

**POLICY FOR MANAGING FINANCIAL CONFLICTS OF INTEREST (“FCOI”)
AT QUADRODOX, INC.**

**Revised Following FCOI 2011 Regulations – 42 CFR Part 50 Subpart F (Grants and
Cooperative Agreements)**

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Screening Form for Identifying Potential Financial
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Disclosure of Significant Financial Interests Form

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I. INTRODUCTION

A. Policy Purpose

The United States Public Health Service (“**PHS**”) 2011 regulations have unique requirements regarding financial conflict of interest (“**FCOI**”) reporting and conflict management. All PHS agencies require awardee institutions to ensure objectivity in research through compliance with its comprehensive FCOI regulations (Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought (42 CFR Part 50, Subpart F) and Responsible Prospective Contractors (45 CFR Part 94)).

The PHS 2011 regulations, located at <https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50/subpart-F> expand and add transparency to investigators’ disclosure of significant financial interests, enhance regulatory compliance and effective institutional oversight, manage investigators’ FCOI, and increasing PHS compliance oversight.

United States PHS agencies required to follow the PHS 2011 regulations include the following:

1. National Institutes of Health (“**NIH**”);
2. Centers for Disease Control and Prevention (“**CDC**”);
3. Health Resources and Services Administration (“**HRSA**”);
4. Substance Abuse and Mental Health Administration (“**SAMHSA**”);
5. Agency for Toxic Substances and Disease Registry (“**ATSDR**”);
6. Indian Health Service (“**IHS**”);
7. Food and Drug Administration (“**FDA**”); and
8. Agency for Healthcare Research and Quality (“**AHRQ**”).

Non-PHS agencies may adopt the PHS FCOI regulations as well, thereby requiring awardee institutions to adhere to these regulations.

Quadridox, Inc. (the “**Company**”) must ensure that the integrity of research grants, cooperative agreements, and contracts, and the safety and welfare of research subjects, are never subordinate to, or compromised by, financial interests or the pursuit of personal gain. The principles articulated herein are intended to provide guidance in the management of formal relationships between employees of the Company and their external constituencies in order to ensure that the design, conduct, and reporting of sponsored research will not be biased by any conflicting financial interests. Each investigator is required to disclose a listing of his or her significant financial interests, as well as those of his or her spouse and dependent children, that would reasonably appear

to be affected by the research proposed for funding by PHS. If, after review of these disclosures, it is determined that the reported financial interests could directly and significantly affect the design, conduct, or reporting of the research, the Company will report the existence of such conflicting interests to the sponsor and act to protect the resulting research from bias due to the conflict of interest. This policy statement is intended to satisfy current federal regulations for disclosure with regard to projects funded by the PHS.

B. Scope

This policy is applicable immediately to all PHS-funded program activities at the Company carried out by Company employees, consultants, scientists, trainees, technicians, and other agents or research collaborators. In addition, this policy applies to non-PHS-funded program activities for which the sponsor has adopted the PHS 2011 FCOI regulations.

II. DEFINITIONS

A. FCOI occur when:

1. A Company Employee or a family member of a Company Employee has an existing or potential financial or other material interest that impairs or appears to impair the Company Employee's independence and objectivity in the execution of his or her responsibilities to the Company;
2. A Company Employee receives a financial or other material benefit through inappropriate use of knowledge or information confidential to the Company; and
3. Financial or personal obligations may compromise or present the appearance of compromising an investigator's professional judgment in conducting, reviewing, or reporting on research or non-research-related projects. This may include, but is not limited to, interests in the research or project itself or in the sponsor (including equity holdings, consulting arrangements, or patent rights), or any other incentive that may bias the collection, analysis, and interpretation of data or may negatively impact scientific objectivity and integrity.

B. Company Employee is any individual employed on a full or part-time basis by the Company and is receiving or will receive compensation for such employment, including consultants, agents, and research collaborators of the Company.

C. Investigator is the principal investigator, co-principal investigators, or any other Company Employee responsible for the design, conduct, or reporting of externally-funded scientific research activities.

D. Family Member includes the Company Employee's spouse or domestic partner, children, or other adults who qualify as dependents under the Internal Revenue Code definitions.

