
FINANCIAL CONFLICT OF INTEREST (FCOI) POLICY

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February 21, 2022

Introduction

This Financial Conflict of Interest Policy (this "**POLICY**") describes certain regulatory obligations applicable to Investigators' disclosure of potential financial conflicts of interest ("**FCOI**"). The purpose of this policy is to comply with applicable laws and regulations and to ensure the objectivity of certain research conducted by Kinetic River Corp. ("**KRC**") and certain of its employees, contractors, and consultants.

Investigators applying for and working on research funded by the National Institutes of Health ("**NIH**") or the National Science Foundation ("**NSF**") must disclose significant financial interests that are related to the Investigator's institutional responsibilities. Investigators are all persons, regardless of title or position, who are responsible for the design, conduct, or reporting of research proposed for funding by NIH or NSF (the foregoing agencies, together with any other organizations providing funding through grant or contract to which the regulations contemplated herein apply, collectively, the "**FUNDING AGENCIES**"), including collaborators or consultants. This policy provides the framework to identify, evaluate and correct or remove real, apparent or potential conflicts of interest.

This policy requires that each investigator, subrecipient, subgrantee and collaborator affiliated with the Institution on a Funding Agency project be in compliance with [42 CFR Part 50, Subpart F](#) for grants and cooperative agreements (and [45 CFR Part 94](#) for contracts). In addition, this legislation spells out NIH's commitment to preserving the public's trust that the research supported by them is conducted without bias and with the highest scientific and ethical standards. KRC intends to use this same FCOI standard for all other Federal agency grant and contract efforts, as tailored or amended accordingly.

With respect to subrecipients, if applicable, the Institution will establish, via a written agreement, whether a subrecipient will follow the Institution's FCOI policy or the FCOI policy of the subrecipient. If applicable, the Institution will obtain a certification from a subrecipient that its FCOI policy complies with the applicable regulation. If applicable, the Institution will include in the written subrecipient agreement a requirement for the subrecipient to report identified FCOIs for its Investigators in a time frame that allows the Institution to report identified FCOIs to the applicable Funding Agencies as required by the regulation. Alternatively, if applicable, the Institution will include in the written agreement a requirement to solicit and review subrecipient Investigator disclosures that enable the Institution to identify, manage and report identified FCOIs to the Funding Agency.

Definitions

The following definitions apply to this policy:

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"FUNDED RESEARCH" means any Institution research funded by a Funding Agency, excluding applications for Phase I support under the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs.

"INSTITUTION" means KRC.

"INVESTIGATOR" means any person (including subrecipients, subgrantees and collaborators) who is responsible for the design, conduct or reporting of Funded Research.

"INSTITUTIONAL RESPONSIBILITIES" means an Investigator's professional responsibilities on behalf of the Institution, including, e.g., project planning and coordination, prototype design and assembly, running experiments, data analysis and reporting.

"TRAINING REQUIREMENT" means training related to Financial Conflict of Interest (FCOI) and required under applicable regulations.¹ All Institution Investigators and all applicable subrecipients are required to complete the Training Requirement. If any conflicts of interest are found or known, they must be disclosed. The training must be updated no less frequently than every four years or as designated based on grant or role circumstances. Information and other resources developed by NIH will be updated as appropriate and can be accessed through the NIH Web site:

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

"SIGNIFICANT FINANCIAL INTEREST" (SFI) means a financial interest consisting of one or more of the following interests of the Investigator (including those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

If...	...then Investigator <u>does</u> need to disclose:
in case of a <u>publicly-traded entity</u> : the value of any remuneration* received by the Investigator [†] from that entity in the twelve months preceding the disclosure, and the value of any equity interest of the Investigator [†] in that entity as of the date of disclosure, when aggregated, exceed \$5,000	aggregated value of such remuneration and/or equity interest
in case of a <u>privately held entity</u> : the value of any remuneration* received by the Investigator [†] from that entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000 or the Investigator [†] holds any equity interest (e.g., stock, stock options, or other ownership interest) in that entity	aggregated value of such remuneration and/or existence of such equity interest
the income received by the Investigator [†] related to intellectual property rights and interests (e.g., patents, copyrights) exceeds \$5,000	income from such rights and interests

* salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); and 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

† or the Investigator's spouse or dependent children

¹ See <https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchor=question52899> (question L.1)

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With respect to Significant Financial Interest, Investigators also must disclose (and such disclosure will constitute an SFI Disclosure, defined below) the occurrence of any reimbursed travel expenses in excess of \$5,000 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; with the exceptions noted in the table below. This disclosure will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. Upon receipt of this disclosure, the Policy Coordinator will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the Funded Research.

Financial interests excluded from SFI disclosure requirements:

If...	...then Investigator does <u>not</u> need to disclose:
Investigator is currently employed or otherwise appointed by the Institution	salary, royalties, or other remuneration paid to Investigator by the Institution
the Institution is a commercial or for-profit organization	any ownership interests in the Institution held by the Investigator
Investigator does not directly control the investment decisions made in investment vehicles, such as mutual funds and retirement accounts	income from such investment vehicles
Investigator's seminars, lectures, or teaching engagements are 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	income from such seminars, lectures, or teaching engagements
Investigator serves on an advisory committee or a review panel 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	income from service on such advisory committees or review panels
Investigator's travel expenses are 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, medical center, or research institute that is affiliated with an institution of higher education	such reimbursed travel expenses

A "**FINANCIAL CONFLICT OF INTEREST**" or "**FCOI**" exists when the Institution reasonably determines that a disclosed SFI could directly and significantly affect the design, conduct or reporting of Funded Research.

An "**SFI DISCLOSURE**" is a report that each Investigator will submit: (a) annually to the Policy Coordinator; (b) in the event of certain sponsored travel, as set forth in the definition of SFI above; (c) within thirty (30) days of an Investigator discovering or acquiring any significant financial interest; and (d) no later than at the time of application for Funded Research.

"**MANAGEMENT**" of an FCOI means 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 Funded Research will be free from bias.

An "**AWARDING COMPONENT**" is the applicable sub-agency of a Funding Agency.

Disclosures/Reporting/Determination Process

Each Investigator will submit SFI Disclosures (using the Institution’s SFI Disclosure Form—attached to this Policy) to the Policy Coordinator as follows:

1. an updated general SFI Disclosure annually;
2. within 30 days in the event of certain sponsored travel, as set forth in the SFI definition above;
3. within 30 days of an Investigator discovering or newly acquiring an SFI; and
4. no later than at the time of application for Funded Research.

Additionally, the Policy Coordinator will solicit SFI Disclosures from each Investigator, if applicable, during a reasonable period of time preceding the commencement of any research conducted hereunder.

Please note that, at present, KRC is not engaged or involved in clinical research.

Institutional Responsibilities on Determining FCOI

Prior to the expenditure of funds, the Policy Coordinator will review each SFI Disclosure and, within 60 days, determine if any SFIs relate to Funded Research, determine if an FCOI exists, and develop and implement management plans as needed to manage FCOIs, if applicable. Criteria for FCOI determination:

1. The SFI was disclosed and is still held by the Investigator for the Funded Research project identified by the Institution in the grant application, progress report, or any other required report submitted to the Funding Agency
2. The Institution determines that the SFI is related to the Funded Research
3. The institution determines that the SFI is an FCOI

An SFI is related to Funded Research when the Institution, through the Policy Coordinator, reasonably determines that the SFI:

- i. could be affected by the Funded Research
- ii. is in an entity whose financial interests could be affected by the Funded Research

The Institution may involve the Investigator in the Policy Coordinator’s determination of whether an SFI is related to the Funded Research.

