



American Sexually Transmitted Diseases Association (ASTDA)

Financial Conflict of Interest (FCOI) Policy

PURPOSE

The purpose of this policy is to document the requirements and responsibilities associated with identifying and managing financial conflicts of interest to safeguard the integrity of the activities of the American Sexually Transmitted Diseases Association (ASTDA) and to comply with federal regulations.

This policy has been developed to address and comply with the specific federal agency requirements as defined in the 2011 Revised Financial Conflict of Interest Regulation, Promoting Objectivity in Research (42 CFR part 50 subpart F). This regulation was developed to promote objectivity in research, by establishing standards that provide a reasonable expectation ensuring that the design, conduct and reporting of research and training funded under National Institutes of Health (NIH) grants or cooperative agreements will be free from bias resulting from financial conflicts of interest of an investigator.

For the purposes of this document the term “investigator” is defined by ASTDA as “Board Member” (see definitions). Furthermore, this document is limited to conflicts of interests of Board Members as they relate to ASTDA grant-funded activities and not to all grant support that ASTDA collaborators, including Board Members, may receive through their primary institutions.

SUMMARY OF PROCESS

Significant Financial Conflicts of Interest (SFCOI) (as defined below) shall be disclosed on the Significant Financial Conflict of Interest Disclosure Form (see Appendix) by a Board Member requesting government-sponsored or company-sponsored funds for an ASTDA activity, as defined below, when a Significant Financial Conflict of Interest arises during the course of activity. Regardless of whether an SFCOI exists, all ASTDA Board Members and key personnel are required to submit an SFCOI Disclosure Form annually.

It is each Board Member’s responsibility to ensure those with financial interests in ASTDA activities are identified and make the required disclosures in conjunction with submission of an activity proposal.

The SFCOI and supporting materials are forwarded to the President of the ASTDA or their designee for review. The ASTDA President and ASTDA's Ethics/Conflict of Interest Committee will be responsible for evaluating and instituting a plan for managing any disclosed financial conflicts of interests, for producing institutional reports and other required reports to external sponsors and governmental agencies, and for the general administration and enforcement of this policy.

Advance approval by the President or their designee is required prior to engaging in government-sponsored research, training, or conference support when ASTDA is the recipient of such support. An SFCOI review must be completed before any expenses are incurred under an award.

Annual updates are required of all Board Members and key personnel participating in activities supported by ASTDA. Any Board Member who has acquired a new or increased financial interest during the course of a research project funded through ASTDA shall report it immediately to the President. Annual updates and newly acquired interests are reported using the SFCOI Disclosure Form.

TRAINING

The NIH Financial Conflict of Interest tutorial was designed by the National Institutes of Health (NIH) to provide education training on what constitutes financial conflict of interest. This course is required for anyone involved with an NIH funded project, which includes all Board Members, consultants and employees of ASTDA engaged in NIH-funded activities or its compliance. The course is accessible at <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>.

Upon completion of the training, a certificate of completion must be turned into the President or their designee and a copy should be retained by the person completing the course. This training is required prior to engaging in activities relating to any NIH-funded grant or as deemed necessary by ASTDA due to changes in the FCOI policy, non-compliance of the Board Member/key personnel or new to the Board. At a minimum, the FCOI training shall be taken every three (3) years.

KEY DEFINITIONS

For the purpose of this policy, the following definitions, based on and adapted from 42 CFR 50.603 apply:

Institution – means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) applying for, or receiving NIH research funding – in this case, the American Sexually Transmitted Diseases Association (ASTDA).

Activities – means activities to support ASTDA objectives, including research, publication of research articles, and workforce development, including the organization of training events, seminars, webinars, and conferences.

Covered Activities – means activities that are supported by NIH or other federal institutions.

Board Members – means ASTDA Board office holders, members, and any other person, regardless of title or position, who is or will be responsible for the design, conduct, or reporting

of ASTDA covered activities as defined above, which may include, for example, collaborators or consultants.

Institutional responsibilities – means a Board Member's professional responsibilities on behalf of ASTDA, and as defined by ASTDA, including but not limited to, activities such as teaching, mentorship, and institutional committee memberships.

Financial interest – means anything of monetary value, whether or not the value is readily ascertainable.

Financial conflict of interest (FCOI) – means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of NIH-funded activities.

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.

Senior/Key Personnel – means Board Members 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 NIH by the institution under the regulation.

