

2017-2018 ANNUAL REPORT



INNOVATION IN ETHICS

Centre universitaire
de santé McGill



McGill University
Health Centre

muhc.ca/cae

Centre d'éthique appliquée
Centre for Applied Ethics

TABLE OF CONTENTS

Executive summary	4
1. Championing MUHC ethics	6
2. Ethics consultation services	9
3. Research ethics review	12
4. Policy development	14
5. Capacity building	16
6. Professional development	18
7. Strategic planning, evaluation, quality improvement and accountability	20



Dr. Eugene Bereza, MD CM, CCFP

Director, Centre for Applied Ethics



Dr. Eugene Bereza is physician and bioethicist with a background in biology, literature, music therapy and palliative care. He studied medicine and completed his residency in family medicine at McGill University before pursuing a post-doctoral fellowship at the MacLean Center for Clinical Medical Ethics at the University of Chicago.

In 2001 he was appointed by the federal Minister of Health as ethicist to the Canadian Council for Donation and Transplantation.

In 2010, Dr. Bereza was awarded the Canadian Medical Association's Dr. William Marsden Award in Medical Ethics in recognition of his contribution and leadership role in Canadian medicine.

In 2015, he was elected President of the Canadian Bioethics Society.

Dr. Bereza has been formally consulted on more than 3,000 clinical cases.

A former Director of the Biomedical Ethics Unit at McGill's Faculty of Medicine, he teaches graduate seminars in bioethics to students in medicine, law, philosophy, and religious studies.

Dr. Bereza has extensive experience in health policy development. He has been Chair on the Committee of Ethics for the Quebec and Canadian Medical Associations, testified before Canadian Senate committees, Quebec Commissions and the Supreme Court of British Columbia on issues that included end-of-life care, reproductive technologies, and reasonable accommodation in health care.

He is currently Director of the newly created MUHC Centre for Applied Ethics, where he has instituted an innovative program for an integrated, multi-disciplinary, professional approach to applied ethics.

Marie Hirtle, LL.B., LL.M.

Manager, Centre for Applied Ethics



Marie Hirtle is a lawyer with graduate training in law and ethics. She specializes in health issues ranging from community-based health and social services, to tertiary and quaternary care, biomedical research and public health. As the current Manager of the Centre for Applied Ethics at the McGill University Health Centre (MUHC), she leads a team of ethics professionals

who provide clinical, organizational and research ethics services to the MUHC community. With 20 years' experience on REBs, she is current Chair of the MUHC Research Ethics Board (REB) as well as of the Central REB of the Québec Ministry of Health and Social services. She was recently appointed to the FRQ Working Group on Artificial Intelligence.

She has extensive expertise in genetic and health data research, biobanking, clinical trials, ethics review mechanisms and research ethics regulation, privacy and privacy impact assessments. Marie co-developed online training material for provincial and international participants. She has authored several publications and commissioned reports. She received her Masters' in Law from *Université de Montréal* and was awarded a visiting scholar fellowship from Stanford University, California, in their Program in Genomics, Ethics and Society.

EXECUTIVE SUMMARY

THE 2017-2018 ACTIVITIES OF THE CENTRE FOR APPLIED ETHICS AT A GLANCE

91

activities

—
CHAMPIONING
MUHC ETHICS

51

activities

—
ACADEMIC
ACTIVITIES

1 340

consultations

—
ETHICS CONSULTATION
SERVICES

761

submitted projects

—
RESEARCH
ETHICS REVIEW

7

policies

—
POLICY
DEVELOPMENT

49

activities

—
CAPACITY
BUILDING

94

trainings

—
CAE PROFESSIONAL
DEVELOPMENT

43

actions planned

—
STRATEGIC PLANNING, EVALUATION,
QUALITY IMPROVEMENT AND ACCOUNTABILITY

INTRODUCING THE CENTRE FOR APPLIED ETHICS (CAE)

The Centre for Applied Ethics (CAE) offers the McGill University Health Centre (MUHC) community integrated services in clinical ethics, research ethics, ethics of innovative care, and organizational ethics. As such, the CAE is a pioneer in Canada in integrating all elements of applied ethics within a university teaching hospital under the auspices of a single ethics centre. Created on April 1, 2014 with the mandate to develop an innovative approach to respond to the ethics needs of the MUHC, the CAE Director was appointed in September 2014 and the CAE team was formed over the subsequent three years.

The CAE plays a leading role in developing a culture of ethical decision-making at the MUHC by virtue of its unique, integrated approach to applied ethics. This rigorous approach extends to multiple initiatives, including ethics support services for patients, families, healthcare professionals and researchers, institutional support in policy development and implementation of ethics frameworks for decision-making, and actions geared towards capacity building in the MUHC community. The expertise developed by the CAE is now recognised locally, nationally and internationally.

