



## ECIBC Guidance to disclose interests

Document history			
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1	11/01/2016	Jesús LÓPEZ, Anke BRAMESFELD	Versions with 'Document history' as agreed during the 2 <sup>nd</sup> GDG/QASDG meeting
2	20/04/2016	Massimo AMBROSIO	Version combining the GDG and the QASDG guidance to disclose interests in a single document

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## Glossary

<b>Conflict of interest (CoI)</b>	Any interest that may affect or reasonably be perceived to affect the expert's objectivity and independence in providing advice to the ECIBC activities (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).
<b>Contributor(s) (to the ECIBC)</b>	GDG/QASDG members, associated members, etc. along what described in the Rules of procedure and ECIBC team.
<b>Declaration of interests (DoI)</b>	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.
<b>Intellectual conflict of interests</b>	Attachment to ideas or 'academic activities that create the potential for an attachment to a specific point of view' (4).
<b>Interest</b>	ANY relationship that could be perceived to be affected by the outcomes 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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## I. Aim of this document

This document aims at providing guidance on how to declare interests in relation with the scope and development process of the European guidelines for breast cancer screening and diagnosis (*European Breast Guidelines*) and of the European Quality Assurance Scheme for Breast Cancer Services (*European QA scheme*).

This document is just a guidance. The person completing the declaration of interests (DoI) form has the responsibility of deciding which interests should be declared, also taking into account the need of protecting the reputation of the ECIBC activities and its contributors.

## II. Sources consulted for elaborating this document

- Rules of procedure SANTE Scientific Committees (5)
- Guidelines International Network: principles for disclosure of interests and management of conflicts in guidelines (6)
- WHO Handbook for guideline development (2<sup>nd</sup> ed.) (1)
- The International Committee of Medical Journals Editors (ICMJE) Form to disclose potential conflict of interest (7)
- Association of Scientific Medical Societies in Germany (AWMF): Guidance manual and rules for guideline development (8)
- Antithrombotic therapy and prevention of thrombosis, 9<sup>th</sup> ed. American College of Chest Physicians evidence-based clinical practice guidelines (4)
- GIN-McMaster Guideline Development Checklist (9)

## III. Introduction

1. Contributors nominated in their personal capacity<sup>1</sup> to the *European Breast Guidelines* and to the *European QA scheme* have the responsibility for declaring their interests.

2. The contributor declares his/her interests as an indication of where a 'conflict of interest' (Col) could arise or could be perceived to exist. Apart from meeting-specific DoIs, contributors are not required to assess whether there is actually a Col or to assess its severity.

3. An 'interest' declared is not automatically considered to create a Col.

4. A Col detected does not automatically imply the exclusion of the contributor from the ECIBC, being revocation of her/his appointment just one of the many options for managing potential ColS.

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<sup>1</sup> Contributors nominated in their personal capacity, that is, not as representatives of public or private bodies, organisations or states. These contributors include, for example, the Guidelines Development Group (GDG) and the Quality Assurance Scheme Development Group (QASDG) members, the scientific advisors, or the members of the systematic review team.

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## IV. What interests should be declared?

Sections IV and V attempt to clarify what interests may be relevant in the context of the *European Breast Guidelines* and of the *European QA scheme* and more in general of the ECIBC.

### 1. Declare all relevant interests, including 'indirect interests'

**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.

**Conflict of interest (Col):** an interest that may affect or reasonably be perceived to affect the contributor's objectivity and independence in providing advice to the ECIBC (1). This definition includes any relationship (financial or intellectual) that may impact individual's approach towards a scientific question (2, 3).

There are two general types of interests (1, 6, 10, 11):

#### a) 'Direct financial interests'

**Definition:** 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 (6).

**Examples:** patents owned, or money received from a commercial company for a lecture about a device assessed in the guidelines / QA scheme or more in general within the ECIBC.

#### b) 'Indirect interests'

**Definition:** 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'. It refers to attachment to ideas or 'academic activities that create the potential for an attachment to a specific point of view' (4, 6).

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.

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Examples of indirect interests:

- Being a recognised expert in a procedure or intervention may make the expert prone to recommend that intervention
- Having been member of a guideline panel that provided recommendations for or against breast cancer screening or of an existing QA scheme which status may be influenced by the *European QA Scheme*
- Prior publication of a study or systematic review that is part of the evidence base under consideration in the guidelines or QA scheme (1)
- Previous public declarations of firm positions or opinions on a topic of the guidelines or QA scheme. Examples: public testimony during a regulatory or judicial process, in an interview or in an editorial journal (1)
- Professional or personal affiliation with an organization advocating for products or services related to the subject of the guidelines or the QA scheme (1)

**Justification for declaring 'indirect interests'**

Indirect interests are less tangible and thus more difficult to identify, measure and manage (1). However, ECIBC recognises the need to declare and manage direct and indirect ColS to reduce the risk of bias in decisions, recommendations, and requirements/indicators. This aims to warrant the credibility of the team developing the guidelines and the QA scheme.

