

		Revision 1.3
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# FINANCIAL CONFLICT OF INTEREST POLICY

This Financial Conflict of Interest (FCOI) on Federal Grants Policy has been adopted by the Institute for Future Intelligence, Inc., of Natick, MA, and applies to all employees and contractors working on behalf of the Institute for Future Intelligence, Inc. This policy covers all the activities funded by federal agencies, including but not limited to the National Institutes of Health, at the Institute for Future Intelligence, Inc.

## Overview

### Purpose

The purpose of this document is to ensure that the Institute for Future Intelligence, Inc. is in compliance with the requirements of the Financial Conflict of Interest (FCOI) on Federal Grants Policy set forth in 42 CFR 50, subpart F, “Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought” (hereafter referred to as “FCOI Regulation”). This policy statement documents the practices and procedures to be followed by the Institute for Future Intelligence, Inc. (hereafter referred to as “IFI” or the “Organization”). These practices and procedures are designed to ensure objectivity in research by establishing standards that result in design, conduct, and reporting of research funded by federal grants to be free from bias resulting from investigators’ financial conflicts of interest. Furthermore, this policy provides procedures to identify, manage, and resolve any investigator FCOI.

### Applicability

This FCOI Policy Statement applies to all investigators, staff, and contractors working on behalf of IFI involved in federally funded research or cooperative agreements, with the exception of projects with funding sources that do not fall directly under the FCOI Regulation. This document was developed in response to the FCOI Regulation, which was used to guide the development of this Policy Statement.

Institute for Future Intelligence, Inc., <https://intofuture.org>

## Definitions

The following definitions apply to this policy.

1. **Designated Official:** person designated by IFI to determine when an investigator's Significant Financial Interest is related to federally funded research and when related, will determine if the Significant Financial Interest is a Financial Conflict of Interest.
2. **Financial Conflict of Interest (FCOI):** a significant financial interest that could directly and significantly affect the design, conduct, or reporting of federally funded research.
3. **FCOI Report:** an institution's report of a financial conflict of interest to the relevant PHS Awarding Component or other federal agencies.
4. **Financial Interest:** anything of monetary value, whether or not the value is readily ascertainable.
5. **Significant Financial Interest (SFI):** defined in the next section.
6. **Investigator:** the project director or principal investigator and any other person, 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.
7. **Institution:** any domestic or foreign, public or private, entity or organization (excluding a federal agency) that applies for or receives federal research funding.
8. **Institutional Responsibilities:** an investigator's professional responsibilities on behalf of the institution and as defined by the institution in its policy on financial conflicts of interest. For example, activities such as research, research consultation, teaching, professional practice, committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.
9. **HHS:** the United States Department of Health and Human Services and any components of the Department to which the authority involved may be delegated.
10. **PHS:** the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority may be delegated, including the National Institutes of Health (NIH).

11. **PHS Awarding Component:** the organizational unit of the PHS that funds the research that is subject to this part.
12. **PHS Act:** Public Health Service Act refers to the statute codified at 42 U.S.C. *et seq.*
13. **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. 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 therapeutic drug). As used in this part, the term includes any 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.
14. **Management Plan:** procedures to identify, manage, report, and remedy financial conflicts of interest.

## Significant Financial Interest

A financial interest consisting of one or more of the following foreign and domestic 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:

- (i) 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;
- (ii) 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 or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
- (iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

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 located within the United States, a United States institution of higher education as defined at 20 United States Code (U.S.C.) 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States institution of higher education. The institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the institution's FCOI policy, the institutional official(s) 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 PHS-funded research.

The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by the institution to the investigator if the investigator is currently employed or otherwise appointed by the institution, including intellectual property rights assigned to the institution and agreements to share in royalties related to such rights; any ownership interest in the institution held by the investigator, if the institution is a commercial or for-profit organization; 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 government agency located within the United States, a United States institution of higher education as defined at 20 United States Code (U.S.C.) 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States institution of higher education; or income from service on

advisory committees or review panels for a federal, state, or local government agency located within the United States, a United States institution of higher education as defined at 20 United States Code (U.S.C.) 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States institution of higher education.

Investigators are required to disclose all foreign and domestic SFIs that are related to the investigator's institutional responsibilities on behalf of the institution, and as defined by the institution in its policy on FCOI. As per NIH's Notice NOT-OD-18-160, investigators must disclose all foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign institutions of higher education or foreign governments (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of \$5,000).

