



CANADIAN
BREAST CANCER
ALLIANCE

REAL
ALLIANCE
Terms of
Reference
(draft):

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Type: Nucleus is a standing committee of clinical-academic oncologists and a patient organization. The Nucleus has oversight for national clinical guideline/consensus statement work development where new evidence is reviewed and informing stakeholders for equitable and timely treatment and care for Breast CA patients in Canada.

Vision: Research Excellence with Active Leadership towards one common goal to improve breast cancer outcomes in Canada.

Mission: When research meets the real world, we save lives. REAL members, health policy makers and patients, work together to ensure evidence-based, equitable breast cancer management across Canada.

Goal: The ecosystem leader with most impactful voice of Breast Cancer therapeutic recommendations for timely health policy, funding approvals and adoption to ensure optimal, equitable outcomes for breast cancer patients in Canada.

RESEARCH EXCELLENCE: We review the latest evidence-based research to create best practices and guidelines/consensus for excellence in care.

ACTIVE LEADERSHIP: We empower decision makers to elevate the latest standards of detection, treatment, and care for all breast cancer patients across Canada.

Review Dates: Every three years or as directed by the REAL Nucleus and Breast Cancer Canada

Objectives: Guided by the principals of:

1. The best interests of patients are acted on
2. High quality of health care is advocated by development of national clinical multi-disciplinary guidelines/consensus statements
3. Actionable advocacy outcomes across all stakeholders towards timely implementation



4. Integrity of profession across multi-disciplinary members and patient advocacy groups

Membership:

Executive leadership term of 4 years with 1 renewal

Members of Nucleus term of 4 years with 1 renewal

Members of sub-committees term of 4 years with 1 renewal

Meetings:

1. Standing monthly (virtual) and 1 annual (in-person, 1-2 days, June)
2. More than half of the members
 - a. (e.g. five if the committee has eight or nine members and six if the committee has ten or eleven members).
3. Refer to Annual Program Operations Plan Appendix A

Responsibilities of Members:

1. REAL Annual clinical guidelines/consensus statements and content direction for Annual Report (published every October)
 - a. See Appendix B for Terms of Reference for Evidence Review, Consensus & Guideline Recommendations
2. HTA clinical input submissions (CADTH / INESSS / Provincial Cancer Agencies)
3. Nucleus & Annual Meeting attendance
 - a. Attend committee meetings and actively participate in discussions at these meetings.
 - b. All members are to RSVP their attendance (via calendar invite acceptance) and (if necessary) send their apologies as early as possible prior to the meeting. If unable to attend

committee meetings, members are encouraged to provide their comments on the meeting documents prior to the meeting.

- c. Read and consider agenda documents and minutes of meetings prior to monthly and annual meetings
4. Timely edit comments on manuscripts (HTA submissions, publication manuscripts, abstract submissions / poster or print presentation materials)
5. Time outside of REAL meetings to support action items:
- a. Government relations clinical evidence presentation support to BCC
 - b. Peer REAL guidelines information / education dissemination
 - c. Provincial advocacy with local/provincial Cancer Program for adoption of REAL guidelines; Support the development of local policies
 - d. Development and submission of REAL guideline outcomes abstracts for clinical publications (congress or print)
 - e. Development of stakeholder relations and partnerships e.g. School Medicine Leadership, Provincial Cancer Program Leadership, HTA partners, other support clinicians etc.
 - f. Keep abreast of key issues, including bi-national and international developments

Confidentiality – *this is standard BCC CDA for scientific advisors*

- 1. As a volunteer Nucleus member or sub-committee member for the Breast Cancer Canada (BCC) / REAL Alliance (REAL), I understand that I may have access to confidential information, both verbal and written, relating to clients, donors, participants, volunteers, staff and the organization.
- 2. I understand and agree that all such information is to be treated confidentially and discussed only within the boundaries of my volunteer role with BCC / REAL.



3. I also agree not to discuss these same matters after I have left my volunteer position at this organization. I understand that breach of this agreement shall constitute grounds for and may result in termination of my volunteer status with BCC / REAL.
4. I further understand the above and agree to uphold the confidentiality terms stated in this agreement both during and following my volunteer service with BCC / REAL.

CONFIDENTIAL INFORMATION: Nucleus member and/or sub-committee member, as a Scientific Advisor, agrees that all material, documents and information provided by BCC / REAL, whether prior to or subsequent to the execution of this Agreement, is and shall be considered as confidential information (collectively, the “Confidential Information”) and the sole property of the BCC / REAL. Confidential Information shall include but not be limited to: study abstracts, proposals and protocols, BCC / REAL personnel and researcher lists, BCC and/or REAL strategic plans, research and development partnerships and any other materials or documents provided by BCC or the agents of BCC / REAL to Nucleus member or sub-committee member. Scientific Advisor agrees to hold such Confidential Information in strict confidence for five (5) years after the date of this Agreement and shall only disclose the Confidential Information to third parties having a need for such Confidential Information and who are bound by similar obligations of confidentiality to BCC / REAL. Scientific Advisor shall have no obligations with respect to any Confidential Information that (a) is now or later becomes publicly available through no fault of the Scientific Advisor (b) is obtained by the Scientific Advisor from a third party not under obligation to the BCC / REAL with respect to such Confidential Information, (c) is already in the possession of the Scientific Advisor, as indicated in their prior written records, or (d) is required by any law, rule, regulation, order, decree or subpoena or other judicial, administrative or legal process to be disclosed, provided Scientific Advisor notifies BCC/ REAL with sufficient advance notice to allow BCC to seek an appropriate protective order with regard to the Confidential Information.