In determining whether an Investigator’s SFI is related to Funded Research, and if so related, whether the SFI is an FCOI, the Policy Coordinator will consider all available evidence in light of the following concepts, in addition to any other concepts the Policy Coordinator may reasonably consider:

Protected Interests

- Research integrity
- Safety of human subjects
- Institution’s reputation
- Investigator’s reputation

Relationship between the SFI and the Research

- Is the subject of the SFI or its products or services involved in the Funded Research, and if so how?
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- Is the SFI in a diversified enterprise generally, or in a specific division or subsidiary more closely related to the Funded Research?

Nature of the SFI

- Equity, cash compensation, or in-kind compensation?
- Part of a diversified portfolio or a specific investment?
- Publicly-traded or privately held company?
- Does compensation exceed fair market value?

Likelihood of influence

- Role of the Investigator in the Funded Research
- Potential gain to Investigator if Funded Research were to yield particular results
- Safeguards built into design

If no FCOI is found, the SFI Disclosure will be filed with the Institution's SFI Disclosure records. If an FCOI is identified, it will be included in the FCOI report through the eRA Commons FCOI module (or, where the Institution is a subgrantee or subawardee, then the Institution will report the FCOI as required under the applicable subgrant or subaward agreement) prior to expending any Funding Agency funds. The Institution will then report any new FCOIs to the Awarding Component within 60 days. If an Investigator with an FCOI conducts Funded Research, the Institution will disclose the FCOI in each public presentation related to the results of the Funded Research.

Prior to the expenditure of funds, the Institution will ensure public accessibility, by written response within five business days of a request, to information concerning identified FCOIs held by senior/key personnel . The information will include the minimum elements as provided in the regulation, be updated at least annually, be updated within 60 days of a newly identified FCOI, and remain available for three years from the date the information was most recently updated.

Records Management

The Institution will maintain records of all SFI disclosures, and records of resulting Institution action, for at least three years from the date of submission of the final expenditures report for the applicable funding, or for such other periods of time as may be required under [45 CFR Part 75.361](#), if applicable.

Compliance and Penalties for Non-Performance

If an FCOI is found, the Institution will outline in its FCOI report an FCOI management plan, including:

- a. the role and principal duties of the conflicted Investigator in the research project;
- b. conditions of the management plan;
- c. how the management plan is designed to safeguard objectivity in the research project;
- d. confirmation of the Investigator's agreement to the management plan;
- e. how the management plan will be monitored to ensure Investigator compliance; and
- f. other information as needed.

Subsequent FCOI reports will include the status of the management plan and any changes to it.

Whenever an FCOI is not identified or managed in a timely manner, including by:

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- failure by an Investigator to disclose an SFI that is determined by the Institution to constitute an FCOI;
- failure by the Institution to review or manage such an FCOI; or
- failure by an Investigator to comply with an FCOI management plan;

the Institution will complete, within 120 days, a retrospective review of the Investigator's activities to determine bias. The Institution shall document the retrospective review which must include at least the following key elements:

- a. project number;
- b. project title;
- c. PD/PI or contact PD/PI if a multiple PD/PI model is used;
- d. name of the Investigator with the FCOI;
- e. name of the entity with which the Investigator has a financial conflict of interest
- f. reason(s) for the retrospective review;
- g. detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed, etc.);
- h. findings of the review; and
- i. conclusions of the review.

If as a result of that determination, or at any other time, any bias is found, the Institution will submit a mitigation report to the applicable Funding Agency, in accordance with [42 CFR Part 50.605\(b\)\(3\)](#), that will address the impact of the bias on the research project and the actions it has taken to mitigate the bias. The Institution will work with the Investigator to set up an FCOI management plan to mitigate the situation. Companywide, the Institution is required to mandate that the Investigator disclose the FCOI in each public presentation with research results, and to request an addendum disclosing the FCOI in previously published presentations, if it was not reported up front. In extreme cases of bias, the Investigator may lose the right to work on the project or receive any future NIH funding.

Policy Coordinator

If you have a conflict of interest or if you have a question to discuss, contact the Institution FCOI Policy Coordinator, Giacomo Vacca, at info@KineticRiver.com.