research Financial Conflicts of Interest in PHS Funded Projects**

For those Sponsored Projects funded by PHS agencies that have a managed Research Financial Conflict of Interest for a Key Personnel, the Conflict of Interest Officer shall be responsible for completing the Public Disclosure of a Research Financial Conflict of Interest Involving Sponsored Research Form (the "Public Disclosure Form") and maintaining the Public Disclosure Form in his or her files. The Conflict of Interest Officer, or his or her designee, shall make the Public Disclosure Form available to any requesting party within five (5) business days of the request (postmark if by letter; date of transmission if by electronic means). The Conflict of Interest Officer shall be responsible for updating the information included in the Public Disclosure Form at least annually and within sixty (60) days of the receipt or identification of information concerning any additional Significant Financial Interest. However, there is no obligation to provide a requesting party with an updated Public Disclosure Form unless it is pursuant to a subsequent request.

#### **G. Disclosure of Research Financial Conflicts of Interest to PHS Agencies**

InLighta is required to disclose specific information on Significant Financial Interests that cause Research Financial Conflicts of Interest to PHS agency sponsors prior to executing award documents or allowing expenditures of funds related to the PHS funded Sponsored Project. OSP shall be responsible for disclosing this information to the PHS agency sponsor in the manner set forth by the sponsor (such report a "COI Report"). In cases where a Research Financial Conflict of Interest is completely eliminated (not simply managed) prior to the expenditure of funds related to the Sponsored Project, no COI Report is required.

Additionally, during the term of the PHS funded Sponsored Project, for each Significant Financial Interest determined to be a Research Financial Conflict of Interest, the Conflict of Interest Officer shall provide OSP with an annual report (the "Annual Report") that addresses the status of the Research Financial Conflict of Interest and any changes to the Management Plan. OSP shall then provide the Annual Report to the PHS agency sponsor in the manner specified by such sponsor.

#### **H. Previously Undisclosed Significant Financial Interests in PHS Funded Sponsored Projects**

Whenever, during the course of an ongoing PHS funded Sponsored Project, (i) a new Investigator participating in the Sponsored Project discloses a new Significant Financial Interest as required by this Policy or (ii) an existing Investigator discloses a new Significant Financial

Interest as required by this Policy, the Conflict of Interest Officer shall, within sixty (60) days, review and manage the Significant Financial Interest in the manner set forth above. OSP shall then promptly provide a COI Report to the PHS agency sponsor regarding the new Significant Financial Interest.

Whenever, in the course of an ongoing PHS funded Sponsored Project, a Significant Financial Interest is identified that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the Conflict of Interest Officer, the Conflict of Interest Officer shall, within sixty (60) days, review the Significant Financial Interest in the manner set forth above. If the Significant Financial Interest creates a Research Financial Conflict of Interest, the Conflict of Interest Officer shall implement a Management Plan in the manner set forth above and implement, at least on an interim basis, a mitigation plan which shall specify actions that have been taken to manage the Financial Conflict of Interest. In these instances where a Financial Conflict of Interest is determined, the Conflicts of Interest Officer shall, within one hundred and twenty (120) days of the disclosure, complete a retrospective review and determination as to whether the Sponsored Project was biased in the design, conduct or reporting of the research involved. The Conflict of Interest Officer must document the retrospective review and Management Plan, such documentation to include the following elements:

- Project number and title
- Contact PD/PI for the project
- Name of the individual with the Research Financial Conflict of Interest
- Name of the entity with which the individual has a Research Financial Conflict of Interest
- Reason for the retrospective review
- Detailed methodology used for the retrospective review
- Findings and conclusions of the review
- A description of the impact of any bias on the project and InLighta's actions to eliminate or mitigate the effect of the bias

The Conflict of Interest Officer shall provide the Management Plan regarding the new Research Financial Conflict of Interest to OSP. The Conflict of Interest Officer will provide OSP with a description of the retrospective review and whether the Sponsored Project was biased in the design, conduct or reporting of the research. OSP shall then provide the COI Report to the PHS agency sponsor in the manner specified by the sponsor.

