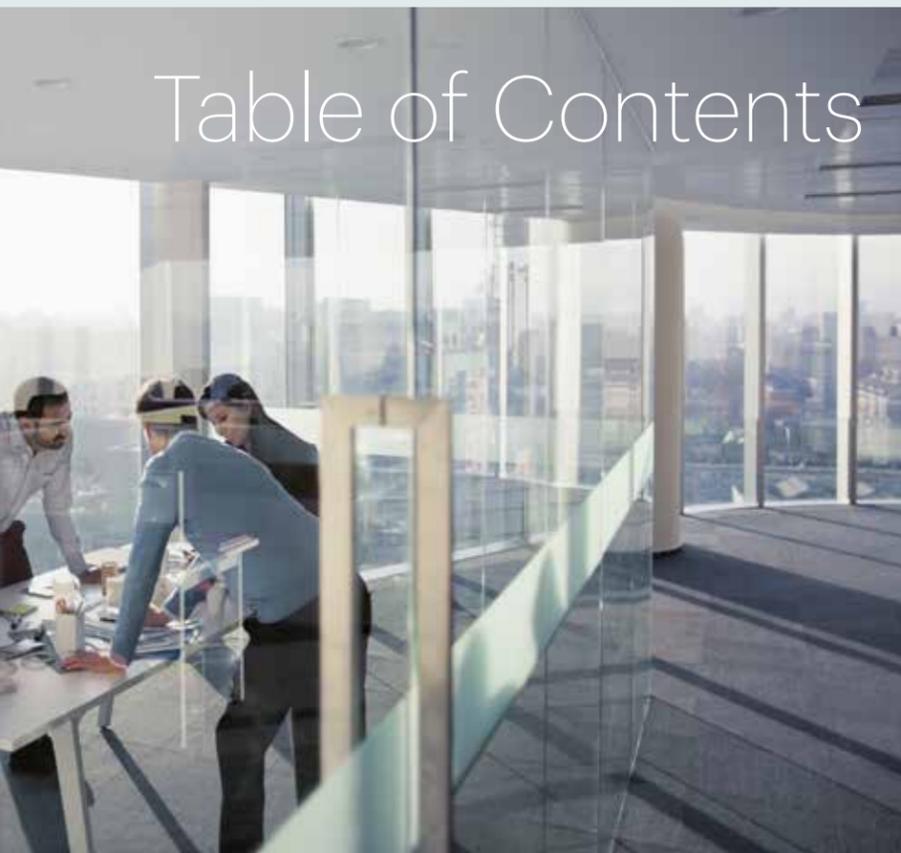




Standards of Conduct



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Understanding and adhering to USP's Standards of Conduct are important components of ensuring integrity in USP's processes and standards. Managing conflicts of interest, in particular, is a critical responsibility shared by all of us. Each Expert Volunteer is required to identify, disclose, and, when necessary, manage real, potential, or perceived conflicts of interest. Managing conflicts of interest may appear complex and perhaps even daunting at times. It is USP's goal to make the process as transparent as possible and, by doing so, strengthen the credibility and rigor of USP's standards-setting process. USP's Expert Bodies are populated by hundreds of scientists and professionals, all of whom bring their rich experience and great expertise to the table. It is therefore to be expected that conflicts of interest may arise and evolve as Expert Volunteers change jobs or other aspects of work and life change. Having a conflict of interest does not preclude Expert Volunteers from participating in many aspects of USP's standards-setting process. Among USP's greatest assets are the transparency, scientific rigor, and independence that Expert Volunteers help bring to USP's standards-setting process. By working together to protect the integrity of USP's standards, we increase the value and impact of those standards in USP's mission to improve global public health.

All USP Expert Volunteers, e.g., Council of Experts (CoE) members, Expert Committee (EC) members, Expert Panel members, and Expert Advisors, are required to adhere to USP's Code of Ethics as well as the Standards of Conduct in accordance with Section 11 of the [Rules and Procedures of the 2020-2025 Council of Experts](#) (CoE Rules). Standards of Conduct include requirements that relate to conflicts of interest, representation, and confidentiality. Your understanding of and adherence to these Standards of Conduct are integral to your role as a USP Expert Volunteer.

- Conflicts of interest requirements help ensure that you appropriately manage real and perceived conflicts that may cause others to question your objectivity. Conflicts are managed by disclosure, transparency, and recusal from voting. USP recognizes that conflicts of interest, perceived or real, are likely to arise for many Expert Volunteers at some point. You are required to proactively disclose to USP and your fellow volunteers any actual or potential conflicts of interest and confidentiality issues that may arise during the course of your standards-setting activities.
- Representation relates to the frame of reference for your interactions as a USP volunteer. It includes how you think about your role serving USP as an individual Expert Volunteer and how you would describe your role to others.
- Confidentiality provisions require you to maintain the confidentiality of all information gained in the course of USP activities as an Expert Volunteer unless it is already publicly available.

This document is intended to help you, as an Expert Volunteer, adhere to USP's Standards of Conduct. It is presented in the following format:

- Frequently asked questions (FAQs)
- References to excerpts from applicable *CoE Rules*

Introduction to Standards of Conduct

How to Identify, Disclose, and Manage Issues Around Conflicts of Interest and Confidentiality—Including Examples to Help You Adhere to USP's Standards of Conduct

- Examples and scenarios, when available, to help illustrate real-life situations. These hypothetical examples illustrate that many issues related to Standards of Conduct are not clear-cut. They may require evaluation and discussion with USP staff and Expert Body Chairs based on individual facts and circumstances to reach the correct course of action. Note that any resemblance in these examples to actual events or persons, living or dead, is purely coincidental.

