

Conflicts of Interest and Confidentiality FAQs

October 1, 2016, Updated August 7, 2017

General

1) Why has AABB updated its conflicts of interest policy?

AABB has updated its Conflicts of Interest and Confidentiality Policy as part of its ongoing efforts to protect AABB's reputation for accurate and unbiased work that optimizes patient and donor care and safety. The revised policy reflects the core values that have guided AABB since its inception — the pursuit of excellence, focus on the patient and donor, integrity, transparency, consensus building and innovation. AABB continues to integrate these core values into daily activities, helping to ensure that AABB's decision-making processes are beyond reproach.

2) What are the major differences between the current and updated policies?

- a. The updated policy applies to all AABB programs, including the "Transfusion" journal editorial board – including the Editor-in-Chief, associate editors and contributing authors. Previously, the "Transfusion" journal had a separate COIP.
- b. The definition of "Financial Interest" has been broadened. The threshold for reporting direct financial holdings was decreased from \$15,000.00 to \$5,000.00 and now includes companies with activities related to AABB's. Also included, if received within the past two years, are --
 - a) Payments from any one source valued at more than \$5,000.00 for any combination of paid consultancies, speaker fees, honoraria, expert testimony, research funding or royalties;
 - b) Any gifts valued at more than \$500.00.
- c. A definition of Professional Interest was added.
- d. The policy was clarified: Those with a disclosed conflict may not vote on an issue giving rise to the conflict.

3) Who is included in the scope of this policy?

This policy applies to the following categories of individuals:

1. AABB individual members who serve on the board and committee members, including representatives from other organizations who serve on AABB committees, members of interorganizational task forces for which AABB serves as the lead organization and AABB work groups;
2. Volunteer assessors;
3. Permanent and Temporary Employees;
4. Editorial Board, including the Editor-in-Chief and Associate Editors (collectively referred to as "Editorial Board") and the contributing authors ("Authors") of the "Transfusion" journal.

4) When do affected individuals have to make these disclosures?

The policy took effect with the 2016-17 committee assignments. Individuals appointed to committees will receive electronic disclosure forms from the Executive Office in September before each new association year. The disclosure forms must be received prior to beginning work on the committee. The disclosures must be made annually and updated prior to every meeting or call as relevant conflicts arise.

5) What kinds of interests must be disclosed?

Financial, professional and/or personal interests — either your own or those of your spouse, domestic partner or minor children — that might directly interfere with any judgments you might make on behalf of AABB, or even those that give the appearance of influencing your ability to act in the best interests of the organization, must be disclosed.

Financial interests include any direct financial holdings — with the exception of mutual funds — valued at \$5,000 or more in any medical or biomedical company, including companies with activities addressed in any of AABB’s standards, such as medical device companies or information technology companies that produce medical software and/or are related to any of AABB’s activities. For example, if Jane Doe owns stock in Medical Company X valued at \$16,000, and she is making a decision on behalf of AABB that might have an effect, negative or positive, on that company’s business, she would need to disclose the fact that she owns stock in Medical Company X. She would *not*, however, need to disclose the actual number of shares or value of the stock owned.

A professional interest that might need to be disclosed is membership on another entity’s board of directors or advisory committee. For example, if an AABB committee member is also on the board of another organization involved in issues related to blood and tissue donor and patient safety, that board membership should be disclosed because the committee member may feel that he or she must balance competing interests of both organizations. On the other hand, an AABB committee member who is on the board of his or her child’s private school need not disclose that relationship because participation is unlikely to affect that person’s judgment or impartiality with regard to AABB activities.

A personal interest that might need to be disclosed is a close friendship between an AABB committee member and the CEO of a company involved in blood banking whose business might be affected by a committee decision. Consider a friendship that is longstanding, involves weekly golf games at the CEO’s golf club and the use of the CEO’s oceanfront summer home for two weeks every summer. Even if this relationship would not actually affect the committee member’s judgment or impartiality with regard to AABB activities, it would certainly rise to the level of an apparent conflict of interest. On the other hand, an occasional golf game with an executive of a company involved in blood banking whose business might be affected by the committee decision probably would not rise to the level of a personal relationship requiring disclosure.

A key consideration in determining whether professional and personal relationships require disclosure is whether the situation is likely to interfere or appear to interfere

with the independent judgment needed to make decisions on behalf of AABB. A good test is whether relevant others (your employer, your clients, professional colleagues or the general public) would trust your judgment if they knew of this personal or professional relationship and you were in a position to influence decisions on behalf of AABB.

6) How will the updated policy affect the way in which committee meetings are run?

The committee chair, with the assistance of the staff liaison, will be responsible for following six steps prior to and during all committee meetings, including conference calls, in order to make sure the policy is fully implemented.