Significant Financial Interest (SFI)

(1) A financial interest consisting of one or more of the following interests of the Board Member (and those of the Board Member's spouse and dependent children) that reasonably appears to be related to the Board Member's ASTDA 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 (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 Board Member (or the Board Member's spouse or dependent children) holds any equity interest (e.g. stock, stock option, or other ownership interest); or (iii) Upon receipt of income related to intellectual property rights and interests (e.g. patents, copyrights)

(2) Board Members also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Board Member and not reimbursed to the Board Member so that the exact monetary value may not be readily available), related to their ASTDA responsibilities, provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by excluded sources provided in regulation. For example, if a Board Member travels to a scientific seminar but does not pay or receive reimbursement by ASTDA directly (i.e. the travel was paid for by a third party/sponsor), the Board Member is required to disclose basic information to ASTDA relating to the trip, such as purpose of the trip, identify of the payer/sponsor, destination and duration. ASTDA is required to determine if additional information is required (e.g. monetary value) and whether the travel constitutes a FCOI with NIH-funded research.

(3) The term *significant financial interest* does not include the following types of financial interests:

(i) salary, royalties, or other remuneration paid by ASTDA to the Board Member if Board Member is currently employed or otherwise appointed by ASTDA; (ii) intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; (iii) income from investment vehicles, such as mutual funds and retirement accounts, as long as the Board Member does not directly control the investment decisions made in these vehicles; (iv) 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; or (vi) income from service on advisory committees or review panels for a federal, state or local government agency, 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.

PROCEDURES

A. Identification of Persons Required to Disclose a Significant Financial Conflict of Interest - It shall be the responsibility of the Board Member leading a covered ASTDA activity to identify all collaborators in the activity who have an SFCOI requiring disclosure under this policy and to ensure that an SFCOI Disclosure Form is prepared and submitted. In addition, the Board Member shall be responsible for ensuring that annual updates and disclosures of new or increased financial interests are disclosed.

B. Submission and Review of Significant Financial Conflict of Interest Disclosure Form (see Appendix) - Every individual having an SFCOI requiring disclosure under this policy shall prepare a fully-completed SFCOI Disclosure Form that shall be submitted to the President or their designee. An initial review of the SFCOI Disclosure Form will be conducted by the President or their designee to determine whether a potential for conflict of interest exists. If it is determined that there is a potential conflict of interest, then steps will be taken to determine what measures are needed to address the SFCOI identified in the SFCOI Disclosure Form. A management plan may be required to outline the terms, conditions and restrictions, if any, to ensure compliance with this policy. The management plan may require one or more of the following actions (but not limited to) to be taken in order to manage, reduce or eliminate any actual or potential conflict of interest:

- Public disclosure of significant financial interests;
- Review of activity protocols by independent reviewers;
- Monitoring of activity by independent reviewers;
- Modification of activity plan;
- Disqualification from participation in all or a portion of the funded activity;
- Divestiture of significant financial interests;
- Severance of relationships that create actual or potential conflicts

All management plans are required to be signed by the Board Member and the ASTDA President. Compliance of the management plan shall be monitored by the President and the Ethics/Conflict of Interest Committee.

B. Annual Reporting and After-Acquired Significant Financial Interests –

All Board Members shall provide annual SFCOI Disclosure reports or more frequently if required by the management plan. Any Board Member who acquires a new or increased SFCOI shall promptly submit a new SFCOI Disclosure Form within 30 days of discovering or acquiring the new SFI. It is the Board Member's responsibility to ensure that any newly acquired collaborator on an activity submits the required SFCOI report to the President.

D. Violations of Conflict-of-Interest Policy – Board Members and collaborators are expected to comply fully and promptly with this policy. Whenever a person has violated this policy, including failure to make a required disclosure of financial interests or failure to comply with a requirement of the management plan, the Board Member shall make recommendations to the President or their designee regarding the impositions of sanctions or disciplinary proceedings against the violating individual. In addition, ASTDA shall follow Federal regulations regarding the notification of the sponsoring agency in the event a Board Members or collaborator has failed to comply with this policy. The federal agency may take its own action as it deems appropriate, including the suspension of the funding for the Board Member until the matter is resolved.

E. Record Keeping – Records of Board Member SFI Disclosure forms, and of actions taken to manage actual or potential conflicts of interest, shall be retained by the Ethics/Conflict of Interest Committee for three (3) years from the date the final expenditure report is submitted to the NIH, or as required by 45 CFR 74.53(b) and 92.42(b) for different situations.

F. Sub-recipient Requirements – Sub-award recipients must comply with this policy or provide certification that their organization is in compliance with the Federal policy, *2011 Revised Financial Conflict of Interest Regulation, Promoting Objectivity in Research (42 CFR part 50 subpart F)* and that their portion of the research project, as detailed in their sub-award agreement, is in compliance with their institutional policies. If an SFI is identified by the sub-award recipient, they are required to notify the President of the existence of the conflicting interest within 30 days of the identification of the interest. In addition, the sub-award recipient must certify and assure that any reported conflicting interest has been managed, reduced or eliminated in accordance with federal regulations.

