

POLICY ON FINANCIAL CONFLICTS OF INTEREST

PURPOSE AND SCOPE OF POLICY

This Policy implements Financial Conflicts of Interest (FCOI) disclosure requirements found in 42 CFR Part 50 and 45 CFR Part 94 which are applicable to Research funded by the U.S. Public Health Service (PHS). As a condition for receiving PHS funding, these regulations require Innovative Biochips to maintain an appropriate written policy on financial conflict of interest disclosure. These requirements are applicable to all Research projects for which Innovative Biochips submits a proposal to or receives Research funding from PHS. Each Investigator who is planning to participate in, or is participating in such Research, must follow this process. Subcontractors/consultants who perform services within the definition of an Investigator must maintain a policy that complies with the aforementioned regulatory requirements or comply with this Policy.

The PHS FCOI Regulations and this Policy are intended to ensure objectivity in which Research projects are designed, conducted or reported by managing FCOI that occur between an Investigator's personal financial interests and his/her professional Research interests. It establishes a process of disclosure and independent review when an Investigator has a Significant Financial Interest (SFI). If Innovative Biochips determines that such an interest might reasonably appear to affect the Research directly and significantly, Innovative Biochips will develop a mitigation plan to manage or eliminate the conflict.

This Policy is available at the following public accessible Website: www.ibiochips.com.

DEFINITIONS

A. Financial Conflict of Interest

A Financial Conflict of Interest (FCOI) is a SFI that could directly and significantly affect the design, conduct or reporting of PHS funded Research.

B. Institution

An institution is any domestic or foreign, public or private, entity or organization (excluding a Federal agency) applying for, or receiving PHS research funding. Innovative Biochips is considered an "Institution" for purposes of this policy.

C. Investigator

An Investigator is any individual responsible for the design, conduct, or reporting of Research funded by the PHS. This includes the Principal Investigator (PI), Co-Investigators, consultants, subcontractors, and any other individual, regardless of title or position, who is responsible for designing, conducting, or reporting of this Research.

D. Institutional Official (IO)

An official designated by Innovative Biochips to solicit and review completed Disclosure Forms from each Investigator who is planning to participate in, or who is participating in, PHS funded Research and to determine whether any reported SFI is a FCOI. References to the IO in this document include his/her delegate.

E. Institutional Responsibilities

Institutional Responsibilities means an Investigator's professional responsibilities performed on behalf of Innovative Biochips.

F. PHS Awarding Component

PHS Awarding Component means the organizational unit of the PHS that funds the Research. National Institutes of Health (NIH) is considered "PHS Awarding Component" for purposes of this policy.

G. Research

Research means 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 as well as product development.

H. Senior/Key Staff

Senior/Key staff means the PI and any other person identified as Senior/Key staff by Innovative Biochips in the grant application, proposal or any other report submitted to the NIH.

I. Significant Financial Interest

Significant Financial Interest (SFI) means either of the following:

1. Any interest of the Investigator, his/her spouse, and dependent children that reasonably appears to be related to the Investigator's Institutional Responsibilities, including, but not limited to, one or more of the following:
 - a. 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 for services not otherwise identified as salary (e.g., consulting fees, honoraria, 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;
 - b. With regard to any non-publicly traded 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 or dependent children) holds any equity interest (e.g., stock, stock option, 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), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

The SFI does not include the following types of financial interests:

- salary, royalties, or other remuneration paid by Innovative Biochips to the Investigator if the Investigator is currently employed or otherwise appointed by Innovative Biochips, including intellectual property rights assigned to Innovative Biochips and agreements to share in royalties related to such rights;
- any ownership interest in Innovative Biochips held by the Investigator;

- income from investment vehicles, such as mutual funds and retirement accounts, provided 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, 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, 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.

DISCLOSURE REQUIREMENT

Each Investigator who is planning to participate in PHS funded Research is required to disclose to Innovative Biochips his/her SFIs, his/her spouse's SFIs and his/her dependent children's SFIs no later than the time of application for PHS funded Research. Each Investigator must do so by completing the Disclosure Form available at the following Website: www.ibiochips.com. This disclosure obligation is created initially by the Investigator's intent to participate in PHS funded Research.

When PHS funded Research opportunities arise, Institution Contracting Officer send by email a reminder to the applicable staff of these obligations. Prior to submission of a proposal or application for PHS funded Research, Institution Contracting Officer shall review all required Disclosure Forms and notify the IO of any SFIs reported on the Disclosure Forms.

Additionally, each Investigator, which includes staff responsible for the design, conduct, or reporting of Research funded by the PHS, is required to submit an updated Disclosure Form to IO either within 30 days of discovering or acquiring a new SFI, or at least on an annual basis. If an Investigator does not have any SFIs to report, the Investigator must still complete the Disclosure Form annually. Innovative Biochips shall ensure applicable staff comply with these disclosure obligations. Failure to comply with these disclosure obligations may result in disciplinary action by Innovative Biochips.

REVIEW OF DISCLOSURE AND MANAGEMENT OF FCOI

A. Review Requirement

Prior to Innovative Biochips' expenditure of any funds under a PHS funded Research project, the IO will review all Disclosure Forms with SFIs to determine whether the SFIs relate to the PHS funded Research and whether a FCOI exists. If a FCOI exists, the IO will develop and implement a management plan that specifies the actions that have been, and will be, taken to manage such FCOI.