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 reach out to USP staff (starting with your EC Manager) if you have any questions about identifying, disclosing, or managing issues related to Standards of Conduct. You may also contact Compliance at compliance@usp.org, call 1-866-492-3365 from the United States and Canada, or access additional resources at usp.ethicspoint.com.

Code of Ethics and Representation

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 Expert Volunteers, representatives, and employees to fulfill USP's mission with a strong sense of integrity and commitment to our Core Values and policies. USP's Code of Ethics and the *CoE Rules* describe Standards of Conduct for volunteers and offer information on how individuals should handle conflicts of interest and confidentiality while working with or for USP.

CoE Rule 1.02: "All USP expert volunteers (e.g., Expert Committee members, Expert Panel members, Expert Advisors) are required to adhere to the USP Code of Ethics, which is available on USP's website; and to the Standards of Conduct, per Section 11 of these Rules."

Expectations

- Always do your part to create a positive environment where everyone can contribute and fully utilize their talents.
- Leverage diverse perspectives, ideas, and experiences, and always listen and encourage open dialogue and curiosity.
- Remember that degrading jokes, slurs, bigotry, physical or verbal intimidation, unwelcome sexual advances, or other

disrespectful conduct are never acceptable and will not be tolerated.

- Treat everyone with respect and dignity, and inspire a spirit of belonging by being inclusive, contributing to an environment where everyone feels valued without judgment.
- We trust and expect you to speak up immediately if you ever have concerns or suspect that someone's conduct may have violated or is going to violate our Standards of Conduct, Code of Ethics, policies, or the law. To do so, you may send an email to Compliance at compliance@usp.org, call 1-866-492-3365 from the United States and Canada, or access additional resources at usp.ethicspoint.com. Note that USP will not tolerate retaliation against anyone who raises a concern in good faith.

Representation

Q: Can CoE/EC members serve an outside interest in their capacity as an Expert Volunteer?

A: No. CoE/EC members do not serve any outside interest; they serve USP only in their capacity as individual experts.

Q: Must CoE/EC members represent USP when participating in USP activities such as Expert Panels, Stakeholder Forums, and USP Workshops?

A: Yes. CoE/EC members represent USP when participating in all USP activities; they do not serve any other interest in their capacity as USP Expert Volunteers.

CoE Rule 11.01(a): "Expert Committee members serve USP as individual experts; they do not serve any outside interest. An Expert Committee 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. Expert Committee members participating in other USP activities (e.g., Expert Panels, Stakeholder Forums, USP workshops) do so as representatives of USP and do not represent any other interest."

Q: Can Expert Panel members and Expert Advisors serve an outside interest?

A: Yes. Expert Panel members and Expert Advisors may serve an outside interest as long as the interest is disclosed to USP, the relevant EC or Expert Panel, as applicable, and USP staff. However, Expert Panel members and Expert Advisors shall not use their relationship with USP in any way that is, or appears to be, motivated by private gain or any outside interest.

Q: Why are Expert Panel members and Expert Advisors allowed to serve an outside interest?

A: Expert Panels issue advisory recommendations only to ECs; they do not make decisions or approve standards. All final standards-setting decisions are made by non-conflicted members of a USP EC. Expert Advisors provide additional expertise and assist in the development of a standard by participating in Expert Body discussions and reviewing documents; however, Expert Advisors are not members of the Expert Body and do not vote on any Expert Body matter.

CoE Rule 5.01: "An Expert Body may engage one or more individuals to provide additional expertise and assist in the development of a standard by participating in Expert Body discussions and/or reviewing documents. Such participating individual shall be deemed an Expert Advisor and shall not be deemed a member of the Expert Body or vote on any Expert Body matter. Expert Advisors shall be appointed by the Chair of the Expert Body, with the approval of the CoE Chairperson. The Chair of the Expert Body may ask an Expert Advisor to excuse him or herself during any discussion in which the Chairperson believes the Expert Advisor's participation would not be appropriate due to confidentiality, conflict, or other reasons."

CoE Rule 11.01(b): "A member of an Expert Panel or Expert Advisor may serve an outside interest provided such interest is disclosed pursuant to Section 11.03(a) of these Rules. An Expert Panel member or Expert Advisor shall not use his or her membership in any way that is, or appears to be, motivated by private gain or any outside interest."

CoE Rule 11.03(a): "Each Expert Committee and Expert Panel member and Expert Advisor shall submit to USP a Disclosure Statement disclosing all employment, professional research, organizational memberships, and other relevant interests. The Disclosure Statement shall be updated by the individual as necessary to keep it current or as requested periodically by USP, and the individual is also obligated to advise the relevant Expert Committee or Expert Panel Chair and USP staff of changing or emerging interests. The information provided in Disclosure Statements shall be considered confidential and shared only among USP staff and expert volunteers to facilitate Conflict of Interest management. USP will not disclose the information provided in Disclosure Statements to GLs [government liaisons] or to members of the public unless compelled to do so by law, e.g., under subpoena or court order."

