

## **BIOCORRX PHARMACEUTICALS, INC.**

### **FINANCIAL CONFLICT OF INTEREST (FCOI) POLICY FOR U.S. PUBLIC HEALTH SERVICE (PHS) FUNDED RESEARCH**

#### **PURPOSE**

BioCorRx Pharmaceuticals, Inc. (BioCorRx) is committed to promoting objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research will be free of bias from conflicting financial interests. This policy provides a framework to comply with requirements of 42 CFR Part 50, Subpart F of the Federal Register pertaining to PHS-funded research. It is intended to ensure the research is free from bias due to financial conflicts of interest.

#### **APPLICABILITY**

This policy applies to all BioCorRx personnel, whether employees, managers, contractors, consultants, or other members, who desire to participate as an Investigator on PHS-funded research.

#### **DEFINITIONS**

**Designated Official(s):** Person(s) responsible for the implementation of the FCOI Policy, designated by BioCorRx.

**Financial Conflict of Interest (FCOI):** A Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of PHS-funded research.

**Financial Interest:** Anything of monetary value, regardless of whether the value is readily ascertainable.

**Equity Interest:** Any stock, stock option or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

**Immediate Family:** Investigator's spouse, domestic partner, and/or dependent children.

**Institution:** Any domestic or foreign, public or private, entity or organization, including biotechnology and pharmaceutical companies, that submits a proposal, or that receives, PHS research funding. BioCorRx is considered an "Institution" for the purposes of this policy.

**Investigator:** The Principal Investigator and any other person who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding.

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

**Research:** A systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research, basic and applied research (e.g., a published article, book or book chapter) and product

development (e.g., a diagnostic test or drug). The term includes any such activity for which research funding is available from PHS.

**Significant Financial Interest (SFI):** 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:

- Any Remuneration (salary and any payment for services, including consulting fees, honoraria, and paid authorship) received from any publicly traded entity in the 12 months preceding the disclosure, and the value of any Equity Interest in such entity as of the date of disclosure, that exceeds \$5,000 when aggregated;
- Any Remuneration received from any non-publicly traded entity in the 12 months preceding the disclosure that exceeds \$5,000 when aggregated or any Equity Interest in such entity of any value;
- Income related to intellectual property rights and interests (e.g. patents, copyrights), upon receipt of such income;
- 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 BioCorRx responsibilities, except as detailed below.

SFI does not include the following:

- Travel reimbursed or sponsored by a US 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;
- Salary, royalties or other Remuneration paid by BioCorRx to the Investigator if the Investigator is currently employed or otherwise appointed by BioCorRx, including intellectual property rights assigned to BioCorRx and agreements to share in royalties related to such rights;
- Any ownership interest in BioCorRx, held by the Investigator;
- Any 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 US 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;
- Income from service on advisory committees or review panels for a US 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.

## **TRAINING**

BioCorRx will inform each Investigator of BioCorRx's FCOI Policy, the Investigator's responsibilities regarding disclosure of all foreign and domestic significant financial interests, federal regulations, and NIH's FCOI training tutorial available [here](#).

Unless otherwise covered by a third-party FCOI Policy as agreed with BioCorRx, each Investigator is required to complete training on BioCorRx's FCOI Policy on the following occasions:

1. Prior to engaging in research related to any PHS-funded grant,
2. At least every 4 years, and
3. Immediately if:
  - a. BioCorRx revises the FCOI Policy in a manner that affects requirements of Investigators,
  - b. An Investigator is new to BioCorRx, or
  - c. An Investigator is not in compliance with the FCOI Policy or management plan.

Investigator training may be conducted by oral review of this policy by phone or in person.

## **IDENTIFICATION OF FCOI**

**Related:** 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.

BioCorRx may involve the Investigator in the Designated Official(s)' determination of whether a significant financial interest is related to the PHS-funded research.

**FCOI:** A financial conflict of interest exists when BioCorRx, 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.

## **INVESTIGATOR RESPONSIBILITIES**

**Disclosure:** Each Investigator is required to disclose foreign and domestic SFIs (and those of the Investigator's immediate family) to the Designated Official those that would reasonably appear to be affected by the PHS-funded research, or is in an entity whose financial interests would reasonably appear to be affected by the research. This disclosure will be made at least annually during the award period to include any information that was not disclosed initially to BioCorRx or updated information regarding any previously disclosed SFI and within 30 days of discovering or acquiring a new SFI.

**Disclosure Updates:** Investigators expected to perform work on a project involving PHS-funded research will also be required to submit a new or updated disclosure before the submission of the grant application, if the Investigator's anticipated role in the project is known before proposal submission.

For any report of an SFI involving travel reimbursement or sponsorship, the Designated Official(s) must be provided information relating to the purpose, destination, and duration of each trip and the identity of the relevant sponsor or organizer. If requested by the Designated Official(s), additional information, including a determination or disclosure of monetary value of the trip, must be disclosed to determine whether the reimbursement or sponsorship constitutes an FCOI.

## **INSTITUTIONAL RESPONSIBILITIES**

### **Designated Official(s) Responsibilities**

The Designated Official(s) will be responsible for the following:

- Training of all Investigators on the BioCorRx FCOI Policy

- Soliciting and reviewing new, annual, and updated disclosures of SFIs belonging to each Investigator (and their immediate family) who is planning to participate in, or is participating in, the PHS-funded research
- Maintenance of records for at least the required period per regulation
- Fulfill initial and ongoing reporting obligations for FCOI reports to the PHS

Before work on a particular PHS-funded research project begins for any Investigator that is known to BioCorRx prior to such time, or within 60 days whenever BioCorRx identifies an SFI that was not disclosed by an Investigator, or not previously reviewed by BioCorRx, the Designated Official(s) shall:

- Review of all Investigator SFI disclosures and determine if any SFIs relate to PHS-funded research, and if so, determine whether a FCOI exists
- Manage FCOI, take such action as develop and implement management plans, and establish a process to monitor an Investigator's (or subrecipient Investigator's) compliance with management plans (that shall specify the actions that have been, and will be, taken to manage such) until completion of the PHS-funded research project

This shall also apply when, 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 Institution.

