



ECIBC assessment of interests and management of conflicts of interests

Document history			
Version	Date	Drafted by	Comments
0	15/11/2015	Jesús LÓPEZ	Final version agreed with co-chair and vice-chair of methodology
1	11/01/2016	Jesús LÓPEZ	Version with 'Document history' as agreed during the 2 nd GDG/QASDG meeting
2	15/02/2016	Donata LERDA	Version that takes into account possible outsourcing
3	10/03/2016	Massimo AMBROSIO	Version that clarifies the responsible of the final decisions on Col
4	27/04/2016	Massimo AMBROSIO	Draft version combining the GDG and the QASDG assessment of interests and management of conflicts of interests in a single document

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Glossary

Conflict of interest (Col)	Any interest that may affect or reasonably be perceived to affect the expert's objectivity and independence in providing advice to the ECIBC (1). This definition includes a financial or intellectual relationship that may impact an individual's ability to approach a scientific question with an open mind (2, 3).
Contributor(s) (to the ECIBC)	GDG/QASDG members, associated members, etc. along what described in the Rules of procedure and ECIBC team.
Declaration of interests (DoI)	Disclosure of interests as an indication of where conflicts of interest could arise. Therefore an 'interest' declared should not automatically be considered to create a conflict of interest.
'Direct financial interests'	Interests that can be directly measured in monetary units (1). They relate to direct financial relationships with entities that have investment in products or services directly relevant to the ECIBC's topics (4).
'Indirect interests'	Interests that cannot readily be measured in monetary units but that could be reasonably perceived to affect an individual's objectivity and independence while providing advice to the ECIBC (1). Indirect interests are ubiquitous and not inherently bad. However, they must be identified and appropriately managed if unbiased, credible guidelines and QA scheme are to be produced (1). Intellectual Col' is one type of 'indirect Col'. Indirect Cols may ultimately lead to financial gain. For example, intellectual interests related to career advancement may have a monetary component (1); or the contribution to the ECIBC may promote increased clinical revenue streams.
Intellectual conflict of interests	Attachment to ideas or 'academic activities that create the potential for an attachment to a specific point of view' (5).
Interest	ANY relationship that could be perceived to be affected by the outcome of the ECIBC. These relationships imply interactions with ANY entity (private or public, for-profit or not for-profit) or ANY person (such as family members) that could be considered as broadly relevant to the work of the ECIBC.

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Overview of the process

This document aims at describing the process for identifying, assessing and reporting interests, and for managing conflicts of interests (Col) of contributors to the ECIBC (e.g. the development of the European guidelines for breast cancer screening and diagnosis (*European Breast Guidelines*), or the European Quality Assurance Scheme for Breast Cancer Services (*European QA scheme*)). It has been prepared with the support of the co- and vice-chair of methodology.

1. In general terms, all the contributors participating in their personal capacity in the ECIBC are asked to complete the declaration of interests (Dol) form.
2. The JRC collects and assesses the Dols, potentially with the support of an external contracted team, to determine the presence and the severity of conflicts of interests (Col).
3. The JRC defines the management strategy for each member with a Col and the actions to be taken, which are approved by the JRC relevant Head of Unit.
4. At the first annual GDG/QASDG meeting, annual Dols are summarised and presented, with the opportunity for ECIBC contributors to update and/or amend their declarations. The management strategy for any detected Col is also presented:

The JRC presents the 'unmanageable Col' (those requiring revocation of the appointment), and

The co-chair or the vice-chair of methodology for GDG and the identified QASDG member(s) present 'manageable Col', e.g. requiring restricted participation.

5. At each GDG/QASDG meeting, new contributors' Dols are summarised and presented and the management strategy for any detected Col from these new contributors is also presented:

The JRC presents the 'unmanageable Col' (those requiring revocation of the appointment), and

The co-chair or the vice-chair of methodology for GDG and the identified QASDG member(s) present 'manageable Col', e.g. requiring restricted participation.

6. In addition, before each GDG/QASDG meeting, meeting-specific Dols, based on the topics included in that meeting agenda, are filled-in by contributors and evaluated by the JRC. Any action related to potential Col will be communicated bi-laterally by JRC to the concerned contributor prior to the meeting.

7. The final ECIBC outputs will report a summary of disclosed interests and of the management plan for detected Col.

The process detailed below is based on chapter 6 of the **WHO Handbook for guideline development, 2nded.** (1). It was adapted, when necessary, to the context of the Commission's rules and of the ECIBC.