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

A: Yes, you may include a reference to your USP volunteer status as part of general information provided in your resume or biography; however, 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 unless you are requested to do so by USP. Note that as a CoE/EC or 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. For presentations made outside of your Expert Volunteer capacity, USP encourages the use of a disclaimer that states, "This course [or training] is not endorsed by or affiliated with USP."

Expectations

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

- The USP logo
- USP materials (including briefing or promotional materials and work products)
- Your affiliation with USP unless it is mentioned as part of general information in a resume, CV, biography, or profile

Unless you are authorized to do so, never give the impression that you are speaking on behalf of USP in any communication that may become public. If you have USP's permission to speak on behalf of USP, it is important to speak with one clear and consistent voice when providing information to the public and the media. For this reason, only certain employees are authorized to speak publicly on behalf of USP.

Representation Scenarios

- An EC member provides a presentation on a topic under consideration by their EC at a non-USP, pay-to-attend event held at a private resort. The EC member's status as a USP volunteer is highly publicized and includes USP's logo—without USP's approval—in the advertising material for registration. This is a representation problem because

the EC member is using their EC membership status in a way that is, or appears to be, motivated by public gain or outside interest and may give the impression that the member is speaking on USP's behalf.

- An Expert Advisor provides a presentation on standards setting at a non-USP event where they are promoted as a USP Expert Body member. This is a representation problem because Expert Advisors may not use their relationship with USP in any way that is, or appears to be, motivated by private gain or any outside interest. Further, Expert Advisors are not members of any Expert Body.
- An EC member strongly advocates for a testing device manufactured by the company they work for to be included as a part of a standard and dominates EC meeting discussions on the topic. This is a representation problem because Expert Volunteers may not use their relationship with USP in any way that is, or appears to be, motivated by private gain or any outside interest. This may also be a violation of conflict of interest requirements described below if the member does not disclose the interest and/or votes on the standard at issue.



Conflicts of Interest

Unbiased input and decision making is critical in the development of science-based quality standards. These are ensured by disclosure, transparency, and recusal from ballot.

Q: What is a conflict of interest?

A: A conflict of interest includes, but is not limited to, any matter in which an Expert Volunteer has a direct or indirect financial interest or any other personal interest of any kind that would preclude or appear to preclude them from exercising impartial judgment or acting in the best interest of USP.

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

A: USP's standards-setting process is based on the independence of our scientific decisions by impartial experts; therefore, the management of conflicts of interest is essential. 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 standards and threatens the reputation of USP as an independent standards-setting organization.

Q: Why is transparency critical to effectively managing conflicts of interests?

A: Transparency in conflicts of interest is essential in the decision-making process because it enables voting members to more fully understand the input and statements made by one another. Our process therefore allows for participation with clear transparency of the conflict, followed by recusal at the vote by members with real or perceived conflicts.

Q: How do I manage my conflicts of interest?

A: Be proactive and diligent. Managing conflicts of interest includes the following:

- Fully disclose relevant interests that could potentially be conflicts of interest.
- Alert your Expert Body of your conflicts when discussing topics for which you have a conflict.
- Recuse from voting where you have a conflict of interest.
- Support the Chair and USP staff in managing conflicts.

CoE Rule 11.02(a): "Pursuant to Article VIII, Section 1 of the Bylaws and the Conflicts of Interest Policy in the Code of Ethics, all Expert Committee and Expert Panel members and Expert Advisors shall adhere to the Conflicts of Interest provisions set forth in these Rules."

CoE Rule 11.02(b): "As used in these Rules, '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: What happens if I declare that I have a conflict of interest?

A: CoE/EC members will have the ability to remain engaged in the standards-setting process by participating in the discussion of issues related to the matter for which they have a conflict. However, you will not be able to vote and must recuse yourself.





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. The Expert Panel's advisory recommendations to the EC must be accompanied by a disclosure of each Expert Panel member's conflicts of interest.

Expert Advisors may participate in Expert Body discussions and review documents. Expert Advisors are not members of the Expert Body and cannot vote on any Expert Body matter. However, Expert Advisors are required to disclose conflicts of interest. The Chair of the Expert Body may ask an Expert Advisor to excuse themselves during any discussion in which the Chair believes the Expert Advisor's participation would not be appropriate due to confidentiality, conflict, or other reasons.

CoE Rule 11.04(a): "No Expert Committee member shall vote in any matter in which he or she has a Conflict of Interest."

CoE Rule 11.05(a): "An Expert Panel member or Expert Advisor may participate in discussions or make recommendations regarding matters in which he or she has a Conflict of Interest provided disclosure of a Conflict of Interest is made pursuant to Section 11.03(a) of these Rules."

Examples

Interests that potentially could constitute conflicts of interest 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 interest in a food ingredient, supplement, drug, or any other product for which your EC is developing or approving a standard
 - 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)
 - Working for a university that is seeking a grant related to a drug for which your EC is developing or approving a standard
 - Being a consultant with a prior relationship with a company that makes the drug for which your EC is developing or approving a standard
 - Having a revenue stream that is related to a given USP standard (e.g., you provide paid training as an expert in an area that overlaps with the USP standard that you are working on)
 - Serving as an expert witness on a subject related to USP standards
 - Receiving gifts, favors, loans, or preferential treatment from any person or entity that seeks to influence a standards-setting activity
 - Receiving contributions for any charity or for any political candidate from any person or entity that does business or seeks to do business with USP
- Personal Interests
 - Having a personal interest in a food ingredient, supplement, drug, or any other product for which your EC is developing or approving a standard
 - 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 preclude your ability to exercise impartial scientific judgment

Conflict of Interest Scenarios

Some of the following scenarios contain elements that clearly warrant EC member recusal due to conflicts of interest; others are more equivocal and may require you to seek guidance from the EC Chair or USP staff. In each case, they need to be addressed directly as part of the USP standards-setting work using USP's processes for disclosure.