**Therefore, if while filling-in the declaration of interest, the contributor has the doubt on whether to declare or not a certain interest, the indication is to declare.**

This is in accordance with the rules of procedure of the [Commission scientific committees on health and food safety](#), which state that 'The principle of independence implies in particular, independence from any external economic or political interests, but also from bias related to political, economic, social, philosophical, ethical or any other non-scientific considerations' (5).

In addition, relevant organisations propose to declare and manage direct and indirect interests. Examples are Institute of Medicine (IOM) (12), World Health Organization (WHO) (1), National Institute for Health and Care Excellence (13), U.S. Preventive Services Task Force (USPSTF) (14), American College of Physicians, American Thoracic Society (ATS), and the American College of Chest Physicians (ACCP) (4, 11, 15).

Finally, the Guidelines International Network (G-I-N) Board of Trustees recently published a set of principles on the disclosure of interests and management of ColS. These principles highlight the importance of disclosing and managing indirect ColS. G-I-N recognizes that ColS cannot be totally avoided when panel members are being chosen for their competence on certain guidelines or in certain settings; thus, the important issue is the management of ColS in a fair, judicious, transparent manner (6).

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## 2. Declare current, past and envisaged activities that may represent an interest

- **'Current activities'**: ongoing activities.
- **'Past activities'**: activities no longer ongoing, but completed in the preceding **five years**.
- **'Envisaged activities'**: activities planned until one year after the finalisation of the contribution to the ECIBC.

## 3. Declare all specific monetary values with actual or approximate amounts, if known

The contributor should declare all specific monetary values. This is important as CoIs may arise at different levels in different settings, and because reporting of actual or approximate amounts increases transparency (6).

The contributor should declare if the money was paid to his/her institution' or paid directly to her/him.

## 4. Declare relationships with entities relevant to the work of the GDG

**Entity**: government agency, foundation, commercial sponsor, academic institution, etc.

The contributor should declare:

- Relationships with ANY type of relevant entity, that is, any entity relating to the ECIBC, remit. Thus, relevant public bodies and not for-profit organisations or foundations need to be included as well
- The name of entity, its location and nature (private, public, etc.)

Relevant entities in the context of the work of the ECIBC:

1. Entities involved in **(breast) cancer care processes** covered by the ECIBC. Examples
  - Private or public healthcare insurance entity, such as a national health service
  - Private or public healthcare centre
  - Medical device company
  - Non-governmental organisation (NGO), foundation, advocacy group, professional society, or journal
2. Commercial entities involved in **breast cancer treatment services**. For example, a company involved in producing oncological treatment or radiotherapy equipment for breast cancer. This may represent a CoI as, although treatment of breast cancer is not the topic of the guidelines, breast cancer screening and diagnosis may be associated with a modification of the treatment strategies due to the change of number and staging of new cancer cases.

A relationship with any of these entities is not automatically considered to create a CoI. This list aims at facilitating the declaration of interests by the contributor. **Especially important is to**

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**declare relationship with commercial enterprises<sup>2</sup> relevant to the topics of the ECIBC (guidelines and QA scheme).**

## V. Examples of interests to declare

### 1. Ownership or financial investments, including shares

Financial interests in a company or other entity operating in a business that can be affected directly by the outcomes of the ECIBC. This includes holding of any form of equity, bonds, partnership interests<sup>3</sup> in the capital of a company.

The holding of financial interests connected with a pension scheme or other complex investment funds would not be considered a financial interest, provided that the individual has no influence on its financial management.

**Example:** Ownership of shares in a drug, medical device or healthcare insurance company.

### 2. Membership of a managing body or equivalent structure

Any participation in the internal decision-making of an entity (private or public, for-profit or not for-profit) that could be perceived to be affected (financially or not) by the scope of work of the ECIBC. Examples of participation in the internal decision-making of an entity are board membership, or directorship. Examples:

#### a) Direct financial interests

Participation in the internal decision-making of an entity (public or private) that could be perceived to be affected **financially** by the scope of work of the ECIBC. Examples:

- Drug or medical device company
- Private healthcare insurance company
- Ownership of a private healthcare centre
- NGO or foundation financially supported by entities that could be perceived to be affected by the scope of work of the ECIBC. For example: NGO receiving funds from the pharmaceutical industry.
- Professional society sponsored by entities that could be perceived to be affected by the outcome of the ECIBC.
- Journal that accepts advertising or reprint incomes from companies perceived to have a financial stake in the outcome.

