

1 PURPOSE AND SCOPE

Purpose

CognifiSense, Inc. (hereafter referred to as "the Company") is committed to maintaining the objectivity and integrity of research. The purpose of this policy is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, or reporting of funded research, grants or cooperative agreements will be free from bias resulting from an Investigator's (and/or of the Investigator's spouse and/or dependent children) financial conflicts of interest.

Scope

This policy applies to Investigators participating in, or planning to participate in the design, conduct, reporting or proposing research funded by the U.S. Public Health Service (PHS) or U.S. National Institute of Health (NIH).

If a research project involves subcontractors, subgrantees, or subawardees (collectively subrecipients), the subrecipient institution must provide written assurance that a financial conflict of interest in research policy is in effect at that institution and compliant with all applicable federal regulations. Should Public Health Service (PHS) or National Institute of Health (NIH) funds be subcontracted by the Company to a subrecipient institution without a conflict of interest in research policy, a written agreement must state that this policy shall apply to the subrecipient.

2 DEFINITIONS

2011 Financial Conflict of Interest (FCOI) Regulation (the Regulation)

Title 42 Code of Federal Regulations (CFR), Part 50, Subpart F, Promoting Objectivity in Research

Investigator

The PD/PI and any other person, regardless of title or position who is responsible for the design, conduct, or reporting of NIH-funded research, or proposed for such funding, and which may include for example, collaborators or consultants. Includes investigators who plan to participate in or who participate in NIH-funded research.

PD/PI

Program Director (PD)/Principal Investigator (PI) – An individual who has overall/full responsibility and authority for the project.

Financial Interest

Financial Interest means anything of monetary value or potential monetary value held by the Investigator, the Investigator's spouse and/or dependent children, regardless of whether or not the value is readily ascertainable.

Financial Conflict of Interest (FCOI)

A financial conflict of interest exists when the Company's designated official(s) ("FCOI official") reasonably determines that an investigator's significant financial interest (SFI) could directly and significantly affect the design, conduct, or reporting of PHS-/NIH-funded research.

Significant Financial Interest (SFI)

Significant financial interest means:

1. 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 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. 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
 - 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. Investigators must provide the following information for such travel: the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The FCOI 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.
3. Note: 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 Institution of higher education or a foreign government (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).

4. The term significant financial interest **does NOT include** the following types of financial interests:
- a. Salary, 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.
 - b. Any ownership interest in the Company held by the Investigator.
 - c. 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.
 - d. 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.
 - e. 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.

3 POLICY

Investigator Responsibilities

Disclosure

Each investigator who conducts research on any Company project must disclose to the Company's designated official ("FCOI official") all of his/her foreign and domestic Significant Financial Interests (SFIs) (and those of the Investigator's spouse and dependent children) that are relevant to an investigator's institutional research responsibilities. Reports must be filed:

1. **Annually.** Investigators are required to complete the annual disclosure form even if they have no financial interest to report
2. **Within thirty (30) days of discovering or acquiring a new SFI.** The discovery or acquirement may be due to purchase, marriage or inheritance
3. **Within thirty (30) days after a financial conflict of interest has been eliminated**

Investigators shall **confirm any changes** to their FCOI report **at the time of application for PHS-/NIH-funded research is submitted** to ensure compliance with Federal disclosure and management requirements.

Training

Each PHS-/NIH-supported Investigator must complete FCOI training:

1. Prior to engaging in research related to any NIH-funded grant
2. At least every four (4) years
3. Immediately, if:
 - a. The Company revises its FCOI policy that affects requirements of Investigators
 - b. An Investigator is new to an Institution
 - c. An Investigator is not in compliance with this policy or management plan

The FCOI official will provide details on training requirements. Investigators are encouraged to utilize resources available on NIH's FCOI Training Webpage at [FCOI Training | grants.nih.gov](https://www.fcoi.gov/) to learn about FCOI regulations.

Review and Management of FCOIs

The Company's FCOI official(s) will review the Investigator SFI disclosures (and those of the Investigator's spouse and dependent children) related to an Investigator's institutional responsibilities for a determination of FCOI (and any other collected information) to determine whether

- an Investigator's SFI is related to PHS/NIH-funded research, and
- if so related, whether the SFI is an FCOI.