## **I. Consultants and Sub-Recipients**

1. Sponsored Projects not funded by PHS agencies. Consultants and subrecipients on Sponsored Projects not funded by a PHS agency are not subject to the training and disclosure requirements set forth in this Policy. However, OSP shall require consultants and sub-recipients of Sponsored Project funds to certify in a written agreement with InLighta that either (a) no Research Financial Conflict of Interest exists or (b) that any Research Financial Conflict of Interest has been disclosed to InLighta.
2. Sponsored Projects funded by PHS agencies. The PI/PD on a Sponsored Project funded by a PHS agency is the most appropriate person to determine whether or not each individual involved on the Sponsored Project through a consulting agreement or sub-recipient agreement will be responsible for the design, conduct, performance, or reporting of the Sponsored Project. Each consultant or sub-recipient that is responsible for the design,

conduct, performance, or reporting of the Sponsored Project shall hereinafter be referred to as a "Subcontractor Investigator."

- a. For those Subcontractor Investigators whose home institutions have a PHS-compliant conflict of interest policy, the written agreement with InLighta shall include a certification that the Subcontractor will comply with its own policy. The written agreement with the Subcontractor shall include:
  - i. a certification by the Subcontractor that its policy complies with all applicable laws, regulations and rules (including, but not limited to, 42 CFR Part 50 and 45 CFR Part 94); and
  - ii. time periods for the Subcontractor to report all identified Research Financial Conflicts of Interest to InLighta; such time periods shall be sufficient to enable InLighta to provide timely COI Reports, as necessary, to the PHS agency sponsor.
- b. Those Subcontractor Investigators whose home institutions do not have a PHS-compliant conflict of interest policy must abide by the following requirements:
  - i. The Subcontractor Investigator must disclose all Significant Financial Interests that are directly related to his or her work on the Sponsored Project to InLighta prior to proposal submission; and
  - ii. The Subcontractor Investigator must complete the Training prior to beginning work on the Sponsored Project.

In addition, the written agreement with the Subcontractor shall state that the Subcontractor is responsible for complying with these requirements.

## **Section V: Monitoring of Management Plans**

The Conflict of Interest Officer will have primary responsibility for monitoring the implementation and effectiveness of a Management Plan. A Management Plan may provide for the appointment of an individual or a special monitoring committee to provide direct oversight of the implementation of a Monitoring Plan, and the Conflict of Interest Officer, at his or her discretion, may appoint such additional monitors to assist with monitoring. Appointed monitors should be disinterested, free of financial or supervisory ties to the Investigator whose conflict is being monitored, and should have or have access to expertise sufficient to allow meaningful review of the conflict being monitored.

At least once a year, the Conflict of Interest Officer should complete a review of all outstanding Management Plans and provide a summary of the review to the Conflict of Interest Committee. To assist in these evaluations, Investigators may be required under their Management Plans to provide annual or other periodic reports on their compliance with the plan.

## **Section VI: Audit**

The Conflict of Interest Officer may conduct audits of any InLighta activities relating to past disclosures under this Policy or any Management Plans in order to assure (1) that all relevant Research Financial Conflicts of Interest have been identified and are being managed appropriately and (2) that any systemic weaknesses in the process of Significant Financial Interest disclosure, review, approval and management at InLighta are identified and resolved. All Investigators shall



cooperate with such audits, including requests for documentation, and failure to do so will be deemed a violation of the Policy.

### **Section VII: IRB Review of Research Financial Conflicts of Interest**

For research involving human subjects, all Significant Financial Interest Disclosure Forms shall be shared with the Institutional Review Board. The IRB retains final authority over human subjects research and may decline to approve an application on grounds of Research Financial Conflict of Interest notwithstanding a decision by the Conflict of Interest Officer or the Conflict of Interest Committee that there is no Research Financial Conflict of Interest or that an identified Research Financial Conflict of Interest is capable of being managed

### **Section VIII: Investigation and Resolution of Policy Violations**

Any person that becomes aware of a potential violation of this Policy should notify the Conflict of Interest officer. Any time the Conflict of Interest Officer becomes aware of a potential violation of the Policy or of any other situation that could indicate that InLighta activities may have been affected inappropriately by a research Financial Conflict of Interest, the Conflict of Interest Officer shall conduct a preliminary investigation to determine whether the concerns appear to be warranted.

