

Policy

Title: Financial Conflict of Interest Policy for Federal Grants and Contracts

Note: This Policy is only applicable to Phase 2 projects

Purpose: External sponsorship of research can result in the development of complex relationships between researchers and the external sponsors who support specific programs. To assure that our research is conducted with the highest integrity and in response to regulations issued by the Public Health Service (PHS) and National Science Foundation (NSF) Rules on Objectivity in Research (Federal Register 42 CFR Part 50 subpart F) and 45 C.F.R § 94.4 regarding institutional responsibility, the Company has developed this policy on Financial Conflict of Interest (FCOI). The intent of this policy is to promote objectivity in research, to identify and eliminate or manage any possible threat to the integrity of the research conducted by the Company and to satisfy current federal rules for disclosure.

Scope: This policy and associated procedures are immediately applicable to all sponsored program activity at the Company carried out by the Company's employees, consultants, students, trainees, or other agents of the Company. These procedures will be followed whenever the Company or its employees submit a request for funding from any external agency, whether it is the PHS, the NSF or another federal agency.

Policy Statement: All Investigators who plan to participate in, or direct a sponsored research project must disclose to the Company any significant financial interest which they or members of their immediate family have in any commercial enterprises that will, in any way, participate in the sponsored program or that potentially may be affected by the performance or completion of the sponsored program. Disclosure is accomplished through the completion of a "Financial Conflict of Interest Disclosure Form" (Attachment A) which is subject to review by the FCOI Oversight Committee (FCOIC) of the Company.

All FCOI disclosure forms will be reviewed by the FCOIC to determine the existence of potential for any financial conflicts of interest. In addition, all contracts for sub-recipient awards will include a requirement that the sub-recipient has a FCOI policy and that the sub-recipient will report any FCOI to the Company in its proposal and within 30 days of any newly discovered FCOI.

Definitions - For purposes of this policy statement the following definitions are provided:

- A. Investigator - Includes the principal investigator and all staff members who will have responsibility for the design and conduct of the research as well as any individuals associated with the reporting of results.
- B. Immediate Family - refers to Investigators spouse and dependent children or other adults who qualify as dependents under the Internal Revenue Code definitions.
- C. FCOI Committee (FCOIC) - A committee, comprised of the Controller and the President, responsible for reviewing all Financial Conflict of Interest Disclosure Forms to identify conflicts of interest as defined below. The committee will meet on an annual basis and when new FCOI Disclosure Forms are completed by Company employees or received from any agent, consultant, or subcontractor.
- D. Financial Conflict of Interest (FCOI) – A financial conflict of interest exists when the Institution's FCOIC reasonably determines that a Significant Financial Interest (defined below) could directly and significantly affect the design, conduct or reporting of PHS-funded research.
- E. Manage - taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.
- F. Person – any legal person, including an employee, agent, consultant, student, trainee, or subcontractor.
- G. 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). As used in this subpart, the term 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.

H. Significant Financial Interest (SFI)

1. Significant Financial Interest is defined by the regulations as 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:
 - a. 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 the 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 in stock, stock options or other ownership interest, as determined through reference to public prices and other reasonable measures of fair market value;
 - b. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remunerations 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 interests (e.g. stock, stock options, or other ownership interest);
or
 - c. Intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests).
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), or an academic teaching hospital, medical center, or research institute that is affiliated with an Institution of higher education. Details of this disclosure must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer,

the destination, and the duration. The Company FCOIC will, in accordance with this policy, determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a FCOI with the PHS-funded research.

3. The term significant financial interest does not include the following types of financial interests: salaries, 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; any ownership interest in the Company held by the Investigator; income from investment vehicles, such as mutual funds and retirements 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, 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.

