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Technical Committee on Academic Health Centres and Clinical Research

Voting Members
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| Amy Pack | Health Standards Organization          | Program Manager | Montreal, Quebec |
Preface

This is the first draft of the first edition of HSO 13002:2018 (E), Academic Health Centres and Clinical Research. It is intended to align with other HSO health service providers’ standards applicable to healthcare institutions that have an academic mandate. The standard criteria are grouped into two sections based on these functions:

- Education
- Clinical research

The draft standard for public review specifies requirements for these academic health centres to conduct educational and research activities, while delivering quality health services to patients and families. The content was prepared by the HSO Technical Committee on Academic Health Centres and Clinical Research, under the authority of HSO Standards Steering Committee.
**HSO 13002:2018 (E)**  
**Academic Health Centres and Clinical Research**

*Introduction*

HSO's *Academic Health Centres and Clinical Research Standard* aims to promote standardized and effective governance and leadership of education and research activities in Academic Health Centres.

Academic health centres (AHCs) have become important organizations in many healthcare systems nationally and internationally. Good leadership and governance of education and research activities in AHCs lead to more knowledgeable and fulfilled learners (e.g., medical, nursing, and physiotherapy students) – and ultimately, the provision of quality health care to the population at large.

It is important to ensure AHCs function at peak levels, as they are the organizations that perform the majority of publicly funded research (Council of Academic Hospitals of Ontario [CAHO], 2017). In Ontario, CAHO member hospitals conduct 80 percent of publicly funded health research. In terms of education, the American Hospital Association reports that AHCs trained over 100,000 medical and dental residents in 2017 (American Hospital Association [AHA], 2009). Additionally, AHCs also provide care to thousands of patients, some of whom cannot receive the specialized care they need at other hospitals (AHA, 2009).

Generally, AHCs are not-for-profit organizations charged with delivering a tripartite mission of clinical service, teaching, and research, with the overriding purpose of improving the health of and the health care for their local communities and society as a whole (CAHO, 2013; Academic Health Science Centres [AHSC], 2010). Over the past two decades, AHCs have operated in an increasingly competitive environment that has stretched private/public partnerships and demanded social accountability.

AHCs face many challenges, including expansion of education from urban to more “distributed” and community-based sites, emerging models of interprofessional learning and collaborative care, more ambulatory patient care, and curricular renewal and calls for invigoration for the future of health professional education. Emerging opinion emphasizes the role of AHCs in knowledge dissemination and knowledge application. Governments are increasingly seeing knowledge as the key indicator of modernization and wealth creation.

A major theme is the emerging desire for meaningful and transparent measures of AHC performance. Governments are interested in developing policy initiatives to encourage the education of learners in AHCs and translate research into practical use for populations. In Canada, numerous policy documents identify the synergistic impact of AHCs tripartite mission and their broader system role. Nevertheless, the increasing plethora of government policies and uncoordinated funding models and sources may hamper the ability of AHCs to achieve their full potential.
1 Scope

1.1 Purpose
This draft standard for public review specifies requirements for leading academic health centres who marry service delivery, education and research mandates, while maintaining quality across all three and still putting people at the centre of what they do. The standard, once approved by the Technical Committee, will provide:

- **academic health centres** with guidance on how to ensure quality and safety within their unique institutional context;
- **policy makers** a blueprint for the requirements to designate academic health centres in their jurisdictions; and
- **external assessment bodies** with measurable requirements to include in assessment programs.

This standard will not be intended to be used alone, but in conjunction with standards that apply to hospitals and specialized hospitals.

The draft standard for public review is intended to be used for review and consultation by the public only and not fit for the purpose specified above until approval by the Technical Committee. To obtain a final copy, please visit HSO e-store when published or one of our participating Assessment Bodies.

1.2 Applicability
This standard is intended to apply to hospitals and specialized hospitals with an academic mandate, affiliated or integrated with a medical school, and conducting academic and/or commercial human subjects’ research under approved clinical protocols involving patients of the hospital.

2 Reference publications

There are no normative reference publications in this draft standard for public review. Informative reference publications (References) are found in Annex A.

3 Terms and Definitions

**Academic health centre**
An Academic Health Centre (AHC) is organizationally or administratively integrated with an academic institution. The AHC conducts academic and/or commercial human subject research under multiple approved protocols involving patients of the AHC. Many AHCs also perform pre-clinical mechanistic research.

**Clinical research**
Systematic investigation into and the study of materials, sources, and patients to establish facts and reach new conclusions. Clinical research attempts to verifying current knowledge and evaluate the effects and outputs of the health care system on people’s health.

**Education program**
This includes education and training programs (e.g., college, undergraduate, post-graduate, residency, fellowship, graduate, masters, PhD) for all recognized health care professionals practicing in a specific jurisdiction.
Leadership
Refers to the CEO, board members and/or president of the health care and academic institutions.

