



1 SUBJECT

Federal Award Conflict of Interest Disclosure Policy [42 CFR 50 Subpart F, 45 CFR 94, and 45 CFR Part 75.112]

2 PURPOSE

This policy outlines how IDRI, which is covered by the regulation as an institution applying for or receiving PHS funding, promotes objectivity in research by establishing this Financial Conflict of Interest Policy and its accompanying procedures to ensure there is no reasonable expectation that the design, conduct, or reporting of federally funded research will be biased by any conflicting financial interest of an Investigator.

3 BACKGROUND

IDRI receives federal grants, contracts and/or cooperative agreements for research. The Public Health Service (PHS) and Office of Secretary of Health and Human Service (HHS) published a financial conflict of interest regulation establishing standards and procedures to be followed by institutions that apply for research funding from PHS granting agencies, including the National Institutes of Health (NIH). This regulation (first promulgated in 1995, revised in 2011, and then revised again with Uniform Guidance) promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, or reporting of research funded under federal grants, contracts, and cooperative agreements will not be biased by any conflicting financial interest of the investigators responsible for the research.

4 SCOPE

Generally, a conflict of interest occurs when there is a divergence between an individual's private interests and his or her professional obligations to IDRI such that an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal financial gain, including use of resources, disclosure of inventions, objectivity in research, certification of compliance of policies, and outside activities.

The NIH defines the existence of a financial conflict of interest when the institution's designated official reasonably determines that a Significant Financial Interest (as defined below) could directly or significantly affect the design, conduct, or reporting of federally funded research. These situations require disclosure and review and approval by IDRI management. Not all Significant Financial Interests are conflicts; however, they need to be disclosed and reviewed in order to make that determination.

An example of a Significant Financial Interest, which must be disclosed to IDRI, is your participation in research that is conducted in collaboration with an entity in which you (or a member of your immediate family, including spouse, dependent children or domestic partner) hold a financial interest.

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IDRI recognizes that financial conflicts of interest are common and often unavoidable. IDRI employees should conduct their affairs so as to avoid or minimize conflicts of interest and must respond appropriately when conflicts of interest arise. To that end, the purposes of this policy are to educate IDRI employees about situations that generate financial conflicts of interest, to provide means to monitor and assess financial conflicts of interest if they arise, and to comply with the revised regulation. All IDRI employees and IDRI principal investigators that affect the design, conduct, or reporting of PHS-funded research have an obligation to become familiar with, and abide by, the provisions of this policy. If a situation raising questions of conflict of commitment or interest arises, employees are urged to discuss the situation with IDRI’s Designated Official.

5 ROLES AND RESPONSIBILITIES

Role	Name & Title
Owner	Legal
Approver	CFO
Responsible	Grant Manager
Participant(s)	PI, PM

6 RECORD OF CHANGES

Date	Description	Version	Author
9/26/2017	Final Approval	1.0	Doug Bradley

7 DEFINITIONS

1. “Financial Conflict of Interest” or “FCOI” means a Significant Financial Interest that is related to a PHS-funded research project and could directly and significantly affect the design, conduct, or reporting of the PHS-funded research project.
2. “Federal Funding” or “Federal Funds” or “Federally Funded” means funding or proposed funding IDRI receives for research grants and contracts, or cooperative agreements from the Public Health Service (PHS), an operating division of the HHS, and any components of the PHS to which the authority involved may be delegated.
3. “Investigator” means Principal Investigator (PI), the Project Manager (PM), and/or any other person, regardless of title or position, and including collaborators, consultants and other subrecipients, who is responsible for the design, conduct, or reporting of research from Federal Funding. For the purposes of this policy the term Investigator also includes the Investigator’s spouse and dependent children.
4. “Research” means a systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health. The term encompasses basic and applied research and product development and includes any such activity for which

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Federal Funding is available through a grant, contract, or cooperative agreement.