First, the committee chair will review the conflicts of interest — which will be sent by the staff liaison before each meeting — to identify whether any conflicts are anticipated.

Second, staff liaisons will email all committee members prior to the meeting or call requesting disclosure of any new actual or apparent conflicts.

Third, at the beginning of every committee meeting, the chair will read the provided COI script and obtain acknowledgment from all present that they understand the policy and agree to abide by it. The chair also will ask whether anyone present has any new actual or apparent conflicts to disclose for purposes of the meeting. Those with new conflicts to disclose will be asked to complete the electronic form ASAP.

Fourth, during committee discussions, those with conflicts relating to specific issues will be expected to make known the fact that they have a conflict. The chair is then responsible for determining whether the conflicted individuals may participate in the discussion. If the chair is aware of a conflict and a conflicted individual doesn't make the conflict known, the chair should raise the issue and may ask that individual to abstain from the discussion.

Fifth, before any vote is taken, the chair will identify anyone who has a conflict relating to the issue at hand. According to the policy, committee members with conflicts relating to an issue will not be permitted to vote on that issue. The staff liaison will record all votes and abstentions by name (e.g., the vote passed 7 to 5; Jane Smith abstained from discussion and Jane Smith and Joe Jones abstained from voting).

Sixth, at the close of the meeting, the chair will review which items are confidential and may not be disclosed. The chair also will remind representatives that reports from committee or task force representatives to their organizations need to be made in writing and approved by the chair before dissemination.

These additional steps will help ensure that the policy is both understood and followed by the committee.

7) Does the conflicts of interest policy simply require disclosure, or must additional action be taken?

This policy is not intended to discourage participation in AABB activities. Rather, by requiring those involved in the decision-making process to disclose actual and apparent conflicts of interest, this policy encourages transparency and safeguards the integrity of AABB's decision-making processes.

Compliance with the policy begins with making the appropriate disclosures. With respect to actual or apparent conflicts that involve board, committee, task force or work group decisions, you must abstain from any related votes. You may also decide or be asked to refrain from participating in related discussions at the discretion of the committee chair; in the case of the board of directors, the president; or, in the case of the "Transfusion" journal, the Editor-in-Chief. In rare cases in which the conflict is so significant that it makes it impossible for you to act in the best interests of AABB, you may be asked to step down from your AABB position.

8) I depend on the financial support of a company to fund my research, but I want to be able to continue providing guidance to AABB in my area of expertise. Can I still be involved in AABB activities?

In most instances, you will still be able to participate in AABB activities. However, if, after full disclosure, the committee chair believes that the conflict is so significant that it makes it impossible for you to act in the best interests of AABB, you may be asked to step down from the specific AABB activity that resulted in the conflict. If you disagree with the decision of the committee chair, you may contact the Audit and Ethics Committee with your concerns.

9) What is the purpose of the whistleblower policy that is related to the conflicts of interest and confidentiality policy?

AABB adopted a related whistleblower policy to protect AABB board, committee, and task force and work group members against any recriminations for their actions in reporting violations of the law, regulations or AABB policies, including the Conflicts of Interest and Confidentiality Policy. A separate whistleblower policy with similar protections applies to AABB staff.

10) What should I do if I have reason to believe others have an undisclosed conflict of interest?

The whistleblower policy directs board members to report concerns to the Audit and Ethics Committee or the CEO, while committee members and representatives are directed to report such concerns to the appropriate board representative, chair of the Audit and Ethics Committee, Editor-in-Chief, or the CEO or president. The Audit and Ethics Committee and the CEO will take the appropriate follow-up action. Of course, if the CEO, president, Editor-in-Chief, board representative or any member of the Audit and Ethics Committee are implicated in the specific issue, these individuals will not participate in any follow-up action.

11) What should I do if I have reason to believe others have an undisclosed conflict of interest, but I'm not 100 percent certain? Will I face any consequences if I report it, and then an investigation fails to find a conflict of interest?

The whistleblower policy encourages disclosure if you have “a reasonable belief” that there have been violations of the law, regulations or AABB policies, or gross mismanagement of AABB funds. Disclosure is critical if we are to safeguard the integrity of AABB. If the report has been made “in good faith,” the whistleblower policy specifically protects one who reports a potential conflict from retaliation and makes every effort to protect his or her confidentiality.

12) In determining whether I need to disclose a stock, do I base its value on the price I paid for it or its current market value?

