



The Aaron Diamond AIDS Research Center's Policy on Financial Conflict of Interest and Conflict of Commitment in Research

Financial Conflict of Interest

Introduction

The objective of this Policy is to maintain the integrity and transparency of financial relationships related to investigators' research at The Aaron Diamond AIDS Research Center ("ADARC"). To accomplish our purpose, all investigators (defined below), regardless of title or position and irrespective of funding source, are expected to complete a Significant Financial Interest Disclosure Form at least annually, disclosing all of their Significant Financial Interests ("SFI") (defined below).

Investigators who are responsible for the design, conduct, analysis or reporting of research are required to disclose their SFI prior to submitting a federal Public Health Service grant application. By requiring all investigators routinely to complete financial disclosures, ADARC can assure that no grant will be withheld from submission due to a disclosure failure.

Investigators must update disclosures within thirty (30) days of discovering or acquiring any new SFI.¹ If an investigator's Significant Financial Interest Disclosure Form reflects a financial conflict of interest, assistance will be provided to eliminate, reduce or manage the conflict.

Definitions

ADARC's definitions of the following terms track the federal regulatory definitions.

Financial conflict of interest

A financial conflict of interest exists when an investigator's Significant Financial Interest could directly and significantly affect the design, conduct, analysis or reporting of the investigator's research.

Significant Financial Interest

Significant Financial Interest means a financial interest consisting of one or more of the following interests of the investigator (and her/his spouse and dependent children) that reasonably appear to be related to the investigator's institutional responsibilities:

¹ This disclosure will not substitute for the required statements that accompany Institutional Review Board filings. Howard Hughes Medical Institute (HHMI) Investigators will continue to meet separate HHMI disclosure requirements

1. Publicly traded entities: (a) remuneration (e.g., salary, consulting fees, honoraria, paid authorship) from the entity in the 12 months prior to disclosure; and (b) equity (e.g., stock, stock options, other ownership interest) held as of the date of the disclosure that (c) when combined (remuneration + equity) exceeds \$5,000;
2. Non-publicly traded entities: (a) all remuneration from the entity in the 12 months prior to disclosure that, when combined, exceeds \$5,000 or (b) any equity interest in the entity;
3. Receipt of income in excess of \$5,000 received in the 12 months prior to disclosure through intellectual property rights and interests (e.g., patents, copyrights) from any source other than ADARC.
4. Travel: any reimbursed or sponsored travel (i.e., that is paid on behalf of the investigator and not reimbursed to the investigator so that the exact monetary value may not be readily available) that exceeds \$5,000 aggregate per entity and is received in the prior 12 months. Disclosure must include, at minimum, the purpose of trip, the identity of the sponsor or organizer, the destination and the duration. This does not include travel reimbursed or sponsored by: a federal, state or local government agency, a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S. institution of higher education.

Significant Financial Interest does not include

- Salary, royalties or other remuneration from The Aaron Diamond AIDS Research Center;
- Income from investments such as mutual funds or retirement accounts so long as the investigator does not directly control these vehicles' investment decision
- Income from seminars, lectures, teaching engagements, service on advisory committees or review panels for a federal, state or local government agency, a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with a U.S. institution of higher education.

Investigator

Investigator means the project director, principal investigator or any other person in or collaborating or consulting with a laboratory, regardless of title or position, who is responsible for the design, conduct, analysis or reporting of research.

Institutional Responsibilities

Institutional responsibilities means an investigator's professional responsibilities on behalf of the ADARC which may include, for example, activities such as research, research consultation, teaching, professional

practice, institutional committee memberships, and service on panels such as the Institutional Review Board or a Data and Safety Monitoring Board.

Training

ADARC will inform through the distribution of ADARC'S policies and Procedures Manual each investigator of the centers policy on financial conflict of interest and the investigator's responsibilities regarding disclosure of significant financial interests, and of the federal regulations and require each investigator to complete all required conflict of interest training prior to engaging in federally-funded Public Health Service research at or under the auspices of ADARC. Every ADARC investigator is also required to be re-trained on the regulations at least every four years. Additionally, investigators will be required to receive training immediately in any of the following circumstances:

- (1) The Institution revises its financial conflict of interest policies or procedures 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 the Institution's financial conflict of interest policy or management plan.

Procedures for Financial Disclosure and For Addressing Conflict

The Faculty Conflict of Interest Committee ("FCIC") manages implementation of ADARC's financial conflict of interest policy. The FCIC, appointed by the Scientific Director is composed of three senior faculty members who serve a staggered three-year term and the Chief Operating Officer.

