



Financial Conflict of Interest (FCOI) Policy

As an employee, you are expected to act at all times in the Company's best interests and to exercise sound judgement unclouded by personal interests or divided loyalties. Both in performing your duties at the Company and in your outside activities, you should avoid the appearance as well as the reality of a conflict of interest.

Federal regulations require all institutions applying for or receiving research funding from a federal agency to maintain a financial conflict of interest policy. The goal of this policy is to "promote objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under federal grants will be biased by any conflicting financial interest of an Investigator (defined below)." This policy has been drafted in accordance with the code of federal regulations 45 CFR § 50.F 2011 revisions.

DEFINITIONS

The following definitions apply to this policy:

Employee refers to any person that is employed by Encodia and includes part-time and full-time personnel.

Investigator means 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 NIH, or proposed for such funding, which may include, for example, collaborators or consultants.

Subrecipient refers to any investigator that is not considered an employee, including collaborators and consultants.

Senior/Key Personnel means the Project Director or Principal Investigator and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution under the regulation.

Institution means Encodia, Inc. and all wholly owned subsidiaries.

Employee's Institutional Responsibilities means an Employee's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Significant Financial Interest (SFI) is a financial interest consisting of one or more of the following interests of the Employee (and those of the Employee's spouse and dependent children) that reasonably appears to be related to the Employee's Institutional Responsibilities. SFIs include:



1. Remuneration

Any form of salary or payment that is received:

- 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. Reimbursed or Sponsored Travel

Employees must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Employee and not reimbursed to the Employee so that the exact monetary value may not be readily available), related to their research and job responsibilities at Encodia, 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.

SFIs do NOT include:

1. Financial Interests that are not considered SFIs

- A. Salary, stock options, intellectual property and/or royalty payments, and income from 401k investments from Encodia.
- B. Income from seminars, teaching engagements, or lectures, 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.
- C. Income from service on advisory committees or review panels 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.
- D. An equity interest that when aggregated for the Employee and the Employee's spouse and dependent children, meets both of the following tests: (1) does not



- exceed \$5,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and (2) does not represent more than a five percent (5%) ownership interest in any single entity; or
- E. Salary, royalties or other payments that when aggregated for the Employee and the Employee's spouse and dependent children over the next twelve months, are not expected to exceed \$5,000.

Financial Conflict of Interest (FCOI) exists when the Company's designated official(s) reasonably determines that an SFI could directly and significantly affect the design, conduct, or reporting of NIH-funded research. The regulations set forth herein and in 45 CFR § 50.F are used as guidance to determine whether an SFI is considered a FCOI.

EMPLOYEE OBLIGATIONS

To comply with federal law, federal regulations, and the Institution's Conflict of Interest Policy, all Employees must perform the following tasks:

1. Complete FCOI training within 30 days of employment commencement.
2. Repeat FCOI training at least every four years.
3. Training must be completed immediately, if:
 - a. Encodia revises its FCOI policy in a manner that affects investigator requirements;
 - b. Employee is not in compliance with the policy or management plan.
4. Disclose any SFI(s) using the SFI Disclosure form provided to you upon completion of training.
5. Update your SFI Disclosure form at the following time points:
 - a. prior to the submission of a research proposal to any federal agency;
 - b. at least every year from the date of last disclosure;
 - c. within 30 days of discovering or acquiring a new SFI.

All training certificates and disclosure forms should be submitted to the Institution's designated official (listed at end of this document). If there is any uncertainty about what classifies as an SFI or if you have questions about our Institutional FCOI policy, please contact the designated official. The designated institutional official will review and determine if there appears to be a potential conflict of interest. Then the designated FCOI committee will review the potential conflict of interest and initiate steps to manage or eliminate the conflict(s) if appropriate.

All Employees must comply with the Institution's FCOI policy to reduce, manage, and eliminate all potential financial conflicts of interest. In the event an FCOI is present or there has been noncompliance of the FCOI policy, the Employee must cooperate with the management plan set forth to remedy the FCOI or noncompliance.

Except to the extent required by law and federal regulations, the information disclosed will be kept confidential. You should know, however, that the Institution is required to report the existence of real or potential conflicts of interest to certain federal agencies. Specifically, the NIH (PHS) requires institutions to report to the PHS the existence of any conflicting interests and to assure that the interest has been managed, reduced or eliminated. NSF requires that only conflicts that have not been managed, reduced or eliminated prior to the expenditure of funds under an award be reported to NSF.



INSTITUTION'S OBLIGATIONS

Policy Creation

Federal Regulations require that Encodia develop, maintain, and enforce a financial conflicts of interest policy in order to discover and eliminate any conflicts of interest in ongoing research programs. Encodia is required to inform all Employees of this policy and appropriately train and enforce this foregoing FCOI policy for all Employees.

Training

Every new employee must be provided a copy of this policy and training materials within 5 business days of start date. The employee must complete training and submit the training certificate to the designated institutional official within 30 days. This certificate must be filed in the employee's record until an updated certificate is received. Training must be completed and a new training certificate must be filed at the following times:

1. If the Institution revises its FCOI policy that affects requirements of Employees;
2. If the Employee is not in compliance with the policy or management plan;
3. At least every four years.

