ROYAL COLLEGE
OF PHYSICIANS AND SURGEONS OF CANADA

Standards for accredited simulation activities (Section 3)

Pre-amble:

Simulation imitates real life situations enabling participants to demonstrate and receive feedback on their application of knowledge (scientific and tacit), clinical reasoning, communication, problem solving and/or their ability to collaborate and work effectively within a health care team. This can be accomplished through role playing, standardized patients, task trainers, virtual simulation, haptic simulation, hi-fidelity simulation or hybrids of any of these examples.

The Royal College values the role of simulation as an innovative formative and summative assessment strategy for postgraduate education and professional development based on its potential to promote interprofessional teamwork and collaboration, enhance performance, and improve quality of care and safety of the health care system.

Each activity that is approved as an accredited simulation-based activity must be reviewed by a Royal College accredited CPD provider and be planned to meet the following accreditation activity standards to be recorded for MOC section 3 simulation credits of the Royal College MOC Program.

Part A: Developing Organization

All accredited simulation-based activities approved under MOC Section 3 must be developed or co-developed by a planning committee consisting of members of a physician organization with a minimum of 2 (two) members as defined by the Royal College.

Physician Organization:
A physician organization is a not-for-profit group of health professionals with a formal governance structure, accountable to and serving, among others, its specialist physician members through:

- *Continuing professional development*
- *Provision of health care and/or*
- *Research.*

This definition includes (but is not limited to) the following groups:

- *Faculties of medicine*
- *Hospital departments or divisions*
- *Medical societies*
- *Medical associations*
- *Medical academies*
- *Physician research organizations*
- *Health authorities not linked to government agencies*
- *Canadian provincial medical regulatory authorities (MRAs)*

This definition excludes pharmaceutical companies or their advisory groups, medical supply and surgical supply companies, communication companies or other for-profit organizations and ventures/activities.

Non-physician Organizations
*Types of organizations that **are not** considered physician organizations*

- *Disease-oriented patient advocacy organizations (e.g. Canadian Diabetes Association)*

- *Government departments or agencies (e.g. Health Canada, Public Health Agency of Canada)*
- *Industry (e.g. pharmaceutical companies, medical device companies, etc.)*
- *Medical education or communications (MEC) companies (e.g. CME Inc.)*
- *'For-profit' on-line educators, publishing companies or simulation companies (e.g. Medscape, CAE)*
- *Small number of physicians working together to develop educational programming*

All activities must be developed by a planning committee that is representative of the target audience. See Part C - Ethical Standards for additional requirements for the planning committee.

Part B: Educational Standards

All approved accredited simulation-based activities must be developed or co-developed to meet each of the following educational standards:

Educational standard 1: Simulation-based activities must be planned to address the identified needs of the target audience within a specific subject area, topic or problem.

Simulation-based activities must be based on an assessment of need including but not limited to changes to the scientific evidence base, established variation in the management or application of knowledge or skills by physicians or teams, variation in the quality of care or health care outcomes experienced by patients. The needs should be determined by considering the identified needs of the target audience or other health professionals. This information will assist in identifying learning objectives, selecting appropriate educational content and format and developing evaluation and assessment strategies.

Educational standard 2: Learning objectives that address the identified needs of the target audience must be created for the simulation-based activity. Learning objectives must be printed on the program, brochure and/or handout materials.

Learning objectives allow learners to determine whether an activity meets their professional learning needs. The identified learning needs of the target audience must be utilized in the creation/development of the learning objectives.

Learning objectives must clearly describe the intent of the simulation-based activity, be written from the perspective of the learner, and express the expected outcomes determined by the planners and faculty.

Educational standard 3: Simulation-based activities must describe the methods that enable participants to demonstrate or apply their knowledge, skills, clinical judgment or attitudes.

Simulation-based activities must provide participants with a strategy to assess their knowledge, skills, clinical judgment and attitudes in comparison to established evidence (scientific or tacit). All simulation-based activities must enable participants to demonstrate

and assess their abilities/competencies across the key areas of the scenario(s), topic(s) or problem(s). Participants must complete all required activities or components of the activity.

Educational standard 4: The simulation-based activity must provide detailed feedback to participants on their performance to enable the identification of any area(s) requiring improvement through the development of a future learning plan.

Providing specific feedback on the performance of the individual or team in achieving the learning objectives and demonstrating the competencies embedded within the simulation scenario(s) enables participants to identify areas for improvement and the creation of a future learning plan. Feedback must be provided based on an assessment of performance as measured against the learning objectives, competencies, and practice standards supported by published evidence. The feedback provided for participants can be completed at the end of the scenario or at a later time. The provision of tools to structure the reflection on performance and time for personal reflection is encouraged.

<u>For online simulation–based activities</u>

1. There must be an established process for how participants will provide responses to online scenarios. For example through the creation of an online response sheet or other web based assessment tools.

2. Participants must be able to receive feedback after the completion of the scenario. This feedback must include references justifying the appropriate answer.

<u>For live simulation-based activities:</u>

1. There must be an established process for how participants will receive feedback on their performance. For example verbally, through the evaluation sheet, etc.

2. Participants must be able to receive feedback after the completion of the scenario. This feedback must include references justifying the appropriate answer.