#### b) Indirect interests

<sup>2</sup> Businesses that are intended to make a profit for their owners

<sup>3</sup> When declaring financial interests *e.g.* stock and shares, only the kind, company name need to be stated.

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Participation in the internal decision-making of an entity (public or private) that has taken a position on a subject to be represented or defended. Examples:

- Board membership of a NGO, foundation *etc.* that is clearly positioned for or against cancer screening (not only breast cancer) irrespective if it is financially supported by entities that could be perceived to be affected by the guidelines.
- Hold an office of an entity that officially supports or recommends against palliative care, or any other topic relevant for the QA scheme, irrespective if it is financially supported by entities that could be perceived to be affected by the QA scheme. For example, a public health authority in charge of the licencing of palliative care providers or re-organisation of (breast) cancer services.
- Head or other person participating in internal decision making of a public breast cancer screening unit or a breast cancer service.

### 3. Membership of another scientific advisory body

Participation in another scientific advisory body (not *the European Guidelines for breast cancer screening and diagnosis* or the *European Quality Assurance Scheme for Breast Cancer Services*) related to the scope of work of the ECIBC with a right to vote on the outputs of that entity.

**Examples:**

a) Member of a scientific advisory body that provided recommendations on cancer screening or diagnosis or cancer care processes.

b) Member of a scientific advisory body that did not provide a recommendation on cancer screening or diagnosis or cancer care processes, but that provided results that might bear on a recommendation. Examples:

- Results on mortality associated with breast cancer screening (without providing any recommendation on screening)
- Results on quality of life associated to a certain treatment (without providing any recommendation on that treatment)

### 4. Employment

All forms of employment, part-time and full-time, either paid or unpaid<sup>4</sup>, in relation to activities of the ECIBC.

**This section does not apply to those participating in the internal decision-making of the entity** (domain ‘Membership of a managing body or equivalent structure’), for example, healthcare professional owing a private clinic.

**a) Direct financial interests:**

Paid employment by an entity that could be perceived to be affected by the scope of work of the ECIBC. Examples:

<sup>4</sup> Example of unpaid employment: volunteer work for a charity

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- Private healthcare centre (for example, the contributor may be paid by patient receiving an intervention addressed in the guidelines)
- Drug or medical device company
- NGO or foundation financially supported by entities that could be perceived to be affected by the scope of work of the ECIBC
- Journal that accepts advertising or reprint incomes from private companies perceived to have a financial stake in the outcome of the ECIBC

## **b) Indirect interests**

Examples:

- Employment at a healthcare centre (there may be clinical revenue streams derived from the participation in the ECIBC activities)
- Employment by an entity that has taken a position on the subject of the guidelines or on the processes covered by the QA scheme, so the employee is expected to represent or defend this position. Examples:
  - NGO that recommends for or against cancer screening
  - Health authority that officially recommends organisational settings that can be affected by the QA scheme requirements

## **5. Consultancy/Advisory**

Any paid or unpaid activity in which the contributor, or his/her depended collaborators, provide technical or scientific advice or services in domains of relevance for the work of the ECIBC.

The contributor should report the following aspects about all relevant activities:

- Whether or not an honorarium was paid
- Who paid; and
- Who received the payment (the contributor or his/her institution).

The following activities should be declared:

### **a) Paid services delivered for a for-profit entity (Direct financial interest)**

These activities will be considered on a case by case basis. It is most problematic if a contributor's potential conflict relates to marketing or post-marketing surveillance activities of a commercial product or if the activities are sponsored by marketing divisions of commercial enterprises (4).

Examples:

- Member of steering committees of industry funded studies
- Paid board memberships
- Consultancy for a manufacturer of a relevant technology/intervention
- Payment for lectures in support of a technology/intervention
- Payment for meeting attendance in support of a technology/intervention

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- Payment for training activities
- Member of a speaker's bureau for a commercial enterprise
- Payment of honoraria or gifts

**b) Paid services delivered for a not for-profit organisation (Direct financial interest)**

Examples:

- External evaluator of research projects funded by a public entity
- Consultancy for a NGO

**c) Paid lectures as part of a professional society meeting (Direct financial interest)**

The contributor must declare if the honorarium was paid by the sponsoring society and not by a commercial enterprise. If paid directly by a commercial enterprise this interest would be a 'service delivered for a for-profit entity'.