This Annual Report is a first for the CAE. While it focuses primarily on activities completed between April 1, 2017 and March 31, 2018, it also includes selective information from previous years.

The figure below depicts seven core activities of the CAE situated within the four applied ethics domains. The current report is structured in relation to these.

THE EXPERTISE DEVELOPED BY THE CAE IS NOW RECOGNISED LOCALLY, NATIONALLY AND INTERNATIONALLY

FIGURE 1. ACTIVITIES OF THE CAE WITHIN THE FOUR DOMAINS OF APPLIED ETHICS



1. CHAMPIONING MUHC ETHICS

91
activities

The expertise developed by the CAE is recognised within the patient, academic, professional and government communities. Between 2017 and 2018, the CAE completed a total of 91 activities that testify to its visibility.

TABLE 1. CAE ACTIVITIES RELATED TO CHAMPIONING MUHC ETHICS 2017-2018

TYPES OF ACTIVITIES	NUMBER
Promotion of ethics services to patients/families (outreach)	4
Academic activities	51
Championing MUHC ethics expertise within the health and social services system	25
Championing MUHC ethics expertise at government levels	11
Total	91

Promotion of ethics services to patients/families (outreach):

CAE staff participate in various outreach activities aimed at increasing ethics knowledge and awareness in the patient community. This includes hosting publicly accessible conferences and lectures as well as participating in media interviews. The CAE also has a regularly updated website with information that is accessible to the public at muhc.ca/cae.

For example, the CAE director regularly participates in media interviews (e.g. CTV, CBC) on topics such as Medical Aid in Dying and patient refusal of treatment. This media presence allows the CAE to communicate important ethical considerations to our community of patients and families. This may lead not only to a better public understanding of important ethical issues in medicine, but ultimately enable MUHC patients to make more informed healthcare decisions.

51

activities

Academic activities: The CAE makes a significant contribution to our academic mission by collaborating in activities at McGill's Faculty of Medicine. The academic responsibilities of CAE staff are presented below. Together, CAE staff participated in over 50 academic activities in 2017-2018.

- **Teaching the Bioethics Practicum** course offered in the Master's Specialization Program at the Biomedical Ethics at McGill
- **Giving numerous guest lectures and seminars** in biomedical ethics
- **Supervising graduate research projects** and thesis/dissertations at the Master's and PhD levels
- Participation in the improvement process of the Master's program in biomedical ethics
- Participation in academic research
- Providing keynote speeches, oral presentations and poster presentations at academic conferences
- Publication of articles in peer-reviewed journals.

For example, in collaboration with investigators from the CISSS Laval, the CAE completed research on requests for Medical Aid in Dying (MAiD) at two university-based hospital centres in Quebec. This research project provides insight into how the regulatory framework for MAiD is being followed by frontline healthcare workers and has important implications for clinical practice. Research results were presented to the MUHC group tasked with overseeing MAiD requests at the MUHC ("Groupe Interdisciplinaire de Soutien" or GIS). Results were also presented at an international conference on End-of-Life care in Halifax in 2017 and the paper was recently submitted for publication to the Canadian Medical Association Journal.

The CAE also **has partnerships** with other groups at McGill University including the Centre for Genomics and Policy, the Ingram School of Nursing and the Department of Family Medicine. CAE staff also occasionally collaborate with other faculties at McGill as well as other academic institutions. Finally, CAE staff are participating members of different professional associations including the Canadian Bioethics Society (CBS) and the Canadian Association of Practicing Healthcare Ethicists (CPAHE).

For example, the CAE organized the 28th Annual Canadian Bioethics Society (CBS) conference in May 2018. The conference was a tremendous success, with over 300 participants attending from across Canada. Renowned keynote speakers included Véronique Hivon, (former Quebec Minister of Social Services and Youth Protection), Dr. Samia Hurst (Geneva University Medical School and Hospitals) and Michelle Mullen (University of Ottawa Children's Hospital of Eastern Ontario).

Championing MUHC ethics expertise within the health and social services system:

The CAE is often consulted by healthcare institutions and professional orders in Quebec. This includes many *centres hospitaliers universitaires* (CHU), *centres hospitaliers* (CH), *centres intégrés universitaires de santé*, the *Collège des médecins du Québec*, etc. which contact the CAE seeking clarification on best practices in applied healthcare ethics.