Learners
Any person following a course of study or continuing education or enrolled in a school, university or other academic institution. Learners include undergraduates, post-graduates, fellows, residents, trainees, apprentices, doctors in training, nurses in training, interns, faculty and staff.

Learning environment
Learning environment refers to the physical locations, contexts, and cultures in which learners learn.

4 Requirements for Academic Health Centres and Clinical Research

EDUCATION

1. The AHC leadership is responsible for ensuring that learners receive education that achieves the goals of the education programs the AHC is supporting.

   1.1 The healthcare institutions and their academic institution partners have a clear agreement defining the roles and responsibilities of each party in relation to the clinical education environment.

   Guidelines
   The agreement should detail which party is accountable for which aspects of the delivery of care as well as research, education, and support for learners. Such an agreement is often called an affiliation agreement. It designates which activities are subject to academic institution authority, which are subject to the health care institution authority, and which are subject to agreement by both. The responsibilities of the partners should be clearly defined.

   1.2 The AHC encourages partnerships with external agencies.

   Guidelines
   Partnerships may be created through collaboration with external bodies using formal or informal links.

   1.3 Learners are appropriately supervised in their clinical, educational, and/or research activities.

   Guidelines
   The AHC provides supervision, in partnership with the academic institution, for each type of learner, at the required frequency and intensity.

   1.4 Appropriate operational support is clearly identified in the AHC organizational chart for the delivery of education activities.

   Guidelines
   Support for education in the AHC is coordinated through a defined operational and management structure.
1.5 The AHC ensures that required evaluation is provided for all learners.

Guidelines
Appropriate evaluation may be provided by the AHC or the partner academic institution.

1.6 The AHC provides learners with an institutional orientation.

Guidelines
As a host institution, the AHC should ensure that any learner in the institution receives adequate orientation, identification passes, and access to necessary areas.

2. Technology and resources are provided to facilitate education.

2.1 Appropriate resources are made available for staff and learners.

Guidelines
The AHC provides the necessary space and other needed resources without jeopardizing the standard of patient care. Appropriate resources are determined in the affiliation agreement. Resources may include financial, physical space, equipment, and infrastructure support.

2.2 Learners have access to current technology and information resources.

Guidelines
Learners have access to the appropriate resources (library, internet connectivity, materials) and information on evidence-based practices, including access to online journals, internet (Wifi), and simulated education tools where appropriate.

3. The role of the faculty and staff in the delivery of the education programs is clearly defined.

3.1 The AHC has a clearly outlined reporting structure related to the delivery of education programs.

3.2 The AHC has clearly defined roles related to the delivery of education programs.

Guidelines
In the case of faculty who are considered staff, the percentage of time protected for teaching should be clearly specified.

4. Policies and procedures that learners must follow are clear.

4.1 Learners and trainees comply with the policies and procedures of the AHC.

Guidelines
The learners and trainees provide care within the quality and patient safety parameters of the hospital. Patient care should be a priority.

4.2 Staff and learners provide compassionate, patient-centred care.

**Guidelines**
Compassionate care is defined in the quality and patient safety parameters of the AHC.

5. **The AHC leadership must ensure that they are efficiently functioning via the use of assessments and a supportive environment.**

5.1 A mechanism is in place for learners to confidentially evaluate the quality of educators.

**Guidelines**
Faculty assessment includes an evaluation of their professionalism by learners and peers.

5.2 A mechanism is in place for learners to confidentially evaluate the quality of the learning environment.

**Guidelines**
The mechanism is organized through the AHC or through the partner academic institution. To determine the quality of the learning environment, the learners must have a way of assessing the space and support provided.

5.3 A mechanism is in place for dispute resolution.

5.4 The AHC provides educators with appropriate training qualification and support in their education role.

**Guidelines**
The AHC leadership supports its educators through training, education research, and technical and laboratory support. Education in the AHC could be provided by staff or by qualified patients as educators.

5.5 The AHC maintains or updates training and support within appropriate time periods.

6. **Learning should occur within an interprofessional environment.**

6.1 The AHC promotes an interprofessional learning environment.

**Guidelines**
The AHC removes barriers to interprofessional education by encouraging cooperation among professional schools and discipline leaders. Learning takes place in an interprofessional, team-based educational environment that may be achieved through, for example, joint rounds, multiprofessional seminar series, or co-learning strategies.
6.2 The AHC regularly assesses the success of the interprofessional environment.

**Guidelines**
The assessment must ensure respect is shown to the partners involved in the interprofessional environment.

**CLINICAL RESEARCH**

7. When performing research with human participants, there must be a clear understanding of who is accountable and for which aspects of the research.

7.1 The AHC leadership ensures safe practice for all human research participants.

**Guidelines**
The AHC leadership must establish a structure, body, or qualified individual to ensure safe practice for all human research participants by overseeing and evaluating research projects conducted in the AHC. The AHC leadership is accountable for the protection of human research participants.