Prior to the submission of a grant application to the Public Health Service (most commonly to the National Institutes of Health), each Investigator who is planning to participate in, or is participating in, the PHS-funded research must disclose to the Institution's designated official(s) the Investigator's significant financial interests (and those of the Investigator's spouse and dependent children). Completed disclosure forms will first be reviewed by the Institution's designated official for the FCIC.

Each disclosure form will be reviewed to determine whether reported SFI reasonably appear to be related to the investigator's research and other institutional responsibilities and, if so, whether a financial conflict of interest exists. No federal funds awarded can be expended until all financial conflicts of interest related to a grant have been addressed. The FCIC will work with an investigator who has a conflict to secure his or her agreement to eliminate, reduce or manage the conflict.

A Financial Conflict of Interest (FCOI) report regarding any investigator's SFI found by the institution, to include the assurance of the implementation of a management plan, will be submitted to the PHS Awarding Component before the expenditure of any funds under a PHS-funded research project. For any significant financial interest that the institution identifies as conflicting subsequent to the institutions initial FCOI report during an ongoing PHS-funded research project, the institution shall provide the PHS-Awarding Component, within 60 days, an FCOI report regarding the financial conflict of interest and ensure that the institution has implemented the appropriate management plan. Additionally, for any previously reported FCOI an annual FCOI report must be submitted to the PHS- Awarding Component at the same time the annual progress report is being submitted.

Working with the FCIC, the institutional designated official shall monitor investigator compliance with the management plan on an ongoing basis until completion of the PHS-funded research project or the conflict is eliminated.

Each Investigator is required to submit an updated disclosure of Significant Financial Interests at least annually. Additionally, investigators must update SFI disclosures within thirty (30) days of acquiring new SFI or discovering previously unreported SFI. Investigators who are new to participating in the research project must disclose their SFI within thirty (30) days. Upon disclosure of a SFI, the designated official of the institute shall, within sixty days, review the disclosure to determine if the significant financial interest is related to the PHS-funded grant and if a conflict of interest exists. If the SFI creates a conflict of interest, working with the FCIC, the institutional official shall implement a management plan to eliminate, reduce or manage the conflict.

If ADARC identifies a significant Financial Interest that was not disclosed timely by an investigator or for whatever reason was not previously reported or reviewed by the FCIC during the course of federally-funded research, ADARC must undertake a documented audit within sixty days to determine whether it is related to PHS-funded research; determine if a conflict of interest exists and if so, implement on at least an interim basis, a management plan that shall specify that actions that have been, and will be, taken to manage such financial conflict of interest going forward;

Whenever a financial conflict of interest is not identified or managed in a timely manner including:

- Failure by the investigator to disclose a significant financial interest that is determined by the institution to constitute a financial conflict of interest;
- Failure by the institute to constitute a financial conflict of interest;
- Failure by the institute to review or manage such a financial conflict of interest; or
- Failure by the investigator to comply with a financial conflict of interest management plan

The institution shall within 120 days of the institution determination of noncompliance, complete a retrospective review of the investigator's activities and the PHS-funded research project, to determine whether any PHS-funded research, or a portion thereof,

conducted during the time period of noncompliance was biased in the design, conduct, or reporting of such research.

The following key elements, at minimum, must be documented in the retrospective review:

- Project number
- Project Title
- PD/PI or contact PD/PI if multiple PD/PI model is used;
- Name of Investigator with FCOI
- Name of entity with which the Investigator has a financial conflict of interest;
- Reason(s) for the retrospective review;
- Detailed methodology used for the retrospective review;
- Findings of the review; and
- Conclusions of the review

If there is evidence of bias, a mitigation report of this activity, and steps taken to eliminate or mitigate the effect of bias must be submitted to the National Institutes of Health or other Public Health Service granting agency. The mitigation report must include the elements above as well as a description of the impact of the bias on the research project.

Subrecipient

When proposed research is to be funded by PHS and carried out through a subrecipient, ADARC will ensure compliance by:

(1) incorporating as part of a written agreement with the subrecipient terms that establish whether this policy, or that of the subrecipient will apply to the subrecipient's Investigators, as well as the time frames within which the subrecipient must provide any information necessary to ensure that ADARC is able to meet its reporting obligations to the PHS awarding agency. Specifically:

(i) 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 referenced above that its policy complies with federal regulations 42 CFR Part 50 Subpart F. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the financial conflicts of interest policy of the awardee Institution for disclosing significant financial interests that are directly related to the subrecipient's work for the awardee Institution;

(ii) 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 to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to provide timely FCOI reports, as necessary, to the PHS as required by this

subpart;

(iii) Alternatively, if the subrecipient's Investigators must comply with the awardee Institution's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to comply timely with its review, management, and reporting obligations under this subpart.