- An EC member who works for a large drug or dietary supplement manufacturer discloses their conflicts to USP regarding certain specific excipients but fails to investigate whether they are also conflicted with other excipients. To avoid even the potential for conflict, the member votes against all proposed revisions to excipient standards. This is problematic because conflicts of interest need to be managed directly as part of the standards-setting work using USP's process; they cannot be resolved by voting against that interest.
- An EC member retires from their job at a drug or dietary supplement company. The member receives a small pension and maintains a nominal financial relationship as a consultant for the company on niche topics that sometimes appear to overlap with their ongoing EC activities. Disclosure and recusal from a vote is required because the EC member now has competing interests between their consultancy engagement and their overlapping EC activities that could preclude or appear to preclude the EC member from acting in the best interest of USP.
- An EC member's son or daughter works as a highly paid drug representative. The EC member learns that the drug company has begun developing a product line that may be the subject of a standard under development as part of the EC's Work Plan. These interests create a conflict of interest that would need to be managed.
- An EC member with a financial interest in a company that makes only devices finds that their EC Work Plan includes revising a standard for a product that combines drugs, devices, and biological products. The member determines that there is partial overlap but that the expected revisions would not likely impact the applicability or requirement for the device they have a financial interest in. While the potential for conflict appears small, there could be at least a perceived conflict. It is important in situations where the answer is not immediately apparent to reach out to USP staff for guidance. You may also send an email to Compliance at compliance@usp.org, call 1-866-492-3365 from the United States and Canada, or access additional resources at usp.ethicspoint.com.
- An EC member has a financial interest in a company that makes only components of a finished drug product. The member learns that their EC has added to its Work

A conflict of interest includes, but is not limited to, any matter in which an Expert Volunteer has a direct or indirect financial interest or any other personal interest of any kind that would preclude or appear to preclude them from exercising impartial judgment or acting in the best interest of USP.

Plan the revision of a standard that could impact the applicability or requirement for the component that they have a financial interest in. This interest creates a conflict of interest that would need to be managed.

- An EC member works for a multinational conglomerate with numerous facilities, subsidiaries, regional divisions, joint ventures, and license agreements. The member is aware of the work performed at their facility and reporting chain. However, they realize that to know their actual or potential conflicts, they need to make reasonable inquiries at work based on their review of the advance agenda items they receive before each EC meeting. By discussing these real or potential conflicts with USP staff and the Chair, they may identify conflicts not previously disclosed. To mitigate risk on an ongoing basis, they should update their Disclosure Statements and disclose these conflicts during meetings as needed.
- An EC member who works for a drug manufacturer has been working to revise a standard for an active pharmaceutical ingredient (API) that is not manufactured by the company for which they work. Just before the standard goes to ballot, the EC member's employer acquires interest in the company that makes the API. Regardless of when the interest was acquired, the conflict of interest should be disclosed as soon as possible so that all EC members are aware of the EC member's conflict and can consider the member's comments in light of the conflict. The EC member should recuse themselves and not vote on the standard at ballot.



If an EC Chair has a conflict of interest, they should recuse themselves; the Vice Chair will serve in their place. If the Vice Chair is also conflicted, a designated non-conflicted member will be selected by a majority of the other non-conflicted members to serve in place of the Chair. To help with this process, an EC Chair should appoint a Vice Chair and identify potential conflicts as far in advance as possible.

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 themselves from a meeting due to a conflict of interest, and these minutes are made publicly available if requested. Conflicts of interest will be disclosed to USP staff who support the Expert Body, other members of the Expert Body, and any other parent Expert Body.

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 should have already been identified, disclosed, and shared with your EC. EC members may not vote to approve or not approve a ballot item if they have an actual or perceived 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 they are 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.

Expectations

- Once a conflict of interest is disclosed, the conflicted CoE or EC member can stay in the meeting venue during the vote on the conflicting matter in question but cannot vote to approve or not approve the ballot item.
- An Expert Panel member who discloses a conflict is permitted to remain in the meeting venue, provided timely and adequate disclosure is made to USP, the Chair, and other members of the Expert Panel.

Conflicts of interest that could arise immediately prior to 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 have transpired that have not previously been disclosed.
- New consulting relationships with a drug company that may benefit from a revision to a USP standard have developed that have not previously been disclosed.
- An emerging relationship with a laboratory that may benefit from revisions to a USP standard has formed that has not previously been disclosed.

Q: Can a CoE/EC member be permitted to work on a USP standard if they have 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 they have a conflict of interest. The CoE/EC member may provide relevant scientific information and may participate in discussions regarding such issue or question. However, the conflicted member cannot vote on the standard.

For Expert Panel members and Expert Advisors, this scenario is handled somewhat differently under the *CoE Rules*. Expert Panel members and Expert Advisors 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 11.04(b): “No Expert Committee member shall be assigned the primary responsibility to work on an issue or question in which he or she has a Conflict of Interest. He or she may, however, provide relevant scientific information and may participate in discussions regarding such issue or question....”