### **MANAGEMENT PLAN**

Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- 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;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- Severance of relationships that create financial conflicts.

Whenever BioCorRx implements a management plan pursuant to this policy, BioCorRx will monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

### **REPORTING**

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.

BioCorRx will send initial, annual and revised reports of Investigators with FCOI to PHS Awarding Component via eRA Commons FCOI Module online:

- Prior to expenditure of funds for PHS-funded research; and
- Within 60 days of identification of a FCOI for an Investigator who is newly participating in an on-going project;
- Within 60 days for new or newly identified, FDOIs for existing Investigators;
- At least annually to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project; and
- Following a retrospective review to update a previously submitted report, if appropriate.

The FCOI report should 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. At a minimum, it should include the following information:

- Grant or Contract number, as appropriate;
- Principal Investigator (PI) or contact PI if the grant/contract is awarded under the multiple PI model;
- Name of the Investigator (if different from the PI) with the FCOI;
- Name of the entity with which the Investigator has a financial conflict of interest; Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- 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;
- A description of how the financial interest relates to the PHS-funded research and the basis for the Institution's determination that the financial interest conflicts with such research; and
- A description of the key elements of the Institution's management plan, including:
  - Role and principal duties of the conflicted Investigator in the research project;
  - Conditions of the management plan;
  - How the management plan is designed to safeguard objectivity in the research project;
  - Confirmation of the Investigator's agreement to the management plan;
  - How the management plan will be monitored to ensure Investigator compliance; and
  - Other information as needed.

For any previously reported FCOI, the Designated Official(s) 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. BioCorRx will 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.

**Clinical Research:** 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 BioCorRx as required, BioCorRx will 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.

**Compliance Failure:** In the event BioCorRx determines that the design, conduct, or reporting of PHS-funded research appears to have been biased due to an Investigator's failure to comply with BioCorRx's FCOI policy or FCOI management plan, BioCorRx will promptly notify the PHS Awarding Component of the corrective action taken or to be taken.

## **SANCTIONS**

BioCorRx will establish and maintain adequate enforcement mechanisms (e.g., employee sanctions or other administrative actions) and provide for appropriate corrective action to promote policy compliance. Examples of administrative sanctions may include, but are not limited to:

- Oral admonishment
- Written reprimand
- Reassignment
- Disqualification from submitting proposals for research support to Federal agencies or other sponsors
- Demotion
- Suspension; or
- Separation.

## **ADDITIONAL CONSIDERATIONS**

**Subrecipients:** When carrying out the PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), BioCorRx must incorporate by written agreement (e.g., subaward contract) that the Investigator of the subrecipient institution is required to either:

- Comply with the BioCorRx FCOI Policy, or
- Comply with the FCOI Policy of the subrecipient institution and have said institution certify that its policy complies with 42 CFR Part 50 Subpart F.

The written agreement, under either policy, must specify the time period for the subrecipient to provide Investigator disclosure and report of any FCOI to BioCorRx. It is suggested that at least 30 days from the reporting deadline for BioCorRx annual disclosures, or in cases of discovery or acquiring new SFI a maximum of 10 business days be considered to which the subrecipient is to report to BioCorRx, to enable BioCorRx to comply timely with its review, management, and reporting obligations. BioCorRx will provide FCOI reports to the PHS Awarding Component regarding all financial conflicts of interest of all subrecipient Investigators prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

**Retrospective Review:** 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 Institution to constitute a financial conflict of interest; failure by the Institution 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, BioCorRx will 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. BioCorRx will document the retrospective review to include at least the following information:

- Project number;
- Project title;
- PD/PI or contact PD/PI if a multiple PD/PI model is used;
- Name of the Investigator with the FCOI;
- Name of the entity with which the Investigator has a financial conflict of interest;
- Reason(s) for the retrospective review;
- Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- Findings of the review; and
- Conclusions of the review.

Based on the results of the retrospective review, if appropriate, the Institution 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, BioCorRx will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the Institution'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).

### **PUBLIC ACCESSIBILITY**

BioCorRx will post this policy to a publicly accessible BioCorRx website. If requested, BioCorRx will provide a written response within 5 business days of the information concerning any SFI that is disclosed and still held by the senior/key personnel, determined to be related to PHS-funded research and that has been determined to be a FCOI. The information in the written response or posted to the website will include:

- 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.

The website will note that the information provided is current as of the date listed and is subject to updates. Written responses will note that the information provided is current as of the date of the correspondence and is subject to updates, which should be subsequently requested by the requestor. Publicly accessible information available on BioCorRx's website will be updated at least annually and within 60 days of identifying any new FCOIs. This information will remain available to the public for at least three years following the most recent update.

## **MAINTENANCE OF RECORDS**

BioCorRx will maintain all FCOI-related records:

- For at least 3 years from the date on which, for grants and cooperative agreements, the final expenditure report is submitted to the relevant PHS organization or, for contracts, final payment is made; or
- For the time periods specified in 45 CFR 74.53(b) and 92.42(b), or 48 CFR Part 4, Subpart 4.7, as applicable.
- Records include all Investigator disclosures of financial interests, BioCorRx's review of, and response to, such disclosures and all actions under this policy or retrospective review.

During the applicable time periods referenced above, BioCorRx will also make all FCOI-related records available to the HHS upon request.