G. Federal Reporting – The ASTDA is responsible for the reporting disposition of matters involving disclosures of SFI in accordance with applicable federal requirements. The following reports are required by the NIH:

- i. Initial report – prior to ASTDA's expenditure of any funds under an NIH-funded research project, ASTDA must provide to the NIH an FCOI report regarding any Board Member SFI found by ASTDA to be a financial conflict of interest in accordance with the regulation.
- ii. During on-going NIH-funded research projects – ASTDA shall submit an FCOI report within 60 days after its determination that a new FCOI exists. If a FCOI was not disclosed timely, ASTDA shall submit an FCOI report to the NIH within 60 days of the discovery, as well as complete a retrospective review within 120 days of discovery of noncompliance.
- iii. Annual FCOI report – For any FCOI previously reported to the NIH, ASTDA shall provide an annual FCOI report addressing the status of the FCOI and any changes to its related management plan.

Appendix: Conflict of Interest From

AMERICAN SEXUALLY TRANSMITTED DISEASES ASSOCIATION (ASTDA)

SIGNIFICANT FINANCIAL CONFLICT OF INTEREST ("SFCOI") DISCLOSURE FORM

Board Members are responsible to read the ASTDA Financial Conflict of Interest (FCOI) policy, including details of all disclosure requirements, and the institutional policy prior to completing this form:

Board Member Name:

Institution:

Project Title:

Proposed Sponsor:

PLEASE CHECK ONE OF THE FOLLOWING:

_____ I have NO significant financial interests to disclose which relate to my institutional responsibilities. *(If NO significant financial interests, please read the Certifications below and sign as "Investigator.")*

OR

_____ I am disclosing significant financial interests (and those of my spouse and dependent children) which relate to my institutional responsibilities. *(Please provide the following details regarding the entity, your financial interest, income and travel, then read the Certifications and sign below as "Investigator.")*

Name of Entity (corporation, partnership, private practice, non-publicly traded entities, etc.):

Address of Entity:

Principal Type of Business:

How does the financial interest relate to PHS-funded research?

Did remuneration from the entity occur the twelve months preceding the disclosure* AND did he value of any equity interest in the entity as of the date of disclosure, **when aggregated**, exceed \$5,000?

Yes ___ No ___

***Exclusions** -- excluded from income disclosure: NOT required to disclose income from seminars, lectures, or teaching engagements sponsored by and service on advisory or review panels for a federal, state or local government agency, an Institution of higher education as defined at 20 USC 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. NOT required to disclose 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.

Do you have income from an interest in any intellectual property rights impacted by the project?

Yes ___ No ___

In the last 12 months, did you receive reimbursed or sponsored travel from the entity**?

Yes ___ No ___

If "Yes," please provide the following trip details:

1. Purpose of trip: _____
2. Sponsor/Organizer: _____
3. Destination: _____
4. Duration: _____

****Exclusions** -- excluded from travel disclosure: NOT required to disclose travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 USC 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. The Institution will determine if any travel requires further investigation, including determination or disclosure of the monetary value.

Investigator Certification:

- I agree to complete FCOI training **prior to** engaging in research related to any NIH-funded grant or contract and at least every four years thereafter; and, immediately upon other events, as defined per campus policy. Upon completion of each training session, I will send an email confirming completion to: astda@astda.org
- If the proposed project is funded by NIH, I agree, for the duration of the project, to update this disclosure either on an annual basis, or within 30 days if new reportable significant financial interests are obtained (such as through purchase, marriage or inheritance, for example).
- I agree to provide additional details needed by ASTDA to meet NIH's institutional filing, annual reporting and other requirements, and to cooperate in the development of a Management Plan to address any actual or potential conflict of interest identified via this Disclosure.
- If I participate in a project involving subrecipient organizations, I agree to assist ASTDA in obtaining required disclosures in a timely manner from all subrecipient Investigators, and to assist CPP, if requested, to manage any FCOIs of a subrecipient Investigator to assure compliance with these regulations.
- I agree to comply with any retrospective reviews, conditions or restrictions imposed by ASTDA to manage, reduce, or eliminate actual or potential conflicts of interest or forfeit the award.

Signed: _____

Investigator

Date: _____

To be Endorsed/Signed Only by Institutional Official:

Institutional Endorsements: I have reviewed the significant financial interest disclosure and believe that no significant financial interest exists or if one does exist that it is possible to develop and execute, prior to award, a Resolution Plan to manage, reduce or eliminate any actual or potential conflict of interest; and, therefore, I recommend that the proposal be submitted to the agency at this time.

Signed: _____

Date: _____