For example, in 2017-2018, the *Centre hospitalier de l'Université de Montréal* (CHUM) and CHU Sainte-Justine's requested information from the CAE about its newly developed practices for research ethics review of early phase clinical trials. The three institutions now collaborate regularly with the goal of harmonizing research ethics review practices and procedures. This partnership draws extensively on previous work of the CAE and incorporates best practices from the CHUM and Sainte-Justine.

Championing MUHC ethics expertise at government levels:

The CAE provides numerous formal opinions and sits on ministerial committees and government taskforces responsible for updating and developing standards of care, health policies, laws and regulations.

In 2017-2108, the CAE provided its expertise on the following issues:

Health Canada:	Tri-Council Policy Statement II (TCPS 2)
Fonds de recherche du Québec (FRQ):	Artificial intelligence and research ethics
Fonds de recherche du Québec (FRQ) et Ministère de la santé et des services sociaux (MSSS):	Harmonizing clauses for informed consent templates;
Health Canada, Canadian Clinical Trials Coordinating Centre (CCTCC) and the Canadian Institute of Health Research (CIHR):	Accreditation of REBs.
Institut national d'excellence en santé et en services sociaux (INESSS):	"Goals of care/levels of intervention" consultations on drafting of a policy and form for dissemination in all healthcare institutions in Quebec;
MSSS: Comité central d'éthique de la recherche (CCER):	The CAE manager was appointed president in March 2018;
MSSS: Commission sur les soins de fin de vie:	The CAE Director was nominated by the <i>Bureau de collaboration interuniversitaire (BCI)</i> to become a member.

Letter from Martine Alfonso, interim President and Executive Director, MUHC and poster of the 28th Annual Canadian Bioethics Society (CBS) Conference, held in May 2017.



It gives me great pleasure to welcome you to the 28th Annual Conference of the Canadian Bioethics Society. Most of us are aware of how challenging the provision of high quality health care continues to be, but fewer of us can fully appreciate the challenges and consequences faced by the most vulnerable members of our society. As we continue to respond to evolving health care reforms and the focus on budget constraints, it is more important than ever to keep the values that have been the foundation of our vision for health care first and foremost in our hearts and minds.

It is for this very reason that the McGill University Health Centre (MUHC) created its own Centre for Applied Ethics in 2014. It is for the same reason that the MUHC committed to hosting this important national dialogue. I wish you all a very successful exchange of ideas and sharing of creative solutions.

Martine Alfonso
Interim President and Executive Director
McGill University Health Centre

Canadian Bioethics Society 2017 Annual Conference

May
24th - 26th
Montréal

Falling Through the Cracks: Equity, Ethics and the Challenges of Vulnerability

Exploring the theme of
**intersecting
vulnerabilities**
in healthcare today

- 140+ speakers
- 4 plenary sessions
- 4 half-day workshops



**Act respecting
end-of-life care &
Medical aid in dying**

Me. Véronique Hivon
National Assembly Member
for Joliette, Official Opposi-
tion critic for end-of-life care



**Understanding vulner-
ability to design appro-
priate protections**

Dr. Samia Hurst
Bioethicist, Geneva University
Hospitals, Lausanne University
Hospitals, Geneva University

Health and justice for Inuit Children and Youth

Michelle Mullen, MHP PhD
Associate Professor of Pediatrics, Uni-
versity of Ottawa, Bioethicist, Children's
Hospital of Eastern Ontario



**Dr. Nicolas
Bergeron**
President,
Médecins du
Monde



**Ms. Jenny
Jeanes**
Coordinator,
Action Réfugiés
Montréal



**Dr. Vania
Jimenez**
Founder,
Maison Bleue

Hosted by:
Centre universitaire
de santé McGill



Canadian
Bioethics
Society



Register and see complete agenda at : cbs-scb.ca

2. ETHICS CONSULTATION SERVICES

Professional ethics consultants at the CAE provide ethics consultation services to members of the MUHC community facing challenging situations in which there are conflicts of values. CAE consultation services are available for each of the four ethical domains.

The CAE is aligned with the vision, mission and values of the MUHC. It recognizes the moral heterogeneity of Quebec's pluralistic society. Its priority is to support all stakeholders when confronting challenging ethical issues, and rejects the view of an ethics expertise based on a single, over-riding moral framework.

In 2017-2018, the CAE completed approximately 1,340 consultations in clinical, research, innovative care and organizational ethics¹. Two professional ethics consultants are available 24 hours a day, seven days a week. Typically, they can respond to calls within the hour. A summary table outlining the number of consultations and key themes is presented at the end of this section.