5. "Significant Financial Interest" means:

(1) One or more of the following financial 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 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. ("Remuneration" includes salary and any payment for services; equity interest; stock options; or other ownership interest.);
- 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 12 months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or his/her 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, and royalties).
- d. Any sponsored or reimbursed travel related to the investigator's institutional responsibilities not including travel that is reimbursed or sponsored by IDRI or a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

Significant Financial Interest does **not** include the following:

- a. Salary, royalties, or other remuneration from IDRI;
- b. Intellectual property rights assigned to IDRI and any agreements to share in royalties related to such rights;
- c. Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities.
- d. Travel that is reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institution that is affiliated with an institution of higher education.
- e. 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.

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8 POLICY

General Compliance

IDRI will maintain an up-to-date, written, enforced policy on financial conflicts of interest that comply with the following:

1. Title 45 CFR Part 94 – Responsible Prospective Contractors,
2. Title 42 CFR Part 50 – Subpart F – Promoting Objectivity in Research, and
3. Title 45 CFR Part 75.112 – Conflict of Interest

These regulations and guidance are hereby referred to as the Relevant CFRs.

Investigator Information and Training

IDRI will inform each Investigator of:

1. IDRI's Financial Conflicts of Interest (FCOI) Policy,
2. the Investigator's responsibilities regarding disclosure of significant financial interests,
3. and these regulations listed in this policy.

IDRI will provide Financial Conflict of Interest training to Investigators on this policy, federal regulations and the Investigators' responsibilities. This training will reflect the current policy and will be updated to meet the requirements of future amendments to the relevant CFRs. Each Investigator is required to complete IDRI's standard training on the FCOI Policy prior to engaging in research related to any PHS-funded contract and at least every four years. Training is also required to be completed within thirty days when any of the following circumstances apply:

1. IDRI revises FCOI policy in any manner that affects the requirements of Investigators;
2. An Investigator is new to an Institution; or
3. An Institution finds that an Investigator is not in compliance with IDRI's FCOI Policy or management plan.

Significant Financial Interest Disclosure (SFID)

All Investigators will complete IDRI's Significant Financial Interest Disclosure (SFID) Form to report the existence or absence of any potential financial conflicts of interest. This form must be completed even if the Investigator has nothing to report. Each Investigator who is planning to participate in the PHS-funded research must disclose to the IDRI's Designated Official(s) the Investigator's significant financial interests (and those of the Investigator's spouse and dependent children) no less than one week prior to the date of submission of the Institution's proposal for PHS-funded research. Each Investigator also is required to complete or update their SFID Form no less than once every 12 months. The SFID must be signed by the Investigator so as to certify the validity of the information listed. Each Investigator who is participating in the PHS-funded research is required to submit an updated SFID to HR within thirty days of discovering or acquiring (e.g.,

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through purchase, marriage, or inheritance) a new significant financial interest.

An Investigator's significant financial interest will be considered to be related to PHS-funded research if the Designated Official reasonably determines that the significant financial interest either:

1. Could be affected by the PHS-funded research;
2. or is in an entity whose financial interest could be affected by the research.

Determination

A financial conflict of interest exists when IDRI, through the Designated Official, reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

IDRI's General Counsel is the Designated Official in charge of the FCOI Determination Process, which consists of:

1. Reviewing all SFIDs;
2. Determining whether Investigator's significant financial interest is related to PHS-funded research and, if so related;
3. Determining whether there is a financial conflict of interest, and, if so;
4. Determining what actions should be taken by IDRI to manage, reduce, or eliminate such conflict of interest.

Mitigation and Management

The Designated Official will report all Financial Conflict of Interests to a FCOI Committee, which will be composed of the following individuals: The CFO, the CSO, the CEO, IDRI's General Counsel, and other appropriate IDRI staff members as determined by the Designated Official. The committee shall discuss the Financial Conflict of Interest and shall draft a written management plan that details the actions that have been, and shall be, taken to manage such financial conflict of interest. IDRI shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

Examples of conditions or restrictions that the committee might impose to manage financial conflicts of interest include, but are not limited to:

1. Public disclosure of Significant Financial Interest;
2. Monitoring of research by independent reviewers;
3. Modification of the research plan;
4. Disqualification from participation in all or a portion of the Federally Funded research;
5. Divestiture of Significant Financial Interest(s); or
6. Severance of relationships that create actual or potential conflicts.