Required Review Prior to the Company's Expenditure of PHS-/NIH-funds:

Prior to the Company's expenditure of funds on a PHS-/NIH-funded project, the FCOI official(s) will:

- Review all Investigator SFI disclosures
- Determine if any SFIs relate to the Investigator's NIH-funded research
- Determine if an FCOI exists (i.e., an SFI that could directly and significantly affect the design, conduct, or reporting of the NIH-funded research)
- Develop and implement a management plan to manage the FCOI(s)

Required Review of New Investigator or New SFI:

When an Investigator who is new to participating in the research project or when an existing Investigator discloses a new SFI, the FCOI official(s) will review within sixty (60) days disclosures of SFIs, determine whether the SFI is related to the Investigator's NIH-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 the FCOI.

Unreported / Unreviewed SFI (FCOI):

Whenever the Company identifies an SFI that was not disclosed timely by an Investigator or, was not previously reviewed by the Company during an ongoing NIH-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the FCOI official(s) will review within sixty (60)

days disclosures of SFIs, determine whether the SFI is related to the Investigator's NIH-funded research; determine whether an FCOI exists; and if so, implement, at least on an interim basis, a management plan that specifies the actions that have been, and will be taken to manage the FCOI going forward. See also Non-Compliance (Retrospective Review).

NOTE: An SFI is related to PHS/NIH-funded research when the Company through its designated official(s), reasonably determines that the SFI:

- could be affected by the PHS/NIH-funded research; or
- is in an entity whose financial interest could be affected by the research.

The Investigator may be involved in making the determination of whether the SFI is related to the PHS/NIH-funded research.

An FCOI exists when the Company, through its FCOI official(s), reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS/NIH-funded research.

Management Plans

If a financial conflict of interest is identified, the FCOI official(s) will determine an appropriate plan of action (management plan). Such a plan may include one or more of the following as deemed appropriate:

- Public disclosure of financial conflicts of interests (e.g., when presenting or publishing the research; to the Institution's Institutional Review Board(s);
- For research projects involving human subjects research, disclosure of financial conflicts of interest 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 Financial Conflict of Interest;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- Severance of relationships that create financial conflicts

The Investigator must sign the approved plan to acknowledge their agreement to comply.

Investigator compliance with plans of action will be monitored by the FCOI official. The frequency of monitoring will be dictated by sponsor/funding agency requirements and action plan provisions.

Monitoring

The FCOI official will take such actions as necessary to manage FCOIs, including any financial conflicts of a subrecipient Investigator, if applicable, and monitor Investigator compliance with management plans until completion of the project.

Non-ComplianceRetrospective Reviews

The Company shall complete a Retrospective Review within 120 days of the Company's determination of noncompliance when an SFI is not disclosed timely or previously reviewed or 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 Company to constitute a financial conflict of interest;
- Failure by the Company to review or manage such a financial conflict of interest;
- Failure by the Investigator to comply with the financial conflict of interest management plan;

The Retrospective Review shall include at a minimum the following key elements:

- Project Number
- Project Title
- PD/PI or contact PD/PI if multiple PD/PI model is used
- Name of the Investigator with the FCOI
- Name of the entity with which the Investigator has an FCOI
- Reasons for the retrospective review
- Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documentation reviewed)
- Findings of the review
- Conclusions of the review

Mitigation Report

If based on a Retrospective Review bias is determined, the Company shall create a report of its plan for mitigating the bias (Mitigation Report). The Mitigation Report shall include the key elements of the Retrospective Review plus information to explain what action(s) have been or will be taken to mitigate the effects of the bias (i.e., a description of the impact of the bias on the research project and the Company's plan of action taken to eliminate or mitigate the effect of the bias.)

Unreported or Improperly Managed FCOI in Clinical research

The Company shall ensure that in any case in which the Department of Health and Human Services determines that an NIH-funded research 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 an FCOI that was not managed or reported by the Company as required by the regulation, the Company shall require the Investigator involved to:

- Disclose the FCOI in each public presentation of the results of the research, and
- Request an addendum to previously published presentations.