Clinical ethics: In 2017-2018, CAE ethics consultants responded to approximately 30 consults on topics as varied and complex as end-of-life care, goals of care and levels of intervention, pre-implantation genetic diagnosis, elective, late termination of pregnancy and differentiating innovative care from standard of care or research. The CAE clinical ethics consultation service is unique in its commitment to:

- 1) **Innovation:** CAE staff stay informed about standards of care, evolving political and legal frameworks, and recent advances in medicine. They are constantly striving to adapt, innovate and develop leading practices based on the latest evidence and peer review.
- 2) **Quality:** CAE ethics consultants have graduate level training in bioethics in addition to years of experience as practicing professionals. The CAE Director has participated in over 3,000 clinical ethics consultations over a period of 30 years. He now assumes a mentorship role to other CAE staff, providing feedback and oversight. Additionally, the CAE is exploring innovative approaches to developing appropriate metrics for ethics evaluation (see section 7).
- 3) **Impact:** Ethics consultation has two primary goals. It has the immediate effect of facilitating analysis and resolving complex cases. Ultimately, it empowers healthcare teams to make better decisions.

1 340
consultations

¹ This number is a conservative estimation of the real number of consults conducted in research ethics.

For example, in 2017, a team of healthcare professionals at the MUHC consulted the ethics service when they had questions about the most appropriate interpretation of a best interests standard for a young patient who was refusing, with the support of the family, medically recommended treatment. The ethics consultant not only provided guidance to the treating team facing this difficult situation, but her written ethics consultation and expert testimony also informed the final decision of the Superior Court of Quebec on this challenging case.

Ethics of innovative care: The CAE has taken a leadership role in developing an MUHC framework and policy on innovative care (see section 3). To date, the Centre has participated in a few consultations on the innovative care for patients at the MUHC where the ethical analysis has focused primarily on scientific validity, unique aspects of informed consent and elements of distributive justice.

Research ethics: The consultation process helps improve the quality of research studies being developed and ensures compliance with regulatory requirements. Research ethics consultation is part of the day-to-day work of the CAE, which completed over 1,300 research ethics consultations in 2017-2018.

Organizational ethics: The most recent addition to CAE consultation services, organizational ethics, consists of providing ethical analysis and recommendations for dilemmas that have a significant impact on the institution as a whole, or which may include administrative or management-related ethics issues. In 2017-2018, the Director of the CAE provided six organizational ethics consults on topics including distributive justice in the allocation of scarce resources and the (mis)alignment of proposed initiatives with the institutional mission.

For example, in 2016, the CAE made a major contribution to the “*Cartographie des services spécialisés et surspécialisés*” exercise at the MUHC. The President and Executive Director of the MUHC tasked the CAE with the mandate of providing an organizational ethics decision-making framework that could be used as a tool by the Medical-Administrative Leadership Table (MALT). The proposed framework was based on the alignment of mission, vision and values of the MUHC with principles of distributive justice and a clear and structured decision making process.

In addition, a new structure supporting the organisational ethics initiative has been developed since 2016. The Organisational Ethics Advisory Council (OEAC) has the mandate to prepare and present recommendations to the Associate President and Executive Director regarding clinical and administrative issues that have important organisational and institutional repercussions.² The role of the CAE is to provide the Council with an initial analysis and support it in its deliberations.

² Preliminary version of the OEAC Terms of reference, April 2018, p. 1.



TABLE 2. NUMBER OF ETHICS CONSULTATIONS IN 2017-2018 ACCORDING TO ETHICS DOMAINS AND KEY THEMES

CLINICAL ETHICS		ETHICS OF INNOVATIVE CARE		RESEARCH ETHICS		ORGANIZATIONAL ETHICS	
End of life/ level of care	11	Scientific validity	1	Confidentiality	Approx. 1,300	Distributive justice/ Prioritization	2
Elective late-termination of pregnancy	7	Informed consent	1	Conflict of interest		Alignment between the institutional mission statement, its obligations, and standards of practice	2
Best interest/ decision making capacity	6	Distributive justice/ resource allocation	1	Biobanks		Professional integrity and safe working environment	1
Other	6	Other	1	Multicentre projects			
Other				Other			
Subtotal	30	Subtotal	4	Subtotal		Subtotal	6
Grand total				1,340			

Dr. Eugene Bereza, Director of the Centre for Applied Ethics (CAE), recognized the enormous generosity of REB members and senior administrators who contribute their time and expertise in conducting high quality reviews of research protocols.



3. RESEARCH ETHICS REVIEW

761
projects

The MUHC REB is designated under Article 21 of the Civil Code of Quebec and its Chair is directly accountable to the MUHC Board of Directors. The CAE staff coordinates and oversees all research ethics related work at the MUHC.

