IADR Financial Conflict of Interest in Research Policy

Purpose

The purpose of this International Association for Dental Research, dba International Association for Dental, Oral, and Craniofacial Research (IADR), policy is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.

This policy is in agreement with the Financial Conflict of Interest (FCOI) Regulation, Promoting Objectivity in Research (42 CFR Part 50 Subpart F) and assures that IADR:

- Has in effect an up-to-date, written, and enforced administrative process to identify and manage FCOI.
- Shall post their FCOI policy on their publicly accessible Web site and submit a copy to the NIH via the eRA Commons Institution Profile Module.
- Shall promote and enforce Investigator compliance with the regulation.
- Shall manage FCOI and provide initial and ongoing FCOI reports to the NIH via FCOI Module.
- Agrees to make FCOI and Significant Financial Interest (SFI) information (including related institutional reviews and determinations) available to the NIH promptly, upon request.
- Shall fully comply with the regulation's requirements.

IADR will inform each investigator of this FCOI, disclosure responsibilities, and federal regulation. The institutional official (IO) responsible for soliciting and reviewing reports and disclosures per this Policy is Dr. Christopher H. Fox, CEO, IADR. In the event that Dr. Fox is an investigator on an IADR grant receiving PHS-supported, the IADR Chief Financial Officer (CFO) (official designee) will serve in this role.

Definitions

A **Financial conflict of interest (FCOI)** exists when IADR, through its IO or official designee, reasonably determines that an Investigator's Significant Financial Interest (SFI) is related to a Federally-funded research project (i.e., the Significant Financial Interest could be affected by the research or the Significant Financial Interest is in an entity whose financial interest could be affected by the research) and could directly and significantly affect the design, conduct, or reporting of the Federally-funded research.

Institutional Official (IO) means the individual at IADR who is responsible for the review of disclosures of significant financial interest. The IO has authority to suspend all relevant activities until the financial conflict of interest is resolved or mitigated. For the purposes of this policy, the IO is IADR's CEO Dr. Christopher H. Fox.

Institutional Responsibilities means teaching, research, research consultation, and institutional committee memberships.

Investigator means the principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded by the Federal sources, or proposed for such funding, which may include, for example, collaborators or consultants. IADR will consider the role rather than title, of those involved in the research and the degree of independence in which those individuals work when determining who meets the definition of "Investigator."

Manage means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

Research means a systematic investigation designed to develop or contribute to generalizable knowledge.

Senior/key personnel means the principal investigator and any other person identified as senior/key personnel by IADR in the sponsored research application, progress report, or any other report submitted to the

funding agency. Note, this definition is related to the public accessibility requirements only as explained under the "Public Accessibility Requirements" stated below.

Significant Financial Interest (SFI) means anything of monetary value that reasonably appears to be related to the Investigator's institutional responsibilities, including:

(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:

(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 in excess of $5,000 related to such rights and interests.

(2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel received in excess of $5,000 (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 in the United States, a United States Institution of higher education, 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.

(3) 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 in the United States, a United States Institution of higher education, 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 in the United States, a United States Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education.

Disclosure of foreign financial interests differs from disclosure of domestic financial interests as it relates to the exclusions described above. 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).

Training Requirements

Prior to engaging in research related to any IADR PHS-funded grant, each investigator must certify that they have completed FCOI training per 42 CFR 50.604(b) at least every 4 years, and immediately upon IADR revising its FCOI policy, if the investigator is new to the institution, or if the investigator is not in compliance with the policy.

Each investigator must complete the following training video and provide the Certificate to IADR:
NIH FCOI Training Video: https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html.

IADR will notify each proposed Investigator seeking Federal funding of this policy, the Investigator's disclosure responsibilities, and the Federal regulation.

Disclosure, Review, and Monitoring Requirements

Each investigator (including spouse and dependent children), that is part of any PHS-supported IADR grants must disclose SFIs related to the Investigator's institutional responsibilities that meets or exceeds the regulatory definition of SFI (see above) no later than at the time of application for PHS-funded research, at least annually during the period of the award, and/or within 30 days of discovering or acquiring a new SFI.

Using the IADR's SFI Disclosure Form, each Investigator will disclose their foreign and domestic SFIs (and those of the Investigator's spouse and dependent children) that reasonably appear to be related to the Investigator's institutional responsibilities.