E. Project implies any externally-funded activity such as basic, applied, or developmental research or other activity conducted by Company Employees on behalf of the Company.

F. Significant Financial Interest ("SFI") includes the following:

1. Publicly Traded Entities – With regard to any publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the 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 or services not otherwise identified as salary (e.g., consulting fees, honoraria, or paid authorship), and 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;
2. Privately Held Entities – With regard to any privately held entity, a SFI exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds \$5,000, or when the investigator (or the investigator's spouse, domestic partner, or dependent child) holds any equity interest (e.g., stock, stock option, or other ownership interest);
3. Intellectual Property – With regard to intellectual property rights and interests (e.g., patents and copyrights), a SFI exists upon receipt of income related to such rights and interests; and
4. Travel Reimbursements – With regard to 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), a SFI exists if the travel reimbursements are related to his or her institutional responsibilities in the 12 months preceding the disclosure. 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 in 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 definition of SFI does not include the following: salary, royalties, or other remuneration paid by the Company to the investigator, if the investigator is currently employed or otherwise appointed by the Company, including intellectual property rights assigned to the Company and agreements to share in royalties related to such rights; 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 governmental agency, an institution of higher education as defined in 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, from an institution of higher education as defined in 20 U.S.C. 1001(a), or from an academic teaching hospital, medical center, or research institute that is affiliated with an institution of higher education.

G. Institutional Responsibilities means an investigator's professional responsibilities on behalf of the institution, including activities such as research, teaching, clinical, or other professional practice, academic activities, scholarly events, and institutional committee memberships.

H. Negative Finding means a determination has been made that no FCOI exists.

I. Positive Finding means a determination has been made that a FCOI does exist and therefore, appropriate administrative action will be required as given under Section III, Part E below.

III. POLICY STATEMENT

A. Investigator Training

In accordance with relevant federal and State of North Carolina regulations, the Company is required to manage, eliminate, or reduce any potential FCOI that may be inherent in the personal financial interest of an investigator. The Company, therefore, will be responsible for ensuring that each investigator is informed about:

1. The Company's FCOI policy;
2. The investigator's responsibilities regarding disclosure of SFIs relating to the investigator's institutional responsibilities; and
3. PHS FCOI regulations.

In accordance with FCOI regulations, the Company requires each investigator to complete a mandatory training module prior to engaging in research related to any PHS-funded grant, cooperative agreement, or contract; at least every four years thereafter; and immediately when any of the following applies:

1. This FCOI policy or the PHS Financial Disclosure Form are revised in any manner that affects the requirements of the investigators;
2. An investigator is newly appointed at the Company; or
3. The Company finds that an investigator is not in compliance with this FCOI policy or management plan (See Section III, Part E).

this policy, including non-adherence to the agreed upon management plan, shall constitute serious misconduct and may be the basis for further administrative or legal inquiry.

H. Subrecipient Requirements

All proposed subrecipients of funds under the Company PHS-funded research shall have a FCOI policy that conforms to the requirements of the FCOI regulations. With respect to these subrecipients, subcontractors, and collaborators, the Company must require these entities to enter into a written agreement and make a certification to the Company at the time of award that its FCOI policy complies with the FCOI regulations. The written agreement shall include all of the terms required under the FCOI regulations.

The Company will report to the PHS funding agency any FCOI that is identified by any subrecipient, subcontractor, or collaborator to the Company in the manner required under the FCOI regulations, prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

I. Policy and Financial Conflicts of Interest Disclosure Procedures

The Company shall ensure public accessibility of the Company's FCOI policy on a publicly accessible website. If a publicly accessible website is not available, for whatever reason, and only in this case, the Company must make the FCOI policy available within five business days of a request. If presence on a publicly accessible website is then acquired, the Company must post the FCOI policy within 30 days.

