

## POLICY ON FINANCIAL CONFLICTS OF INTEREST

### 1. PURPOSE OF POLICY

**1.1.** This Policy entitled “Policy on Financial Conflicts of Interest” implements Financial Conflicts 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 U.S. Public Health Service (PHS). These requirements are applicable to all PHS funded Research projects for which Eitr Biologics, Inc. (“Eitr”) applies for, or receives, except for Phase I SBIR or STTR Research projects.

**1.2.** This Policy is intended to ensure objectivity in which proposed or ongoing Research projects are designed, conducted, or reported by managing any FCOI that occurs between an Eitr Investigator’s personal financial interests and their professional interests with respect to Research conducted with PHS funding. The Policy establishes a process of disclosure and independent review when an Investigator has a FCOI. If Eitr determines an FCOI might reasonably appear to affect the Research directly and/or significantly, Eitr will develop a mitigation plan to either manage or eliminate the conflict in accordance with this Policy.

### 2. SCOPE OF THE POLICY

**2.1.** Each Investigator, as defined in the Policy, who will participate, or is participating, in PHS funded Research, must follow this Policy and complete the required FCOI training. An acceptable training resource can be found at the following url:

[https://grants.nih.gov/grants/policy/coi/tutorial2018/story\\_html5.html?lms=1](https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html?lms=1)

Subcontractors and consultants who perform services within the definition of an Investigator must either maintain a policy that complies with the requirements of 42 CFR Part 50, Subpart F and 45 CFR Part 94 or comply with this Policy. Questions and concerns regarding this Policy should be directed to the Eitr Chief Executive Officer, Dr. Zachary Bornholdt ([zach.bornholdt@eitrbio.com](mailto:zach.bornholdt@eitrbio.com)) or the Chief Scientific Officer, Dr. Crystal Moyer ([crystal.moyer@eitrbio.com](mailto:crystal.moyer@eitrbio.com)).

### 3. DEFINITIONS

**3.1.** Financial Conflict of Interest (“FCOI”) is a Significant Financial Interest (SFI) that could directly and significantly influence 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 Eitr, and as defined by Eitr in this Policy, which may include but not limited to: activities such as research, research consultation, professional practice, committee memberships, and service on panels such as Institutional Review Boards (IRB) or Data and Safety Monitoring Boards.

**3.5.** “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, including investigators, consultants, and subcontractors.

**3.6.** “PD/PI” means a project director or principal investigator of a PHS-funded Research project; the PD/PI is included in the definitions of Senior/Key Personnel and Investigator.

**3.7.** “PHS Awarding Component” means the organizational unit of the PHS that funds the Research.

**3.8.** “Research” means a systematic investigation, study or experiment designed to develop or contribute to general knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research as well as product development (e.g., a drug or an assay) and includes any such activity for which research funding is available from a PHS Awarding Component 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, institutional training grant, program project, or research resources award.

**3.9.** “Senior/Key Personnel” means the PD/PI and any other person identified as senior or key personnel staff by Eitr in the grant application, proposal or any other report submitted to the PHS Awarding Component.

**3.10.** Significant Financial Interest (“SFI”) means the following:

**3.10.1.** 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 Institutional Responsibilities:

**3.10.1.1.** With regard to any publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the twelve (12) 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, warrant, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

**3.10.1.2.** 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, warrant, or other ownership interest); or,

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

**3.10.2.** 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, 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.

**3.10.3.** The term SFI does not include the following types of financial interests: salary, royalties, or other remuneration paid by Eitr to the Investigator if the Investigator is currently employed by Eitr, including intellectual property rights assigned to Eitr and agreements to share in royalties related to such rights; any ownership interest in Eitr held by the Investigator; 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.

**3.11.** 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.

#### **4. TRAINING REQUIREMENTS**

**4.1.** Each Investigator must complete training prior to engaging in PHS funded research. An acceptable training resource can be found at the following url:

[https://grants.nih.gov/grants/policy/coi/tutorial2018/story\\_html5.html?lms=1](https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html?lms=1)

**4.2.** Investigators must complete training at least every four years and must immediately complete training under the following circumstances:

**4.2.1.** Eitr’s FCOI policy changes in a manner that affects the requirements of Investigators;

**4.2.2.** An Investigator is new to Eitr; or,

**4.2.3.** Eitr determines that an Investigator is not in compliance with Eitr's FCOI policy or management plan.

## **5. DISCLOSURE REQUIREMENTS**

**5.1.** Each Investigator who is planning to apply for or participate in PHS funded Research is required to disclose to Eitr any SFIs, including any SFI of their spouse or dependent children, no later than the time of application for and/or participation in PHS funded Research.

**5.2.** Each Investigator who is participating in the PHS-funded Research is required to submit an updated disclosure of SFIs (including any SFI of their spouse or dependent children) within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.

**5.3.** Eitr shall ensure applicable staff comply with these disclosure obligations. Failure to comply with these disclosure obligations may result in disciplinary action by Eitr.

## **6. REVIEW AND MANAGEMENT REQUIREMENTS**

**6.1.** An Investigator's SFI is related to PHS-funded Research when Eitr reasonably determines that the SFI: could be directly affected by the PHS-funded Research; or is in an entity whose financial interest could be directly affected by the Research; or reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded Research.