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If during the course of an ongoing PHS-funded research project, an Investigator who is new to participating in the research project discloses a significant financial interest or an existing Investigator discloses a new significant financial interest to the IDRI, then a new FCOI Determination Process will be completed within forty-five days. If a financial conflict of interest exists the FCOI Committee will implement a management plan, that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward. IDRI shall provide to the PHS Awarding Component, within sixty days, an FCOI report regarding the financial conflict of interest and ensure that the Institution has implemented a management plan in accordance with the relevant CFRs

If IDRI identifies a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by IDRI during an ongoing PHS-funded research project, then a new FCOI Determination Process will be completed within forty-five days. If a financial conflict of interest exists the FCOI Committee will implement a management plan, that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward. IDRI shall provide to the PHS Awarding Component, within sixty days, an FCOI report regarding the financial conflict of interest and ensure that the Institution has implemented a management plan in accordance with the relevant CFRs

Reporting

Prior to IDRI's expenditure of any funds under Federally Funded research, IDRI will provide to the Federal Funder an FCOI report regarding any Investigator Significant Financial Interest found by the Designated Official to be a FCOI and ensure that the Institution has implemented a management plan in accordance with this part. For any FCOI previously reported, IDRI shall provide an annual FCOI report that addresses the status of the Significant Financial Interest and any changes to the management plan. IDRI will notify the Federal Funder promptly if bias is found with the design, conduct, or reporting of the Federally Funded research and will submit a mitigation report to such Federal Funder in accordance with this regulation. IDRI will notify the Federal Funder promptly if an Investigator fails to comply with IDRI's FCOI policy or FCOI management plan, or if such plan appears to have biased the design, conduct, or reporting of the Federally Funded research.

Any FCOI report 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 the IDRI's management plan. Elements of the FCOI report shall include, but are not necessarily limited to the following:

1. Project/Contract number;
2. PM/PI or Contact PM/PI if a multiple PM/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, honorarium);
6. Value of the financial interest, or a statement that the interest is one whose value cannot be

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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 the Institution's determination that the financial interest conflicts with such research; and
8. A description of the key elements of the Institution'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.

IDRI shall provide to the PHS Awarding Component an annual FCOI report that addresses the status of the financial conflict of interest 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 financial conflict of interest no longer exists. IDRI will 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.

Retrospective Review

If a financial conflict of interest is not identified or managed in a timely manner, then within 120 days of the determination of noncompliance the Designated Official shall 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.

IDRI is required to document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements:

1. Project number;
2. Project title;
3. PM/PI or contact PM/PI if a multiple PM/PI model is used;
4. Name of the Investigator with the FCOI;
5. Name of the entity with which the Investigator has a financial conflict of interest;
6. Reason(s) for the retrospective review;
7. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
8. Findings of the review; and
9. Conclusions of the review.

Based on the results of the retrospective review, if appropriate, the IDRI shall update the previously

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submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, IDRI is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report will 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 Institution'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, the IDRI will submit FCOI reports annually, as specified elsewhere in the relevant CFRs.

Records Retention

IDRI will maintain all records relating to all Investigator disclosures of financial interests and the IDRI's review of, and response to, such disclosures (whether or not a disclosure resulted in the Institution's determination of a financial conflict of interest), and all actions under the IDRI's policy or retrospective review, if applicable, at least three years from the date of final payment or, where applicable, for the time periods specified in 45 CFR 75.361 and 48 CFR 4.7.