The CAE distinguishes itself by the significantly increasing **number** of studies it reviews each year, the modernization of the review process, as well as on the diverse areas of **expertise** it develops to address rapidly evolving research methodologies, issues, and tools:

- In 2017-2018, 761 new projects were submitted to the five panels of the MUHC REB (see table below). **This is twice as many projects as any other REB in Quebec.** In total, 2,182 studies were being conducted as of March 31, 2017.
- The research studies evaluated by the MUHC REB cover a multitude of health issues and make the MUHC one of **the most innovative university health centres in the world.** This reality demands that members of the MUHC REB have scientific, clinical and ethics expertise as well as the ability to adapt to new and emerging issues.

TABLE 3. NUMBER OF PROJECTS RECEIVED PER MUHC REB PANEL IN 2017-2018

PANELS OF THE MUHC REB	NUMBER OF NEW PROJECTS
Pediatrics	131
Neurosciences/psychiatry	104
Clinical trials 1	101
Clinical trials 2	224
Cells, tissues, genetics, and qualitative research	201
Total	761

The MUHC REB was the first in the McGill University Integrated Health Network (RUIS-McGill) to adopt *Nagano* – a **computer software program designed** to manage the entire process of research ethics evaluation and approval. The CAE is constantly in the process of adapting and improving the Nagano platform to better meet the specific needs of the MUHC research community. The CAE also provides continuing Nagano training for users (CAE staff, research teams, staff in the contracts office, pharmacy department, etc.). Nagano has also made the research ethics review process entirely electronic, reducing the resources required and improving the overall **efficiency** of the REB.

The coordinators of the five REB panels provide **ongoing support** to the research community by responding to frequent requests for information on the research ethics submission and review process. The REB coordinators respond to several thousand questions a year and MUHC researchers regularly express **satisfaction** with the quality and efficiency of this support.

In the pursuit of achieving **excellence** in research ethics, the CAE has implemented an **evaluation and quality improvement program** for research ethics review. This program is presented in greater detail in section 7 of this report.



For example, Dr. Vassilios Papadopoulos, Director of the Research Institute, gave a speech in 2016 on the value of the work performed by the members of the REB; pointing out that we could not conduct as much research as we do without them.



4. POLICY DEVELOPMENT

7 policies

As a university teaching hospital offering tertiary and quaternary care to thousands of patients, the MUHC is continually faced with **new and complex realities**. This context makes the development of clear and well justified institutional policies¹ essential. CAE staff ensure that institutional policies are ethically justifiable according to substantive and procedural ethical principles. The CAE plays a central role in both the **development of new institutional policies and in the revision of existing policies**.

CAE ethics consultants participate in numerous committees and working groups with various mandates and assist in the development of clinical, innovative care, research, and organizational policies. Members of the CAE **take a proactive role in developing and drafting various policies and procedures**. Since its creation in 2014, the CAE has played a significant role in the development of 17 policies, the list of which is presented below. In 2017-2018, the process of writing seven of these policies was underway.

The MUHC has two **clinical ethics committees**, one for pediatrics and one for adult medicine. These interdisciplinary committees, which report to the Council of Physicians, Dentists and Pharmacists (CPDP), have as their primary objective to ensure that the updating of clinical policies is supported by a strong normative framework that takes into account and proactively addresses any substantive ethical issues. CAE ethics advisors assume a leadership role on each of these committees, often leading the discussion and bringing up important ethical issues.

In recent years, several **Ethics Working Groups (EWGs)** have also been created on specific topics, for example, medical assistance in dying and preimplantation genetic diagnosis. These groups are coordinated and often led by a CAE ethics consultant. EWGs focus on creating policies that include an ethical dimension. In total, almost a dozen EWGs were formed between 2014 and 2018.

¹ The term “policy” is used broadly and may include regulations, standards, guidelines, and procedures.

For example, given the growing importance of biobanks and databases for health research, an EWG was established in 2016 to clarify the MUHC's approach. An ethics consultant coordinated and guided the working group and took the lead in drafting a biobank and database policy. This included revising policy drafts based on comments from the working group and soliciting feedback from key stakeholders, including a group of approximately a hundred researchers from the MUHC. The new "Policy on the Use of Biobanks and Databases for Research Purposes" is currently awaiting approval from the MUHC Board of Directors.

