



ECIBC Rules of Procedure

Document history			
Version	Date	Drafted by	Comments
0	01/12/2015	Jesus LOPEZ, Silvia DEANDREA	Draft version discussed at the GDG/QASDG kick-off meeting
1	18/01/2016	Asli ULUTURK	Version developed according to the agreements of the second GDG/QASDG meeting.
2	15/09/2016	Massimo AMBROSIO, Asli ULUTURK	Draft version combining GDG and QASDG Rules of Procedure in a single document

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Scope

JRC has the scientific and technical responsibility for the European Commission Initiative on Breast Cancer (ECIBC) whilst the policy responsibility is with DG SANTE. In this context JRC coordinates the ECIBC development and implementation, ensuring synchronisation of all ECIBC objectives, the delivery of quality outputs, and that deadlines are met.

In this framework, the Guidelines Development Group (GDG) is the working group directly involved in the processes required for producing and implementing the European guidelines for breast cancer screening and diagnosis (*European Breast Guidelines*), while a voluntary European Quality Assurance Scheme for Breast Cancer Services (*European QA scheme*) is to be developed and piloted with the support of the Quality Assurance Scheme Development Group (QASDG).

A full description of the ECIBC's activities and timeline is available on the [ECIBC web hub](#), while the guidelines team and the QA scheme team are described in detail in the *ECIBC team* document.

The scope of this document is to describe the Rules of Procedure (hereinafter called 'Rules') of the GDG and QASDG in order to guide and facilitate the GDG/QASDG functioning in respect to independence, transparency and confidentiality.

This document is inspired by the rules for Commission expert groups¹ and is approved by the GDG/QASDG. The updated version of the Rules is published on the ECIBC web hub.

¹ Framework for Commission expert groups: horizontal rules and public register. [C\(2010\) 7649](#)

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Section 1: Glossary of terms and abbreviations

Associated member	Experts chosen from the GDG/QASDG reserve list contributing to the GDG/QASDG's work on specific issues or disciplines. They have voting rights on the activities they have contributed to and can formulate recommendations.
(Co)-Editor(s)/ Coordinator(s)	The GDG/QASDG member(s) primarily responsible of tasks forces, of a chapter or section of the <i>European Breast Guidelines</i> , of a subgroup or quality dimension of the <i>European QA scheme</i> .
External experts/individuals	Experts/individuals contributing temporarily to the GDG/QASDG's work. They ARE NOT chosen from the GDG/QASDG reserve list. They don't have voting rights neither do they formulate recommendations.
Guidelines Development Group (GDG) and Quality Assurance Scheme Development Group (QASDG)	The working groups chosen through an open call and directly involved in in the development of the <i>European Breast Guidelines</i> and in the development and piloting of the <i>European QA scheme</i> respectively.
GDG/QASDG member	Member of the GDG/QASDG appointed in his/her individual capacity by DG SANTE following an open call.
'In agreement with the GDG/QASDG'	The case where there is no objection to a proposal. In case of an objection, voting takes place.
Minority opinions	Declared objections to the opinion adopted.
Qualified majority	A majority in a vote that reaches a minimum two thirds or 80% of the votes according to specific rules.
Reserve list	List with the applicants to the ECIBC's calls that accepted the nomination for the GDG/QASDG reserve list. Those allocated to this list were not appointed as GDG or QASDG members, but this list can be used to choose associated members, scientific advisors, or to nominate new members of the GDG/QASDG in case of need.
Scientific advisor	Experts contributing to the GDG/QASDG's work temporarily. They ARE chosen from the reserve list. They don't have voting rights neither do they formulate recommendations.
Simple majority	A single vote more than half of the number of the members who voted (abstentions and absent are not counted).
Steering group	Includes (co)-chairs, vice-chairs, specific coordinators and individual citizens or patients.

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Systematic review team	A multidisciplinary group of systematic reviewers, information specialists, health economists, and qualitative researchers. This team supports the GDG/QASDG by performing the systematic reviews and by developing the evidence profiles used to inform the recommendations.
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Section 2: Functioning of the GDG/QASDG

Article 1

Agenda

1. The draft agenda is proposed by the JRC in consultation with the GDG/QASDG chairs and sent to the members of the group.
2. The agenda shall be adopted by the GDG/QASDG members at the beginning of each meeting.

Article 2

Rules of Procedure

They must not be in contradiction with the [Framework for Commission expert groups](#) and other legislations already in place. Any modification to the Rules is adopted by simple majority.

