

United States Association for the Study of Pain (USASP) Financial Conflict of Interest (FCOI) Policy

OVERVIEW

Description:

All USASP members and non-members have the responsibility to disclose financial conflicts of interest (FCOI) when presenting as a speaker at any USASP-sponsored events (hereinafter the "Speakers") or participating in USASP leadership activities (e.g., member of the Board of Directors, member of a committee or task force) and/or acting as key personnel in USASP-sponsored activity (hereinafter the "Leaders").

Purpose/Rationale:

To promote objectivity by establishing standards that preserve the integrity of leadership, decision making, and activity; protect the rights and safety of activity subjects; and prevent bias.

Applicability:

For purposes of financial disclosure only, this regulation also covers the spouse and dependent children of Speakers and Leaders.

Failure to Comply:

Failure to comply with this policy may lead to disciplinary or corrective action including but not limited to removal from leadership or other USASP activities, and any other remedies that may be legally available.

Policy

1. Employee and Member Responsibility

- a. Any USASP employee or member who is acting as a Speaker or Leader must disclose to the USASP-FCOI Officer (USASP's program coordinator or Board president) any significant financial interest (and those of the individual's spouse and dependent children) no later than the date of the USASP-related work using the FCOI form provided by the USASP-FCOI Officer (USASP's program coordinator or board president).
- b. Annual disclosures of significant financial interest (and those of each individual's spouse and dependent children) must be made no later than April 15, 2022, and every year thereafter, using the prescribed FCOI form.
- c. Annual FCOI reports submitted to the USASP-FCOI Officer (USASP's program coordinator or Board president) shall include any information that was not previously disclosed.

d. Within 30 days of discovering or acquiring a significant financial interest, any USASP employee or member who is acting as a Speaker or Leader shall submit an updated FCOI form to the USASP-FCOI Officer (USASP's program coordinator or Board president).

2. Institution Responsibility

a. USASP shall update and enforce this written policy in accordance with 42 CFR 50, Subpart F and will make the policy and applicable federal regulations available on the association's website (USASP.org).

b. USASP will inform each Speaker and Leader about the following:

A. Information about this policy and the corresponding federal regulations;

B. Responsibility to disclose any significant financial interest to the USASP-FCOI Officer (USASP's program coordinator or Board president);

C. Mandatory FCOI training requirements include:

i. Completion of FCOI training every four years;

a) Completion of the NIH training module

(https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html) OR a similar FCOI module required by the individual's primary institution of higher education, provided the institution meets the definition provided in 20 U.S.C. 1001(a), will be required.

b) Submission of the FCOI form to the USASP office serves as the individual's certification that training has been completed as required.

ii. Additional training when USASP-FCOI Officer (USASP's program coordinator or Board president) finds that a Speaker or Leader is not in compliance with this policy or a prescribed management plan; and

iii. Updated information on any revisions to this policy that affects the responsibilities of Speakers and Leaders to report FCOI.

c. If USASP subcontracts elements of a PHS-funded activity to an outside entity, each subrecipient investigator or key personnel shall be required to comply with this policy or provide documentation that the subrecipient institution is in compliance with 42 CFR Part 50, Subpart F.

A. A written agreement with the subrecipient must identify whether the subrecipient investigator and key personnel will comply with the FCOI provisions of the subrecipient institution or USASP;

B. If the subrecipient will comply with his or her institutional FCOI policy, the written agreement must specify that any FCOI disclosures reported to the subrecipient's institution must be reported to the USASP-FCOI Officer (USASP's program coordinator or Board president) within 30 days.

C. USASP will report subrecipient significant financial interest to the PHS prior to the expenditure of any funds or within 60 days of receiving subrecipient disclosure of significant financial interest.

d. USASP will identify an official to seek and review disclosures of significant financial interest. This official will serve as the USASP-FCOI Officer (USASP's program coordinator or Board president).

e. All records relating to disclosures of financial interest, including any review and actions taken by USASP, will be maintained by the USASP-FCOI Officer or designee for a period of at least five years. In the case of disclosures relevant to a PHS grant, records will be maintained at least five years from the date the final grant expenditure report is submitted to the PHS.

f. The USASP shall certify in each application for PHS-funded activities that it:

A. Has in effect a financial conflict of interest policy for all PHS-funded activities;

B. Shall promote and enforce compliance with this policy;

C. Shall manage financial conflicts of interest and provide initial and ongoing reports to the organizational unit of the PHS that funds the activity; and

D. Agrees to make information promptly available to PHS relating to the disclosure and review of any financial conflict of interest.

