

**Mission:** To promote scientific advances that reduce the burden of pain. Our goal is to bring diverse perspectives, including those of scientists, clinicians, health-care providers, and policymakers, together to stimulate and support the study of pain and to translate that knowledge into improved pain relief.

USASP.org

## **Conflict of Interest (COI) Policy**

*(Financial and Non-Financial)*

### **Purpose/Rationale**

To promote objectivity by establishing standards that preserve the integrity of leadership, decision making, and institutional activities; to prevent bias; to ensure that decisions, recommendations, and actions are made in the best interests of the USASP and are not improperly influenced, or perceived to be influenced, by personal, professional, or financial considerations; and to protect the rights and safety of individuals involved in Public Health Service (PHS)-funded activities.

USASP recognizes that individuals engaged in scientific, professional, and nonprofit work often maintain multiple roles and relationships. The goal of this policy is not to prohibit such relationships, but to ensure transparency, appropriate management, and continued public trust.

### **Scope**

This policy applies to all individuals acting on behalf of the USASP or presenting at USASP-sponsored events, including but not limited to:

- Board members and officers
- Committee members and chairs
- Grant, abstract, or award reviewers
- Editors, guideline authors, and advisors
- Speakers at any USASP-sponsored event
- Employees of the USASP

### **Definition of a Conflict of Interest**

A conflict of interest exists when an individual has a financial or non-financial interest that could reasonably be expected to influence, or appear to influence, the individual's judgment, objectivity, or actions. Conflicts may be actual, potential, or perceived.

Other definitions of terms in this policy are **provided in Appendix A.**

### **Relationships Requiring Disclosure**

Relationships should be disclosed when such relationships could reasonably affect decisions involving funding; awards, or recognition; appointments or leadership roles; peer review, evaluation, or recommendations; or contracts, partnerships, or endorsements. This policy includes financial and non-financial conflicts for **spouses and dependent children.**

**Leadership roles that must be disclosed** include paid or unpaid positions such as:

- Officer, board member, trustee, or committee leader
- Editor or editorial board member
- Advisor or representative

held in:

- Other professional or scientific societies
- Advocacy organizations
- Trade, industry, or standards-setting bodies
- Accrediting or regulatory organizations

Such roles may present conflicts when missions, policy positions, funding sources, or decision-making authority overlap.

## **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.

## **Individual Responsibilities**

Individuals acting on behalf of the USASP or presenting to USASP members must disclose to the USASP-COI Officer (USASP's administrative leader or Board president) any conflict of interest (and those of the individual's spouse and dependent children) no later than the date of the USASP-related work using the COI form provided by the USASP-COI Officer.

- 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 COI form.
- Required Annual COI reports submitted to the USASP-COI Officer shall include any information that was not previously disclosed.
- Disclosure is required within 30 days of discovering or acquiring a conflict of interest by submitting an updated COI form to the USASP-COI Officer.

Mandatory COI training requirements include completion of COI training every four years. This can be done through either of the following:

1. completion of the NIH training module ([https://grants.nih.gov/grants/policy/coi/tutorial2018/story\\_html5.html](https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html)) OR
2. a similar COI 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);

and (2) submission of the COI form to the USASP office serves as the individual's certification that training has been completed as required.

## **USASP Responsibility**

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).

USASP will inform individuals acting on behalf of the USASP or presenting to USASP members about the following:

- Information about this policy and the corresponding federal regulations
- Responsibility to disclose any significant interest to the USASP-COI Officer
- Mandatory COI training requirements and additional training when USASP-COI Officer finds that an individual is not in compliance with this policy or a prescribed management plan
- Updated information on any revisions to this policy that affects the responsibilities of Individuals acting on behalf of the USASP or presenting to USASP members to report COI.

**USASP-COI Officer:** USASP will identify an official to seek and review disclosures of significant financial interest. This official will be either the USASP's administrative leader or the USASP Board president).

All **records relating to disclosures** of financial interest, including any review and actions taken by USASP, will be maintained by the USASP-COI Officer or designee for a period of **at least five years**.

## **Reviewing Disclosures**

Within 60 days of receipt of a disclosure, the USASP-COI Officer shall review the report to determine whether each COI is related to USASP and/or PHS-funded activities, and if so, whether it is a conflict of interest. In reviewing a disclosure, the USASP-COI Officer may seek additional information from the individual in determining whether the disclosure relates to the activity.

