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All USP Expert Volunteers—whether serving on the Council of Experts (CoE), an Expert Committee (EC), or Expert Panel—are responsible for adhering to the Standards of Conduct concerning conflicts of interest and confidentiality in the Rules and Procedures of the Council of Experts (CoE Rules), USP Code of Ethics, and other USP policies. Identifying, disclosing, and resolving issues related to representation, conflicts of interest, and confidentiality is integral to your role as a USP Expert Volunteer. You also are required to proactively disclose to USP any actual or potential conflicts of interest and confidentiality issues that may arise during the course of your standards-setting activities.

This document is intended to help you, as an Expert Volunteer, resolve standards of conduct issues. It is presented in the following format:

- Frequently asked questions (FAQs);
- References to excerpts from the applicable CoE Rules; and
- Examples, when available, to help illustrate real-life situations.

The FAQs and examples that follow are not intended to be an exhaustive list of the types of issues that may arise. As always, please feel free to reach out to USP staff if you have any questions about identifying, disclosing, or resolving issues related to Standards of Conduct.

This brochure focuses on Section 2 of the CoE Rules on Standards of Conduct concerning representation, conflicts of interest, and confidentiality. It covers the following topics: definition of conflicts of interest, recusal, assignment of work, conflict of Chair, disclosure requirements, identification and resolution of conflict issues, and maintaining confidentiality.
The USP Code of Ethics is intended to provide guidance as well as tools to help you make the right decisions.

**Code of Ethics**

Q: What is USP's Code of Ethics and how does it apply to me?

A: USP's Code of Ethics represents USP's shared values and expectations of ethical conduct. It outlines how USP expects its employees, Board of Trustees, volunteers, and representatives to act and what they in turn can expect from USP. Standards of conduct for volunteers can be found in two of USP's governing documents: 1) USP's Code of Ethics; and 2) the CoE Rules.

Both documents offer information on how individuals should handle conflicts of interest and confidentiality while working with or for USP. The CoE Rules specifically apply to you as a CoE/EC member.

CoE Rule 2.01: “Members of the Council of Experts, Expert Committee (CoE/EC) and Expert Panels shall be required to adhere to USP's Code of Ethics, which is available on USP’s website.”

**Representation**

Q: Can CoE/EC or Expert Panel members serve an outside interest?

A: CoE/EC members serve USP in their capacity as individual experts; they are not allowed to represent any outside interest, including that of their employer. Expert Panel members, however, may serve an outside interest as long as the interest is disclosed to USP, the Chair, and the members of the Expert Panel.

CoE Rule 2.02: “A CoE/EC or Expert Panel member shall not use his or her membership in any way that is, or appears to be, motivated by private gain or any outside interest.”
Q: Why are Expert Panel members allowed to serve an outside interest?

A: Expert Panels only issue advisory recommendations to ECs; they do not make decisions or approve standards. All final standards-setting decisions are made by a USP EC. An Expert Panel member must timely and adequately disclose any conflict of interest to USP, the Chair, and the other members of the Expert Panel.

CoE Rule 5.05(a): “Conflicts of Interest, as defined in Section 2.03(a), will not be a bar to participation on an Expert Panel or in any deliberations or recommendations of the Expert Panel, including voting, provided the Expert Panel member timely and adequately discloses any Conflict of Interest as required by Sections 2.03, 2.04 and 2.05 of these Rules to other members of the Expert Panel including the chairperson.”

Q: When engaging in professional activities outside of USP, am I allowed to include as part of my qualifications my status as a USP CoE/EC or Expert Panel member?

A: While you may include a reference to your USP volunteer status as part of general information provided in your resume or bio, you cannot use that status to advertise or promote any speaking, consulting, or other professional activity you are involved in, unless you are specifically engaging in that activity on behalf of or at the direction of USP.

Q: Can I present an educational course and training on USP standards?