REAL Nucleus and/ or sub-committee member as a Scientific Advisor agrees that it will not use or disclose the Confidential Information for any purpose except for the purpose of advisor activities performed with BCC / REAL. Scientific Advisor agrees to use its best efforts to protect the secrecy of, and avoid the disclosure or use of, the Confidential Information in order to prevent it from falling into the public domain or the possession of persons other than those persons



authorized hereunder to have such information. Scientific Advisor also agrees to notify BCC / REAL in writing of any misuse or misappropriation or inadvertent disclosure of the Confidential Information that may come to Scientific Advisor's attention. Scientific Advisor shall immediately return to BCC any Confidential Information upon request. Disclosure of Confidential Information under this Agreement shall create no license, right, interest, or ownership in the Confidential Information. Scientific Advisor's obligations to maintain confidentiality under this Agreement shall remain in full force and effect for a period of five years.

Code of Ethics: Values and principles that underpin the best practice of clinical multi-disciplinary oncology and makes explicit the standards of ethical conduct the Colleges of Physicians & Surgeons expects of its members. These apply to members of committees in their work for the committee and committee members.

Conflict of Interest: Members will be required to declare any potential conflicts of interest that may arise. These are to be recorded in the minutes/reports of the relevant meeting.

Government Relations, Advocacy and Lobbying:

1. Led by BCC
2. Supported by evidence reviews and clinical expertise of REAL Alliance Nucleus Members
3. Government relations and public affairs includes leading all advocacy to federal, provincial and regional government stakeholders (Members of Parliament, Health Canada, Canadian Partnership Against Cancer), health technology authorities (e.g. Canadian Drug Agency, INESSS, provincial technology review boards), payer groups (e.g. PCODR, insurance industry)
4. Media releases and responses will be managed by BCC on behalf of REAL Alliance with notices provided to Nucleus and Nucleus members requested for quotes and short video statements pertaining to REAL Canadian evidence based guidelines.



Administration and Oversight: Breast Cancer Canada

1. Program management with hired agency, liV
 - a. Monthly activities will be conducted by email and virtual meetings; Annual meeting will be in-person every June, when possible
 - b. Project management of monthly & annual meetings and follow up actions, medical writing, document development
 - c. In consultation with the Chair, the agency will prepare and distribute meeting documents, take and distribute minutes of meetings, and prepare and receive correspondence.
2. Cost of Program Operation
 - a. Project management
 - b. Venue and travel for Annual meeting Members & invited participants
 - c. Medical writing
 - d. Publication costs
3. Communications on REAL outcomes
 - a. Public facing communications with BCC PR and social media agencies
 - b. Clinical Guideline Annual Report Publication project management with agency support

APPENDIX A

ANNUAL PROGRAM PLANNING

Description of perpetual calendar of program planning and execution here



APPENDIX B

EVIDENCE REVIEW PROCESS & RECOMMENDATIONS

Terms of reference for evidence review, consensus and guideline recommendations here

Modified Delphi Process

General Principles:¹

- As per accepted standards:
 - Voting on consensus statements will be anonymous
 - Anonymous responses will be made available to respondents without amendment prior to further discussion
 - The process will be iterative allowing adequate discussion on all statements
 - Consensus is pre-established as 75% of respondents selecting 'agree as is'
 - Abstainers are not counted in the denominator
 - A weighted average is not used
 - Voting will be reported in the appendix of the manuscript showing the distribution of responses among available answers as well as the denominator for each statement

Modified Delphi Process:

The process to get to consensus statements for voting is outlined below:

- Develop evidence tables based on relevant literature
- Meet with sub-committee to discuss clinical issues, treatment decisions, available evidence, and best practice
 - Draft preliminary consensus statements for review and voting
 - Circulate among sub-committee and finalize draft statements for voting

¹Savic LC, Smith AF. Anaesthesia 2023;78:247-250

James Madden A practical guide to consensus-based decision making. London, Ontario, 2017



- Distribute consensus to full group for voting
 - Receive voting and summarize comments for review (without amendment)
 - If consensus is not reached, a second round is initiated by the co-chairs.
 - In the case of live discussion, in the subsequent round, each member in turn has an equal amount of time to comment on the issue, without interruption and without comments from the others (although questions may be asked for clarification only, when the person is finished).
 - Co-chairs to summarize the discussion and propose a revised statement
 - Conduct Round 2 of voting statements
 - If consensus is not reached on the second round, co-chairs can elect to report the results as is (indicating that there is controversy or insufficient evidence to achieve consensus) or they may opt for a third round (in the case where further discussion is likely to achieve consensus)
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- Reviews include the patient perspective as represented by PROs data review (where available) and Breast Cancer Canada Nucleus member as a single vote