CoE Rule 11.05(b): “Expert Panel members or Expert Advisors 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 pursuant to Section 11.03(a) of these Rules.”

CoE Rule 11.08(a): “Each Expert Committee or Expert Panel member and Expert Advisor shall maintain the confidentiality of all information gained in the course of his or her activities as an expert, and shall not use or disclose such information for any purpose, unless such information is already publicly available. Confidential treatment serves purposes that include, but that are 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. In case of doubt as to whether information is deemed confidential, the information shall be treated as confidential until otherwise indicated by USP staff. Expert Committee and Expert Panel members and Expert Advisors should receive and send any electronic communications related to their USP service from a private email address, not shared with or accessible to their employer or any other 3rd party.”

CoE Rule 11.08(b): “Each Expert Committee and Expert Panel member and Expert Advisor shall sign a confidentiality agreement reflecting the confidentiality obligations set forth in Section 11.08(a). If an Expert Committee or Expert Panel member or Expert Advisor fails to sign and submit a confidentiality agreement, that individual will not be allowed to receive any confidential information or participate in any Expert Body activities until such agreement is submitted to USP.”

Examples

The conflicted CoE/EC member may, at their discretion, do the following:

- Work on the matter to help the EC achieve its objectives.
- Provide relevant scientific information on the matter creating the conflict.
- Participate in discussions on the matter.

The conflicted CoE/EC member cannot do the following:

- Be the primary person responsible for developing a USP standard.
- Have primary authorship of a *Stimuli* or journal article or other USP publication.

- Chair a Subcommittee or Expert Panel that is working on the matter creating the conflict.
- Lead a discussion on the matter upon which they are conflicted.

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, they should recuse themselves; the Vice Chair will serve in their place. If the Vice Chair is also conflicted, a designated non-conflicted member will be selected by a majority of the other non-conflicted members to serve in place of the Chair. 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 they have disclosed the conflict of interest in a timely manner. The Expert Panel Chair’s conflict of interest must also be included in the Expert Panel’s recommendation to the EC for its consideration during the standards-setting decision process.

CoE Rule 11.04(c): “In the case where the Chairperson of an Expert Committee has a Conflict of Interest, the Vice Chairperson will serve. If the Vice Chairperson also is conflicted, a designated non-conflicted member shall be selected by a majority of the other non-conflicted members to lead the discussions.”

CoE Rule 11.05(c): “The Chairperson of an Expert Panel that has a Conflict of Interest may continue to serve as Chairperson provided disclosure of such Conflict of Interest is made pursuant to Section 11.03(a) of these Rules.”

Examples

Conflicts of interest that could arise for the Chair include, but are not limited to, the following:

- During the initial discussion phase, comments are made about a pharmaceutical company that has an interest in the standard and with which the Chair has financial ties. This impacts the Chair’s ability to lead during the standards-setting process.
- During a question and answer session, the line of questioning shifts toward a company with which the Chair has a current or prior business relationship that will impact their ability to lead during the standards-setting process.
- During a presentation, the speaker unexpectedly focuses on a topic in which the Chair harbors strong personal sentiments that will preclude or appear to preclude their ability to lead impartially during the standards-setting process.



Disclosure of Conflicts of Interest

CoE/EC members, Expert Panel members, and Expert Advisors are required to submit to USP a Disclosure Statement of all employment, professional research, organizational memberships, and other relevant interests. Individuals who fail to submit a Disclosure Statement will not be allowed to participate in any Expert Body activities until such statement is submitted to USP.

Q: What is the most important thing to know about conflicts of interest?

A: When in doubt, disclose. Whether a conflict of interest exists is 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 address any issues you may have.

In order to ensure the integrity of the standards-setting process, it is critical that CoE/EC members, Expert Panel members, and Expert Advisors keep their Disclosure Statements up to date with information regarding potential conflicts, because interests can evolve during the five-year cycle. For EC members, full disclosure is essential even if you think that your interest does not amount to a conflict (it still may create the appearance of one) or you believe you can make an impartial decision. This will support transparency in the process and help USP staff and EC Chairs ensure that everyone is adhering to USP's Standards of Conduct, thus protecting USP's reputation as an objective, science-based standards-setting organization. In addition, you should develop and maintain awareness of others' conflicts of interest to help understand their points of view and possible biases.

Q: How do I disclose my actual or potential conflicts of interest to USP?

A: CoE/EC members, Expert Panel members, and Expert Advisors are required to submit to USP a Disclosure Statement of all employment, professional research, organizational memberships, and other relevant interests. They 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 that Expert Volunteers update their Disclosure Statements. The

Disclosure Statement is kept confidential except to fellow EC or Expert Panel members and necessary USP staff members.

Because not all relevant interests may be apparent when completing or updating your Disclosure Statement, it also is important that you disclose potentially competing interests discovered/recognized during your engagement as a volunteer. For example, when reviewing the agenda or briefing materials for a USP meeting, you might recognize a potential conflict you had not previously considered. If that occurs, the potential conflict should be declared in advance or at the time of discussion of that agenda item. You must add this conflict to your Disclosure Statement if not sufficiently described there. Contact uspvolunteers@usp.org if you need assistance updating your Disclosure Statement.

