Circumvent Pharmaceuticals Company Policy – Financial Conflict of Interest (FCOI) Policy

PURPOSE

The purpose of this policy is to document the requirements and responsibilities associated with identifying and managing financial conflicts of interest.

Circumvent Pharmaceuticals, Inc. (Circumvent) seeks to safeguard the integrity of its research and to be in conformance with the federal Public Health Service's (PHS) requirements for institutions that seek research funding. The PHS has implemented Financial Conflict of Interest 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* (FCOI Regulations), to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under PHS grants or cooperative agreements will be free from bias resulting from investigator financial conflicts of interest. The FCOI Regulations are applicable to institutions that receive PHS grants and to each investigator participating in such research. These regulations do not cover Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) Program Phase I awards but do apply to recipients under the SBIR/STTR Program Phase II. This policy (FCOI Policy) is implemented to fulfill Circumvent's obligation under the FCOI Regulations to maintain an up-to-date, publicly accessible, and enforced policy on investigator financial conflicts of interest.

Effective January 1, 2021, Circumvent's requires that each investigator and subrecipient affiliated with Circumvent be in compliance with FCOI Regulations. All investigators participating in PHS-funded research are required to disclose to Circumvent his/her, and those of his/her spouse and dependent children, significant financial interests which meet or exceed the regulatory definition of significant financial interest and that reasonably appear to be related to the investigator's institutional responsibilities.

Circumvent may be asked to provide records related to this FCOI Policy, including disclosure forms, to the Department of Health and Human Services or other federal agencies or entities. Circumvent will provide the requested information and make any other disclosures necessary to comply with this FCOI Policy or as required by law.

KEY DEFINITIONS

I. Designated Official- the Designated Official for the purposes of this Policy will be the Signing Official and will be responsible for the procedures under this FCOI Policy but may designate one or more individuals to assist in any or all of these responsibilities.

II. Investigator- the project director or principal investigator and any other person including subrecipients, subgrantees and collaborators regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

III. 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. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).

IV. Institutional responsibilities - an investigator's professional responsibilities on behalf of Circumvent, including research, research consultation, clinical or other professional practice, participation in scholarly events, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

V. Senior/key personnel -the project director or principal investigator and any other person identified as senior/key personnel in the grant application, progress report or any other report submitted to the PHS.

VI. Manage/Management plan - taking action to address an FCOI, which can include reducing or eliminating the FCOI to ensure, to the extent possible, that the design, conduct and reporting of research will be free from bias.

VII. Significant financial interest (SFI) - a financial interest, defined as anything of monetary value whether or not readily ascertainable, consisting of one or more of the following interests of the investigator (or those of the investigator's spouse and dependent children) that reasonably appears to be related to the investigator's institutional responsibilities.

a. Publicly Traded Entities - 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 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.

b. Privately Held Entities - with regard to 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 (or the investigator's spouse and dependent children) holds any equity interest (e.g., stock, stock option or other ownership interest).

c. Intellectual Property - intellectual property rights and interests (e.g., patents, copyrights), must be disclosed upon receipt of income (e.g., royalties) related to such rights and interests.

d. Travel Expenses - 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 in the twelve months preceding the disclosure if the value of such travel, when aggregated from all sources, exceeds $5,000; 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. Code 1001(a), an academic teaching hospital, a medical center or a research institute that is affiliated with an institution of higher education. Disclosures relating to travel expenses must specify at a minimum the purpose and duration of the trip, the identity of the sponsor/organizer and the destination.

e. Not included are the following types of financial interests: salary, royalties or other remuneration paid by Circumvent to the investigator if the investigator is currently employed or otherwise appointed by Circumvent, including intellectual property rights

assigned to Circumvent 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; and income from seminars, lectures or teaching engagements sponsored by, and 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. Code 1001(a), an academic teaching hospital, a medical center or a research institute that is affiliated with an institution of higher education.

A. Mandatory Investigator Training Requirements

The Signing Official is responsible for ensuring that each investigator is informed about the FCOI Regulations, this FCOI Policy, the investigator's responsibilities regarding disclosure of SFIs relating to the investigator's institutional responsibilities.

Investigators are required to complete the FCOI training module (https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html) prior to engagement in PHS-supported research and at least every four years.

The Signing Official also shall ensure that each investigator completes training immediately when any of the following applies: (1) this FCOI Policy or procedures are revised in any manner that affects the requirements of the investigators (2) an investigator is new to Circumvent or (3) Circumvent finds that an investigator is not in compliance with Circumvent's FCOI Policy.