I. Who should declare interests?

Responsible: any contributor participating in her/his personal capacity in the ECIBC may be asked to complete the Dol form. **Annex I** details who must declare interests.

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II. Collection of interests

Responsible: The JRC, potentially with the support of an external contracted team.

Annual and new interests are collected using the standard DoI form of the *Commission scientific committees on health and food safety (6)*. The completed forms, together with the profiles of the experts, are publicly available at the ECIBC web hub. Meeting-specific interests are collected via agenda-based forms and not published.

III. Assessment of interests

Responsible:

- The JRC, potentially with the support of an external contracted team, checks that the DoI forms are correctly filled-in.
- The JRC, potentially with the support of an external contracted team, assesses the interests, determines if CoIs exist, and, finally, determines their severity. The JRC makes the final decision on the presence and severity of the CoI and how they are managed.
- The JRC relevant Head of Unit signs the documents stating the actions to manage CoIs which are bi-laterally communicated to the concerned contributors.

The assessment of the interests declared follows the steps detailed in the table below.

Table 1: Steps to assess the interests declared

	Step 1: Are the interests properly declared?	Step 2. Does a CoI exist?	Step 3. Is the CoI severe?
Options	Yes; No	Yes; No	Yes; No
Responsible	JRC (potentially with the support of an external contracted team)	JRC (potentially with the support of an external contracted team)	JRC (potentially with the support of an external contracted team)
Tasks	<ul style="list-style-type: none"> • Revise DoI • Check if the DoI is complete and clear • Request clarifications (if needed) 	Determine if there is a CoI, that is, any interest that may affect or reasonably be perceived to affect the contributor's objectivity and independence in providing advice to the ECIBC.	Decide if a CoI is severe enough to result in high risk of bias or decreased credibility

Determination of the severity of a CoI

CoIs represent a spectrum; they are not absolute situations. Their severity vary and hence the risk that they pose to the ECIBC. The severity of a CoI depends on two factors:

1. The likelihood that decisions in respect of the primary interest¹ will be unduly influenced by the secondary interest

¹ **Primary interest:** to contribute to the ECIBC

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2. The seriousness of the adverse outcomes that could result from that influence.

Annex II details the factors that are considered to determine the severity of the Col's. According to their severity, Col's are classified as '**Not severe**' or '**Severe**'.

Table 2: Classification of the Col's severity

	1. Not severe Col	2. Severe Col	
Definition	Col probably not resulting in high risk of bias or decreased credibility of the ECIBC	Col probably resulting in high risk of bias or decreased credibility of the ECIBC	
Needs to be managed?	No	Yes	
Management	No need of management	'Manageable Col'	'Unmanageable Col'
	Declaration only	<ul style="list-style-type: none"> • Group level management • Individual management (<i>e.g.</i> restricted participation) 	Revocation of the appointment

IV. Management of conflicts of interest

The lack of good evidence to guide the management of Col's makes this process difficult and decisions taken in this context are challenging. Therefore, it is critical to implement processes, procedures and rules that are explicit, transparent, consistent, thoughtfully constructed and defensible. Col's have to be managed both at individual level and at group level.

Contributors need to be involved and to perceive the usefulness of a rigorous yet appropriate management of Col's for ensuring the credibility of the work they are carrying out within the ECIBC.

IV.1 Managing Col's at group level

While direct financial Col are usually managed at individual level, indirect Col (including intellectual ones) may be managed at both individual and group level.

a. Minimising the risk posed by Col when constituting the GDG and QASDG

Group composition is influential in any decision-making process. Observational evidence shows a correlation between the composition of GDGs and specific recommendations or between the composition of QASDG and specific QA scheme requirements. For example, physicians tend to recommend procedures that they personally deliver, whereas multidisciplinary groups tend to be more conservative in their recommendations, or physicians may tend to recommend requirements that they normally already fulfil. (7, 8).

There is scant evidence about optimal composition of groups to minimise the risk that intellectual conflicts of interest can bias their decisions (*e.g.* on the strength of the recommendations or on requirements). The following principles are applied (9):

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1. The selection panel of the GDG/QASDG

The GDG/QASDG selection panel had six members, none of them with a particular viewpoint or a dominant role in the selection process. Therefore, the GDG and QASDG members were not selected based on their (potential) support to a particular recommendation or set of requirements (or scheme) (so called 'committee stacking')(10).