Prior to expending any funds under a PHS-funded grant, cooperative agreement, or contract, the Company shall ensure public accessibility of information about the FCOI, via a public website or written response to any requestor within five business days of a request. The information shall consist of the information required to be provided under the FCOI regulations, including:

Investigator's name;

Grant/Contract Number;

Project Director/Principal Investigator;

Investigator with the FCOI;

Investigator's (with the FCOI) title and role with respect to the research project;

Provide disclosure on intellectual property rights and interests;

Name of entity in which the SFI is held and whether it is publicly traded or privately held and nature of relationship to the entity consulting fees travel reimbursement honoraria etc. ;

8. Approximate dollar value of the SFI (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;
9. A description how the financial interest relates to PHS-funded research and the basis for the FCOI determination; and
10. How the FCOI is being managed, reduced, or eliminated.

J. Maintenance of Records

The Company is required pursuant to the FCOI regulations to maintain all Disclosure of SFI Forms and all related records of actions taken by the Company with respect to disclosures of financial interests for a period of three years from the date of submission of the final expenditures report to PHS or, for awards that are renewed quarterly or annually, from the date of the submission of the quarterly or annual financial report or, where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42(b) for different situations.

IV. BOARD OF DIRECTORS ADMINISTRATIVE PREROGATIVE

During the course of any inquiry or investigation, the Board of Directors shall have the prerogative to take interim administrative actions, as appropriate, to protect external funds and ensure that the purposes of the external financial assistance are protected.

**SCREENING FORM FOR IDENTIFYING
POTENTIAL FINANCIAL CONFLICTS OF INTEREST
(Attachment A)**

Name: _____ Title: _____

1. Do you have a significant financial interest* in a commercial organization (other than Quadridox, Inc. (the “**Company**”)) that is directly related to or would be affected by your research or directly relates to a business decision you are participating in? Yes ___No ___

* For this purpose, see definition of “Significant Financial Interest” in the Company’s FCOI policy.

2. Do you have some involvement or financial interest that is or could be perceived to be in conflict with the completion of your duties at the Company? Yes ___No ___

3. Do you or a member of your family serve as a director, trustee, officer, or other key employee in a for-profit corporation, partnership, business, or other entity in a field of your research or in a company that does business with the Company? Yes ___No ___

4. Do you or a member of your family own stock or hold stock options with a publicly-traded or privately-owned entity in a field of your research or in a company that does business with the Company? Yes ___No ___

5. Do you or a member of your family have rights to or receive royalties from intellectual property (including patents, copyrights, and trademarks but excluding academic or scholarly works) licensed to or owned by a for-profit entity in a field of your research or in a company that does business with the Company? Yes _____No ___

6. Have you or a member of your family received compensation for activities such as travel expenses, consulting, expert witness, or advisory board membership from an entity in a field of your research or in a company that does business with the Company? Yes _____No ___

7. Do you or any member of your family have any relationships, commitments, or activities that may, in your good faith judgment, present or appear to present a conflict of interest with your research activities? Yes ___No ___

If you answered yes to any of the above questions, you will be asked to disclose in further detail any Significant Financial Interest.

Affirmation

In signing this form, I affirm to the following:

- 1) The above information is true and accurate. If at any time during my employment any of the above answers are no longer accurate, I will complete a new screening form detailing the change.

**Attachment A – Policy for Managing Financial
Conflicts of Interest at Quadridox, Inc.**

- 2) I have read and understand the Company's Policy for Managing Financial Conflicts of Interest.
- 3) I have completed the online tutorial (link below) provided by the NIH and understand my responsibilities related to identifying and managing financial conflicts of interest at the Company:

<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>

Signature: _____

Date: _____

Company Officer

Signature: _____

Date: _____

Negative Findings: _____ Positive Findings: _____

DISCLOSURE OF SIGNIFICANT FINANCIAL INTERESTS FORM

Name: _____ Title: _____

Grant Proposal Title: _____

Intended Government Funding Agency: _____

Name of Constituent Organization or Institution in which you claim a Significant Financial Interest:

Name

Address

City, State, Zip

1. Describe your significant financial interest in the organization (other than Quadridox, Inc.) that is directly related to your research interest (or would be affected by your research) or directly relates to a business decision you are participating in:

2. Describe your involvement or financial interest that is or could be perceived to be in conflict with the execution of your duties for Quadridox, Inc.:

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