In consultation with the Legal Affairs Consultant, the Conflict of Interest Officer may: investigate the matter and make a written memorandum of his or her conclusions or appoint a special consultant to conduct an investigation and file a written report of the results of that investigation. Any such investigation should, at a minimum, include a personal interview with the person bringing the allegations or concerns and a personal interview with the Investigator, who should be informed with specificity of the allegations or concerns that have arisen. The President shall have the authority to direct that the research activities of the Investigator affected by the violation be suspended pending conclusion of an investigation

Upon determination that a violation of this Policy has occurred or of the existence of a situation that could indicate that InLighta research may have been affected inappropriately by a Conflict of Interest, the Conflict of Interest Officer shall notify the President and recommend measures to ameliorate the effects of the violations, and the President shall take any steps necessary to correct the situation, including and up to disallowance of an activity previous allowed to continue under a Management Plan. In addition, when appropriate, the President shall recommend to the relevant officials the imposition of disciplinary or other actions.

### **Section IX. Appeals**

Investigators may appeal SAC decisions in writing within 15 days of receipt of the finalized action plan or other decision of the committee. The written appeal should include details regarding circumstances which support the request for a proposed revision to a SAC decision. An Appeals Committee will be formed for purposes of investigating the appeal and making a final decision. A meeting of the Appeals Committee will be convened to review the SFI information, the Management and Monitoring Plan, and previous meeting minutes, to make a decision. The Investigator may be invited to describe reasons for the appeal and to address further questions. The appeals process will take no more than 60 days from the date requested by the Investigator. The decision of the Appeals Committee is final and binding.

### **Section X. Sanctions for Policy Violations**

Possible sanctions for violation of this Policy by an Investigator may range from administrative intervention to termination of employment, all in accordance with applicable InLighta policies.

Violations may include but are not limited to: (a) failure to comply with the disclosure and evaluation process provided under this policy (by failing to report timely a potential conflict as required, by failing or refusing to respond to requests for additional information, by providing incomplete or knowingly inaccurate information, or otherwise) and (b) failure to comply with a Management Plan.

### **Section XI: Additional Reporting Requirements**

The following **additional** requirements also apply to all research funded by the PHS of the U.S. Department of Health and Human Services and any PHS Awarding Component including the NIH.

InLighta will provide to the PHS Awarding Component a FCOI report as outlined in the regulations:

Initial Report: Prior to expenditure of any funds under the NIH-funded research project, the Institution will provide a FCOI report regarding any SFI found to be a FCOI. InLighta will also provide a FCOI report within 60 calendar days from the date of a new SFI disclosure determined to be a FCOI, a new Investigator with an identified FCOI becomes engaged in the project or when the Institution identifies a FCOI not previously disclosed. This report will include the following information:

- Grant/Contract Number
- PD/PI
- Name of Investigator with FCOI
- Nature of the FCOI (e.g., equity, consulting fees, travel reimbursement or honoraria)
- Value of the financial interest 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
- Description of how FCOI relates to PHS-funded research and the basis for the determination that the financial interest conflicts with such research
- Key elements of the FCOI action plan

Annual updates to this report will be submitted to the PHS Awarding Component for the duration of the research project. The annual report will include:

- Status of the FCOI
- Changes to the action plan
- Justification that an FCOI no longer exists

If InLighta is unable to satisfactorily manage a conflict of interest involving NIH funding, it will appropriately notify NIH's Office of the General Counsel.

### **Section XII: Records Management**

OSP and the Conflict of Interest Officer shall maintain all records relating to the disclosure and management of Significant Financial Interests under this Policy. All such documents will be retained for period of at least three (3) years beyond the termination or completion of the Sponsored Project to which they relate or until the resolution of any action involving such records, whichever is longer.

### **Section XIII: Publication of Policy**

The Conflict of Interest Officer shall ensure that the most recent version of this Policy is at all times accessible to the public on the InLighta website.

In addition, information concerning identified FCOIs held by senior/key personnel will be made available to requestors via **an email** response within five business days from when the Research Official receives the request. This information may be requested by **emailing [jjyang@inlighta.com](mailto:jjyang@inlighta.com)**

The written response will include:

- Senior/key personnel name
- Senior/key personnel's role in the research project
- Name of the entity in which the FCOI is held
- Nature of the FCOI
- Approximate dollar value of the FCOI or a statement that the value cannot be readily determined

This information will remain available for three years from the date the information was most recently updated.