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POLICY ON FINANCIAL CONFLICT OF INTEREST IN PUBLIC HEALTH SERVICE FUNDED RESEARCH

1. PURPOSE

- 1.1. This Policy entitled “Policy on Financial Conflict of Interest in Public Health Service Funded Research” implements Financial Conflict of Interest (FCOI) Disclosure requirements found in 42 CFR Part 50, Subpart F, “Promoting Objectivity in Research” and 45 CFR Part 94, “Responsible Prospective Contractors” which are applicable to research funded by the Public Health Services (PHS). These requirements are applicable to all research projects for which InBios International, Inc. (InBios) applies for, or receives, research funding from PHS except for Phase I SBIR or STTR Research project.
- 1.2. The purpose of this policy is to ensure objectivity in which research projects are designed, conducted, or reported by managing any FCOI that occurs between an investigator’s personal financial interest and their professional interests with respect to research conducted with PHS funding. This policy establishes process of disclosure and review when an investigator has a FCOI. If InBios determines that such an FCOI might reasonably appear to affect the research directly and or significantly, InBios will work with the Investigator to develop a mitigation plan to manage or eliminate the conflict in accordance with this policy.

2. SCOPE

- 2.1. Each Investigator, as defined in the Policy, who will participate, or is participating, in such research, must follow this policy and complete the required training. Subcontractors and consultants who perform services within the definition of an Investigator must either maintain a policy that complies with the requirement of 42 CFR Part 50 Subpart F and 45 Part 94 or comply with this policy.

3. DEFINITIONS

- 3.1. The following definitions are provided as reference and are considered Key definitions in understanding the FCOI federal regulations. A complete list of official definitions can be found at 42 CFR 50.603.
- 3.2. **Financial Conflict of Interest (FCOI)** is a Significant Financial Interest (SFI) that could directly and significantly affect the design, conduct or reporting of PHS Funded Research.
- 3.3. **Financial Interest** means anything of monetary value, whether or not the value is readily ascertainable.
- 3.4. **Institutional Responsibilities** means an Investigator's professional responsibilities performed on behalf of InBios, and as defined by InBios in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and safety monitoring board.



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3.5. **PD/PI** means a project director or principal investigator of a PHS-Funded Research project, the PD/PI is included in the definition of senior/key personnel and investigator.

3.6. **Investigator** is any individual, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed such funding which may include consultants and subcontractors.

3.7. **Significant Financial Interest (SFI)** means:

3.7.1. 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 appear to be related to the investigator's institutional responsibilities:

3.7.1.1. With regard to any publicly traded entity, a SFI 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

3.7.1.2. With regard to any non-publicly traded entity, a SFI 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

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

3.7.2. 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 institutional 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 located in the United States, a United States 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 a United States Institution of higher education.

3.7.3. The term SFI does **not** include the following types of financial interests:

3.7.3.1. Salary, royalties, or other remuneration paid by InBios to the Investigator if the Investigator is currently employed or otherwise appointed by InBios.

3.7.3.2. Intellectual property rights assigned to InBios and agreements to share in royalties related to such rights.

3.7.3.3. Any ownership interest in InBios held by the Investigator

3.7.3.4. 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.

3.7.3.5. Income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency located in the United States, a United States Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education.

3.7.3.6. Income from service on advisory committees or review panels for a Federal, state, or local government agency located in the United States, a United States Institution of higher education, an academic



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teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education.

4. TRAINING REQUIREMENTS

4.1. Each investigator who plan on participating in or are currently participating in NIH-Funded research must be informed of InBios's FCOI policy, the federal regulation 42 CFR 50 subpart F, and the responsibility to disclose FCOIs. It shall be the responsibility of the PI of the research project to identify all investigators who have an SFI requiring disclosure under this policy and to ensure that an SFI Disclosure Form is prepared and submitted.