B. Disclosure/Identification of SFI

1. Whenever, in the course of an ongoing PHS funded Research project, (1) an Investigator who is new to participating in the Research project discloses a SFI; (2) an existing Investigator discloses a new SFI; or (3) Innovative Biochips identifies a SFI that was not disclosed timely by an Investigator or was not previously reviewed by Innovative Biochips during an ongoing PHS funded Research project, the IO within 60 days of the disclosure will review the SFI to determine whether it is related to PHS funded Research and whether a FCOI exists. If a FCOI exists, the IO will develop and implement, on at least an interim basis, a management plan that specifies the actions that have been, and will be, taken to manage such FCOI. Depending on the nature of the SFI, Innovative Biochips may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS funded Research project between the date of disclosure and the completion of Innovative Biochips' review.

2. Prior to Innovative Biochips' expenditure of any funds under a PHS funded Research project, Innovative Biochips must post to its publicly accessible Website, information concerning any SFI disclosed to Innovative Biochips that is (1) held by Senior/Key Staff performing services for the project, (2) related to the PHS funded research, and (3) determined by Innovative Biochips to be a FCOI. This information must be updated at least annually as well as within 60 days of the following events:
 - a) Innovative Biochips' receipt or identification of information concerning any additional SFI of the Senior/Key Staff for the PHS funded Research project that was not previously disclosed; or
 - b) upon disclosure of any SFI of Senior/Key Staff new to the PHS funded Research project and meeting the disclosure criteria.

C. Management of FCOI

Examples of conditions or restrictions that may be imposed to manage a FCOI include, but are not limited to the follow actions:

- Public disclosure of the FCOI (e.g. when presenting or publishing research);
- For Research projects involving human subjects, disclosure of the FCOI 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 FCOI;
- 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; or
- Severance of relationships that create financial conflicts.

D. Retrospective Review

Whenever a FCOI is not identified, disclosed or managed in a timely manner or an Investigator fails to comply with a FCOI management plan, Innovative Biochips has additional review and reporting obligations. If in these situations Innovative Biochips determines that a SFI constitutes a FCOI, the IO will, within 120 days of Innovative Biochips' 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. Innovative Biochips is required to document the retrospective review.

E. Monitoring

Whenever Innovative Biochips implements a management plan, Innovative Biochips will monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS funded Research project.

REPORTING OF FINANCIAL CONFLICTS OF INTEREST

A. Initial FCOI Report

Prior to Innovative Biochip's expenditure of any funds under a PHS funded Research project, Innovative Biochip will provide to NIH a FCOI report regarding any Investigator's SFI found by Innovative Biochip to be a FCOI. In situations in which Innovative Biochip identifies a FCOI and eliminates it prior to the expenditure of PHS awarded funds, Innovative Biochip is not required to submit a FCOI report to NIH.

B. Subsequent FCOI Reports

For any SFI that Innovative Biochip identifies as a FCOI after Innovative Biochips' initial report during an ongoing PHS funded Research project, Innovative Biochips will provide to NIH a FCOI report regarding the FCOI within 60 days of identification of the FCOI.

C. Annual FCOI Report

For any FCOI previously reported by Innovative Biochips regarding an ongoing PHS funded Research project, Innovative Biochips will provide to NIH an annual FCOI report that addresses the status of the FCOI and any changes to the management plan for the duration of the PHS funded Research project. The annual FCOI report will specify whether the FCOI is still being managed or explain why the FCOI no longer exists. Innovative Biochips will provide annual FCOI reports to NIH for the duration of the project period (including extensions with or without funds) in the time and manner specified by NIH.

ENFORCEMENT

If the failure of an Investigator to comply with this Policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS funded Research, Innovative Biochips is required to promptly notify NIH of the corrective action taken or to be taken by Innovative Biochips. NIH will consider the situation and, as necessary, take appropriate action, or refer the matter to Innovative Biochips for further action, which may include directions to Innovative Biochips on how to maintain appropriate objectivity in the PHS funded Research project. Sponsors may impose special award conditions or may suspend or terminate the award and/or debar an Investigator from receiving future awards in the event of failure to comply with applicable federal regulations on disclosure, review, and management of SFI related to federally sponsored projects.

RECORD RETENTION

Records regarding Disclosure Forms, determinations made by the IO, and Innovative Biochips' actions regarding management of a FCOI will be retained by Innovative Biochips for 3 years beyond the date of the final expenditure report submitted to NIH under an award or, where applicable, from other dates specified in 45 CFR 74.53(b) and 45 CFR 92.42(b).

TRAINING

Each Investigator must complete training prior to engaging in PHS funded research by the NIH Office of Extramural Research FCOI online tutorial that can be accessible at https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html.

Additionally, Investigators must complete training at least every 4 years and must immediately complete training under the following circumstances:

- Innovative Biochips' FCOI policy changes in a manner that affects Investigator requirements;
- An Investigator is new to Innovative Biochips; or
- Innovative Biochips determines that an Investigator is not in compliance with Innovative Biochips' FCOI policy or management plan.

SUBCONTRACTORS/CONSULTANTS

Subcontractors/consultants who perform services within the definition of an Investigator must maintain a policy that complies with the aforementioned regulatory requirements or comply with this Policy. All applicable subcontract/consulting agreements must contain a clause that requires compliance with the applicable federal regulations either through a policy maintained by the subcontractor/consultant or this Policy.