**d) Paid lectures delivered at not-for-profit institutions (e.g. medical schools, public hospitals) (Direct financial interest)**

The contributor must declare if the honorarium was paid by the sponsoring institution and not by a commercial enterprise. If paid directly by a commercial enterprise this interest would be a 'service delivered for a for-profit entity'.

**e) Giving expert testimony as part of a regulatory of judicial process related to the subject matter (Indirect interest)**

**6. Influence on definition of research priorities**

Any influence on the definition of research priorities, the drafting of research programmes or the selection of research projects and current funding of research in relation to the work of the ECIBC **(Indirect interest)**.

**7. Research grants and other funding**

Research work supported by an entity (private or public, for-profit or not for-profit) that could be perceived to be affected by the outcome of the ECIBC **(Direct financial interests)**. This support includes:

- Financial support, such as grants received or pending, rents, sponsorships and fellowships
- Non-financial support, such as drugs, equipment supplied by the entity, research assistants, travel to meetings, writing assistance, administrative support, etc.

**Examples:**

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- Financial support from the industry to the specific product considered by a guideline recommendation (for example, the guideline addresses breast cancer screening with device A and the applicant/member received funding for research on device A),
- Financial support from the industry to other products in the therapeutic area addressed by the QA scheme requirements (for example, the QA scheme addresses radiotherapy with requirements that may indicate use of device A and the applicant/member received funding for research on device B )
- Financial support from government related to an intervention that is the subject of a requirement (for example, the QA scheme addresses radiotherapy and implies use of device A and the applicant/member received funding for research on device A)
- Financial support from the industry to other therapeutic areas (that is, other clinical problems) that could be affected by the outcome of the ECIBC. Example: the guideline recommendation addresses breast cancer screening with device A and the applicant/member received funding for research on treatment of early breast cancer.

## 8. Principal investigator or investigator

Participation in research that creates the potential for an attachment to a specific point of view (**Indirect interest-Intellectual**). Examples:

- Research on the effectiveness of an intervention implies an intellectual interest for any recommendation/QA scheme requirement addressing that intervention
- Member of a guideline panel that provided a recommendation on intervention A would have an intellectual interest for any recommendation addressing use of intervention A

## 9. Member of a QA scheme panel that included a requirement on intervention A would have an intellectual interest for including such requirement also in the *European QA Scheme Intellectual property rights (IPR)*

Rights granted to creators and owners of works that are the result of human intellectual creativity that bring personal financial benefit to the contributor (**direct financial interest**). Only the IPR falling within the remit of the work of the ECIBC need be taken into account. These can be copyrights, patents, trademarks, etc.

The contributor must detail the following:

- If the rights are granted to the applicant or to his/her institution
- State of the patents and copyrights<sup>5</sup>:
  - Pending: the patent has been filed but not issued
  - Issued: the patent has been issued by the agency
  - Licensed: the patent has been licensed to an entity, whether earning royalties or not
- Royalties: funds are coming in due to the patent (detail if 'paid to you' or 'paid to your institution')

<sup>5</sup> <http://www.icmje.org/conflicts-of-interest/>

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**Examples:**

- Proprietary interest in an anti-cancer drug (any cancer, not only breast cancer)
- Proprietary interest in a medical device used in cancer screening (not only breast cancer screening)
- Proprietary interest in a prosthesis for women that have undergone mastectomy

**10. Other membership or affiliation**

Any membership or affiliation other than the above which can be perceived as an interest in the field of activity of the ECIBC.

**11. Interests of others**

Known interests as described under points 1 to 10 held by others who may, or may be perceived, to unduly influence the contributor's views. This includes:

1. Family members and relatives (spouse, parents, children, brothers and sisters) or other persons under the household of the contributor. In order to maintain privacy, their names do not need to be declared. There is no need to specify the relationship (*e.g.* wife). 'Spouse' includes a partner with whom the contributor has a similar close personal relationship

2. Other people with whom the contributor has substantial common interests, whether personal, professional or financial, that would benefit or adversely affect the ECIBC outputs. Examples include the employer, close professional colleagues, administrative unit or department, or a personal relationship to an authorised representative of a company in the healthcare industry

**12. Other**

Any interest other than the above which can be perceived as a potential source of conflict in an activity included in the ECIBC remits.

**Examples:**

- Being an acknowledged expert in the intervention (Indirect interest) as the expert is prone to recommend that intervention
- Previous public statements (Indirect interest-intellectual). For example, having declared in an interview that screening or a certain intervention should not be recommended

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