**6.2.** Eitr will take actions as necessary to manage FCOIs, including any financial conflicts of a subrecipient Investigator pursuant to this Policy. Management of an identified FCOI requires development and implementation of a management plan and, if necessary, a retrospective review and a mitigation report pursuant to this Policy.

**6.3.** Review Requirement: Prior to Eitr's expenditure of any funds under a PHS funded Research project, Eitr will determine whether the SFIs relate to the PHS funded Research and whether a FCOI exists. If a FCOI exists, Eitr will develop and implement a management plan that specifies the actions that have been, and will be, taken to manage such FCOI.

**6.4.** Disclosure and Identification of SFI: Whenever, in the course of an ongoing PHS funded Research project: (1) an Investigator who is new to participating in the Research project discloses a SFI; (2) an existing Investigator discloses a new SFI; or (3) Eitr identifies a SFI that was not disclosed by an Investigator during an ongoing PHS funded Research project, Eitr within sixty (60) days of the disclosure will review the SFI to determine whether it could directly affect the PHS funded Research and whether a FCOI exists. If a FCOI exists, Eitr will develop and implement, on at least an interim basis, a management plan that specifies the actions that have been, and will be, taken to manage such FCOI.

## **6.5. Retrospective Reviews:**

**6.5.1.** Whenever Eitr identifies a SFI that was not disclosed by an Investigator or, for whatever reason, was not previously identified by Eitr during an ongoing PHS-funded research project (e.g., was not reported by a subrecipient), Eitr shall, within sixty (60) days: review the SFI; determine whether it is related to PHS-funded research; determine whether a FCOI 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 the identified FCOI going forward.

**6.5.2.** In addition, whenever a FCOI is not identified or managed in a timely manner including failure by the Investigator to disclose a SFI that is determined by Eitr to constitute a FCOI; or failure by the Investigator to comply with a FCOI management plan, Eitr shall, within one hundred twenty (120) days of its determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded Research 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.

**6.5.3.** Based on the results of the retrospective review, Eitr will update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, Eitr will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.

**6.6. Monitoring:** Whenever Eitr implements a management plan, Eitr will monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS funded Research project.

## **7. REPORTING OF FINANCIAL CONFLICTS OF INTEREST**

**7.1. Initial FCOI Report:** Prior to Eitr's expenditure of any funds under a PHS funded Research project, Eitr will provide to the PHS Awarding Component a FCOI report if any Investigator's SFI found by Eitr to be a FCOI related to the PHS funded Research. Additionally, Eitr will ensure that it has implemented a FCOI management plan in accordance with this Policy. In cases in which Eitr identifies a FCOI and eliminates it prior to the expenditure of PHS awarded funds, Eitr is not required to submit a FCOI report to the PHS Awarding Component.

**7.2. Subsequent FCOI Reports:** For any SFI that Eitr identifies as a FCOI subsequent to Eitr's initial report during an ongoing PHS funded Research project, Eitr will provide to the PHS Awarding Component a FCOI report regarding the FCOI within sixty (60) days of identification of the FCOI. Additionally, Eitr will ensure that it has implemented a management plan in accordance with this Policy and, if required, complete a retrospective review and a mitigation report according to this Policy.

**7.3. Contents of a FCOI Report:** Any FCOI report required under this Policy will include sufficient information to enable the PHS Awarding Component to understand

the nature and extent of the FCOI and to assess the appropriateness of Eitr's FCOI management plan.

## **8. ENFORCEMENT**

**8.1.** If the failure of an Investigator to comply with this Policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS funded Research, Eitr will promptly notify the PHS Awarding Component of the corrective action taken or to be taken by Eitr. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to Eitr for further action, which may include directions to Eitr on how to maintain appropriate objectivity in the PHS funded Research project.

**8.2.** Failure by Eitr staff to comply with this Policy may be grounds for disciplinary action up to and including termination.

**8.3.** 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 FCOI that was not managed or reported by Eitr as required by this subpart, Eitr shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

## **9. RECORD RETENTION**

**9.1.** Records regarding Disclosure Forms, determinations made by Eitr regarding management of a FCOI will be retained by Eitr for three years beyond the date of the final expenditure report submitted to the PHS Awarding Component under an award or, where applicable, from other dates specified in 45 CFR 75.361, where applicable.

## **10. SUBCONTRACTORS AND CONSULTANTS**

**10.1.** Subcontractors/consultants who perform services within the definition of an Investigator must maintain a policy that complies with the aforementioned regulatory requirements or comply with this Policy. All applicable subcontract/consulting agreements must contain a clause that requires compliance with the applicable federal regulations either through a policy maintained by the subcontractor/consultant or this Policy.

## **11. PUBLIC ACCESSIBILITY**

**11.1.** Prior to Eitr's expenditure of any funds under a PHS funded Research project, Eitr shall ensure public accessibility by written response to any requestor within five (5) business days of a request, concerning any SFI disclosed to Eitr that is: (a) held by Senior/Key Personnel performing services for the Research, (b) related to the PHS funded research, and (c) determined by Eitr to be a FCOI.