A COI is related to any USASP or PHS-funded activity if it:

- could be affected by the activity;
- is in an entity whose interest could be affected by the activity; or
- could directly and significantly affect the activity.

If the USASP-COI Officer determines that COI exists that is related to the USASP and/or a PHS-funded activity, the Officer shall identify actions, if any, that must be taken by the

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

- Public disclosure of the conflict of interest when presenting at an activity;
- Informing activity participants directly about the conflict of interest;
- Appointment of an independent monitor that is capable of taking appropriate measures to protect the activity against bias resulting from the conflict of interest;
- Modifying the activity;
- Changing the individual in all or part of the activity;
- Disqualifying individuals from participating in the activity;
- Reducing or eliminating the conflict of interest; or
- Severing relationships that create the conflict.

The actions required to manage the conflict of interest shall be identified in a management plan and compliance with the management plan shall be monitored by the USASP-COI Officer or designee on an ongoing basis until completion of the activity.

Depending on the nature of the conflict, the USASP-COI 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-COI Officer review.

If the USASP-COI Officer identifies that a conflict exists that was either not disclosed or not disclosed in a timely manner by an individual, the USASP-COI Officer shall follow the same procedures as outlined in this section.

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

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

## **Reporting financial COI to DHHS, Public Health Service**

The USASP-COI Officer or designee shall provide initial and ongoing conflict of interest reports to the DHHS, PHS. Reports as **outlined in Appendix B** shall be issued no less than once per year for the duration of the project period.

## **Remedies**

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

### **Public Accessibility to COI Information**

Conflict of interest disclosures will be treated as confidential and shared only with those responsible for review and management, except where public disclosure is required or determined to be appropriate to protect the credibility and integrity of the USASP. USASP may choose to post COI disclosures on its website and if posted will update information every six months. For example, conflicts of board members and officers will be listed on the USASP website (USASP.org) and speakers will be expected to include a disclosure slide or statement prior speaking.

### **Form(s) that apply:**

USASP Financial Conflict of Interest Disclosure

### **Contact(s):**

Jennifer Haythornthwaite, Chief Administrative Officer

Phone: (443) 858-2811

Email: [admin@usasp.org](mailto:admin@usasp.org)

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## **Appendix A**

### **USASP Conflict of Interest Policy Definitions**

**Disclosure of conflict of interests:** An individual's disclosure of financial and non-financial conflict(s) of interest using the USASP COI form.

**Conflict of interest (COI):** An interest that could reasonably be expected to influence, or appear to influence, the individual's judgment, objectivity, or action, including the design, conduct, or reporting of research, presentation of educational material, and the review of abstracts, awards, or grants. Conflicts may be actual, potential, or perceived.

**COI report:** An institution's report of a financial or personal 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.

**Non-Financial interest:** Any circumstances, commitments, or strongly held positions that could reasonably be perceived as influencing objectivity or independence. Examples of non-financial conflicts are family members, close personal or close professional relationships, and professional rivalries or academic competition.

**Institutional responsibilities:** Professional responsibilities on behalf of the USASP (one institution) or the individual's employer (another institution) which may include the following activities: research, research consultation, teaching, professional practice, committee memberships, and service on review panels.

**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 COI, which can include reducing or eliminating the 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 (HHS), and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

**Activity:** Any discussion, presentation, or evaluation contributing to the work of the USASP, including meetings of the membership, board, committees and Special Interest Groups; any 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), the production of educational material (e.g., literature overview or review or presentation of treatment approaches), and most of the work of the USASP.

**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 USASP in the grant application, progress report, or any other report submitted to the PHS by the USASP.

**Significant financial interest (SFI):**

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 USASP responsibilities:

1. 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;
2. 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 individuals acting on behalf of the USASP or presenting to USASP members (or their spouse and dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
3. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

In addition to disclosures identified in above, individuals must also disclose the occurrence of any reimbursed or sponsored travel (that which is paid on behalf of the individual 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:

- Purpose of trip;
- Name of sponsor/organizer;
- Destination (city and state or country if outside the U.S.);
- Duration of trip; and
- 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**:

- Salary, royalties, or other remuneration paid by the institution to the individual 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;
- Salary, royalties, or other remuneration paid for any ownership interest in the institution held by the individual or key personnel 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 Speaker, Leader, or Employee 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; 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
- 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 USASP (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

## **APPENDIX B**

### **Reporting financial COI to DHHS, Public Health Service**

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

- Has in effect a conflict of interest policy for all PHS-funded activities;
- Shall promote and enforce compliance with this policy;
- Shall manage conflicts of interest and provide initial and ongoing reports to the organizational unit of the PHS that funds the activity; and
- Agrees to make information promptly available to PHS relating to the disclosure and review of any conflict of interest.