2a. GDG co-chairs and vice-chairs

1. The co-chair and vice-chair of methodology should have no Col (direct financial or intellectual).
2. The clinical co-chair or vice-chair should have no severe direct financial Col. Being experts on the topic of the guidelines, they probably have intellectual Col. In order to minimise the consequences they should have diverse opinions and perspectives.

2b. QASDG chair and vice-chair

The chair and the vice-chair should have no Col (direct financial or intellectual). Being experts in one or more topics of the QA scheme, and/or being involved in existing schemes, they probably have intellectual Col. In order to minimise the consequences they should have diverse opinions, perspectives and be involved in different existing QA schemes.

3. Other ECIBC contributors

1. **Ideally Col**s, either direct financial or indirect, should be minimised.
2. **Individuals with direct severe financial Col should generally not contribute.** This applies especially to individuals with substantial financial interests in an intervention or requirement under consideration within the ECIBC.
3. The inclusion as contributors with financial and/or intellectual Col implies that, within a group, **balanced perspectives of these individuals have to be ensured.** This can be achieved by selecting people whose opinions are known to differ, including a variety of stakeholders.
4. **Contributors involved in either primary research or systematic reviews relating to the ECIBC topics should disclose those activities.** A group within the ECIBC should be composed of individuals with **diverse perspectives, training and experiences** to avoid that the ECIBC outcomes would reflect a single viewpoint.
5. Contributors with **methodologist profile** are supposed to have a particularly low risk of holding a Col, in particular of clinical nature. Therefore, they support JRC in some processes related to Col management (see page 3).

4. Contractors

An outsourcing policy to further prevent Col is applied across the diverse ECIBC activities. For instance, the systematic reviews and/or the evidence profiles needed are outsourced to a team that is separate and independent from the ECIBC; similarly, the search and evaluation of requirements and indicators for the QA scheme is outsourced.

5. Stakeholders

In addition to contributors, a variety of stakeholders, including experts in implementation, programme managers, healthcare workers, and people who will be affected by the ECIBC outcomes, are involved.

For instance, stakeholders are asked to provide feedback both on the draft scope of the Guidelines/QA scheme and on their final version.

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6. Editors and external reviewers

Editors and external reviewers are involved in the pre-publication processes of the ECIBC outcomes before they are submitted to the Commission for the final approval.

b. Minimising the risk posed by Col(s) during the ECIBC outcomes development

The JRC holds the responsibility of continuous assessment of interests and management of Col(s) for the whole duration of the project according to Tables 1 and 2 and Annexes

IV.2 Managing conflicts of interest at individual level

This management process relates only to the development phase of the ECIBC. **Decisions on the severity and the management of Col are made on a case-by-case basis.** DoIs collection and management of potential Col(s) is carried out according to point 4, 5 and 6 of the Overview (see page 3).

In particular, the following applies:

1. No action (not severe Col)

No action required beyond declaration of the interest(s) at the meetings and their inclusion in the dedicated reports of the ECIBC outcomes.

2. Restricted participation in an ECIBC activity (severe Col-manageable)

The Col is not serious enough to revoke the appointment to related group but it has to be managed. Possible actions include:

2.1. No exclusion from the activity **but no participation in the decision phase** (e.g. voting)

2.2. Exclusion from the activity and also from the decision phase

2.3. Revocation of the role (as co-chair, vice-chair, chapter editor, steering group member, etc.)

3. Exclusion from participation in an ECIBC activity (severe Col-unmanageable)

The Col is serious enough, and potentially covering the whole concerned activity scope, hence precluding that specific contribution.

V. Reporting declarations of interest

Together with the final versions of the ECIBC outcomes, a dedicated report summarising how interests were collected, assessed and managed. A summary of the interests declared and the way Col(s) were managed will be presented in either tabular or narrative form. If no interests were declared, this will be stated as well.

In addition, the completed and constantly updated DoI forms, together with the contributor's profile, are made publicly available at the ECIBC web hub.