## Institutional Responsibilities and Procedures

### Record Keeping

The Institute for Future Intelligence, Inc. will maintain an up-to-date, written, and enforced policy on financial conflicts of interest that complies with the FCOI Regulation, and will make such policy available via a publicly accessible Web site (<https://intofuture.org/fcoi.pdf>), and will be provided to any requestor within five business days of the request. IFI shall adhere to this FCOI Policy and shall provide FCOI Reports regarding identified FCOI to the PHS Awarding Component in accordance with the FCOI Regulation and within the required timeframe. Specifically, IFI will:

1. Inform each investigator of the FCOI Policy and train each investigator on their responsibilities regarding disclosure of SFI.
2. Require that each investigator submit an FCOI Disclosure in a timely manner and maintains up-to-date training at least every four years or immediately if:
  - a. IFI revises this FCOI Policy

- b. An investigator is new to IFI
  - c. IFI finds that an investigator is not in compliance with this FCOI Policy or Management Plan for FCOI.
3. Require that each investigator submit an updated FCOI Disclosure annually, and an updated FCOI Disclosure within thirty days of discovering or acquiring, through marriage, purchase, or inheritance, a new SFI.
  4. Certify that subrecipient's investigator(s) will comply with the subrecipient's FCOI policies or IFI's FCOI policies and procedures.
  5. Provide guidelines consistent with the FCOI Regulation to the Designated Official to determine whether an investigator's SFI is related to PHS-funded research, and if so, whether the SFI is an FCOI. An FCOI exists when the Designated Official reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.
  6. Provide initial and ongoing FCOI Reports to the PHS Awarding Component regarding all financial conflicts of interest from each investigator participating or planning to participate in the PHS-funded research.
  7. Maintain records related to all investigator disclosures of financial interests and the Organization's review of, and response to, such disclosures even when it did not result in a determination of FCOI. IFI agrees to make these records available promptly upon request and shall make every effort to comply with the FCOI Regulations.
  8. Take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subrecipient investigator.

## Training

The Institute for Future Intelligence, Inc. will be responsible for investigator training, collecting and evaluating FCOI disclosure forms, and enforcement of this FCOI Policy in order to facilitate and promote compliance with the FCOI Regulation. This policy is available, and updated as needed, on <https://intofuture.org/fcoi.pdf>, and FCOI Disclosure forms are made available to all investigators. Training will be repeated at least every four years and immediately if FCOI policies

and procedures have been modified, or if an investigator is found to be in non-compliance with the FCOI Policy or with IFI's management plan related to FCOI.

## Disclosure Requirements

All participating investigators are required to fill out and submit an FCOI Disclosure statement on the form provided (the FCOI Form) which will be reviewed by the Designated Official to assess the potential for a conflict and initiate the review and response procedures outlined below. In addition, all investigators must submit an updated FCOI Disclosure form annually during the period of the PHS award and update any information regarding any previously disclosed SFI. Any newly discovered or acquired SFI, be it through marriage, purchase, or inheritance, must be disclosed by the investigator within thirty days. New investigators added to a project after the start date of the project must also complete a disclosure form, including situations when previously non-investigator employees take on the role of an investigator. New or changed investigators will also complete the training as described above.

## Subcontracts

If the federally funded research involves a subrecipient (e.g., subcontractors or consortium members), IFI will take reasonable steps to ensure that any subrecipient investigator complies with the federal policies by:

1. Establishing with the subrecipient whether FCOI policies of the subrecipient institution or of IFI will apply to the subrecipients investigators on the project:
  - a. If the subrecipient's investigators must comply with their institution's FCOI policies, the subrecipient shall certify that these policies are in compliance with the federal policies. In the absence of this certification, the agreement will state that the subrecipient's investigators are subject to the FCOI policies of IFI and will disclose SFI that are related to the work for IFI.
  - b. Whether the subrecipient's investigators must comply with their institution's FCOI policies or the FCOI policies of IFI, the written agreement will specify a deadline for

the subrecipient to submit an FCOI disclosure so that FCOI may be identified, and reported, if necessary, to the relevant federal agency.

2. Maintain records of FCOI Disclosures and provide FCOI Reports to the federal agency regarding all financial conflicts of interest of all subrecipient investigators consistent with the FCOI Regulation.