If USASP subcontracts elements of a Public Health Service-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 written agreement with the subrecipient must identify whether the subrecipient investigator and key personnel will comply with the COI provisions of the subrecipient institution or USASP;
- If the subrecipient will comply with his or her institutional COI policy, the written agreement must specify that any COI disclosures reported to the subrecipient's institution must be reported to the USASP-COI Officer within 30 days.
- 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.

The annual report for financial COI previously reported where the activity is an ongoing PHS-funded activity shall address the status of the COI and any changes to the management plan for the duration of the project. The annual report shall also specify whether the financial COI is still being managed or explain why the COI no longer exists.

### **Reviewing Disclosures**

Prior to the expenditure of any funds under a PHS-funded activity, the USASP-COI Officer shall provide the organizational unit of the PHS that funds the activity a financial COI report regarding any investigator's or key personnel's interest determined to be conflicting and that includes information about the management plan. In the event that USASP identifies a financial COI and eliminates it prior to expending any PHS funds, the USASP-COI Officer or designee shall not submit a financial COI report to the PHS.

Subsequent to any initial financial COI 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).

Financial COI 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 financial COI and assess the appropriateness of USASP's management plan. Information in the report shall include, but not limited to, the following:

- Project number;
- Investigator or key personnel contact;
- Name of investigator or key personnel with the financial conflict;
- Name of the entity with which the individual has the conflict;
- Nature of the financial interest;
- Value of the financial interest;

The report will include a 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 and a description of the key elements of the management plan including:

- Role and principal duties of the conflicted investigator or key personnel;
- Conditions of the management plan;
- How the management plan is designed to safeguard objectivity in the activity;
- Confirmation of the Investigator's agreement to the management plan;  
How the management plan is monitored to ensure compliance; and
- Additional information as needed

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 Public Health Service (PHS).

## **Retrospective Review**

If a retrospective review has occurred the review will be documented and include the following elements:

- Project number;
- Project title;
- Name(s) of project director or principal investigator;
- Name of the investigator or key personnel with the COI;

- Name of the entity with which the investigator or key personnel has a COI;
- Reason(s) for the retrospective review;
- Detailed methodology of the review process, composition of the review panel and the documents reviewed;
- Findings and Conclusions of the review.

If the retrospective review determines that the activity was biased, the USASP-COI 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:

- All information described in (3)(f)(B);
- A description of the impact of the bias on the activity;
- 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.

## **Remedies**

If an individual fails to comply with this policy or a financial COI management plan appears to have biased a PHS-funded activity, the USASP-COI 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. The PHS will consider the information submitted and may require or recommend additional action.

USASP will submit, or permit on site review, all records pertinent to the review of a financial disclosure or COI to the PHS. The PHS may determine on the basis of any review that the financial COI 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.

## **Public Accessibility of Financial COI Information**

Prior to the expenditure of any funds under a PHS-funded activity, the USASP-COI 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:

- Any significant financial interest disclosed and is still held by the investigator or key personnel;
- The significant financial interest was determined to be related to the PHS-funded activity and
- The significant financial interest was determined to be a financial COI.

The information released to the requestor must include the following:

- Investigator or key personnel name and title;
- The role of the investigator or key personnel in the activity;
- The name of the entity in which the COI is held; and
- The nature of the significant financial interest and the approximate dollar range of the significant financial interest; or
- A statement that the value cannot be readily determined through reference to public prices or other reasonable measures.
- The written response will note that the information provided is current as of the date of the correspondence, that COI information is updated biannually or within 60 days of identification of a new COI. Requestor would have to make subsequent request to receive information.

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-COI Officer has determined that the updated information relates to the PHS funded activity and is considered a COI, will be posted to the web within 60 days. 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. 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.