3. Reviewing Disclosures

a. Within 60 days of receipt of a significant financial disclosure, the USASP-FCOI Officer shall review the report to determine whether each significant financial interest is related to USASP-funded activities, and if so, whether the significant financial interest is a financial conflict of interest.

b. A significant financial interest is related to any PHS-funded activity if the significant financial interest:

A. could be affected by the PHS-funded activity;

B. is in an entity whose financial interest could be affected by the activity; or

C. could directly and significantly affect the design, conduct or reporting of the PHS-funded activity.

c. In reviewing a disclosure, the USASP-FCOI Officer may seek additional information from the individual in determining whether the disclosure is a significant financial interest that relates to the PHS-funded activity.

d. If the USASP-FCOI Officer determines that a significant financial interest exists that is related to the USASP activity, the Officer shall identify actions, if any, that must be taken by the individual to manage the financial conflict of interest.

A. Actions to manage the financial conflict of interest may include but are not limited to:

i. Public disclosure of the financial conflict of interest when presenting at an activity;

ii. Informing activity participants directly about the financial conflict of interest;

iii. Appointment of an independent monitor that is capable of taking appropriate measures to protect the activity against bias resulting from the financial conflict of interest;

iv. Modifying the activity;

v. Changing the individual in all or part of the activity;

vi. Disqualifying individuals from participating in the activity;

vii. Reducing or eliminating the financial interest; or

viii. Severing relationships that create the financial conflict.

B. The actions required to manage the financial conflict of interest shall be identified in a management plan and compliance with the management plan

shall be monitored by the USASP-FCOI Officer or designee on an ongoing basis until completion of the activity.

C. Depending on the nature of the significant financial interest, the USASP-FCOI Officer may determine that additional interim measures are necessary with regard to the individual's participation in activities between the date of disclosure and the completion of the USASP-FCOI Officer review.

e. If the USASP-FCOI Officer identifies that a significant financial interest exists that was either not disclosed or not disclosed in a timely manner by a Speaker or Leader, the USASP-FCOI Officer shall follow the same procedures as outlined in this section.

f. If a financial conflict of interest is not identified or managed in a timely manner including failure by a Speaker or Leader to report a significant financial interest that constitutes a FCOI, failure of USASP to review or manage a FCOI, or failure by the Speaker or Leader to comply with a management plan, the USASP-FCOI Officer shall:

A. Within 120 days, complete a retrospective review of the individual's activities to determine whether the work conducted during the time period of the noncompliance was biased in design, conduct or reporting of such work.

B. In the case of PHS funded activities, the retrospective review will be documented and include the following elements:

- i. Project number;
- ii. Project title;
- iii. Name(s) of project director or principal investigator;
- iv. Name of the investigator or key personnel with the FCOI;
- v. Name of the entity with which the investigator or key personnel has a FCOI;
- vi. Reason(s) for the retrospective review;
- vii. Detailed methodology of the review process, composition of the review panel and the documents reviewed;
- viii. Findings of the review; and
- ix. Conclusions of the review.

C. Based on the findings of the retrospective review, if appropriate, the USASP-FCOI Officer shall update any previously submitted FCOI reports, specifying actions taken to manage the FCOI.

D. In the case of PHS funded activities and if the retrospective review determines that the activity was biased, the USASP-FCOI Officer will promptly notify the PHS organizational unit that funds the activity and submit a mitigation report. The mitigation report will include, but is not limited to, the following information:

- i. All information described in (3)(f)(B);
- ii. A description of the impact of the bias on the activity;
- iii. USASP's plan of action or actions taken to eliminate or mitigate the effects of the bias. Such a plan may include requesting an addendum to previously published presentations.