A: Yes, you may present educational and training courses on USP standards as an individual and not as a CoE/EC or Expert Panel member. Note that as a CoE/EC and Expert Panel member, the CoE Rules and standards of conduct are still applicable to you. For example, the confidentiality of information obtained during USP standards-setting activities must be maintained unless the information is already publicly available. Further, the CoE Rules permit you to make mention of your USP affiliation in your biography or profile attached to the course description; however, your USP affiliation should not be used in any advertisement to induce participation. USP also encourages the use of a disclaimer that states: “This course [or training] is not endorsed by or affiliated with USP.”

Examples

Unless you have USP permission, you may not use any of the following for promotional purposes:

- The USP logo
- USP materials
- Your affiliation with USP unless:
  - It is mentioned in a resume, c.v., biography, or profile; or
  - It is presented at a USP-sponsored event and you are attending or speaking on behalf of USP.
Unbiased input and decision-making is critical in the development of science-based quality standards.

Q: What is a conflict of interest?

A: These situations have the actual or potential impact to undermine the objectivity and impartiality of an Expert Volunteer. Expert Volunteers must avoid conflicts of interest that interfere with their standards-setting responsibilities to USP. As an organization, USP must avoid conflicts of interest that have the potential to affect the impartiality and objectivity of the organization.

CoE Rule 2.03(a): “Conflict of Interest’ includes, but is not limited to, any matter in which an Expert has a direct or indirect financial interest or any other personal interest of any kind which would preclude or appear to preclude such individual from exercising impartial judgment or otherwise acting in the best interest of USP.”

Q: Why are conflicts of interest a concern to USP?

A: As a standards-setting organization, USP must balance its ability to receive information from objective and impartial experts that will enable the development of scientifically sound standards. Unbiased input and decision-making is critical in the development of science-based quality standards. Any adverse impact caused by the influence of conflicts, whether real or perceived, undermines the legitimacy of USP’s standards and threatens the reputation of USP as an independent standards-setting organization.
Q: What happens if I am a CoE/EC or Expert Panel member and I recuse myself due to a conflict of interest?

A: If you are a CoE/EC member and have a conflict of interest, you may participate in the initial discussions of issues. However, you must recuse yourself from participation in the final discussion or deliberation on any matter in which you have a conflict of interest. Upon recusal, you must leave the room, teleconference, or WebEx during final discussion or deliberation on the conflicting matter. Afterward, USP staff will contact you to rejoin the meeting.

Expert Panel members may participate in deliberations or recommendations regarding matters in which they have a conflict of interest, provided disclosure of the conflict of interest has been made to USP staff, the Chair, and other members of the Expert Panel. However, the Expert Panel’s advisory recommendations to the EC must be accompanied by a disclosure of each Expert Panel member’s conflicts of interest.

CoE Rule 2.03(b): “No CoE/EC Expert shall vote nor take part in the final discussion or deliberation of any matter in which he or she has a Conflict of Interest.”

Examples

Conflicts of interests that should be disclosed include but are not limited to the following:

- **Financial Interests**
  - Owning, directly or indirectly, a significant financial interest in any entity that does business, seeks to do business, or competes with USP
  - Having a financial or personal interest in a food ingredient, supplement, or drug for which your EC is developing or approving a monograph
  - Taking personal advantage or allowing a family member to benefit from a USP standards-setting activity
  - Being employed by an organization that would financially benefit from a standard you are working on (includes employment, training, or service on the board of a customer, supplier, or service provider)
  - Having a revenue stream that is related to a given USP standard (i.e., you provide paid training as an expert in an area that overlaps with the USP standard that you are working on)
  - Soliciting or accepting gifts, favors, loans, or preferential treatment from any person or entity that seeks to influence a standards-setting activity
  - Soliciting contributions for any charity or for any political candidate from any person or entity that does business or seeks to do business with USP

- **Other Competing Interests**
  - Being a consultant with a prior relationship with a company that makes the drug
  - Working for a university that is seeking a grant related to the drug

- **Personal Interests**
  - Having strong personal feelings for or against the use of a type of drug for which your EC is developing a standard

because of philosophical, religious, political, or moral feelings about a particular issue that could influence your judgment.
Q: Will the facts behind conflicts of interest be made public?