Additional Requirements

The following additional requirements also apply to all research funded by the PHS of the U.S. Department of Health and Human Services and any PHS Awarding Component including the NIH.

Reporting

The Company will provide to the PHS Awarding Component an FCOI report as outlined in the regulations:

1. Send initial, annual (i.e., ongoing) and revised FCOI reports for the Company's Investigators and those of its subrecipients, if applicable, including all required information to the NIH (PHS) via the eRA Commons FCOI Module, as required by the Regulation and as stated below:
 - a. Prior to expenditure of any funds under the NIH-funded research project
 - b. Within sixty (60) days of identification for an Investigator who is newly participating in the project
 - c. Within sixty (60) days for new, or newly identified, FCOIs for existing Investigators
 - d. At least annually (at the same time as when the Institution is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension). The annual report will provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project
 - e. After a Retrospective Review to update a previously submitted report, if new information is discovered following completion of the review
2. Based on the results of a Retrospective Review, the Company shall notify NIH promptly if bias is found with the design, conduct or reporting of NIH-funded research and submit the required Mitigation Report. The Mitigation report will include the key elements of the Retrospective Review plus information to explain what action(s) have been or will be taken to mitigate the effects of the bias (i.e., a description of the impact of the bias on the research project and the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias.)
3. Notify NIH promptly if an Investigator (or subrecipient Investigator) fails to comply with the Institution's FCOI policy or noncompliance with a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS/NIH-funded research.
 - a. Notify NIH promptly and take corrective action for noncompliance with the Company's / Institution's policy or the management plan.

Maintenance of Records

The Company shall maintain all FCOI-related records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures (whether or not a disclosure resulted in the Company's determination of a financial conflict of interest) and all actions under the Company's policy or retrospective review, if applicable,:

- For at least three (3) years from the date the final expenditures report (Final Federal Financial Report) is submitted
- Or, where applicable, from other dates specified in 45 CFR 75.361 for different situations
- Or, if no PHS-/NIH-funded project is involved: for three (3) years after the date of record creation

Enforcement

Failure on the part of an Investigator to comply with this policy may result in disciplinary action and/or sanctions which may include formal reprimand, additional training requirements, closing existing research or restricting future research by the Investigator, and/or any other enforcement action mandated by the Company or the applicable funding agency.

Subrecipients Requirements

For PHS-funded research that involves subcontractors, subgrantees or subawardees (collectively subrecipients) at other Institutions, the Company requires a written agreement that includes terms that establish whether the FCOI policy of the awardee Institution or that of the subrecipient Institution will apply to subrecipient Investigators. This agreement will include a requirement that the subcontractor report identified financial conflicts of interests to the Company in sufficient time to allow the Company to report the FCOI to the PHS Awarding component. Alternatively, the written agreement may include a requirement to solicit and review subrecipient Investigator disclosures that enable the awardee Institution (the Company) to identify, manage and report identified FCOIs to the NIH.

Subrecipient Institutions who rely on their Financial Conflict of Interest policy must provide a certification that its FCOI policy complies with the Regulation.

Subrecipients who do not have such a conflict of interest policy will be required to follow the Company's FCOI policy.

Public Accessibility

This policy will be posted, on the Company's public website.

Information concerning identified FCOIs held by senior/key personnel (as determined by the Regulation) will be made available to requestors via an email response within five business days from when the Company receives the request. This information may be requested by emailing collaborate@cognifisense.com

The written response will include:

- Senior/key personnel name Senior/key personnel's role in the research project
- Name of the entity in which the FCOI is held
- Nature of the FCOI
- Approximate dollar value of the FCOI or a statement that the value cannot be readily determined

This information will remain available for three years from the date the information was most recently updated.

Confidentiality

Financial and other information disclosed in compliance with this policy will be kept confidential to the extent possible in order to comply with Federal regulations and disclosed only on a need-to-know basis as required to perform appropriate review and evaluation required by the policy, except in the case of required public accessibility of identified financial conflicts of interest held by senior/key personnel.

Policy Revision

The Company may modify this policy to conform to organizational changes and circumstances including revisions to federal or state law or regulations.