Article 3

Election of co-chairs of the GDG

1. There are two co-chairs in the GDG: the clinical co-chair and the co-chair of methodology.
2. The election procedure for the co-chairs takes place during the kick-off meeting as follows:
 - The JRC asks for candidates. Members may present themselves as candidates or be proposed by another member.
 - The election process is chaired by the Commission. Each co-chair is voted separately.
 - Prior to the vote, the members presenting themselves as candidates must declare that they are prepared to accept the post of co-chair.
 - The co-chairs are elected by a simple majority of the GDG members voting. In case there is only one candidate for a co-chair, he or she may be elected by acclamation.

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- If none of the candidates receive the simple majority, a second ballot is held between the two candidates with the highest number of votes.
 - In case there is a tie, the role is awarded via a drawn by lot.
3. One co-chair steers each meeting. The co-chairs agree for each meeting which co-chair steers. In case of no consensus, the chairing is agreed within the GDG.
4. If the co-chair relevant to the subject of the meeting is absent, the corresponding vice-chair steers the meeting. If both the co-chair and the vice-chair are absent a member of the group chairs the meeting.
5. If a co-chair withdraws from his/her duty as a co-chair, s/he is replaced by another GDG member chosen according to the procedure previously described for the election of co-chairs.

Election of the chair of the QASDG

1. The election procedure for the chair takes place during the kick-off meeting as follows:
- The JRC asks for candidates. Members may present themselves as candidates or be proposed by another member.
 - The election process is chaired by the Commission.
 - Before the voting session, the members presenting themselves as candidates must declare that they are prepared to accept the post of chair.
 - The chair is elected by simple majority. In case that there is only one candidate, he or she may be elected by acclamation.
 - If none of the candidates receives a simple majority, a second ballot is held between the two candidates having the highest number of votes.
 - In case of a tie, the chair is awarded by lot.
2. The chair steers each meeting.
3. If the chair cannot chair a meeting, the vice-chair does so. If both the chair and the vice-chair are not available for a meeting, a member of the group chairs the meeting.
4. If the chair withdraws from her/his duties as chair, s/he is replaced by another QASDG member chosen according to the procedure described above for the election of chair.

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Article 4

Election of vice-chair of the GDG and QASDG

1. There are a vice-chair of methodology and a clinical vice-chair for the GDG and a vice-chair for the QASDG.
2. The election for the vice-chair(s) takes place in combination with the election of the chair.

Article 5

Replacement of members of the GDG/QASDG

If a GDG/QASDG member resigns, or needs to be replaced due to unmanageable conflict of interests (Col) or impossibility to further contribute to the GDG/QASDG tasks, s/he may be replaced. The (co-)chair(s), in agreement with the group, appoint(s) an associated member from the reserve list, taking into account, whenever possible, the relevant field of competence that needs to be covered. In case the competence is not covered by the reserve list, an external expert/individual is nominated. The document *ECIBC rules: replacing/integration of experts/individuals* details the procedure.

Article 6

Steering group

The Steering group is a restricted group interacting with the JRC for agreeing on the QASDG and GDG strategies.

Article 7

Convening a meeting

1. Meetings of the GDG/QASDG are convened by the JRC in agreement with the (co-) chair(s).
2. Joint meetings of the QASDG with the GDG or other ECIBC groups may be convened to discuss matters falling within their respective areas of responsibility.

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3. Meetings of the GDG/QASDG shall be held at JRC Ispra site, or at least close to it. The location is decided on by the Commission.

4. The meetings are not open to the public.

Article 8

Documentation to be sent to GDG/QASDG members

1. The JRC shall send the invitation for the meetings and the draft agenda to the GDG/QASDG members no later than thirty calendar days before the date of the meeting.

2. The JRC shall send documents on which the GDG/QASDG is consulted to GDG/QASDG members no later than fifteen calendar days before the date of the meeting.

Article 9

Opinions of the GDG/QASDG

1. The GDG/QASDG should strive to adopt its opinions, recommendations or reports by consensus of GDG/QASDG and associated members whenever possible.

2. In the case where consensus is not reached:

2.1 the position of the GDG shall be taken according to voting rules. For the direction of the recommendation (i.e., to recommend for or against an option), a simple majority would be sufficient (a single vote more than half of the votes). For the strength of the recommendation (strong or weak recommendation), a qualified majority of 80% would be needed. For the remaining decisions of the GDG, the threshold of 2/3 for qualified majority applies.