Disclosures of travel must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The IO or official designee will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes an FCOI regarding the Investigator's research. The initial disclosure of reimbursed or sponsored travel should include income received over the previous 12 months. Investigators must submit an updated disclosure of reimbursed or sponsored travel within 30 days of each occurrence.

Review of Disclosures
The IO or official designee will review 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 prior to the expenditure of any funds and determine whether an FCOI exists.

An FCOI exists when IADR, through its IO, reasonably determines that an Investigator's SFI is related to a Federally-funded research project **(i.e., the SFI could be affected by the research or is the SFI in an entity whose financial interest could be affected by the research) and could directly and significantly affect the design, conduct, or reporting of the Federally-funded research.**

Management of FCOI

If the IO or official designee determines that there is an FCOI, the IO or official designee must approve a written management plan to manage, reduce, or eliminate the conflict before any related research commences. Such plans will be designed to meet applicable legal requirements, facilitate the resolution or management of any conflict, and protect the sensitivity of disclosed information. The affected Investigator is responsible for developing and submitting a proposed management plan to, and in consultation with, the IO or an official designee. Management plans may contain one or more elements, including:

- Public disclosure of financial conflicts of interests (e.g., when presenting or publishing the research; to staff members working on the project; to the Institutional Review Committee(s) and Institutional Animal Care and Use Committee(s), if applicable, and to IADR's Board of Directors).
- 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 FCOI.
- 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 management strategies will be incorporated into a written Agreement between IADR and the Investigator, which will detail the conditions or restrictions imposed upon the Investigator in the conduct of the project or in the relationship with the business entity. The Agreement will be signed by the Investigator and the IO and filed with the IADR Board of Directors (BOD). The BOD will certify that FCOIs will be satisfactorily managed, reduced, or eliminated in accordance with these guidelines prior to forwarding to the Finance Department for approval of expending any funds from the applicable Federal award, or they will be disclosed to the sponsoring agency in writing for action.

If the IO determines that imposing the conditions or restrictions would be ineffective or inequitable, or that the detrimental effects that may arise from an SFI are outweighed by interests of scientific progress, technology transfer, or the public health and welfare, then the IO may decide that, to the extent permitted by Federal regulations, the research go forward without imposing such conditions or restrictions. In these cases, the IO shall make the final decision regarding resolution.

Reporting Requirements

The regulation requires that the FCOI report contain a description of the key elements of the Institution's management plan including the following:

- The role and principal duties of the conflicted Investigator in the research project;
- Conditions of the management plan;
- How the management plan is designed to safeguard objectivity in the research project;
- Confirmation of the Investigator's agreement to the management plan;
- How the management plan will be monitored to ensure Investigator compliance; and
- Other information as needed.

Updated or annual FCOI reports must include the status of the management plan (i.e., whether the financial conflict is still being managed or explain why the financial conflict no longer exists) and a description of any changes to the management plan since the last FCOI report was submitted to the NIH.

The review of disclosures and development of any necessary management strategies shall be conducted prior to IADR's expenditure of funds, and within the required compliance timelines of the sponsoring Federal agency for Investigators newly assigned to an existing project or for newly identified FCOIs for existing Investigators.

If any identified conflict or noncompliance requires reporting to the sponsoring Federal agency, the IO will provide such a report in accordance with applicable regulations.

Review, determination of whether a conflict exists, the creation and implementation of the management plan, and any required reports to the Federal sponsor will occur within 60 days of submission of the SFI Disclosure Form.

The IO or official designee shall send initial, annual, and revised FCOI reports, including all reporting elements required by the regulation, to the NIH for the IADR and its subrecipients, if applicable, as required by the regulations in 42 CFR 50.604(h) and/or 42 CFR 50.605(b). This shall be performed:

- Prior to the expenditure of funds
- Within 60 days of identification for an Investigator who is newly participating in the project
- Within 60 days for new, or newly identified, FCOIs for existing Investigators
- At least annually (at the same time as when IADR is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension) to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project.
- Following a retrospective review to update a previously submitted report, if new information is discovered following completion of the review.