B. Disclosure Requirements

Prior to submission to PHS of an application for a research grant, the principal investigator shall identify to the Signing Official (1) all investigators anticipated to be participating in the research, (2) those who are senior/key personnel and (3) those who are subrecipients and the institution(s) employing them.

Also prior to submission of the application, the Signing Official shall ensure that each investigator submits a listing of his/her known SFIs and those of his/her spouse and dependent children that reasonably appear to be related to the investigator's institutional responsibilities. The Signing Official shall ensure that subrecipient investigators either comply with this FCOI Policy or, in the case of a subrecipient, that their institution(s) provides assurances to enable Circumvent to fulfill the requirements of this FCOI Policy.

All disclosures must be updated annually or within 30 days of discovering or acquiring a new SFI. The Signing Official shall ensure that annual update forms are sent to and promptly returned by each investigator. One annual disclosure is sufficient to cover ongoing PHS awards. Each investigator is responsible for submitting disclosure forms within 30 days of discovering a new SFI. Disclosures shall be provided by an investigator at any other time upon request.

C. Reviewing, Monitoring and Reporting FCOI

Prior to the expenditure of funds or within 30 days of the disclosure or discovery of a significant financial interest, the Signing Official shall:

(1) review all disclosure forms and determine whether (a) an investigator's SFI is related to PHS-funded research and (b) if so related, whether the SFI is a Financial Conflict of Interest (FCOI); and

(2) in the case of a FCOI, develop and implement a management plan specifying actions that have been and shall be taken to manage the FCOI; and

(3) submit initial and ongoing FCOI reports through the eRA Commons FCOI module to the PHS Awarding Component as required under the FCOI Regulations.

The Signing Official shall be responsible for reviewing all forms disclosing a SFI, making the requisite determinations and taking any subsequent action. A FCOI exists when the Signing Official reasonably determines that a SFI could directly and significantly affect the design, conduct or reporting of PHS-funded research or if the SFI is in an entity whose financial interests could be affected by the research. In determining whether an investigator's SFI is related to PHS-funded research the Signing Official will consider all relevant factors and information, including but not limited to whether there is an ongoing relationship between the investigator and the payer, the nature of the research, the magnitude of the financial interest and degree to which it is related to the research, the extent to which the interest could be directly and substantially impacted by the research, and the degree of risk to the human subjects, if any, that is inherent in the research protocol.

Prior to making the decision whether an FCOI exists, the Signing Official may impose interim measures, may ask the investigator to submit additional information and may meet or communicate with the investigator. The investigator may be encouraged to suggest procedures, protocols, or other measures designed to manage the FCOI.

Examples of conditions or restrictions that might be imposed to manage an FCOI include, but are not limited to:

1. Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
2. For research involving human subjects, disclosure of financial conflicts to research participants;
3. Monitoring of the research by independent reviewers;
4. Modification of the research plan;
5. Change of personnel or personnel responsibilities or disqualification from participation in all or a portion of the research;
6. Reduction or elimination of the financial interest; and/or
7. Severance of relationships that create such conflicts.

For all management plans, the Signing Official shall monitor ongoing investigator compliance and submit annual updates to the PHS Awarding Component at the time and in the manner specified by the PHS Awarding Component, both until the completion of the PHS-funded research project to which the FCOI relates. Annual FCOI reports will be submitted through the eRA Commons FCOI Module for the duration of the project period.

If the FCOI is identified and eliminated prior to the expenditure of any PHS-awarded funds, no FCOI report need be submitted.

D. Maintenance of Records

The Signing Official shall maintain all disclosure forms and related records of determinations made and actions taken for a period of three years from the date of submission of the final expenditures report to the PHS.

E. Enforcement Mechanism and Sanctions

All researchers to whom this FCOI Policy applies are expected to fully and promptly comply with it. The Signing Official may impose sanctions for noncompliance which may include, but is not limited to, the following:

- Failure to make timely, full or accurate disclosures;
- Failure to provide information requested;
- Failure to update a disclosure form as necessary; or
- Failure to comply with a management plan.

For Circumvent employees, sanctions may include suspension or dismissal, denial of eligibility to engage in the research at issue or other appropriate penalties. Such sanctions may require giving notice of relevant information to funding agencies, professional bodies or journals, or the public. The Signing Official will determine what sanctions, if any, are to be applied.