(2) providing FCOI reports to the PHS Awarding Component regarding all financial conflicts of interest of all subrecipient Investigators consistent with this subpart, i.e., prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

Enforcement Mechanisms, Remedies and Noncompliance

In the event an Investigator fails to comply with this policy or an FCOI management plan imposed hereunder, the Scientific Director, CEO (when the FCOI involves the Scientific Director, CEO, the ADARC Chairman of the Board) may impose a wide variety of sanctions, including but not limited to restricting or conditioning the Investigator's ability to apply for grants through ADARC, as well as imposing one or more of the sanctions outlined below:

- Formal admonition;
- The inclusion in the Investigator's file of a letter from the Scientific Director, CEO calling into question the individual's good standing as a member of ADARC;
- Ineligibility of Investigator to submit grant applications, apply for Institutional Review Board (IRB) approval of Research, or supervise graduate students in Research activities;
- Non-renewal of the individual's Faculty appointment, if applicable;
- Dismissal from the ADARC; or
- Any other restriction, limitation or punishment determined by the Scientific Director, CEO to be warranted by the circumstances

Additionally, if the failure of an Investigator to comply with this policy or an FCOI management plan appears to have biased the design, conduct or reporting of PHS-funded Research, ADARC shall promptly notify the PHS awarding agency of the corrective action taken or to be taken.

Sanctions or other administrative actions to ensure Investigator compliance will be fully implemented depending on the nature and severity of the noncompliance. These sanctions may include anything from a written warning to termination of employment. The designated institutional official will complete and document retrospective reviews within 120 days of the Institution's determination of noncompliance for SFIs not disclosed timely 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.

Final ADARC Conflict of Interest Authority

If the FCIC is unable to reach agreement with an investigator on an appropriate conflict elimination, reduction or management plan, the FCIC will provide the investigator with a written impasse letter. Within two weeks of the date of the written impasse letter, the investigator or the FCIC shall seek the intervention of ADARC's Scientific Director.

The Scientific Director will address the impasse as he determines appropriate. The Scientific Director's decision on the conflict and its handling is final, except that this final authority does not extend to the decisions and actions of the Institutional Review Board in carrying out its independent function of protecting human study participants in clinical research.

In the event the investigator is the Scientific Director, then the FCIC will consult with the Chair of the ADARC Board of Directors.

Conflicts Involving Human Subjects

Conflicts in research involving human participants will be managed differently than conflicts arising in other research.² As ADARC carries out all human subject research at the Rockefeller University Hospital, ADARC will comply with the additional requirements imposed by the University's IRB. Please refer to the Rockefeller University Conflict of Interest Policy on Human Subjects.

http://www.rockefeller.edu/ifcoi/pdf/Financial_COI_in_Human_Participant.pdf

However, in any case in which the HHS determines that a PHS-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 the institution as required by regulation 42 CFR.606(c), the institution shall require the investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

Public Access

This policy is posted on the ADARC website so that it is readily available to the Public.

Within five (5) business days of receiving a written request from the public for information about federally-funded research involving a conflicted investigator the ADARC will respond to the request in writing, providing the name of the conflicted investigator, the entity in which the investigator holds SFI, the nature of the SFI and the approximate dollar value of the SFI, in dollar ranges, if known.

² The Rockefeller University Human Research Protection Program describes the Hospital's conflict of interest standard and process governing research involving human subjects.

Record Retention

ADARC will maintain records relating to all Investigator disclosures of financial interests, and its review of, and response to, such disclosures (whether or not a disclosure resulted in a determination of a financial conflict of interest) and all actions taken in pursuant to this policy or any retrospective review, for a minimum of three (3) years from the date the final expenditures report is submitted to the **PHS** or where applicable, from other dates specified in 45 CFR 74.53 (b) and 92.42 (b) for different situations.

Conflict of Commitment in Research

This conflict of commitment in research policy has been adopted by the ADARC and is not subject to external requirements.

Investigators' external activities should not interfere with the primary professional commitment of their time and intellectual energies to the education and research programs of The Aaron Diamond AIDS Research Center.

Up to 52 days per year may be devoted to external activities provided that an investigator's ADARC work is not adversely affected. Government service and service with not-for-profit institutions do not count against the guideline stated here.

ADARC postdoctoral appointees are not permitted to engage in extramural activities for compensation.

Requests to engage in activities outside of these guidelines should be addressed to the Scientific Director or his or her designee and may be approved if extraordinary circumstances warrant.

Consulting arrangements with outside entities cannot compromise the ADARC's rights to intellectual property as established in ADARC policy.

Entities outside ADARC may not impose restrictions on investigators' rights to disseminate results of research performed at ADARC in published or other form, except for reasonable delays not to exceed ninety (90) days to allow for patent processing.

Amended and adopted by the Board of Directors on June 19, 2012, effective August 24, 2012,
Amended November 2015.