A: No, conflicts of interest are not disclosed to the public; however, the minutes of a meeting will indicate when a member recuses himself or herself from a meeting due to a conflict of interest and these minutes are publicly available if requested. Conflicts of interests will be disclosed to USP staff supporting a volunteer group (e.g., CoE, EC, Expert Panel, and fellow members of the volunteer group). In addition, conflicts of Expert Panel members are disclosed to the members of the EC overseeing the work of the Expert Panel prior to reaching a final decision on any recommendation.

Q: What should I do if I have a conflict of interest on an issue or question that is being balloted?

A: By the balloting period, your conflicts of interest must already have been identified and disclosed. EC members must refrain from voting to approve or not approve a ballot item if they have a conflict of interest. There is a voting designation on the ballot for abstention. In the event of a conflict of interest on an issue being balloted, an EC member should indicate that he or she is abstaining on the ballot, which will still be counted toward the requirement for establishing a quorum for the ballot. Only if you mark “abstain” is your participation in the balloting considered an abstention; otherwise your participation in the balloting will not be noted and is not counted toward the quorum.

Examples

Conflicts of interest that could arise during balloting include but are not limited to the following:

- New financial ties to a drug company that would benefit from a new or revised USP standard or reference standard have arisen that have not previously been disclosed.
- New consulting relationships with a drug company that may benefit from a revision to a USP standard have arisen that have not previously been disclosed.
- An emerging relationship with a laboratory that may benefit from revisions to a USP standard has arisen that has not previously been disclosed.
Q: Can a CoE/EC member be permitted to work on a USP standard if he or she has disclosed a conflict of interest?

A: Yes; however, the conflicted CoE/EC member cannot be assigned the primary responsibility to work on an issue or question in which he or she has a conflict of interest. The CoE/EC member may provide relevant scientific information and may participate in discussions regarding such issue or question as long as he or she doesn’t participate in the final discussion or deliberation.

For Expert Panel members, this is handled differently under the CoE Rules. Expert Panel members who have a conflict of interest may be assigned work on matters in which they have a conflict of interest, provided disclosure of such conflict of interest is made to the Chair, USP, and other members of the Expert Panel.

CoE Rule 2.03(c): “No CoE/EC Expert shall be assigned the primary responsibility to work on an issue or question in which he or she has a Conflict of Interest.”

Examples

The conflicted CoE/EC member may at his or her discretion:

- Work on the matter to help the EC achieve its objectives;
- Provide relevant scientific information on the matter creating the conflict; and
- Participate in discussions on the matter in person or by telephone to provide an additional resource of information to the EC.

The conflicted CoE/EC member cannot:

- Be the primary person responsible for developing and completing a USP standard;
- Have primary authorship of a USP Stimuli or journal article, or other USP publication;
- Chair a Subcommittee or Expert Panel that is working on the matter creating the conflict; or
- Lead a discussion on the matter upon which he or she is conflicted.
Q: Will a conflicted CoE/EC member have access to briefing materials that include confidential information on a matter in which he or she has a conflict?

A: Yes. While the conflicted member will receive confidential information that will enable him or her to participate in the manner allowed by the CoE Rules, the member must comply with the confidentiality restrictions and use the data and information only for purposes of participating in that discussion (see CoE Rule 2.06(a)). The conflicted member, however, will not be allowed to participate in the final discussion or deliberation on the conflicting matter.

Q: What happens if the Chair of an EC or Expert Panel has a conflict of interest?

A: If an EC Chair has a conflict of interest, he or she should recuse himself or herself, and the Vice Chair will serve in his or her place. If the Vice Chair is also conflicted, a designated non-conflicted member will be selected to serve in place of the Chair by a majority of the other non-conflicted members. To help with this process, an EC Chair should appoint a Vice Chair and identify potential conflicts as far in advance as possible.