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VI. Bibliography

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Annex I: Who should declare the interests

Contributor	Annual DoI required?	Specific DoI required?	Annual DoI published?	Who assesses?	CoI admitted
Commission staff	According to Commission's rules	According to Commission's rules	No	According to Commission's rules	According to Commission's rules
GDG Co-chair and vice-chair of methodology and QASDG chair and vice-chair	Yes	Yes	Yes	JRC (potentially with the support of an external contracted team)	No CoI (direct financial or indirect)
GDG clinical co-chair and vice-chair	Yes	Yes	Yes	JRC (potentially with the support of an external contracted team)	No severe direct financial CoI (manageable or not)
ECIBC contributors: GDG/QASDG members and associated members, chapter editor content experts, chapter editor methodologists, task force coordinators, systematic review team members	Yes	Yes	Yes	JRC (potentially with the support of an external contracted team)	No severe unmanageable CoI (direct or indirect)
CCIB and EA collaborators, scientific advisors and external experts, external reviewers (including peer-reviewers) and editors	Yes	No	Yes	JRC (potentially with the support of an external contracted team)	No severe unmanageable CoI (direct or indirect)
National contacts (call for feedback)	No	No	Not applicable	Not applicable	Not applicable
Stakeholder organisations (call for feedback)	No	No	Not applicable	Not applicable	Not applicable
Individual stakeholders (call for feedback)	No	No	Not applicable	Not applicable	Not applicable

The management strategy and the actions to be taken are decided by the JRC and approved by the JRC relevant Head of Unit.

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Annex II: Criteria to determine the severity of a Col

Corresponds to the Table by WHO Handbook for guideline development (2nd edition), adapted from Lo BFM, editor, taking into account the ECIBC specificity. Conflict of interest in medical research, education, and practice. Washington (DC): The National Academies Press; 2009 (<http://www.ncbi.nlm.nih.gov/books/NBK22935/>, accessed 11 Nov 2014).

I. Likelihood of undue influence by the conflicted individual		
Criteria	Definition	Considerations
1. Value of the secondary Interest	Monetary or other value to the recipient	<ul style="list-style-type: none"> •The higher the monetary value, the greater the effect may be on the recipient's decisions. However, even small gifts can change the behaviour of the recipient. •Effect may depend on whether the payment is direct to the individual (<i>e.g.</i> an honorarium) or indirect (<i>e.g.</i> to an academic institution).
2. Scope of the relationship	Duration and depth of the relationship between the individual and the secondary interest	<ul style="list-style-type: none"> •Longer and/or closer relationships may increase the risk of bias in decision-making. •For example, a one-time relationship, such as a presentation for industry, is less concerning than a long-term relationship, such as employment by a relevant company.
3. Extent of discretion	Amount of authority the conflicted individual has in making important decisions	<ul style="list-style-type: none"> •The role of the conflicted ECIBC contributor in decision-making and the amount of her/his oversight and of the ECIBC outputs in general affect the risk of bias. For example, the (co-)chair(s) generally has more discretion, so her/his COIs may have a greater effect than those of other contributors.

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II. Seriousness of the possible harm from the conflict of interest		
Criteria	Definition	Considerations
1. Value of the primary interest	The potential effect of the recommendations/requirements on individuals and populations	<ul style="list-style-type: none"> •Requires an assessment of the intended outcomes of the guidelines recommendations and QA scheme requirements in the clinical and testing practice. •Recommendations/requirements that affect health outcomes, such as survival or quality of life, can cause significant harm to the recipients of an intervention if the balance of benefits and harms has not been assessed in an unbiased manner.
2. Scope of the consequences	The potential for harms caused by an invalid (biased) recommendation/requirements across populations	<ul style="list-style-type: none"> •The more individuals that are potentially affected by a recommendation or a requirement, the greater is the potential effect of any Col. For example, recommendations that impact the health or well-being of large populations can have tremendous health consequences. •The consequences of contributors affected by a Col when developing guidelines or QA scheme also include diminished trust in these contributors and in the organization sponsoring the <i>European Breast Guidelines</i> or owning the <i>European QA scheme</i> (i.e. Commission).
3. Extent of accountability	The degree of accountability for, and oversight of, the ECIBC outputs development	<ul style="list-style-type: none"> •Increased accountability or oversight may lead to lower levels of risk from a Col. •The external systematic review process of the evidence and the public consultations planned for the guidelines/QA scheme may help to identify bias derived from Col. The external peer review process also increases accountability. Similarly the externalisation of other evaluation processes (for instance for the requirements of existing QA schemes).

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