

QIBA Conflict of Interest (Col) Policy

Rationale and Policy re: Conflicts of Interest

The Quantitative Imaging Biomarkers Alliance (QIBA) is organized for the purpose of developing and promoting standards for quantitative imaging biomarkers. The integrity of its active members, including committee chairs, co-chairs, vice-chairs, and participants, is essential to achieving this purpose. All decisions and actions must be made solely for the benefit of QIBA, without regard to personal considerations. Concern is raised when financial, organizational, intellectual, emotional, or other personal considerations may compromise, or have the appearance of compromising, an individual's professional judgment. When making decisions on behalf of QIBA, all active members shall act in the best interests of QIBA.

The purpose of this statement is to guide QIBA in its management of potential conflicts primarily through disclosure of all financial or other interests which might be construed as resulting in an actual, potential, or apparent conflict in regard to decisions that may arise from recommendations, assessments, or opinions, given individually or as part of a group. See the RSNA COI Policy for further qualification of financial interests (https://www2.rsna.org/re/RSNA_Conflict_of_Interest_Policy).

RSNA/QIBA policy requires all active members of QIBA to acknowledge and agree to (i.e., sign) the RSNA COI Policy. "Active members" are determined and contacted by RSNA Staff based on participation in QIBA activities.

Active members of QIBA are required to disclose potential conflicts of interest in two ways. First, interests that may create a conflict of interest are disclosed annually as part of the active member completing the RSNA COI Policy form. Second, during any meeting where an active member has an actual or potential conflict of interest related to topics before the committee, the active member will state the potential conflict, which will be noted in the minutes. The active member might also propose potential remediation steps such as recusing themselves from voting on a motion or from participating in a decision on the associated topic. Depending on the nature of the conflict, no remediation beyond disclosure might be needed. Ultimately, the committee Chair(s) will determine how to appropriately handle the potential conflict. The remediation steps taken will also be noted in the minutes. In the event that the potential COI involves a committee Chair, it will be handled by the other Chair(s) of that committee, or may be referred to the Chair(s) of parent committee.

What is a Conflict of Interest?

Conflicts of Interest (COIs) are relationships or associations with organizations or persons that may affect, or be perceived to affect, the impartiality of one's judgment or decision-making, i.e., a relationship that could cause a reasonable person with all the relevant facts to question the impartiality of the QIBA active member when performing his or her professional responsibilities in QIBA. COIs may be, but are not limited to, financial, organizational, intellectual, or emotional.

A conflict of interest may occur whenever an active member, their immediate family, or close associate has a direct or indirect interest or relationship, financial or otherwise, that may influence the active

member's ability to exercise independent judgment in any action affecting QIBA activities or its members.

A conflict of interest may exist in those instances where the actions or activities of an active member on behalf of QIBA would (a) result in personal gain or advantage, (b) have an adverse effect on QIBA's interests, or (c) obtain a gain or advantage for a third party. A conflict of interest does not necessarily make an active member ineligible to serve but may limit the active member's ability to participate in certain activities or discussions. The existence of an actual or apparent COI does not necessarily imply fault or wrongdoing on the part of an active member.

Handling Potential Conflicts

The most likely scenario is that a relevant COI would prompt an active member to disclose a potential conflict during a committee meeting as described above.

In some cases, it might be appropriate for an active member to recuse himself or herself from participating in a QIBA committee discussion on a specific topic or issue entirely, although this would be unusual. Often the root of a potential COI is also the basis for expertise that would be useful to the committee. By disclosing the potential conflict, the other committee members are then able to take it into consideration when balancing comments from the active member in much the same way as disclosure slides at the beginning of presentations.

As part of the opening activities of meetings where decisions will be made and potential conflicts might exist (e.g., during resolution of public comments), the Chair(s) and Secretariat are encouraged to remind committee members of the QIBA COI disclosure policy.

If a QIBA active member believes another active member has failed to disclose actual or potential conflicts of interest, he or she should inform the Chair(s) of the corresponding QIBA Committee and/or the Chair(s) of the QIBA Executive Committee. Those Chair(s) shall then communicate with the named active member and take appropriate actions to clarify the situation and forward the results to the QIBA Executive Committee. The QIBA Executive Committee will be responsible for determining whether a violation of the QIBA COI Policy occurred, and if so what appropriate disciplinary and corrective action(s) will be taken.

Example Situations

1. Active member A of a Biomarker Committee (BC) is an employee of a software company that markets an algorithm relevant to the imaging biomarker under review by the BC. The company's FDA-approved algorithm uses one method (*method m*) of calculating a metric used in extracting the imaging biomarkers, but other methods exist. As the committee debates the text of specifications describing how to calculate the metric used in the Profile, active member A strongly advocates for language favoring *method m*, saying that published literature supports *method m* as being the most reproducible. During Public Comment, active members from other companies say that the Profile should allow for alternative methods, because other methods would also provide results in the same clinically relevant range. However, during resolution of Public Comments, active member A argues against allowing alternative methods, saying they

will not lead to the same degree of precision as *method m*. Other committee members accede to active member A's expertise on this topic and agree not to allow alternative methods.

Comment. Active member A should have disclosed to BC members his/her COI on this matter during Profile development. During Profile development, he/she does not have to recuse himself/herself from the discussions and decisions, but other BC members should have had the benefit of knowing about A's COI so they can judge his/her opinions accordingly. During the resolution of Public Comments, A may contribute to the discussion, but should recuse himself/herself from the decision-making on whether or not alternative methods would be allowed in the Profile specifications.

2. Active member B of a Biomarker Committee (BC) is an academic investigator with a 10-year history of NIH funding for a research program on the imaging biomarker under review by the BC. His/her lab has promulgated a particular theory about the biologic basis of the imaging biomarker, and they have a Memorandum of Understanding (MOU) with a phantom development company to partner in the potential commercialization of a phantom (*test object p*) based on their theory.

This QIBA profile does not specify that a particular phantom must be used, but the parameters described in the Profile correspond to the parameters of *test object p*. Several Public Comment respondents question the justifications for writing the phantom specifications in such a prescriptive way. During resolution of Public Comments, active member B emphasizes that his research team has accumulated years of data supporting their approach, and points out that the Profile allows for the use of any "equivalent" phantom. Because other BC members are not knowledgeable enough about the technical details to be confident as to whether the specifications need to be as stringent as written or not, and although there are as yet no commercially available phantoms based on the Profile specifications, they defer to B's track record and expertise and leave the specifications section unchanged.

In this example, Active member B has both a potential intellectual conflict (e.g., using the existence of a publicly confirmed QIBA Profile as supportive justification in future NIH grant applications) and a potential financial conflict. However, in other situations either potential conflict might exist on its own.

Comment. Active member B should disclose his/her intellectual and financial COI and recuse himself/herself from the decision-making on specifications, particularly during resolution of related issues that were called into question by Public Comments. While BC members would presumably welcome B's contributions to the discussions and recommendations based on his/her research track record in this arena, Committee members other than B would need to study the issue(s) and come to an independent decision based on sufficient justification or validation.