An Expert Panel Chair who has a conflict of interest may continue to serve as the Chair during the meeting, provided he or she has disclosed the conflict of interest in a timely manner. The Expert Panel Chair’s conflict of interest must also be included in the Panel’s recommendation to the EC for its consideration during the standards-setting decision process.

CoE Rule 2.03(d): “In the case where the Chairperson of an EC has a Conflict of Interest, the Vice Chairperson will serve.”
Disclosure of Conflicts of Interest

CoE/EC and Expert Panel members are required to submit to USP a Disclosure Statement of all employment, professional research, organizational memberships, and other relevant interests.

Q: What is the most important thing to know about conflicts of interest?
A: When in doubt, disclose. Many conflicts of interest are fact-based. Therefore, if you are having trouble determining whether an interest presents a conflict, disclose it to USP staff so they can help you identify and resolve any issues you may have.

Q: How do I disclose my actual or potential conflicts of interest to USP?
A: CoE/EC and Expert Panel members are required to submit to USP a Disclosure Statement of all employment, professional research, organizational memberships, and other relevant interests. Members also are required to update the Disclosure Statement as necessary to keep it current and to advise the EC or Expert Panel Chair and USP staff of changing or emerging interests. In addition, USP may periodically request Expert Volunteers to update their Disclosure Statements. The Disclosure Statement is kept confidential except for periodic disclosure to fellow EC or Expert Panel members and monitoring by USP staff.

CoE Rule 2.04(a): “Each CoE/EC and Expert Panel member shall submit to USP a Disclosure Statement disclosing all employment, professional research, organizational memberships, and other relevant interests.”

Examples
- Disclose all interests that relate to the USP standards or activities of the EC or Expert Panel on which you serve as a member.
- Interests not relevant to USP or your EC or Expert Panel’s activities need not be disclosed.
- You must report to USP that you, your spouse, any of your dependents, or your employer have an equity or other financial interest in companies affected by your work at USP in excess of $10,000. (Note that there is no requirement to report investments through mutual funds or other vehicles in which there is no direct control over investment decisions.)
Q: Must I disclose that I’m engaged in consulting work involving education and training on USP standards?
A: Yes. Reportable interests include any educational training, courses, or presentations at conferences or seminars on USP standards that you provide during your service as an EC or Expert Panel member.

Q: What if I cannot disclose a conflict because of a contractual obligation that requires me to maintain confidentiality and not disclose my employer?
A: If you are prevented by a confidentiality and nondisclosure agreement from fully disclosing consultant work or other work you performed, you will need to provide a general description of the essential nature of the work performed. This disclosure is made under the Restricted Disclosure section in your Disclosure Statement. You must provide a general description of the activity of the work performed under the confidentiality agreement that is sufficient for USP and the Chair to determine whether a conflict of interest exists.

Q: How often must I update my Disclosure Statement form?
A: Update it as necessary to keep it current or as requested by USP. You are also obligated to advise USP staff and the Chair of your EC or Expert Panel of changing circumstances that may give rise to an actual or potential conflict of interest.

Q: Who reviews my Disclosure Statement form?
A: USP staff members, together with the Chair and/or Vice Chair of an EC or Expert Panel will review your Disclosure Statement periodically to identify conflicts of interest and to help ensure that they are disclosed to the other members of the EC or Expert Panel.

Examples
Restricted Disclosures include but are not limited to the following:

- I consult with a venture capital firm on emerging opportunities related to monoclonal antibodies.
- I consult with pharmaceutical companies developing biosimilars.
- I consult with a company involved in compounding medicines.

Examples
You should update your Disclosure Statement form whenever you have a change in:

- Your affiliations with companies or institutions;
- Your professional employment positions including editorial, consultant, and training work; or
- Your sources of income, finances, or equity that may affect your ability to objectively engage in USP standards-setting activities.
Identifying and Resolving Conflicts of Interest

Examples

CoE/EC conflicts of interest are handled in the following ways:

- A CoE/EC member proactively discloses a conflict of interest to USP as soon as he or she becomes aware of it.