F. Noncompliance and Remedies

If an investigator has failed to comply with a management plan or, for whatever reason, an FCOI is one that was not identified, reviewed or managed in a timely manner, the Signing Official shall, within 120 days of the determination of noncompliance, conduct a retrospective review of the investigator's activities and the research project to determine whether any PHS-funded research or portion thereof conducted during the period of noncompliance was biased in design, conduct or reporting. The review shall be documented consistent with the FCOI Regulations. If bias is found during the course of the review, the Signing Official will promptly notify the PHS Awarding Component (which may take its own action and/or require further action by Circumvent and/or the investigator, as it deems appropriate) and submit a mitigation report consistent with the FCOI Regulations. If appropriate, the Signing Official will update the previously submitted FCOI report. In any event, the Signing Official shall submit FCOI reports annually thereafter.

For clinical research projects supported by the PHS, if the Department of Health and Human Services 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 was designed, conducted, or reported by an investigator with an FCOI that was not properly disclosed or managed as required under the FCOI Regulations, the investigator shall disclose the FCOI in each public presentation of the results of the research (such as articles, manuscripts and oral presentations) and Circumvent shall request an addendum to previously published presentations.

G. Public Accessibility Requirements

This FCOI Policy will be posted on Circumvent's publicly accessible website, as required by the FCOI Regulations.

Prior to expending any funds under a PHS-funded grant, Circumvent shall ensure public accessibility to information concerning a FCOI held by a senior/key personnel member by providing a written response to any written request, such response to be postmarked or dated (if replying by electronic means) within five business days of the receipt of the written request. Such information shall consist of that required to be provided under the FCOI Regulations and shall be updated at least annually and within 60 days of the receipt or identification of information concerning an additional significant financial interest, and shall remain available for three years from the date the information was most recently updated.

Financial Conflict of Interest Disclosure Form

Persons completing this form are expected to have read and understood Circumvent Pharmaceuticals' Financial Conflict of Interest Policy on PHS Funded Grants and Contracts. If you have any questions regarding the policy, contact the Circumvent Signing Official prior to signing this document.

Name: _____

I am reporting on activities: ☐ pursuant to the submission of a PHS application
☐ for the year _____
☐ as an addendum to my most recent report

1. Do you, your spouse, or dependent children have a significant financial interest (SFI) (as defined on the Circumvent Pharmaceuticals Company Policy Financial Conflict of Interest (FCOI) Policy) in an external entity that would reasonably appear to be affected by your institutional responsibilities as defined in the FCOI Policy? ☐ Yes ☐ No

2. Do you, your spouse or dependent children have a significant financial interest (SFI) in any business or legal entity whose financial interests would reasonably appear to be affected by this covered research? ☐ Yes ☐ No

If yes to either 1 or 2, please complete the following and describe in the space below the nature and extent of your/their affiliation.

☐ Yes	☐ No	1. Compensation (including travel expenses). Have you or a member of your immediate family received compensation from a for-profit entity for activities such as consulting, expert witness, advisory board membership, or the like?
☐ Yes	☐ No	2. Equity. Do you or a member of your family own stock or hold stock options with a publicly-traded or privately-owned entity?
☐ Yes	☐ No	3. Role. 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 outside of Circumvent Pharmaceuticals?
☐ Yes	☐ No	4. Intellectual Property. Do you or a member of your family have rights to and/or receive royalties from intellectual property (including, patents copyrights and trademarks but excluding academic or scholarly works) licensed to and/or owned by a for-profit entity? Do NOT include intellectual property owned or managed by Circumvent Pharmaceuticals.
☐ Yes	☐ No	5. Foreign Interests. Do you or a member of your immediate family have financial interests received from a foreign institution of higher education or the government of a foreign country not covered by US Code 20 USC 1001(a)?

Name of External Entity: _____
Address of External Entity: _____

Reporting for ☐ Self/Investigator ☐ Immediate family member
Name: _____
Relationship: _____

Type of external relationship: (Check all that apply)

☐	Consultant
☐	Speaker
☐	Advisory Board or Committee
☐	Equity Holdings ☐ Public ☐ Non-Public
☐	Governing Board or Officer
☐	Intellectual Property Rights
☐	Royalty Income
☐	Other (describe below)

Amount of compensation or financial interest in reporting period: $_____

Amount of travel compensation $ _____
Destination _____

Comments or further information:

Certification:

I have read and understand Circumvent Pharmaceuticals' policy on Financial Conflict of Interest and have completed this report to the best of knowledge and belief. If required, I will comply with any conditions or restrictions imposed by Circumvent or the awarding PHS institution to manage any real or perceived conflicts. Should my outside financial interests, or those of my immediate family, change in a way that results in different answers to any of the questions asked in this report, I agree to submit a revision.

Name: _____

Signature: _____ Date: _____