

Program in Evidence-Based Care (PEBC) Conflict of Interest Policy

Policy Version: May 15, 2018

Rationale

The rationale of this policy is to foster balance, independence, objectivity, and scientific rigor in the development of all PEBC documents by ensuring that the participation of persons who have actual or potential conflicts of interest regarding each individual guideline that they are involved with is managed appropriately and transparently.

Definitions

Relevant Business Entity: A company, corporation, or other commercial organization that produces, sells, or has a vested interest in any of the *objects of study*.

Objects of Study: The procedures, drugs, techniques, tests, modalities, systems, or other activities that are covered by the topic of the document being developed by the PEBC. This includes both the *objects of study* of primary interest and possible competing *objects of study*.

Participant: Any person who is directly involved in the development of the document. This includes members of the Working Group actually developing the document, Ontario Health, (Cancer Care Ontario)[OH-(CCO)] staff actively contributing to the development of the document, and any staff of the PEBC, including the Director and Assistant Directors, who work and/or provide feedback on the document.

Reviewers: Any person who is involved in the internal review (i.e., evaluation and assessment) of a document, as well as those persons selected as targeted peer reviewers for the external review process. This term includes the members of the Disease Site Groups (DSGs) or Guideline Development Groups (GDGs) who are responsible for and will ultimately approve the document and the members of the Report Approval Panel who review and approve the document.

General Policy

All participants and reviewers will declare any interests that they or their spouses or partners may have that are in actual or potential conflict with the object(s) of study of the specific guideline that the participants are involved with at that time, or may be perceived to be in conflict with by a reasonable person, in order to meet the PEBC objective of developing unbiased and evidence-based advice documents. This policy provides a number of categories of interests that must be declared, but the participant's or reviewer's responsibility is to disclose any interests that may be in conflict or be perceived to be in conflict, even if that interest is not explicitly described in this policy.

The PEBC conflict of interest policy focuses on the guideline documents that the PEBC produces. That is, all conflict of interest declarations and the management of any potential conflicts of interest that might arise relate specifically to PEBC documents undergoing development.

Frequency and Mechanism of Declaration

Working Group/Authors

For each guideline document, the Working Group and/or authors must declare their interests in writing (i.e., completing the PEBC Conflict of Interest Form) at two points in that process. The initial declaration is made as soon as they become involved in the project, which is usually at the time of project planning. The same participants must also update their declarations in writing at the point when the document is completed. If a participant gains a financial interest during the development of the document, that participant should declare that interest to the PEBC and may be asked by the relevant DSG/GDG Chair or the Director of the PEBC to withdraw from participation in accordance with the Management details described below.

Reviewers: DSG/GDG/Expert Panel & Report Approval Panel members and Targetted Peer Reviewers

All reviewers of the document must declare their interests in writing when they are first asked to review a specific, individual document.

The PEBC Research Coordinator assigned to the document project, in conjunction with the PEBC Project Research Assistant, is responsible for ensuring that all declarations are made prior to or soon after document development begins (and, in the case of the Working Group/Authors, prior to the finalization of the document).

At any meeting (either in person or via conference call) of the DSG or GDG responsible for a document, and prior to discussion of that document, the Chair, assisted by the assigned PEBC Research Coordinator, is responsible for announcing which members of the DSG or GDG have declared interests and for requesting a verbal update of those interests or a verbal statement of any new interests.

Interest Declaration and Management

For each category of interest below, the participant or reviewer must declare, for each document that they are involved with, whether they have an interest in that category; the business entity, organization, or other group that is the source of the interest; and any other pertinent details of the interest. The “Management” column, below, states the policy specific to the level of participation and review that interest may allow involving the document.

Interest	Management
<p><i>Financial Interests</i></p> <p>Has a relevant business entity provided you or your spouse or partner, within the past five years, with:</p> <ul style="list-style-type: none"> • Employment, regardless of salary and benefits? • \$500 or more in a single year to act in a consulting capacity? (“consulting capacity” includes such work as, for example, a consultant, investigator, advisory board member, lobbyist, or speaker.) • Other financial or material support (for example, gifts or travel support.) Of \$500 or more in a single year? <p>Do you or your spouse or partner currently own:</p> <ul style="list-style-type: none"> • A relevant business entity, in whole or in partnership? • Stocks, bonds, or stock options valued at \$500 or more in a relevant business entity? This excludes shares or participation in mutual funds, pensions, or similar funds where you do not have any direct control over the purchases and sales of shares the fund makes. <p>Across all categories above, and including sources not listed above, do you and your spouse or partner have combined financial interests totalling \$1000 or more?</p>	<p><i>Participants:</i> The lead author should have no financial interests. Of the other participants, less than half can have any declared financial interests. In rare circumstances the Director of the PEBC may decide to waive this requirement for the participants, with the waiver being reported in the final document.</p> <p><i>Reviewers:</i> The Chair of any document-specific Expert Panel should have no declared financial interests, unless the Director of the PEBC waives this requirement; that waiver is reported in the document. The Chair of any DSG or standing Expert Panel that is responsible for multiple documents should not act in that capacity for any discussions relating to the document, instead nominating someone who has no declared financial conflicts. The Chair may ask that members with declared financial interests recuse themselves from meetings or conference calls regarding the document.</p> <p><i>Reporting:</i> All financial interests of all participants and reviewers will be reported in the final document, including the specific business entities that are the source of the interest. The exact value of the financial interest will not be reported.</p>
<p><i>Financial Interests from Professional Income</i></p> <p>Could your professional income (i.e., billings after sharing in your business group, if applicable) increase or decrease by more than \$10,000 per year depending on the outcome of the guideline (see Appendix for examples and discussion)?</p>	<p>If a participant or reviewer reports significant financial interest from professional income, the Chair(s) of the relevant Expert Panel or DSG are responsible for deciding what restrictions, if any, with regard to the development of the document are necessary. However, the interest should be reported.</p>