According to the policy, you are required to disclose any direct financial holdings — with the exception of mutual funds — valued at \$5,000 or more in any medical and biomedical companies, including companies whose activities are addressed in any of AABB’s standards, such as medical device companies or information technology companies that produce medical software and/or are related to any of AABB's activities. Therefore, the disclosure should be based on *current market value*, not the purchase price. Some financial holdings may not need to be disclosed when you purchase them, but rather as they grow and reach a value of \$5,000.

13) Is there anyone I can consult to determine whether or not disclosure is required?

If this FAQ does not answer your question, the AABB Executive Office or the General Counsel can provide further guidance.

14) Who is permitted to view the disclosure statements? Are there any safeguards to protect the privacy of my information?

The policy requires that disclosure statements be made available to all those present at a specific board, committee, task force or work group meeting. The Executive Office has responsibility for maintaining these disclosures and will, therefore, have access to all disclosures. Human resources will have access to employee disclosure materials. Transfusion-related disclosures will be maintained by the Editorial Office of Transfusion. Disclosed information is considered confidential and, therefore, is protected under the conflicts of interest and confidentiality policy. The materials will be stored securely and shared only with those individuals requiring access.

15) As a committee representative from another organization, what should I do if someone from my own organization asks me to report on what occurred at the committee meeting?

While one of your responsibilities as a representative to an AABB committee may be to report any developments from the meeting back to colleagues within your organization, you also have a responsibility as a member of an AABB committee or task force led by AABB to respect the confidentiality of certain information that may be shared at meetings. At the end of each meeting, it is the chair’s responsibility to determine and communicate to committee members which information is and is not confidential. You may share information that the chair has indicated is *not* confidential; however, reports

on that information must be made in writing and approved in advance by the committee chair. Examples of confidential committee business that *cannot* be disclosed include results of personnel issues, unpublished data, draft standards and policies, and deliberations relating to variance requests.

16) I found out that a consultant serving on an AABB standards-setting committee has disclosed confidential committee information to one of his industry colleagues who is not on the committee. What should I do?

The whistleblower policy is intended to encourage reporting of any conflicts of interest or inappropriate disclosure of confidential information. If a committee member has reason to believe that confidential information has been inappropriately shared, he or she should report the actions in accordance with the whistleblower policy. An investigation of the alleged wrongdoing will be conducted, and appropriate actions will be taken depending on the outcome. Similar protections apply to AABB employees for reporting suspected misconduct.

17) I am being considered for a high-level position with a medical device manufacturer, but I do not want to share that information at this stage of the employment negotiations. However, I am on a standards-setting committee that is currently discussing and preparing to vote on an issue that could have a significant impact on this company. Do I have to remove myself from discussions and abstain from voting on this topic? If so, do I need to provide an explanation?

Although the AABB Conflicts of Interest and Confidentiality Policy is intended to encourage disclosure, there may be situations in which disclosure may cause concern or may violate a confidentiality provision in an existing contract. In those cases, you should simply announce that you have an unidentified conflict and abstain from voting on or participating in discussion about the related topic. Please contact the Executive Office or the General Counsel for further guidance on sensitive issues.

18) I serve on a few different committees. Do I need to complete separate disclosure forms for each committee?

You only need to complete one disclosure form annually, as long as you identify all committees on which you serve and include conflicts of interest relating to each of those committees. Prior to and at the beginning of each meeting or conference call, you will be asked whether any new conflicts have arisen.

19) I am on the “Transfusion” editorial board, and I am co-authoring an article about pathogen reduction technology. My employer receives funding from a company that is developing a new PRT. How does the policy affect me?

Editorial board members and authors are required to complete disclosure forms consistent with this policy. You must disclose the conflict of interest at the Editorial Board meeting, and as part of the article submission process. The disclosure will accompany the article when published in “Transfusion.”

Employees

20) When I hire a contractor to do work for AABB, I believe that I choose the most qualified company or person for the job — typically someone I've worked with for a long time. In some cases, I've developed personal relationships with those individuals. Does the policy restrict my ability to choose a vendor with whom I have a relationship, even if I believe hiring them is in the best interests of the organization?

No, but as a practical matter, you need to disclose the conflict. Similar to AABB's policies relating to selection of vendors, this conflicts of interest and confidentiality policy does not restrict your decisions, but it does provide the safeguards necessary to ensure that you are acting in the best interests of AABB in making those decisions.

21) I serve as a staff liaison to a committee, and I'm confused about what my responsibilities will be under the policy. Where can I go for guidance?

AABB will conduct training sessions for staff liaisons and provide guidance on your specific responsibilities under the updated policy. Additional questions can be directed to the Executive Office or General Counsel.

22) If I have nothing to disclose, do I still need to return the form to HR?

Yes, even if you have no declared conflicts, you need to return the form to HR so we have a record that you have no conflicts to disclose.