- After the member’s disclosure:
  - USP staff members meet with the Chair of an EC, review the member’s Disclosure Statement, and ensure that the member’s conflict of interest is disclosed to the other members of the EC.
  - If the member’s conflict of interest cannot be resolved through voluntary recusal or intervention by the EC Chair, then the matter is referred to the Chair of the CoE and the USP Executive Secretariat.

- The CoE Chair has the final authority for resolving matters involving the member’s conflict of interest.

- USP does not disclose particular conflicts of interests publicly; however, the minutes of a meeting will indicate a member’s recusal from the meeting and the minutes are publicly available if requested.

- EC Chairs are authorized to resolve conflict of interest issues that arise during a meeting. USP staff, such as Scientific Liaisons, may also offer assistance to resolve a member’s conflict of interest during a meeting.

Q: How are conflicts of interest raised by CoE/EC members identified and resolved?

A: The CoE Chair becomes involved in resolving conflicts when a conflict of interest is identified by a CoE/EC member and cannot be resolved by voluntary recusal and/or intervention by the EC Chair. The CoE Chair has final authority in resolving conflicts of interest. Meeting minutes will indicate the disclosure and resolution of a conflict of interest identified by a CoE/EC member.

CoE Rule 2.05(a): “The CoE Chairperson shall have final authority for resolving matters involving Conflicts of Interest.”
Confidentiality

Expert Panel members must sign and submit confidentiality agreements to USP because confidentiality may be required in certain instances.

Q: As a CoE or EC member, what information is deemed confidential by USP?

A: All information received during the course of your volunteer work as a CoE/EC member with USP shall be maintained as confidential unless otherwise indicated by USP.

CoE Rule 2.06(a): “Each CoE/EC member shall maintain the confidentiality of all information gained in the course of his or her activities as a CoE/EC, and shall not use or disclose such information for any purpose, unless such information is already publicly available.”
Q: Are CoE/EC members obligated to maintain confidentiality?

A: Yes. USP respects and protects the confidentiality of proprietary, business, and trade secret information, whether belonging to USP or provided by third parties. CoE/EC members are required to sign confidentiality agreements with USP that obligate them to maintain the confidentiality of such information they receive from USP.

The reasons for maintaining the confidentiality of information are to:

• Prevent the premature disclosure of a USP standard;
• Preserve the confidentiality of proprietary, business, or trade secret information belonging to USP or to a third party (e.g., Sponsor); or
• Comply with third-party confidentiality obligations.

Q: Are Expert Panel members obligated to maintain confidentiality?

A: All Expert Panel members—unless specifically exempted—must sign and submit confidentiality agreements to USP because confidentiality may be required in certain instances identified by the Expert Panel Chair and USP staff.

CoE Rule 5.05(b): “Expert Panel members are not necessarily obligated to maintain confidentiality of materials obtained and issues discussed during the course of the Expert Panel’s task. However, pursuant to Section 2.06(b) and except as otherwise provided therein, Expert Panel members must sign and submit confidentiality agreements to USP because confidentiality may be required in certain instances as identified by the Expert Panel Chairperson and USP staff including, but not limited to, protecting third party confidentiality obligations, preventing the premature disclosure of a standard, or maintaining the confidentiality of proprietary, business, or trade secret information.”

Examples

CoE/EC members must maintain all information they receive from USP as confidential unless otherwise indicated. Administrative staff, teaching assistants, company personnel, etc., should not review information designated as confidential by USP. Examples include but are not limited to the following:

• Briefing materials shared at meetings
• Discussion during closed sessions of meetings
• Information identified as proprietary, business, or trade secret belonging to USP or a third party
• Information designated as “Confidential”
• Ballot results unless publicly available
• The status of a standard that has not yet been approved
• Monograph submission documents from donors, including validation materials