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 or 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 in the Restricted Disclosure section in your Disclosure Statement. You must provide a general description of the activity or the work performed under the confidentiality agreement that is sufficient for USP and the Chair to determine whether a conflict of interest exists.

Examples

The following are examples of Restricted Disclosure:

- 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 compounded preparations.

Expectations

- Disclose all interests that relate to the USP standards or activities of the EC or Expert Panel on which you serve. Providing such a comprehensive Disclosure Statement is important. You do not need to list all of your employer's products and interests when you list interests on your Disclosure Statement. However, it is critical that you be broad and inclusive when disclosing interests. Presume that your Disclosure Statement needs to be particularly broad regarding issues that may have cross-cutting impact or may set a precedent for future standards, such as determining approaches to the control of impurities. Then, you must carefully review the topics on each meeting agenda and do your due diligence to determine whether you have a conflict of interest with respect to any agenda item.
- Considering the intersection of your interests with items on each meeting agenda is critical to maintaining impartiality as well as transparency. Once these potential interests are disclosed, other members of the Expert Body will know where each member stands, and they will be able to take that into consideration during the standards-setting process.
- Disclose your organizational memberships and affiliations. Organizations can have strong interests and opinions on standards that could preclude or appear to preclude an individual from exercising impartial judgment. However, simply being a member of a professional or trade organization doesn't necessarily create a conflict of interest. Factors such as your role within the organization (e.g., whether you hold a leadership position), level of involvement (e.g., whether you are frequently engaged in specific topical matters or merely attend a general annual meeting), and the nature of the organization itself (e.g., to what extent the organization is active in discussing, critiquing, or even submitting comments on USP standards) must be considered when determining whether a real or potential conflict exists.

- You must report to USP if you, your spouse, or any of your dependents 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 need to report investments through mutual funds or other vehicles in which there is no direct control over investment decisions.) For example, recusal is warranted if your spouse or dependent has a financial interest in a company that 1) has a product on the EC Work Plan or 2) may be affected by specific revisions to the EC Work Plan. However, recusal may not be necessary where a spouse or dependent has a continuing modest financial relationship, such as a pension, with a former employer whose product is on the EC Work Plan.

Disclosure and Management of Conflicts of Interest Scenarios

Disclosure and management of conflicts of interest aim to protect the integrity of the science-based standards-setting process and manage risks, as the following scenarios illustrate:

- An EC member has listed their employer on their Disclosure Statement but has not researched whether the company makes a drug component that is the subject of a standard under review. During the cycle, the EC member learns that their employer manufactures the drug component. The EC member discloses the conflict prior to voting on the standard and abstains from voting due to the conflict. This is still problematic because the conflicted EC member may have influenced the EC's work or discussion in the company's favor. This situation has the potential to undermine the objectivity and impartiality of the Expert Body.
- An Expert Advisor joins an organization that represents manufacturers of drug and dietary supplement ingredients but does not declare the potential conflict or update their USP Disclosure Statement until after participating in several EC meetings in which the ingredients were under review. This is problematic because the membership might represent a conflict and, if so, the conflicted Expert Advisor may have influenced the EC's work or discussion without the other members being able to appropriately consider the Expert Advisor's interest.

Considering the intersection of your interests with items on each meeting agenda is critical to maintaining impartiality as well as transparency.



Q: How often must I update my Disclosure Statement form?

A: You must update it as often as necessary to keep it current or as requested by USP. If you acquire a relevant new interest or have any changes, your Disclosure Statement must be updated prior to engaging in any Expert Volunteer activities, and no later than 15 days after the new interest is acquired. 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 a conflict of interest, such as a change in employer or other engagement with organizations outside of USP.

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. ECs may review a consolidated list of members' disclosures during closed sessions of EC meetings to ensure transparency of conflicts of interest.

CoE Rule 11.03(a): "Each Expert Committee and Expert Panel member and Expert Advisor shall submit to USP a Disclosure Statement disclosing all employment, professional research, organizational memberships and other relevant interests. The Disclosure Statement shall be updated by the individual as necessary to keep it current or as requested periodically by USP, and the individual is also obligated to advise the relevant

Expert Committee or Expert Panel Chair and USP staff of changing or emerging interests. The information provided in Disclosure Statements shall be considered confidential and shared only among USP staff and expert volunteers to facilitate Conflict of Interest management. USP will not disclose the information provided in Disclosure Statements to GLs or to members of the public unless compelled to do so by law, e.g., under subpoena or court order."

CoE Rule 11.03(b): "If an Expert Committee or Expert Panel member or Expert Advisor fails to submit a Disclosure Statement, that individual will not be allowed to participate in any Expert Body activities until such statement is submitted to USP."

Expectations

You should update your Disclosure Statement form whenever you have a change in relevant interests, including the following:

- Your affiliations with companies or institutions, organizational memberships, and other relevant interests
- Your professional employment positions including editorial, consultant, and training work
- Your sources of income, finances, or equity that may affect your ability to objectively engage in USP standards-setting activities

Q: How are issues related to 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.

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 they become aware of it.
- After the member's disclosure:
 - USP 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.
 - The CoE Chair has the final authority for resolving matters involving the member's conflict of interest, including a determination of whether a conflict exists.
 - USP does not disclose particular conflicts of interest publicly; however, the minutes of a meeting will indicate a member's recusal from the meeting, and the minutes are publicly available if requested.