4.2. Investigators must be trained to 42 CFR Part 50 Subpart F, and InBios's FCOI policy:

4.2.1. Prior to engaging in NIH Funded Research

4.2.2. Every four years

4.2.3. Immediately if:

4.2.3.1. InBios's FCOI policy is revised

4.2.3.2. Investigator is new to the company

4.2.3.3. Investigator is not in compliance with FCOI policy or management plan

4.3. Training constitutes investigator certifying they have read and reviewed:

4.3.1. InBios's FCOI policy

4.3.2. NIH's "FCOI Training" on regulation 42 CFR Part 50 Subpart F. Upon completion of the training, A certificate of completion must be stored in the company's secured Financial Records drive on company server. NIH's online tutorials can be accessed at: <https://grants.nih.gov/grants/policy/coi/fcoi-training.htm>

4.4. The FCOI policy has been added to the company's shared "Document Control" management software and on InBios's publicly available website.

5. DISCLOSURE REQUIREMENT

5.1. Each Investigator who is planning to participate in PHS funded research is required to disclose to InBios any SFIs, including any SFI of their spouse or dependent children by completing the disclosure form provided by InBios:

5.1.1. No later than the time of application for PHS funded research

5.1.2. At least annually during the period of award

5.1.3. Within thirty days of discovering or acquiring a new SFI.

5.2. If Investigator does not have any SFIs to report, the investigator must still complete the disclosure form both initially and annually.

6. REVIEW AND MONITORING REQUIREMENTS



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- 6.1. InBios will designate an Institutional Official (IO) to review SFI disclosure to determine FCOI.
- 6.2. An Investigator's SFI is related to PHS-funded research when InBios through the IO reasonably determines that the SFI: could be affected by the PHS-funded research; or is in an entity whose financial interest could be affected by the research, InBios may involve the Investigator in the InBios IO's determination of whether a SFI is related to the PHS-funded research.
- 6.3. A FCOI exists when InBios, through the IO reasonably determine that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. If so, then then steps will be taken to determine what measures are needed to address the SFI identified in the SFI Disclosure Form. A management plan may be required to outline the terms, conditions, and restrictions, if any, to ensure compliance with this policy. (See under Enforcement)
- 6.4. In the case an SFI is determined to be an FCOI, the company will manage the FCOI at its discretion. This may include full public disclosure, appointment of an independent monitor, modification of the research plan, change of personnel on the NIH-funded research, etc.
- 6.5. Prior to InBios's expenditure oh NIH funds the Institutional Official must:
 - 6.5.1. Review all Investigator SFI disclosures
 - 6.5.2. Determine if any SFIs relate to the Investigators NIH-funded research
 - 6.5.3. Determine if an FCOI
 - 6.5.4. Design and implement a management plan to manage the FCOI.
- 6.6. In the case a new Investigator begins to work on the NIH-funded research project or an existing Investigator discloses a new SFI, the IO shall within 60 days review the SFI disclosures, determine whether an FCOI exists, and, if so, implement a management plan that specifies the actions that have been and will be taken to manage the FCOI.
- 6.7. In the case the company identifies an SFI that was not disclosed timely by an Investigator or was not previously reviewed by the company during an ongoing NIH- funded research project, the IO shall within 60 days review the SFI disclosures, determine whether an FCOI exists, and, if so, implement a management plan that specifies the actions that have been and will be taken to manage the FCOI going forward.
- 6.8. The company will manage FCOIs of all Investigators, including those of a subrecipient Investigator, if applicable, and monitor Investigator compliance with management plans until completion of the project.

7. REPORTING OF FCOI

- 7.1. InBios must send initial, annual and any revised FCOI reports to the NIH via Era Commons FCOI Module for the institution and subrecipients as required by the regulation and as stated below:
 - 7.1.1. Prior to expenditure of funds
 - 7.1.2. Within sixty (60) days of identification for an investigator who is newly participating in the project.
 - 7.1.3. Within sixty (60) days for new, or newly identified, FCOIs for existing investigators



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- 7.1.4. At least annually, at the same time as when the company is required to submit the annual progress report. The annual report will provide the status of the FCOI and any changes to the management plan until completion of the project
- 7.1.5. After a retrospective review to update a previously submitted report if new information is discovered following completion of the review.
- 7.2. InBios must notify NIH promptly if bias is found with the design, conduct or reporting of NIH-funded research and submit the required Mitigation Report that will detail the action(s) taken to mitigate the effects of the bias. The company will report all elements as required by 42 CFR Part 50 Subpart F. (Entity name.; name of Investigator with FCOI; Nature of the SFI; Value of the SFI; etc.)
- 7.3. InBios must notify NIH promptly if an Investigator fails to comply with the company FCOI policy or if an FCOI management plan appears to have biased the design, conduct, or reporting of the NIH-funded research. The company will take corrective action for noncompliance with InBios's FCOI policy or the management plan.