<p><i>Professional Interests</i></p> <p>Have you or your spouse or partner, within the past five years:</p> <ul style="list-style-type: none"> • Received any grants or other research support, either as principal or co-investigator, in any amount, from a relevant business entity? • Been a principal investigator for a clinical trial involving any of the objects of study, regardless of the source of funding? • Published an editorial, commentary, or other clear opinion regarding any of the objects of study? • Provided advice or guidance regarding the objects of study in a public capacity (for example, testified in court or provided commentary to a news organization)? • Had managerial responsibility for an organization or department that has received \$5,000 or more in a single year from a relevant business entity, even if you did not personally benefit? 	<p><i>Participants:</i> Lead authors of documents should not have any professional interests. This requirement may be waived by the Director of the PEBC if the circumstances warrant it, with such waiver being reported in the final document.</p> <p><i>Reviewers:</i> Chairs of Expert Panels and DSGs who have professional interests should consider nominating another member with no interests to act as Chair in all discussions relating to the document.</p> <p><i>Reporting:</i> All professional interests will be reported for all participants and reviewers in the final document.</p>
<p><i>Other Interests not Described Above</i></p> <p>Examples include, but are not limited to:</p> <ul style="list-style-type: none"> • Member of a professional or advocacy organization (including lobby groups, special interest groups, or other groups that use various forms of advocacy to influence public opinion and/or policy) that has expressed a public opinion on the objects of study • Personal situation relevant to any of the objects of study (for example, having personally undergone or received an intervention) • Recommendations made in the document may require a substantial and potentially involuntary change in the nature or location of one’s professional practice 	<p>If a participant or reviewer reports interests not outlined above, the lead author, Chair of the relevant Expert Panel or DSG, and the Director of the PEBC have a joint responsibility to decide what restrictions with regard to the document development, if any, are necessary and whether or not the interest should be reported.</p>

Dispute Resolution

If a dispute should arise regarding whether and how a particular interest might affect participation in the document development process, or how that interest should be reported, the Director of the PEBC has the final decision-making authority.

Appendix: Examples of Potential Conflicts of Financial Interest from Professional Income

Participants and reviewers are not required to itemize or otherwise calculate an estimated change to their professional income to answer this question. If your intuitive, rough estimation of the potential change to your professional income would be greater than \$10,000, you should answer yes and provide details; otherwise, leave this section blank. If you are unable to estimate the potential effects of the guideline, write “Unsure” in the details box and provide a brief summary of the situation.

Example 1: You are a Radiation Oncologist reviewing a guideline on the use of postoperative adjuvant radiation therapy (RT) for high-risk prostate cancer post-radical prostatectomy. You are able to bill a significant amount for the radiation planning for a patient who requires postoperative radiation. Historically, very few of these patients are referred to you. You are in a business group where you share 50% of your billings equally with your partners.

Action: You would declare a potential financial conflict to the DSG Chairs.

Discussion: If you and the DSG Chairs feel that the number of patients planned for postoperative radiation would not be significantly different (i.e., the urologists involved traditionally referred all patients for late salvage RT), or your business group arrangement is such that you share all your billings, then it might be reasonable for the Chairs to conclude that there is a low potential for financial conflict and neither a declaration nor an action would be needed.

Example 2: You are Thoracic Surgeon specializing in Oncology who performs a significant number of lobectomies and/or wedge resections of localized non-small cell lung cancer (NSCLC) per year. You are co-authoring a guideline evaluating the role of high dose per day radiation for the primary treatment of stage 1 and 2 NSCLC. You bill for these procedures and share office costs with your colleagues (i.e., take home most of your billings as income).

Action: You would declare a potential financial conflict to the DSG Chairs.

Discussion: If you did very few thoracotomies for early lung cancer or the guideline was addressing the role of postoperative RT (i.e., that would affect the number of thoracotomies you did per year), no conflict would need to be declared.

Example 3: You are a Medical Oncologist who treats breast cancer and are the lead author in a guideline evaluating the role of taxane-based chemotherapy for metastatic breast cancer. Your colleagues and your incomes are mainly from base funding, but there are incentive payments tied to specific clinical services that are awarded to the individual (i.e., not shared). You receive some incentive payments for treating patients with chemotherapy, but the payments are unaffected by whether a taxane or an alternative type of chemotherapy is used.

Action: No declaration would be required.

Discussion: If the incentive received is for administering one type of chemotherapy rather than another and is significant or if you work outside the Medical Oncology Alternative Financing or Procurement (AFP) model (i.e., you bill OHIP directly), you should consider reporting this potential conflict with the DSG Chairs.