Educational standard 5: The simulation-based activity must include an evaluation of the learning objectives and the learning outcomes identified by participants.

Accredited simulation-based activities must include a system that provides participants with the opportunity to evaluate the following:

- whether the stated learning objectives were achieved
- relevance of the simulation to the participant's practice
- the appropriateness or relevance of the scenario
- ability to identify CanMEDS professional competencies
- identification of bias
- program design i.e. sufficient instruction time, sufficient practice time, etc.
- whether instructors provide each participant with individual feedback on their performance
- whether instructors evaluate competencies, skills and/or attitudes

The evaluation form should include an open text box where learners may offer further details if content was not balanced, free of commercial or other inappropriate bias.

Part C: Ethical standards

All accredited simulation-based activities must meet the ethical standards established for all learning activities included within the MOC Program of the Royal College. Each of the following ethical standards, derived from the *CMA Guidelines for Physicians interactions with Industry*, must be met for accredited simulation-based activities to be developed and approved for MOC Section 3. For educational activities occurring in Quebec, the Code of Ethics for parties involved in Continuing Medical Education of the Conseil de l'éducation médicale continue du Québec must also be met.

Ethical standard 1: The planning committee must be in complete control over the selection of the scenario(s), topic(s), and author(s) recruited to develop the simulation and cannot be influenced by commercial interests.

Ethical standard 2: **The planning committee must assume responsibility for ensuring the scientific validity, objectivity and balance of the content of the activity.**

The scientific integrity and balance is a joint responsibility between the planning committee and faculty. The planning committee and faculty cannot be influenced by commercial interest(s). No representative from industry may, either directly or indirectly, participate on the planning committee that selects the scenario(s), topic(s), or author(s) for the activity. This includes, but is not limited to, members from pharmaceutical, medical supply, medical education, or other for-profit companies.

Ethical standard 3: The planning committee must disclose to participants all financial affiliations of faculty, authors or members of the planning committee (within the past two years) with any commercial organization(s), regardless of its connection to the topic or themes of the simulation.

The Royal College defines a conflict of interest as a situation(s) that may occur where the personal and professional interests of individuals may have actual, potential or apparent influence over their judgment and actions. There must be policies and procedures place for the planning committee to manage identified conflicts of interest once they are disclosed.

All members of the planning committee, faculty, authors, etc. must:

1. Disclose, in writing, all financial or 'in kind' relationships, regardless of the relevance to the subject being discussed, for the previous two years.

2. It is the planning committee's responsibility to ensure that the program (and any recommendations) must be balanced and reflect the current scientific literature. Unapproved use of products or services must be declared within the program. The only caveat to this guideline is where there is only one treatment or management strategy.

3. All disclosures must be visible and/or displayed at the beginning of the program or included in the written or electronic activity materials.

4. Examples of relationships that must be disclosed include (but are not limited to):
    - Any direct financial interest in a commercial entity such as a pharmaceutical organization, medical devices company or communications firm (" the Organization")

- Investments held in the Organization
- Membership on the Organization's Advisory Board or similar committee
- Current or recent participation in a clinical trial sponsored by the Organization
- Member of a Speakers Bureau
- Holding a patent for a product referred to in the CME/CPD activity or that is marketed by a commercial organization

5. Failure to disclose or false disclosure may require the planning committee modify the planned program.

Ethical standard 4: All funds received in support of the development of this simulation-based activity must be provided in the form of an educational grant payable to the physician organization.

Sponsors may provide support for a simulation-based activity in the form of an educational grant payable to the physician organization or "in kind" support. In kind support can include (but not limited to) logistical support, goods or services to support the educational activities, learning resources or tools.

Additional funds management responsibilities of the physician organization(s) include:

- The physician organization(s) must assume responsibility for the distribution of funds to all faculty, authors, and moderators, including the payment of honoraria, travel, accommodations or hospitality.

- The expenses of participants (or their families) may never be paid by the activity host(s)/planner(s).

- The physician organizations is accountable to ensure that all hospitality and other in kind arrangements are modest.

- Sponsors must be recognized on a general sponsorship page of the program brochure which must be located separately from the educational content.

- Tagging (defined by the Royal College as the linking or alignment of a sponsor's name to a specific educational session within an accredited group learning activity) is strictly prohibited.

Ethical standard 5: **No drug or product advertisements may appear on, or with, any of the written materials (preliminary or final programs, brochures, slides, or advanced notifications) for the simulation-based activity.**

Ethical standard 6: Generic names must be used, or both generic and trade names, on all content related to the simulation-based activity.

It is the responsibility of the planning committee and faculty to ensure that all related content and materials be consistent in their use of just generic names, or both generic and trade name. Therapeutic recommendations for medications that have not received regulatory approval ("off-label" use of medication) must be declared to the participants during the activity and in all materials.

Approved simulation-based learning activities must include the statement.

“This activity is an Accredited Simulation Activity (Section 3) as defined by the Maintenance of Certification Program of The Royal College of Physicians & Surgeons of Canada, and approved by [Accredited Providers’ Name] on dd/mm/yy’ and expires mm/yy. Remember to visit MAINPORT to record your learning and outcomes. You may claim a maximum of # hours (credits are automatically calculated).”