The training presentation can be found [here](#).

Disclosures, Review, and Monitoring SFI

Encodia must collect SFI disclosure form(s) from every employee after completion of training and within 30 days of employment commencement. A separate disclosure form is required for each entity with which the employee holds an SFI. It is the responsibility of the designated institutional official to ensure he/she receives the disclosure form(s) from each employee upon the respective due dates as designated above.

The disclosure form(s) should be collected by the designated institutional official and reviewed for potential conflict of interest within five (5) business days of receipt. The designated official must complete the SFI review form and attach it to the original SFI disclosure form. If the designated institutional official suspects a potential conflict of interest, he or she will bring it to the attention of the President. At that time, a review committee will be selected by the designated official and President to consist of at least two (2) unbiased personnel to review the SFI. The review committee will meet to discuss and determine whether or not they feel the SFI is a conflict of interest.

If it is determined that an FCOI exists, a management plan must be developed by the review committee to report, manage and eliminate the conflict of interest within sixty (60) days. This management plan must be shared with the employee along with a list of tasks and/or sanctions to resolve the conflict of interest. The review committee must meet at least monthly to ensure the management plan has been appropriately executed until the conflict has been sufficiently resolved.

Encodia will comply with federal agency requests to make information available about any conflicts of interest and how they have been managed, reduced, or eliminated.



Reporting

Encodia is required to certify in each application for research funding from federal agencies the existence of this policy and to identify any existing conflicts of interest and assure that they have been managed, reduced or eliminated. Encodia also must report any conflicting interests to the appropriate federal agency at the following time points:

1. prior to expenditure of any grant funds;
2. within sixty (60) days of any new conflicts of interest that become apparent after the initial report to the relevant federal agency;
3. within sixty (60) days of the identification of a new employee or investigator participating in the research project;
4. at least annually based on the requirements for the annual progress report, multi-year report, if applicable, or at time of extension to provide status of the FCOI and updates to the management plan, if applicable, until end of the project;
5. following a retrospective review to make appropriate changes to the previously submitted report. If applicable, a mitigation report must be filed when bias is found as a result of a retrospective review.

Encodia is required to submit all FCOI reports to the NIH through the eRA Commons FCOI Module.

Maintenance of Records

Encodia is required to keep all FCOI-related documents including the review and response to each SFI disclosure on file for at least three (3) years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 C.F.R. 74.53 (b) and 92.42 (b) for different situations.

Enforcement Mechanisms and Remedies and Noncompliance

Federal regulations require Encodia to impose sanctions where appropriate. Encodia maintains the right to impose sanctions on Employees for failure to disclose SFIs and for failure to abide by this policy. Sanctions may include restrictions on future submission of research proposals and other disciplinary actions up to and including dismissal.

If it has been determined that an Employee or the Institution is in noncompliance with this policy (e.g. SFIs not disclosed, reviewed or managed in a timely or appropriate manner), then Encodia must complete and document a retrospective review within 120 days. The retrospective review should be conducted by the SFI disclosure review committee as designated by the President and designated institutional official. The results of the retrospective review shall be documented and attached to the disclosure documents. If bias is found, Encodia must immediately notify the NIH by submitting a mitigation report.

Encodia must enforce any sanctions or actions required by the Department of Health and Human Services pertaining to a PHS-funded research project involving clinical research. If an FCOI was not reported or managed according to regulations for a project whose purpose is to evaluate safety or effectiveness of a drug, medical device, or treatment, then Encodia must require the Employee or Investigator to disclose the FCOI in each public presentation of the results or research and request an addendum to previously published results or presentations.



Subrecipient Requirements

If a subrecipient is not employed by Encodia, then they may comply with their institution's FCOI policy provided that their institution has a suitable policy in place and that they supply Encodia with the necessary disclosure information to meet all reporting obligations and deadlines. Prior to the subrecipient's participation in the research project, they must submit details demonstrating that their institutional FCOI policy complies with regulations. If the subrecipient's institution does not have a suitable FCOI policy in place, then they shall adhere to this policy set forth for Employees of Encodia. The subrecipient must agree in writing to comply with the FCOI policy and to provide the required information to Encodia.

Public Accessibility

This FCOI policy is publicly available on our website at encodia.com/FCOI. Information regarding FCOIs held by senior/key personnel must be accessible via the website prior to expenditure of any research funds received. The website must be updated annually and within sixty (60) days of a new FCOI being identified. The FCOI information shall remain publicly available for three (3) years. The required FCOI information that shall be publicly posted is provided below:

1. Investigator's name;
2. Investigator's title and role with respect to the research project;
3. Name of the entity in which the SFI is held;
4. Nature of the SFI; and
5. Approximate dollar value of the SFI (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through references to public prices or other reasonable measures of fair market value.

Encodia is required to submit to NIH, or permit on site review of, all records pertinent to compliance with the regulation.

RESOURCES

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

FCOICompliance@mail.nih.gov

Designated Institutional Official: (as of 01/04/2021)

Ann Collins

acollins@encodia.com

(858) 345-6272 x7010