Roles and Responsibilities:

Company Responsibilities

1. The Company's President is responsible for overall Company compliance with the regulation by developing, communicating, following, and enforcing a written FCOI policy, and for the following:
 - a. Collecting disclosures of participating investigators significant financial interests:
 - i. That would reasonably appear to affect the research for which the PHS funding is sought and;
 - ii. In entities whose financial interests would reasonably appear to be affected by the research.
 - b. Determining which disclosures are FCOI;

- c. Managing, reducing, or eliminating these FCOI;
 - i. If an FCOI exists, develop and implement a management plan that shall specify the actions that have, and shall be, taken to manage such FCOI.
 - ii. 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 the PHS Awarding Component, per 42 C.F.R § 50.605(b)(1).
- d. Reporting to PHS, according to the requirements of 42 C.F.R § 50.605(b)(1), any FCOI that exists prior to expenditure of funds;
- e. Reporting any FCOI identified subsequent to the Institution's initial FCOI report during an ongoing PHS-funded research project to PHS, according to the requirements of 42 C.F.R § 50.605(b)(2), within sixty (60) days;
- f. Conducting retrospective reviews of noncompliance: Whenever a FCOI is not identified or managed in a timely manner (including any failure by the Investigator to disclose a SFI that is determined by the FCOIC to constitute a FCOI, or any failure by the Company to review or manage such a FCOI, or failure by the Investigator to comply with a FCOI management plan), the Company shall, within 120 days of the Company's 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; FCOI reports shall be made and updated as required by 50 C.F.R. § 50.605;
- g. Ensuring investigator training; and
- h. Ensuring accessibility of the Company's Policy by making it available to the public on the Company's Web site.

Investigator Responsibilities:

A participating Investigator is responsible for:

1. Reviewing and understanding this FCOI Policy and 42 C.F.R Part 50, Subpart F;
2. Complying with all Company policies and procedures; and
3. Executing the attached Financial Conflict of Interest Disclosure Form for disclosing the required information to Company upon hire, annually, for any grant application when it is discovered no current disclosure is in place (for whatever reason), and when an SFI arises or becomes known in-between other required disclosures.

Procedure:

1. Prior to the expenditure of any funds under a PHS-funded research project, the Company FCOIC will ensure that all associated Investigators have completed a Financial Conflict of Interest Disclosure Form (“disclosure forms”).
2. Financial Conflict of Interest Disclosure Forms will be completed upon hire; within 30 days of discovery of a change in significant financial interest and at least annually.
3. For each new grant submitted, the Company FCOIC will identify the subcontractors and confirm that they have FCOI assurance in their agreements. If language is not in a subcontract or master agreement by any name with a subcontractor, an agreement addendum will be completed adding the requirements of the PHS grant policy and published regulations for FCOI to the controlling agreement. If new subcontractors are added the FCOIC will ensure FCOI language is included in the contract. When new grants are submitted a list of participants and subcontractors will be kept in the FCOI binder.
4. The Company FCOIC will review all “disclosure forms” and evaluate whether they contain any conflict of SFI.
5. If no conflict of SFI is found, the “disclosure forms” will be filed in the FCOI binder. For negative finding no further review is required.

6. If a FCOI is identified it will be evaluated by the Company FCOIC who will work with the principal investigator or researcher to prepare a management plan that will reduce, minimize, or eliminate the conflict of interest. The management plan must be approved by the FCOIC before any expenditures are incurred against the federal grant.
7. If the Company FCOIC is unable to eliminate a FCOI, THE Company will notify the appropriate official at the funding agency within sixty (60) days of identifying the FCOI. Prior to the Institutions expenditure of any funds under a PHS-funded research project, the Institution shall provide an FCOI report regarding any Investigator's SFI found by the Institution to be conflicting and ensure that the Institution has implemented a management plan in accordance with 42 C.F.R § 50.605(b)(3).
8. In the event circumstances change, regarding a SFI of an investigator engaged in a sponsored project, the investigator must notify the Company's FCOIC as soon as the change becomes known and a revised disclosure form must be completed. The revised form will undergo the same review process as the original form. The new disclosure must be completed within 30 days of discovery.
9. Company will maintain the confidentiality of the disclosure statements except as required by federal law or agency award terms. In no case will a disclosure statement be released to a federal agency without prior notification to the affected individual.
10. In the event a SFI is determined to be a FCOI, and is still in existence, the Company will post on its website, or make available within 5 days of any written request, the nature of the FCOI. The information provided will be in accordance with 42 C.F.R Part 50, Subpart F and will be released before the expenditure of any funds.
11. If a FCOI is not identified or managed in a timely manner (including any failure by the Investigator to disclose a SFI that is determined by the FCOIC to constitute a FCOI, or any failure by the Company to review or manage such a FCOI, or failure by the Investigator to comply with a FCOI management plan), the Company shall, within 120 days of the Company's 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;
 - a. The Institution will document the retrospective review as required by 42 C.F.R § 50.605(a)(3)(ii)(B).