## Management and Reporting of FCOI

Prior to the Organization's expenditure of any funds under a PHS-funded research project, the Designated Official shall review all investigator disclosures of SFI to determine whether any SFI is related to PHS-funded research and whether an FCOI exists. If it is deemed that an FCOI exists, IFI will develop and implement a management plan that specifies the actions that have been, and shall be, taken to manage such financial conflict of interest. Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest 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 projects involving human subjects research, disclosure of financial conflicts of interest directly to the participants of the study
3. Appoint an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias that may result from the FCOI.
4. Modify the Research Plan as necessary
5. Change the investigator, or other personnel or the responsibilities of the investigator or other personnel or disqualify personnel from participation in all or a portion of the research.
6. Reduce or eliminate the financial interest (e.g., sale of an equity interest); or
7. Severance of the relationships that create financial conflicts.

Whenever, in the course of an ongoing PHS-funded research project, an investigator new to the research project discloses an SFI or an existing investigator discloses a new SFI to the Organization, the Designated Official shall, within sixty days, review the disclosure of the SFI,



determine whether it is related to PHS-funded research, determine whether an FCOI exists, and if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest. Depending on the nature of the SFI, the Organization 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 the review.

Whenever IFI identifies an SFI that was not disclosed timely by an investigator or, for whatever reason, was not previously reviewed by the Organization during an ongoing PHS-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the Designated Official shall review the SFI within sixty days, determine whether it is related to PHS-funded research, determine whether an FCOI exists, and if so:

1. Implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such FCOI going forward
2. Whenever an FCOI is not identified or managed in a timely manner including failure by the investigator to disclose an SFI that is determined by the Organization to constitute an FCOI or failure by the Organization to review or manage such an FCOI or failure by the investigator to comply with an FCOI management plan, IFI shall, within 120 days of the Organization's determination of non-compliance, 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 non-compliance, was biased in the design, conduct, or reporting of such research. The Organization is required to document the retrospective review; such documentation shall include, but not necessarily be limited to, all of 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)
    - h. Findings of the review; and
    - i. Conclusions of the review.
3. Based on the results of the retrospective review, if appropriate, the Organization shall update the previously submitted FCOI report(s), specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, the Organization is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the Organization's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, IFI will submit FCOI reports annually, as specified elsewhere in this subpart. Depending on the nature of the financial conflict of interest, IFI may determine that additional interim measures are necessary with regard to the involved investigator's participation in the PHS-funded research project between the date that the financial conflict of interest or the investigator's noncompliance is determined and the completion of the Organization's retrospective review.

Whenever IFI implements a management plan, the Organization shall monitor its investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

Prior to the expenditure of any funds under a PHS-funded research project, IFI shall ensure public accessibility, via a publicly accessible Web site or written response to any requestor and within five business days of a request, of information concerning any significant financial interest disclosed to the Organization that meets the following three criteria:

1. The SFI was disclosed and is still held by the senior/key personnel.

2. IFI determines that the SFI is related to the PHS-funded research; and
3. IFI determines that the SFI is an FCOI.

The information that the Organization makes available via a publicly accessible Web site or written response to any requestor within five business days of a request, shall include, at a minimum, the following:

1. the investigator's name
2. the investigator's title and role with respect to the research project
3. the name of the entity in which the significant financial interest is held
4. the nature of the significant financial interest
5. and the approximate dollar value of the significant financial interest using the following dollar ranges:
  - a. \$0-\$4,999
  - b. \$5,000-\$9,999
  - c. \$10,000-\$19,999
  - d. amounts between \$20,000-\$100,000 by increments of \$20,000
  - e. amounts above \$100,000 by increments of \$50,000
6. 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.

If IFI uses a publicly accessible Web site for the purposes of this subsection, the information that the Organization posts shall be updated at least annually. In addition, IFI shall update the Web site within sixty days of the Organization's receipt or identification of information concerning any additional SFI of the senior/key personnel for the PHS-funded research project that was not previously disclosed, or upon the disclosure of SFI of senior/key personnel new to the PHS-funded research project, if the Organization determines that the SFI is related to the PHS-funded research and is an FCOI. The Web site shall note that the information provided is current as of the date listed and is subject to updates, on at least an annual basis and within sixty days of the Organization's identification of a new FCOI. If IFI responds to written requests for the purposes of this subsection, the Organization will note via a written response that the

information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within sixty days of the Organization's identification of a new FCOI, which should be requested subsequently by the requestor.