4. Reporting FCOI to DHHS, Public Health Service

a. The USASP-FCOI Officer or designee shall provide initial and ongoing financial conflict of interest reports to the DHHS, PHS. Reports shall be issued no less than once per year for the duration of the project period.

A. The annual report for FCOI previously reported where the activity is an ongoing PHS-funded activity shall address the status of the FCOI and any changes to the management plan for the duration of the project.

B. The annual report shall also specify whether the FCOI is still being managed or explain why the FCOI no longer exists.

b. Prior to the expenditure of any funds under a PHS-funded activity, the USASP-FCOI Officer shall provide the organizational unit of the PHS that funds the activity an FCOI report regarding any investigator's or key personnel's significant financial interest determined to be conflicting and that includes information about the management plan.

c. In the event that USASP identifies a FCOI and eliminates it prior to expending any PHS funds, the USASP-FCOI Officer or designee shall not submit an FCOI report to the PHS.

d. Subsequent to any initial FCOI reports during an ongoing PHS-funded activity, any new disclosures that are determined conflicting shall be reported within 60 days to the PHS in accordance with section (3).

e. FCOI reports submitted to the organization unit of the PHS that funds the activity shall include sufficient information to allow the PHS to understand the nature and extent of the FCOI and assess the appropriateness of USASP's management plan. Information in the report shall include, but not limited to, the following:

A. Project number;

B. Investigator or key personnel contact;

C. Name of investigator or key personnel with the financial conflict;

D. Name of the entity with which the individual has the conflict;

E. Nature of the financial interest;

F. Value of the financial interest;

G. Description of how the financial interest relates to the PHS-funded activity and basis for the determination that the financial interest conflicts with the activity;

H. Description of the key elements of the management plan including:

i. Role and principal duties of the conflicted investigator or key personnel;

ii. Conditions of the management plan;

iii. How the management plan is designed to safeguard objectivity in the activity;

iv. Confirmation of the Investigator's agreement to the management plan; v. How the management plan is monitored to ensure compliance; and

vi. Additional information as needed.

5. Remedies

a. If a Speaker or Leader fails to comply with this policy or a FCOI management plan appears to have biased an activity, the USASP-FCOI Officer or designee shall promptly notify the Board of Directors of the USASP for consideration.

b. In the case of a PHS-funded activity and if a Speaker or Leader fails to comply with this policy or a FCOI management plan appears to have biased an activity, the USASP-FCOI Officer or designee shall promptly notify the organizational unit of the PHS that funds the activity about any corrective action taken or to be taken.

i. The PHS will consider the information submitted and may require or recommend additional action.

b. USASP will submit, or permit on site review, all records pertinent to the review of a financial disclosure or FCOI to the PHS. The PHS may determine on the basis of any review that the FCOI will bias the objectivity of the activity to such an extent that further corrective action is needed. This may include the imposition of special award conditions or suspension of funding or other enforcement action.

6. Public Accessibility to FCOI Information

a. Prior to the expenditure of any funds under a PHS-funded activity, the USASP-FCOI Officer or designee must respond in writing within five days to a requestor for information concerning any significant financial interest disclosures that meet the following criteria:

A. Any significant financial interest disclosed and is still held by the investigator or key personnel;

B. The significant financial interest was determined to be related to the PHS-funded activity and

C. The significant financial interest was determined to be an FCOI.

b. The information released to the requestor must include the following:

A. Investigator or key personnel name and title;

B. The role of the investigator or key personnel in the activity;

C. The name of the entity in which the significant financial interest is held;
and

D. The nature of the significant financial interest and the approximate dollar range of the significant financial interest; or

E. A statement that the value cannot be readily determined through reference to public prices or other reasonable measures.

F. The written response will note that the information provided is current as of the date of the correspondence, that FCOI information is updated biannually or within 60 days of identification of a new FCOI. Requestor would have to make subsequent request to receive information.

c. USASP may choose to post FCOI disclosures on its website and if posted will update information every six months.

A. Additional financial interest not previously disclosed or disclosure of financial interest of an investigator or key personnel new to a PHS-funded activity where the USASP-FCOI Officer has determined that the updated information relates to the PHS funded activity and is considered a FCOI, will be posted to the web within 60 days.