8. MAINTENANCE OF RECORDS

- 8.1. InBios will maintain all FCOI-related records relating to all Investigator disclosure of financial interest and the company's review of, and response to, such disclosures (whether or not a disclosure resulted in the company determining of a FCOI) and all actions under InBios's policy or retrospective review, if applicable:
 - 8.1.1. For at least three (3) years from the date the final expenditure report is submitted
 - 8.1.2. Or, where applicable, from other dates specified in 45 CFR 75.361.

9. ENFORCEMENT

- 9.1. The management plan may require one or more of the following actions (but not limited to) to be taken to manage, reduce or eliminate any actual or potential conflict of interest:
 - 9.1.1. Disqualification from participation in all or portion of the research funded.
 - 9.1.2. Modification to research plan
 - 9.1.3. Public disclosure of significant financial interests
 - 9.1.4. Severance of relationships that create actual or potential conflicts
 - 9.1.5. In the case an Investigator fails to comply with InBios's FCOI policy or an FCOI management plan, employee sanctions, or other administrative actions will be implemented. These may include a letter of reprimand, restriction on the use of funds, or termination from the company.
- 9.2. InBios will perform a retrospective review with 120 days of determination of noncompliance when either an SFI is not disclosed timely or not previously reviewed or when an FCOI is not identified or managed in a timely manner including:
 - 9.2.1. Failure by the Investigator to disclose a significant financial interest that is determined by the company to constitute an FCOI.
 - 9.2.2. Failure by the company to review or manage an FCOI.
 - 9.2.3. Failure by the Investigator to comply with the FCOI management plan.



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9.3. The retrospective review will be documented and will include, at minimum, the following

- 9.3.1. Project Number
- 9.3.2. Project Title
- 9.3.3. PD/PI and contact information
- 9.3.4. Name of Investigator with FCOI
- 9.3.5. Name of the entity with investigator with FCOI
- 9.3.6. Reason for the retrospective review
- 9.3.7. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documentation reviewed)
- 9.3.8. Findings of the review
- 9.3.9. Conclusion of the review

10. SUBRECIPIENT REQUIREMENT

- 10.1. When applicable, InBios will comply with all subrecipient requirements according to 42 CFR 50.604(c) and NIH Grants Policy Statement 15.2.1.
- 10.2. InBios will establish, via a written agreement, whether the subrecipient will follow InBios's FCOI policy or the FCOI policy of the subrecipient. In the case of the latter:
 - 10.2.1 InBios will obtain a certification from the subrecipient that its FCOI policy complies with 42 CFR Part 50 Subpart F
 - 10.2.2 Include in the written subrecipient agreement requirement for the subrecipient to report identified FCOIs for its Investigators in a time frame that allows the awardee institution to report identified FCOIs to the NIH as required by the regulation
 - 10.2.3 Alternatively, include in the written agreement a requirement to solicit and review subrecipient Investigator disclosures that enable the awardee institution to identify, manage and report identified FCOIs to the NIH

11. PUBLIC ACCESSIBILITY

- 11.1. InBios's FCOI policy will be stored on the company's shared Document Control management software and on a publicly available website and will:
 - 11.1.1. Should a written request be received, in lieu of accessing the FCOI policy on a publicly accessible Web site, the policy will be made available within five (5) business days of the written request.
 - 11.1.2. Be updated at least annually.
 - 11.1.3. Be updated with sixty (60) days of newly identified FCOI, but response to written request should include the updated information.
 - 11.1.4. Remain available for three (3) years from the date the information was most recently updated