Enforcement Mechanisms, Remedies, and Noncompliance

IDRI will complete and document retrospective reviews within 120 days of determining noncompliance for Significant Financial Interests not disclosed in a timely manner or previously reviewed or whenever an FCOI is not identified or managed in a timely manner and to document the reviews consistent with the regulation. IDRI will ensure that in any case in which a Federally Funded research project of clinical research has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by IDRI, IDRI 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.

Remedies

If the failure of an Investigator to comply with IDRI's FCOI Policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, the IDRI 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 Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the PHS-funded research project.

In any case in which 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 IDRI as required by the relevant CFRs, IDRI shall require the Investigator involved to disclose

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the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

Subrecipient Requirements

If Federally Funded research is carried out through subgrantees, contractors, or collaborators, IDRI shall take reasonable steps to ensure that subrecipient Investigators working for such entities comply with 42 CFR 50, 45 CFR 94, and 45 CFR Part 75, either by ensuring such subrecipient Investigators have their own Financial Conflict of Interest policy or by requiring the entities to provide assurances to IDRI that they will comply with IDRI's policy.

The agreement with the subrecipient will clearly indicate the method by which the subrecipient complies with the relevant CFRs.

1. If the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the subrecipient shall certify as part of the agreement that its policy complies with all of the relevant CFRs. IDRI's GM will request a copy of the subrecipient's Conflict of Interest Disclosure policies and completed Significant Financial Interest Disclosure Forms to confirm that they match the CFR requirements. Additionally, if the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest IDRI. Such time period(s) shall be sufficient to enable IDRI to provide timely FCOI reports, as necessary, to the PHS as required by the relevant CFRs.
2. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to IDRI's FCOI Policy for disclosing significant financial interests that are directly related to the subrecipient's work for IDRI. They will then be sent a copy of the FCOI for their files and they will be asked to complete and return a SFID for all key personnel working on the subaward. If the subrecipient's Investigators must comply with the IDRI's FCOI Policy, the agreement referenced above shall specify time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests to IDRI. Such time period(s) shall be sufficient to enable IDRI to comply timely with its review, management, and reporting obligations under this part.

IDRI will submit FCOI report to the PHS Awarding Component regarding all financial conflicts of interest of all subrecipient Investigators consistent with the relevant CFRs, i.e., prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

Certification

IDRI's will certify in each contract proposal to which 45 CFR 75 and 48 CFR 4, hereby referred to as the relevant CFRs, apply, that IDRI:

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1. Has in effect at that Institution an up-to-date, written, and enforced administrative process to identify and manage financial conflicts of interest with respect to all research projects for which funding is sought or received from the PHS;
2. Shall promote and enforce Investigator compliance with the requirements listed the relevant CFRs, including those pertaining to disclosure of significant financial interests;
3. Shall manage financial conflicts of interest and provide initial and ongoing FCOI reports to the PHS Awarding Component consistent with the relevant CFRs;
4. Agrees to make information available, promptly upon request, to the HHS relating to any Investigator disclosure of financial interests and the Institution's review of, and response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of a financial conflict of interest; and
5. Shall fully comply with the requirements of the relevant CFRs.

Public Accessibility

In accordance with the revised regulations, IDRI will post this FCOI Policy on IDRI's publicly accessible web site. The FCOI policy listed on the website will be maintain and updated as necessary.

Additionally, prior to the Institution's expenditure of any funds under a PHS-funded research project IDRI shall ensure public accessibility, via an email address specifically established for FCOI requests that is listed on the company website, of information concerning any significant financial interest disclosed to IDRI's HR department by an IDRI employee that meets the following three criteria:

1. The significant financial interest was disclosed and is still held by key personnel as defined in this part;
2. IDRI determines that the significant financial interest is related to the PHS-funded research; and
3. IDRI determines that the significant financial interest is a financial conflict of interest.

The information that IDRI makes available to a requestor, 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; the name of the entity in which the significant financial interest is held;
3. the nature of the significant financial interest;
4. and the approximate dollar value of the significant financial interest, 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.
5. IDRI will note in its 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 60 days of the Institution's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

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