Information concerning the SFI of an individual shall remain available for responses to written requests or for posting via the Organization's publicly accessible Web site for at least three years from the date that the information was most recently updated.

In addition to the types of FCOI that must be managed, IFI may require the management of other FCOI in its policy on financial conflicts of interest, as deemed appropriate.

## **Reporting Financial Conflicts of Interest**

Prior to the Organization's expenditure of any funds under a PHS-funded research project, IFI shall provide to the PHS Awarding Component an FCOI Report regarding any investigator's SFI found by the Organization to be conflicting and ensure that the Organization has implemented a management plan accordingly. In cases in which the Organization identifies an FCOI and eliminates it prior to the expenditure of PHS-awarded funds, IFI will not submit an FCOI Report to the PHS Awarding Component.

For any SFI that the Organization identifies as conflicting subsequent to its initial FCOI Report during an ongoing PHS-funded research project (e.g., upon the participation of an investigator new to the research project), IFI shall provide to the PHS Awarding Component, within sixty days, an FCOI Report regarding the FCOI and ensure that the Organization has implemented a management plan in accordance with this subpart. Where such an FCOI Report involves an SFI that was not disclosed in a timely manner by an investigator or, for whatever reason, was not previously reviewed or managed by IFI (e.g., was not timely reviewed or reported by a subrecipient), the Organization is also required to complete a retrospective review to determine whether any PHS-funded research, or portion thereof, conducted prior to the identification and management of the FCOI was biased in the design, conduct, or reporting of such research. Additionally, if bias is found, IFI shall notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.

Any FCOI Report required shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of IFI's management plan and response. Elements of the FCOI report shall include, but not be limited to the following:

1. Project number
2. PD/PI or Contact PD/PI if a multiple PD/PI model is used
3. Name of the investigator with the financial conflict of interest
4. Name of the entity with which the investigator has a financial conflict of interest
5. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, or honorarium)
6. Value of the financial interest using the following dollar ranges:
  - a. \$0-\$4,999
  - b. \$5,000-\$9,999
  - c. \$10,000-\$19,999
  - d. amounts between \$20,000-\$100,000 by increments of \$20,000
  - e. amounts above \$100,000 by increments of \$50,000
  - f. 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
7. A description of how the financial interest relates to the PHS-funded research and the basis for IFI's determination that the financial interest conflicts with such research; and
8. A description of the key elements of IFI's management plan, including:
  - a. 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

For any financial conflict of interest previously reported by the Organization with regard to an ongoing PHS-funded research project, IFI shall provide to the PHS Awarding Component 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 shall specify whether the financial conflict is still being managed or explain why the FCOI no longer exists. IFI shall provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

In addition to the types of FCOI defined, IFI may require the reporting of other types of FCOI in its policy on FCOI, as deemed appropriate.

## Remedies

If the failure of an investigator to comply with IFI's financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, the Organization shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to the Organization for further action, which may include directions to the Organization on how to maintain appropriate objectivity in the PHS-funded research project. PHS may, for example, advise IFI to require the responsible investigator to enforce any applicable corrective actions prior to a PHS award or when the transfer of a PHS grant involves such an investigator.

The PHS Awarding Component and/or HHS may inquire at any time before, during, or after award into any investigator disclosure of financial interests and IFI's review (including any retrospective review) of, and response to, such disclosure, regardless of whether the disclosure resulted in the Organization's determination of a financial conflict of interest. IFI is required to submit all records pertinent to compliance with this subpart. To the extent permitted by law, HHS will maintain the confidentiality of all records of financial interests. On the basis of its review of records or other information that may be available, the PHS Awarding Component

may decide that a particular FCOI will bias the objectivity of the PHS-funded research to such an extent that further corrective action is needed or that IFI has not managed the FCOI appropriately. The PHS Awarding Component may determine that imposition of specific award conditions under 45 CFR 75.207, or suspension of funding or other enforcement action under 45 CFR 75.371, is necessary until the matter is resolved.

In any case where the HHS 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 has been designed, conducted, or reported by an investigator with a financial conflict of interest that was not managed or reported by IFI as required, the Organization shall require the investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

## Revision History

Rev #	Doc #	Effective Date	Description of Change
1.2	NIH-002	March 26, 2023	Revised Version
1.3	NIH-002	March 27, 2023	Revised Version