B. If information is posted on the website, the web page will note that the information provided is current as of the date listed and is subject to updates within 60 days of receiving updated information or on a biannual basis.

d. Information concerning significant financial interests that meet the criteria in (5)(b) shall remain available for public information requests for at least three years from the date that the information was most recently updated.

Form(s) that apply:

Financial Conflict of Interest Disclosure

Definition(s):

Disclosure of significant financial interests: A Speaker or Leader's disclosure of significant financial interests.

Financial conflict of interest (FCOI): A significant financial interest that could directly and significantly affect the professional duties or responsibilities of a Speaker or Leader, including the design, conduct, or reporting of research or presentation of educational material.

FCOI report: An institution's report of a financial conflict of interest; for example, to an organization unit of the PHS that funds an activity.

Financial interest: Anything of monetary value, whether or not the value is readily ascertainable.

Institutional responsibilities: Investigator's professional responsibilities on behalf of the Institution which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, or service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Leader: An individual participating in USASP leadership activities (member of the Board of Directors, member of a committee or task force).

Investigator: The project director or principal investigator and any other person, regardless of title or position who is responsible for the design, conduct or reporting of activities funded by the PHS, or proposed for funding. The investigator may include collaborators or consultants.

Manage: Taking action to address a FCOI, 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 and other professional activities will be free from bias.

PHS: The Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

Activity: A systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social sciences investigations. The term encompasses basic and applied research (e.g., a published article, book or book chapter), product development (e.g., a diagnostic test or drug), and the production of educational material (e.g., literature overview or review or presentation of treatment approaches).

Speaker: A speaker at a USASP-sponsored event.

Key personnel: The Investigator(s) and any other person identified as senior or key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution.

Significant financial interest (SFI):

1) A financial interest consisting of one or more of the following interests of the individual (or those of the individual's spouse and dependent children) that reasonably appears to be related to the individual's institutional responsibilities:

- a. With regard to any publicly-traded entity, an SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when combined with the value of any equity interest in the entity at the time of the disclosure, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
- b. With regard to any non-publicly traded entity, an SFI 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 a Speaker or Leader (or their spouse and dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
- c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

2) In addition to disclosures identified in (1), individuals must also disclose the occurrence of any reimbursed or sponsored travel (that which is paid on behalf of the Speaker or Leader or Key Personnel and not reimbursed to the individual so that the exact monetary value may not be readily available) related to their institutional responsibilities. Travel disclosure is not required if the travel 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 an institute that is affiliated with an institution of higher education. The following travel details are required:

- a. Purpose of trip;
- b. Name of sponsor/organizer;
- c. Destination (city and state or country if outside the U.S.);
- d. Duration of trip; and
- e. Total cost of trip including lodging; registration; fare for mode of travel (air, train, car, etc); per diem and any other miscellaneous expenses.

3) Significant financial interest does not include:

- a. Salary, royalties, or other remuneration paid by the institution to the Speaker, Leader or key personnel if the individual is currently employed or otherwise

appointed by the institution. This includes intellectual property rights assigned to the institution and agreements to share in royalties related to such rights;

b. Salary, royalties, or other remuneration paid for any ownership interest in the institution held by the Speaker or Leader or key personnel if the institution is a commercial or for-profit organization;

c. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Speaker or Leader does not directly control the investment decisions made in these vehicles;

d. Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency; an institution of higher education; an academic teaching hospital, a medical center, or an institute that is affiliated with an institution of higher education; or

e. Income from service on advisory committees or review panels for a federal, state, or local government agency; an institution of higher education; an academic teaching hospital, a medical center, or an institute that is affiliated with an institution of higher education.

Subrecipient: An organization or individual that participates in an activity with the awardee Institution (e.g. subcontractors or consortium members).

Reference(s): 42 CFR 50 – Policies of General Applicability 45 CFR 94 – Responsible Prospective Contractors DHS/OHA Policy: Conflict of Interest

Contact(s): Name: Jennifer Haythornthwaite Phone: (443) 858-2811; Email: admin@usasp.org