The FCOI report will be submitted through NIH's eRA Commons FCOI Module by the Signing Official (SO). In order for NIH to assess an FCOI report, IADR will ensure that each report contains the following information:

- Project number;
- PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- Name of the Investigator with the FCOI;
- Name of the entity with which the Investigator has an FCOI;
- Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- Value of the financial interest (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 reference to public prices or other reasonable measures of fair market value);
- A description of how the financial interest relates to the NIH-funded research and why IADR determined that the financial interest conflicts with such research;
- A description of the key elements of IADR's management plan, including:
- Role and principal duties of the conflicted Investigator in the research project;
- Conditions of the management plan;
- How the management plan is designed to safeguard objectivity in the research project;
- Confirmation of the Investigator's agreement to the management plan;
- How the management plan will be monitored to ensure Investigator compliance; and other information as needed.

Based on the results of a retrospective review (see 'Investigator Noncompliance'), the IO or official designee 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 must include, at a minimum, the key elements of the retrospective review and a description of the impact of the bias on the research project and IADR'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).

The IO or official designee shall notify NIH promptly if an Investigator (or subrecipient Investigator) fails to comply with this policy or if an FCOI management plan appears to have biased the design, conduct, or reporting of the NIH-funded research.

This policy confirms IADR's requirement to notify NIH promptly and take corrective action for noncompliance with this policy or any management plan that has been developed.

Violations of FCOI in Research Policy

The IO or official designee shall complete and document retrospective reviews within 120 days of the IADR's determination of noncompliance whenever an FCOI is not timely identified or managed, including: :

- Failure by the Investigator to disclose an SFI that is determined by IADR to constitute an FCOI;
- Failure by IADR to review or manage such an FCOI;
- Failure by the Investigator to comply with the FCOI management plan.

The retrospective review shall be documented to 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; and
- Conclusions of the review

The IO or official designee shall ensure that in any case in which the Department of Health and Human Services determines that a PHS or 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 IADR as required by the regulation, the IADR 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.

Whenever an Investigator has violated this policy or the terms of any resolution plan required by the IO (including failure to file or knowingly filing incomplete, erroneous, or misleading disclosure forms), the IO, in consultation with the IADR Board of Directors, will impose sanctions or institute disciplinary proceedings against the Investigator. In addition, the IO or official designee shall follow Federal regulations regarding the notification of the sponsoring agency in the event an Investigator has failed to comply with this policy. The sponsor may take its own action as it deems appropriate, including the suspension of funding for the Investigator until the matter is resolved.

Maintenance of Records

The Chief Financial Officer (CFO) shall maintain all FCOI-related records pertaining to all Investigator disclosures of SFIs and the IADR's review of, and response to, such disclosures and all actions under this policy or retrospective review, if applicable, shall be retained for at least three years from the date the final expenditure report is submitted, or, where applicable, from other dates specified in 45 CFR 75.361.

Subrecipient Requirements

Collaborators/subrecipients from other organizations must either comply with this policy or provide a certification or written agreement that their organizations are in compliance with Federal policies regarding Investigator SFI disclosure and that their portion of the project is in compliance with their institutional policies.

IADR is responsible for ensuring any subrecipient's compliance with the regulation and reporting identified FCOIs for subrecipient Investigators to the NIH. IADR will incorporate as part of a written agreement with a subrecipient terms that establish whether the FCOI policy of IADR or that of the subrecipient will apply to subrecipient Investigators and include time periods to meet disclosure and/or FCOI reporting requirements.

Subrecipient institutions who rely on their FCOI policy must report identified FCOIs to IADR in sufficient time to allow IADR to report the FCOI to the NIH to meet its reporting obligations.

Subrecipient institutions that must comply with the IADR's policy must submit all Investigator disclosures of SFIs that are directly related to the subrecipient's work for the IADR. The submission of disclosures to the IADR must be in sufficient time to allow the IADR to review, manage, and report identified FCOIs to the NIH.

IADR is responsible for monitoring subrecipient's compliance with the FCOI regulation, management plans, and for reporting all identified FCOIs to the NIH.

Public Accessibility Requirements
This IADR FCOI Policy will be publicly accessible on the IADR website at: www.iadr.org.

Information concerning identified FCOIs held by senior/key personnel (see 'Definitions), will be publicly accessible at www.iadr.org prior to the expenditure of funds and:

- Include the minimum elements as provided in the regulation.
- Available within five calendar days of a written request.
- Be updated, at least annually.
- Be updated, within 60 days of a newly identified FCOI.
- Remain available for three years from the date the information was most recently updated.