2.2 the position of the QASDG shall be taken according to the voting rules (simple majority and qualified majority of 2/3).

3. Transparency should be ensured. Any minority opinion arising from the group and its supporting argumentation should be reported.

4. With the exception of minority opinions referred to in Article 8.3, individual views, whether expressed orally or in writing by GDG/QASDG members, associated members, scientific advisors or external experts/individuals during deliberations within the working group, shall be considered as confidential. Aggregated opinions are included in the minutes of the meeting (see confidentiality at section 5).

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Article 10

Sub-groups

The GDG/QASDG may, in coordination with the JRC, set up sub-groups focused on specific sections or components of the *European Breast Guidelines* or the *European QA scheme*; such sub-groups shall be disbanded as soon as their mandate is fulfilled.

The GDG sub-groups and task forces are co-ordinated by the chapter co-editors and task forces coordinators; they shall report to the group via the co-chairs/coordinators. In analogy, the QASDG subgroups, task forces and quality dimensions are coordinated by specific coordinators and shall report to the group via those coordinators.

Article 11

Associated members

1. Whenever additional expertise is needed to fulfil the mandate, in agreement with the JRC and the GDG/QASDG, 'associated members' may join the GDG/QASDG to contribute to the work of the GDG/QASDG on specific issues or disciplines.

2. Associated members are invited according to their area of expertise.

3. The associated members are chosen from the GDG/QASDG reserve list. The JRC provides a shortlist of suitable candidates according to the fields of competence declared upon the call. The (co-)chair(s), with the agreement of the GDG/QASDG, propose(s) a candidate to be approved by the GDG/QASDG. The selection process should be properly recorded in order to document its transparency. The document: *ECIBC rules: replacing/integration of experts/individuals* details the procedure.

4. The associated members shall vote on the activities that they have contributed to.

Article 12

Scientific advisors and external experts/individuals

1. Whenever additional expertise is needed to fulfil the mandate on a specific topic, a 'scientific advisor' can be temporarily invited to a meeting.

2. The scientific advisors is chosen from the GDG/QASDG reserve list. The JRC provides a shortlist of suitable candidates according to the fields of competence declared upon the call. The (co-)chair(s) propose(s) a candidate to be approved by the GDG/QASDG. The selection process should be properly recorded in order to warrant its transparency.

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3. If no suitable candidates are identified on the reserve list, the GDG/QASDG may launch a call for 'external experts/individuals'.

4. To appoint external experts/individuals, a specific call for experts/individuals may be organised or experts/individuals may be directly invited in coordination with the JRC.

5. The nature of the scientific advisor's or external expert's/individual's participation depends on the specific needs expressed by the GDG/QASDG. Scientific advisors and external experts/individuals do not have voting rights.

Article 13

Observers

There are no observers (apart from Commission officials) at the GDG/QASDG meetings.

Article 14

Written procedure

1. If necessary, the GDG/QASDG's (or the subgroup's) opinion on a specific question may be delivered via a written procedure. In this case, the JRC sends the GDG/QASDG members the document(s) on which the group (or subgroup) is being consulted.

2 For the acceptance of a written consultation by the GDG/QASDG members, 'silence gives consent' rule applies.

3. The outcome of the written procedure is adopted by consensus. In the case where consensus is not reached, outcome is adopted by simple majority of the concerned members.

4. If a simple majority of GDG/QASDG members requires that the issues proposed for a written procedure should be discussed in a meeting of the group, the written procedure shall be terminated without result and the JRC shall convene a meeting of the group as soon as possible.

Article 15

Minutes of the meetings

1. The JRC, under the responsibility of the (co)-chair(s), prepares draft minutes of the meetings. The draft minutes contain at least the following points:

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- The list of participants and justifications for absence
- Declarations of interests of participants including the relevant details, the action taken and its rationale
- The adopted agenda
- A summary of discussions, including minority opinions and agreed actions
- A record of decisions taken and opinions adopted
- Any abstentions during voting

2. With the exception of minority opinions, the minutes shall not mention the personal position of the members during the group's deliberations.

3. The draft minutes are circulated among the GDG/QASDG members and if applicable, among associated members. Disagreements shall be notified to the JRC

4. The final minutes shall be approved by the GDG/QASDG members. Each GDG/QASDG member is expected to explicitly approve the minutes; the 'silence gives consent' rule is automatically applied after five calendar days from the delivery of the final minutes.