TABLE 4. POLICIES THE CAE HAS CONTRIBUTED TO SINCE ITS CREATION (2014-2018)

POLICY TITLE

1. Policy on end-of-life care (MUHC)
2. Policy on pre-implantation genetic diagnosis
3. Pediatric/neonatal non-emergent tracheostomy: decision-making.
4. Policy on neonatal resuscitation
5. Tri-Council Policy Statement II, Panel on Research Ethics (response to the public consultation by Health Canada)
6. Policy on cloud-based storage solutions for research purposes
7. Information and Consent Form for early phase clinical trials (MUHC)
8. Tri-Council Policy Statement II, Panel on Research Ethics (response to the public consultation by Health Canada)
9. Goals of care and levels of Intervention
10. Clinical research regulations (response to the public consultation by Health Canada)
11. Policy on the Use of Biobanks and Databases for Research Purposes
12. Policy on data safety
13. REB Standard Operating Procedures (several SOPs developed or updated, others in progress)
14. Ethics conceptual framework (in progress)
15. Research ethics regulatory framework (in progress)
16. Oversight of quality assurance initiatives (in progress)
17. Framework on innovative care (in progress)

5. CAPACITY BUILDING

49
activities

Operating on the principle that ethical decision-making is everyone's responsibility, the CAE plans and implements activities aimed at **building ethics capacity**. These activities generally consist of disseminating ethical decision-making tools, providing information on ethical "hot topics", teaching methods of ethical analysis and publicizing the services of the CAE and how to access them.

In 2017-2018, CAE staff organized 49 ethics capacity building initiatives (see table below). These initiatives included **information and training sessions, writing and distributing memos, and creating tools** for various MUHC groups such as physicians, nurses, medical residents, research teams, managers, senior administrators, and patients/families.

TABLE 5. ETHICS CAPACITY BUILDING INITIATIVES LED BY THE CAE IN 2017-2018

ACTIVITY	NUMBER OF ACTIVITIES
Information and training sessions	32
Memos	9
Tools	6
Information sessions/general presentations	2
Total	49

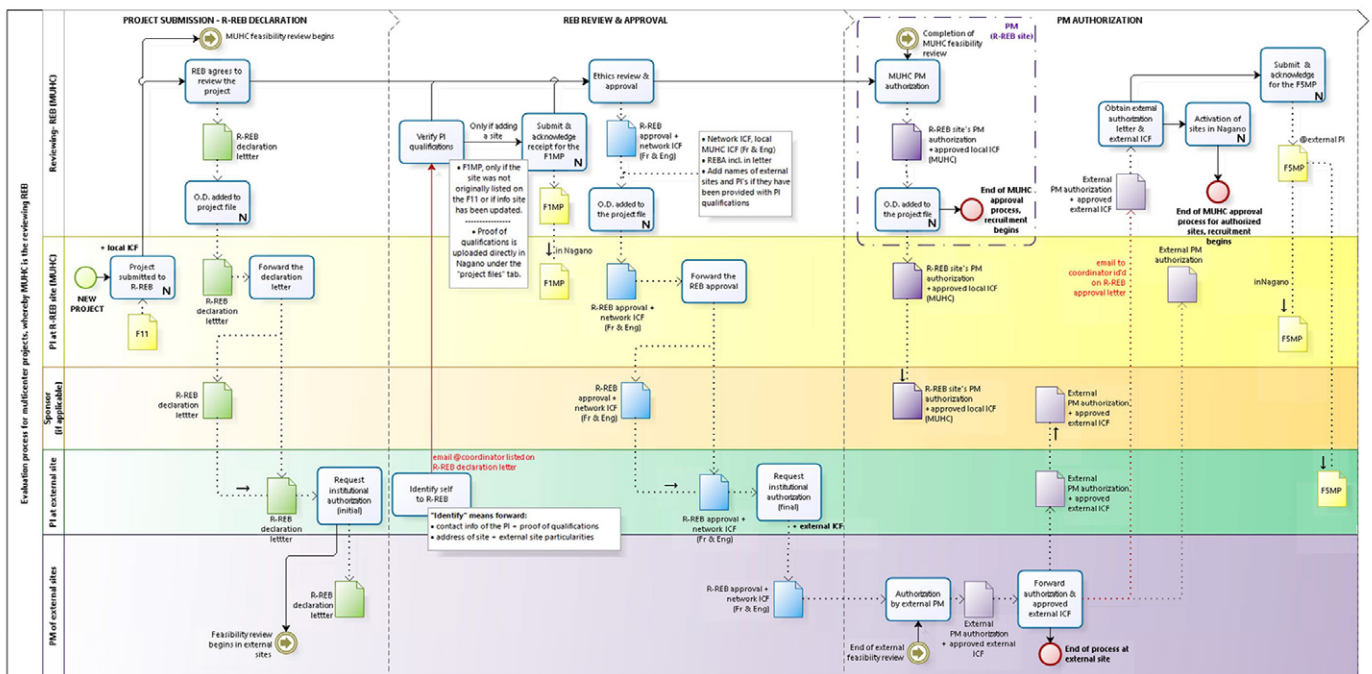
The **information and training sessions** took the form of lectures, rounds, clinical-academic half-days, e-learning courses, targeted teaching sessions, journal clubs, and peer training sessions.