7.2 All parties involved in research conducted in the AHC act in accordance with clearly defined responsibilities.

**Guidelines**
The parties may include researchers, leadership, and patients (as collaborators and/or as research participants). When performing research with human participants, there must be a clear understanding of who is accountable and for which aspects of the research. Such responsibilities follow national and international guidelines on ethical research.

7.3 The AHC clearly defines the accountability of the principal investigator.

**Guidelines**
The principal investigator is the primary individual responsible for preparing, conducting, and administering a research grant, cooperative agreement, training or public service project, contract, or other sponsored project in compliance with applicable laws and regulations and institutional policy governing the conduct of sponsored research.

8. The AHC leadership must ensure all parties follow research standards and fulfil their job requirements.

8.1 The AHC has a strategic plan detailing its research priorities.

**Guidelines**
The strategic plan must be based on community needs and updates in health knowledge. This does not preclude the emergence of new research directions that are not in the plan. New ideas should be welcomed and given a chance to be proven. Research and education must be emphasized in the organization’s strategic plan.
8.2 The AHC leadership provides an orientation to research staff that includes a review the strategic plan and research priorities.

8.3 The AHC leadership is responsible for ensuring research is delivered in alignment with the mission, vision, and strategic goals of the AHC.

8.4 The AHC leadership is provided with training on the requirements regulating research and quality control.

8.5 The AHC has a committee or designated qualified individuals to ensure the ethical conduct of researchers.

**Guidelines**
The AHC must verify that the principal investigator and other researchers have been vetted for research by a committee of qualified individuals. The assessment includes a review of researcher CVs and other certifications. Performance reviews are used to assess the conduct of research staff.

8.6 The AHC demonstrates leadership in reciprocal learning with end users.

**Guidelines**
Knowledge is being translated to best practice by way of benchmarking, for example.

9. The AHC must adhere to all research regulations to ensure research is being conducted in an ethical manner.

9.1 The AHC leadership abides by a process to provide initial and ongoing review of all human participant research.

9.2 Researchers follow the policies and regulations of their jurisdiction.

**Guidelines**
Approval and initiation of clinical research studies is as efficient as possible while following policies and regulations.

9.3 The AHC leadership identifies and manages conflicts of interest with research conducted in the AHC.

**Guidelines**
The AHC manages potential conflicts of interest, particularly commercial conflicts of interest, as they pertain to the teaching and research activities conducted in the AHC. There should be a mechanism to ensure transparency and access to conflict of interest recourse.

9.4 The AHC establishes and implements a standardized process for informed consent.

**Guidelines**
The details of consent must correspond to the risks incurred by the research project.

9.5 The AHC establishes and implements a standardized process for permission to contact.

Guidelines
Permission to contact may be implemented differently in AHCs depending on the use of electronic health record (e.g. Meditech, EPIC) and the online registration process. The permission to contact process should include a notification mechanism, a process to confidentially store patient information, and the patient’s choice to opt out of being contacted for future research studies.

10. The AHC makes information on how to participate and be engaged in research available to participants and other community members while ensuring informed consent and patient safety.

10.1 Participants are able to make informed and voluntary decisions about participating in research.

Guidelines
Participants (including learners and trainees when they are participating in education research) are involved and engaged throughout the research project’s lifetime.

10.2 The AHC provides information about how families and patients can gain access to research results.

Guidelines
Families and patients are informed of how to access research outputs if they desire access.

10.3 The AHC shares research findings and processes with the rest of the AHC as well as with the public.

Guidelines
The AHC must ensure research findings are shared in a timely and appropriate fashion.

The AHC must create a culture of transparency by reporting key research information, such as percentage of patients involved in research, number of projects, amount of funding, number of researchers, and number of published articles. These should be reported on a regular basis.

Disclosure of research activity should be a regular event and should be planned and announced in advance. Research projects should be formally registered in countries where formal registration is required. Positive and negative results should be reported. Publishing peer-reviewed publications should be encouraged.

Additional knowledge transfer and exchange should be encouraged, such as direct engagement with the public about the research results.
11. The research environment must include all resources needed to conduct quality research in an efficient manner.

11.1 The AHC must be equipped with all resources required for the research program.

Guidelines
The AHC provides core facilities that bring together appropriate equipment, instrumentation, methodologies and/or expertise that are crucial to the success of fundamental (pre-clinical) and other health research activities. Research resources may be provided by both the AHC and the academic institution. In addition, research resources may be provided by granting agencies and industry, with care being taken to avoid conflicts of interest.

The use of information technologies enables health research in the AHC.

11.2 The AHC leadership maintains procedures to prioritize research resource allocation according to the strategic plan.

Guidelines
The procedures should be transparent, fair, efficient, and comprehensive.

12. Interprofessional collaboration should be established, encouraged, and promoted in the research environment.

12.1 The AHC actively supports interprofessional research.

Guidelines
The AHC should support interprofessional teams to collaborate on innovative research, such as having clinical, fundamental, and social-science researchers working together.

The AHC must lead the development of collaborative research partnerships with patients, institutions, agencies, communities, and industries.
Annex A - References


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