CoE Rule 11.07(b): "Where a potential Conflict of Interest is identified by an Expert Committee member and cannot be resolved through voluntary recusal and/or intervention by the EC Chair, the matter shall be referred to the CoE Chairperson for resolution. The CoE Chairperson shall have final authority for resolving matters involving Conflicts of Interest. The minutes of any meeting at which a Conflict of Interest issue has been identified shall reflect disclosure and resolution of such issue, including any recusal of an Expert Committee member due to Conflict of Interest."



Identifying and Resolving Issues Related to Conflicts of Interest

EC Chairs are authorized to resolve questions on conflict of interest issues that arise. USP staff may also offer assistance to help resolve a conflict of interest issue.



Confidentiality

EC members, Expert Panel members, and Expert Advisors must sign and submit confidentiality agreements to USP.

Q: What information is deemed confidential by USP?

A: All information received during the course of your volunteer work as a USP CoE/EC member, Expert Panel member, or Expert Advisor shall be assumed to be confidential unless it has already been made publicly available; in case of doubt, the information should be treated as confidential unless otherwise indicated by USP staff.

Q: Will a conflicted CoE/EC member, Expert Panel member, or Expert Advisor have access to briefing materials that include confidential information on a matter in which they have a conflict?

A: Yes. While the conflicted individuals will receive confidential information that will enable them to participate in the manner as allowed by the *CoE Rules*, they must comply with the confidentiality restrictions (see *CoE Rule 11.08*). The conflicted CoE/EC member, however, must abstain from the vote on the conflicting matter.

CoE Rule 11.08(a): “Each Expert Committee or Expert Panel member and Expert Advisor shall maintain the confidentiality of all information gained in the course of his or her activities as an expert, and shall not use or disclose such information for any purpose, unless such information is already publicly available. Confidential treatment serves purposes that include, but that are 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. In case of doubt as to whether information is deemed confidential, the information shall be treated as confidential until otherwise indicated by USP staff. Expert Committee and Expert Panel members and

Expert Advisors should receive and send any electronic communications related to their USP service from a private email address, not shared with or accessible to their employer or any other 3rd party.”

CoE Rule 11.08(b): “Each Expert Committee and Expert Panel member and Expert Advisor shall sign a confidentiality agreement reflecting the confidentiality obligations set forth in Section 11.08(a). If an Expert Committee or Expert Panel member or Expert Advisor fails to sign and submit a confidentiality agreement, that individual will not be allowed to receive any confidential information or participate in any Expert Body activities until such agreement is submitted to USP.”

Q: Are CoE/EC members, Expert Panel members, and Expert Advisors 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, Expert Panel Members, and Expert Advisors are required to sign confidentiality agreements with USP that obligate them to maintain the confidentiality of such information they receive from USP.

The following are reasons for maintaining the confidentiality of information:

- 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).
- Comply with third-party contractual confidentiality obligations.

Expectations

CoE/EC members should assume that all information they receive from USP is confidential unless it has already been made publicly available; in case of doubt, the information should be treated as confidential, unless otherwise indicated by USP staff. Administrative staff, teaching assistants, company personnel, etc., who are affiliated with the Expert Volunteer may not have access to information shared by USP, including the following:

- Information shared by email or meeting invitation
- Information shared via online file systems
- Briefing materials shared at or in advance of meetings
- Ballot results unless publicly available
- The status of a standard that has not yet been approved and made publicly available

In addition, never allow anyone to listen in on an Expert Body meeting without USP staff permission.

Insider trading: In the course of your work, you may receive confidential USP information about a USP donor, partner, or product before it is publicly available to ordinary investors. Do not use this information for personal gain or share it with others. Not only is it unfair to other investors, it is also illegal.

Closed sessions in USP meetings: If an official meeting is closed, the EC Chair will determine whether any member or non-member participants (e.g., observers, invited guests, government liaisons) will be excused from the meeting. In addition, the Chair may invite a technical expert or sponsor of a standard under development to attend a closed meeting or closed session to share their confidential information; however, the technical expert or sponsor will not be given access to any other confidential information.

USP staff is responsible for managing observers and invited guests who attend in person or via teleconference and ensuring that observers and invited guests leave the meeting during closed sessions or for other purposes at the discretion of the Chair (e.g., to facilitate candid discussion). Observers and invited guests are not bound by confidentiality restrictions and thus are not to be given access to confidential information.

Q: For what reasons is an EC Chair likely to close a meeting?

A: Any meeting or portion of a meeting of a USP Expert Body may be closed if the Chair of the Expert Body or the CoE Chair determines, at any time, that there is good and sufficient reason for closure (see *CoE Rule 12.01[a]*).

The most frequent reason for closing an otherwise open meeting or portion of a meeting is to protect confidential information, such as proprietary sponsor data or information included in a member’s Disclosure Statement (see Section 11.03). In such cases, non-member participants (see Section 12.01[b]) are generally excused during the closed session. At the Chair’s discretion, depending on the nature of the information, government liaisons may be allowed to remain in sessions otherwise closed for the review of confidential information. In any case where volunteers’ Disclosure Statements are being reviewed, only Expert Volunteers may remain.

Meetings also may be closed to prevent premature disclosure of material that may cause an inequity in the release of information. For example, an EC may review comments submitted to *Pharmacopeial Forum* to determine the final content of a standard, which would be unpublished at the time and thus not universally available. In cases like this, all non-member participants would be excused during the closed session, while government liaisons would be allowed to remain unless determined otherwise by the Chair. The Chair may also close a meeting to certain individuals in order to maintain order and decorum during meetings.