Memos are written by the CAE manager and/or ethics consultants to help establish a consistent application of rules and/or ethical standards in a given area. They are disseminated to members of the CAE staff and to other teams at the MUHC.

The CAE also creates practical **tools** to support clinical, research and administrative teams. For example, the CAE provides a clinical ethics analysis model developed by the CAE Director that provides a step-by-step process for engaging in the ethical analysis of challenging cases. This tool is especially valuable to residents, medical students and nurses. Several tools have also been developed and made available on the CAE website to support MUHC researchers and those involved in research ethics. This includes various templates, memos, process diagrams, etc.

For example, the CAE has developed innovative flowcharts depicting the approval process for multicentre research which has been emulated by other institutions in the network (see flow-chart at the end of this section). The *Consortium de recherche en oncologie clinique du Québec (Q-CROC)* will produce an adapted version of the CAE flowcharts to provide to other Q-CROC member health centres in Quebec.

Initial submission MP Study – MUHC = Reviewing-REB (R-REB)
 Communication and document pathway for the evaluation of multicenter projects where the MUHC is the reviewing REB



- Legend**
- EXT = external
 - O.D. = official document
 - ICF = Informed Consent Form
 - ICF (external) = Informed Consent Form of an external site
 - ICF (local) = Informed Consent Form of the R-REB's site
 - MP = multicenter project that was evaluated by the MUHC R-REB
 - N = Nagano
 - PI = principal investigator
 - PM = « personne mandatée », the person mandated by the institution to authorize research
 - R-REB = reviewing REB

- Forms**
- F11 = MUHC submission form for a new research project
 - FIMP = amendment form for adding a new site
 - FSMP = form to process external ICF receipt



6. CAE PROFESSIONAL DEVELOPMENT

94
activities

The CAE team includes a manager, ethics consultants, planning, programming and research officers, administrative technicians, and administrative clerks (REB panel coordinators). Continuing education is a significant contributing factor in the CAE's accomplishments. To remain successful and competitive in a complex and fast-paced environment, all CAE staff regularly participate in professional development activities.

In 2017-2018 alone, CAE staff participated in 94 such activities on a variety of topics, including clinical ethics consultation, epidemiology and public health, research ethics review procedures and best practices, and ethical issues in early phase clinical trials (see table below).

TABLE 6. CAE PROFESSIONAL DEVELOPMENT ACTIVITIES 2017-2018

TOPIC	NUMBER OF TRAINING SESSIONS
Clinical ethics	42
Clinical ethics consultation	27
Specialized topics in clinical ethics	15
Research ethics	45
REB review procedures	19
Early phase clinical trials	9
Best practices for health-related research	8
Other	9
Other	7
Total	94

Professional development activities included participation in symposiums and academic conferences, online training (e-learning) as well as several peer-training sessions (mentoring, community of practice, peer training, case debriefing, etc.).



**TO REMAIN SUCCESSFUL AND COMPETITIVE
IN A COMPLEX AND FAST-PACED ENVIRONMENT,
ALL CAE STAFF REGULARLY PARTICIPATE IN
PROFESSIONAL DEVELOPMENT ACTIVITIES.**



For example, the CAE has developed a ‘Continuing Professional Development Series’ which uses a peer-training model. The 2017-2018 version included seven 90-minute sessions on topics identified by CAE staff members as areas where they wanted to develop greater understanding and expertise. One of the topics selected for three of these sessions was advanced skills in clinical ethics consultation. This advanced and specialized training is unique to the CAE and is not currently available elsewhere in Canada.