Training

1. At least annually, the Company will provide this policy, as well as applicable federal regulations, to each Investigator.
2. The Company will collect from each Investigator the disclosure form during training.
3. In addition, Investigators are required to complete the NIH Conflict of Interest Training Course, available at:

https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html.
4. The NIH course certification will be printed, signed by the Investigator, and collected by THE Company's FCOIC. This is required with the Investigator's first disclosure form, and at least every four years thereafter.
5. Each investigator must repeat the training if he or she is found by the FCOIC not to be in compliance with THE Company's FCOI Policy, or with a management plan.

Federal Compliance and Record Retention:

1. Upon hire and on an annual basis, all Company employees that qualify as Investigators per the definition above shall be provided with a copy of this policy and be required to complete and sign the disclosure form – Attachment A. All completed forms as well as all other conflict information shall be provided to and reviewed by the FCOIC.
2. All completed disclosure forms shall be retained by the FCOIC for a period of no less than 3 years after date of submission of the final expenditures report submitted to PHS under an award.
3. Violations:
 - a. If the Company FCOIC has reasonable cause to believe any person (employee, agent, consultant, student, trainee, or subcontractor) has failed to disclose actual or possible conflicts of interest, they shall inform the person of the basis for such belief and afford the person an opportunity to explain the alleged failure to disclose.
 - b. If, after hearing the person's response and after making further investigation as warranted by the circumstances, the Company FCOIC

determines the person has failed to disclose an actual or possible conflict of interest, the FCOIC will report the failure to the Company President who shall take appropriate disciplinary and corrective action up to and including termination of employment, subcontracts, or consulting agreements.

4. Training on the Financial Conflict of Interest Regulations and Company policy will be required:
 - a. Upon hire;
 - b. When the Company policy is changed such that it affects the requirements of the investigator;
 - c. If an investigator is not in compliance with the policy;
 - d. No less than every 4 years.

Publication

The Company President will ensure accessibility of the Company's Policy by making it available to the public on the Company's Web site.

Forms: Financial Conflict of Interest Disclosure Form –Attachment A

Attachment A

Koronis Biomedical Technologies – Financial Conflict of Interest Disclosure Form

Disclosure Type:

☐ New Hire ☐ Change of Financial Interest

☐ Annual/Project Specific:

Employee Name & Title: _____

Persons completing this form are expected to have read and understood the Company's Financial Conflict of Interest Policy on Federal Grants and Contracts and to have an understanding of 42 C.F.R Part 50, Subpart F. If you have any questions regarding that policy contact a member of the Financial Conflict of Interest Committee prior to signing this document.

1. Are you, or is any member of your Immediate Family, an employee, consultant, officer, director, partner, trustee, or any other agent of any commercial enterprise (other than the Company) participating or anticipating to participate in a Company project?

☐ Yes ☐ No If yes, please describe below the nature and extent of your/their relationship(s).

2. Do you, or does any member of your Immediate Family, have any Significant Financial Interest, such as ownership, equity, stock or stock options, within any commercial enterprise (other than the Company) participating or anticipating to participate in a Company project?

☐ Yes ☐ No If yes, please describe below the nature and extent of your/their relationship(s), and the value of the financial interest.

3. Do any other conditions exist between you, or any member of your immediate family, and any commercial enterprise which could reasonably be perceived by an outside observer as a potential conflict of interest?

☐ Yes ☐ No If yes, please describe below the nature and extent of your/their relationship(s).

Project Title/Grant # (if applicable): _____

Description for #1-3 above (if applicable): _____

Value of Financial Interest for #2 above (if applicable): _____

I certify that:

I have read the Company's Policy on Financial Conflict of Interest on Federal Grants and Contracts and to have an understanding of 42 C.F.R Part 50, Subpart F.

I have made all required financial disclosures.

(If the program leader, principal investigator or project director) I have made every effort to ensure that all Investigators (see policy for definition) responsible for the design, conduct or reporting of the research have submitted required disclosures.

Signature _____ **Date:** _____

Typed/Printed name: _____