5. The final approved minutes are publicly available.

Article 16

Attendance list

At each meeting, the JRC shall draw up, under the responsibility of the (co-)chair(s), an attendance list of the participants including GDG/QASDG members, associated members, scientific advisors, and external experts/individuals.

Article 17

Correspondence

Correspondence relating to GDG/QASDG shall be addressed to the Commission:

Email: jrc-cancer-policy-support@ec.europa.eu

Postal address

European Commission - Joint Research Centre
 Directorate F – Health, Consumers and Reference Materials
 Health in Society Unit - Healthcare Quality Team
 Via E. Fermi, 2749. TP127
 I-21027 Ispra (VA)/Italy

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Article 18

Protection of personal data

All processing of personal data for the purposes of these Rules of Procedure shall be in accordance with [Regulation \(EC\) No 45/2001](#). Details on management of data at the JRC are defined in the document "PERSONAL DATA PROTECTION" that is provided to GDG/QASDG members and other participants to GDG/QASDG meetings.

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Section 3: Rules and procedures related to independence

Article 1

The GDG/QASDG members and GDG/QASDG associated members shall be nominated in a personal capacity. They shall not delegate their responsibilities to any other person.

Article 2

GDG/QASDG members, associated members, scientific advisors, external experts/individuals are requested to contribute according to the mandate and along their personal capacity. In this line, they shall make in writing a **declaration of commitment** at the beginning of their mandate.

Article 3

GDG/QASDG members, associated members, scientific advisors, external experts/individuals, the European co-operation for Accreditation (EA)/Cochrane Centre Iberoamerican (CCIB) team members, any external reviewer and editor shall make in writing prior to their appointment, annually and at each meeting, a **declaration of interests** indicating any interest which may compromise or may reasonably be perceived to compromise their independence, including any relevant circumstances relating to their close family members. Assessment and management of conflict of interest procedures are handled by JRC in line with European Commission rules.

Article 4

The principle of independence implies in particular, independence from any external economic or political interests, but also from bias related to social, philosophical, ethical or any other non-scientific considerations.

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Section 4: Rules and procedures related to transparency and data protection

Article 1

The GDG/QASDG shall operate with high transparency without prejudice to legitimate requests for confidentiality or the need to safeguard the freedom and scientific integrity of the scientific debate and the independence from external influence. The rules for European Commission expert groups are applied.

Article 2

Applications for access to documents held by the GDG/QASDG is handled in accordance with [Regulation \(EC\) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents](#) (OJ L 145, p.43) and the detailed rules for its application ([Commission Decision 2001/937](#)).

Article 3

The documents of the GDG/QASDG that are published on the Commission's website(s) are subject to respect of confidentiality requirements as well as protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data.

Approved documents are published on the project-dedicated website under the responsibility of the JRC.

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Section 5: Rules and procedures related to confidentiality

Article 1

Availability of preparatory and draft working documents shall be restricted to GDG/QASDG members and associated members, external experts/individuals, JRC and representatives of the Commission's services with competence for a specific question. They shall not be given to third parties unless a different decision is taken in specific cases by the GDG/QASDG or the subgroup concerned in coordination with the JRC in view of a specific need to involve or inform urgently a third party as part of the process to complete the relevant work.

Article 2

GDG/QASDG members, associated members, scientific advisors, external experts/individuals, and the European co-operation for Accreditation (EA)/Cochrane Centre Iberoamerican (CCIB) team members shall sign a **declaration of confidentiality** in line with the rules applied for European Commission expert groups.

Article 3

The obligations accepted signing the confidentiality declaration shall continue after the participation of the individual as GDG/QASDG member, associated member, scientific advisor, external expert/individual, European co-operation for Accreditation (EA)/Cochrane Centre Iberoamerican (CCIB) team member, external reviewer and editor has ceased.

Article 4

Any person contacted by third parties in connection with their participation in GDG/QASDG meetings or any other activity of the GDG/QASDG shall inform the GDG/QASDG and the JRC.

Article 5

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Any person invited to represent the GDG/QASDG shall ensure that s/he conveys the views of the GDG/QASDG, and should use the formats, templates and logos provided by the JRC in order to make visible the attribution of their presentations to the GDG/QASDG.

Article 6

No GDG/QASDG member, associated member, scientific advisor, external expert/individual, European co-operation for Accreditation (EA)/Cochrane Centre Iberoamerican (CCIb) team member, external reviewer and editor shall speak on behalf of the Commission unless officially requested by the Commission to do so.

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