Confidentiality Scenarios

- An EC member who works at a dietary supplement firm prints the briefing materials they received using their company’s printer, which is monitored by that organization’s IT staff. Among the papers are documents that are not specifically marked “Confidential” but that still detail USP ballot results that are not publicly available. This is problematic because EC members must maintain all information they receive from USP as confidential unless otherwise indicated.
- An EC member receives documents that include confidential information. The EC member forwards one of the documents to their work email address, which is checked regularly by their scheduler. This is problematic because the EC member has failed to maintain their confidentiality obligations, which could result in the premature disclosure of a standard or other proprietary, business, or trade secret information.
- An Expert Advisor mentions on social media the content or status of a USP standard that has not yet been approved. This is problematic because Expert Advisors must maintain all information they receive from USP as confidential unless otherwise indicated. Although USP does not seek to restrict the personal use of social media, when engaging in social media on your own behalf, you must comply with all USP confidentiality requirements concerning the sharing of USP information.

- An Expert Panel member discusses at a family gathering the details of a new product that is coming to market soon, but is not yet public. They learned about this product during the course of their work with USP. The member is excited about the potential for this product to progress the field of cancer research and treatment. The member's cousin uses this information to purchase shares of the company's stock in anticipation of a jump in the company's value and posts about it in a public online forum, citing a USP volunteer as their source. This is problematic, even in a close familial setting, as there is a risk that you could engage in insider trading, which is illegal and would also put USP's reputation as a trusted organization at risk.

CoE Rule 12.01(a): "In accordance with USP's Open Meeting Policy, all official meetings of an Expert Body shall be open to the public, except that a meeting or a portion of a meeting may be closed if the Chairperson of the Expert Body, or the CoE Chairperson determines that there is good and sufficient reason for closure. Such reasons may include, but are not limited to: review or discussion of trade secret or confidential, commercial information; standards of conduct discussions or review or discussion of matters the premature disclosure of which could be detrimental to the USP. An official meeting is a face-to-face meeting or teleconference held by an Expert Body where decisions or formal recommendations are intended to be made if a quorum is reached. If a quorum is not reached, the meeting remains classified as an official meeting; however, no decisions or formal recommendations may be made."

CoE Rule 12.01(b): "If the determination is made to close an official meeting, such determination and the reason for closure shall be announced at the beginning of the meeting or during the meeting and noted in the meeting minutes. Any non-member participants (observers, invited guests, etc. described in Section 12.03 (a) and (b) below) attending such meeting shall be excused from the meeting. GLs may participate in closed meetings unless excused by the Chairperson for the reasons described in Section 6.02 above, related to standards of conduct discussions or other reasons determined by the Chairperson. The Chairperson may invite a sponsor of, or a technical expert on, a standard under development, to attend a closed meeting, or portion thereof, for the limited purpose of sharing confidential information related to a proposed revision with the Expert Body. In such limited cases, the invited sponsor or technical expert shall not be given access to any USP-confidential or third-party confidential information. Meetings of the CoE shall be closed unless otherwise indicated."

CoE Rule 12.03(a): "Invited guests are parties who are invited specifically to share a particular expertise or express their particular point of view. This shall be carried out under the control of the Chairperson of the Expert Body and shall be subject to these Rules. These nonmembers may be provided with appropriate briefing materials, excluding confidential information. The Expert Body Chairperson shall ask the invited guest to excuse himself or herself during a closed session of the meeting."

CoE Rule 12.03(b): "Observers, including press and representatives of government agencies not officially designated as GLs or serving as expert volunteers, are parties who themselves choose to attend an Expert Body meeting. Observers should notify USP at least five business days in advance of the meeting (or as soon as possible after posting of the meeting notice and agenda) of their proposed attendance, and provide necessary background information about themselves. Observer requests received less than 5 days in advance of the meeting may be granted at the discretion of USP. At the discretion of the Chairperson of the Expert Body, observers may or may not receive briefing materials. USP retains the right to refuse permission for an observer to attend a meeting. The Expert Body Chairperson shall ask the observer to excuse him or herself during a closed session of the meeting. Observers will be permitted to make presentations or otherwise speak at the meeting only if approved in advance by the Chairperson of the Expert Body."

CoE Rule 12.04: "Two or more members of an Expert Body or Expert Advisors may engage in informal dialogue and working sessions as part of their work. An Expert Body may hold informal teleconferences to review the status of work being performed by members, without the need to call or conduct an official meeting as defined in Section 12.01(a). Working sessions are closed to the public to maintain confidentiality and facilitate discussion. However, a sponsor of, or a technical expert on, a standard under development, may be invited to a working session for the limited purpose of sharing confidential information with the Expert Body. In such limited cases, the invited sponsor or technical expert shall not be given access to any USP-confidential or third-party confidential information. Except as provided in Section 9.06 above, any decision on any substantive issue shall be made by an Expert Body only at an official meeting called and conducted in accordance with the provisions of Sections 12.01 through 12.03 above."

Each Expert Committee or Expert Panel member and Expert Advisor shall maintain the confidentiality of all information gained in the course of their activities as an Expert Volunteer and shall not use or disclose such information for any purpose unless such information is already publicly available.