7. STRATEGIC PLANNING, EVALUATION & MONITORING, QUALITY IMPROVEMENT AND ACCOUNTABILITY

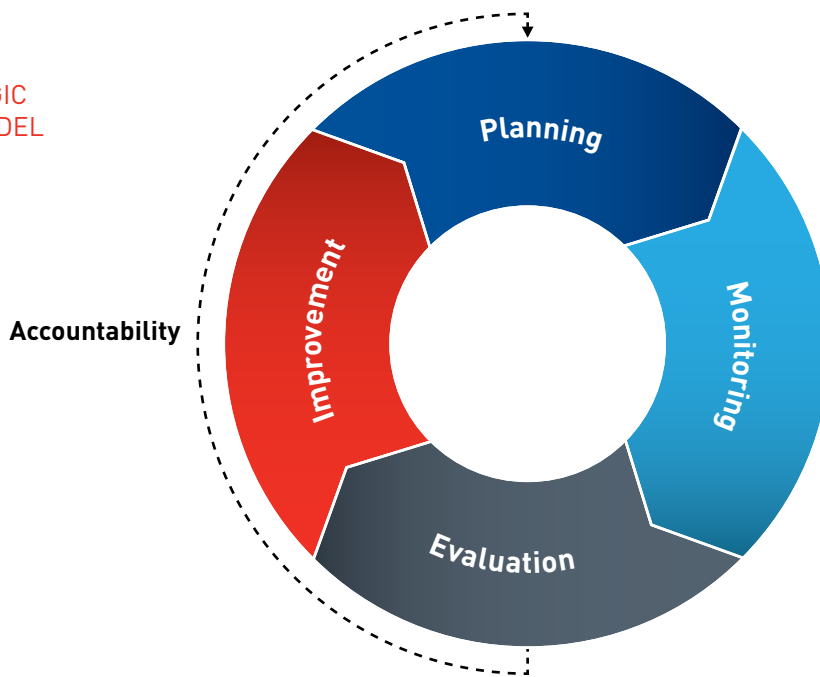
The CAE's commitment to strategic planning is operationalized in a rigorous, sequenced approach that focuses on planning activities, monitoring and evaluation, quality improvement, and accountability. The figure below highlights the cyclical nature inherent in the strategic management of CAE activities.

43
actions

Planning: The CAE engages in strategic planning of its activities in collaboration with other teams at the MUHC. The most recent planning exercise was done in collaboration with the *Direction de la qualité, de l'évaluation, de la performance et de l'éthique (DQEPE)* and resulted in the development of a “*Plan d'actions sectoriel 2018*” which consists of 43 action items. In addition, the CAE Director and manager participated in **strategic planning for the MUHC at an organizational level** by serving on the following committees: Comité de gouverne clinique, Comité de gouverne de la recherche, Comité de gouverne administrative et de soutien, the Medical Administrative Leadership Table (MALT), the Governance and Ethics Committee of the Board of Directors (observer member), and the Information Security Committee. CAE staff also participate in statutory meetings with DQEPE Department Heads, senior management of the Research Institute and with the senior management of the Montreal Neurological Institute and Hospital (Neuro).

Monitoring: The CAE ensures regular monitoring of its activities (including internal and external information) needed to foster an ethical culture at the MUHC. In 2017-2018, the CAE developed tools to monitor performance indicators in research ethics, notably with respect to delays in the approval of research projects. The data produced will allow each REB panel to track the timelines of the REB review process. In order to ensure systematic monitoring of all CAE activities, an “Access” database covering all ethics domains will be implemented in 2018. In addition, information on internal and external environmental factors affecting the MUHC are frequently collected and reported to appropriate decision-makers through several mechanisms (the presence of CAE staff on committees, requests for consultations, etc.). This helps the CAE to understand and adapt its practice to emerging trends in bioethics.

FIGURE 2.
CAE STRATEGIC
PLANNING MODEL



Evaluation: The CAE believes that to continue to improve, ensure effectiveness of its services and spread its expertise, it must adopt self-assessment measures. As such, the CAE is developing a system to assess its activities and their impact. In the past three years, the CAE has taken the following steps:

- Hired staff with expertise in program evaluation;
- Conducted literature reviews and participated in knowledge transfer activities on applied ethics evaluation;
- Collaborated and consulted with other ethics groups in Quebec and Canada on ethics program evaluation and monitoring strategies.

In 2017-2018, the CAE pursued various ethics evaluation strategies. For instance, the CAE conducted an ethics needs assessment for MUHC nurses. Results from this survey were presented at the National Nursing Ethics Conference at UCLA. The CAE also created a Quality Improvement Program in research ethics and has initiated three evaluation projects in this area: (1) compliance assessment (2) performance evaluation and (3) evaluation of operational excellence.

Continuing improvement: The CAE is committed to the continuous improvement of its activities. To achieve this, the CAE generates data through its monitoring mechanisms, analyzes this data regularly (with more in-depth analysis given to projects flagged for evaluation) and identifies steps for improvement in collaboration with key stakeholders.

For example, as part of its quality improvement program in research ethics, the CAE has developed electronic reporting models as well as evaluation and analysis grids for the Nagano platform that collect data on key performance indicators. These results will be presented to the 5 REB panels in order to: (1) identify and analyze the causes of the most important delays in research ethics review for which there are implementable solutions (2) analyze the variation in performance results by period, type of project, etc. and (3) facilitate discussion of practical and effective ways to improve research ethics review with an approach tailored to the successes and challenges of each panel.

The CAE actively participates in the MUHC's Accreditation process, not only complying with existing standards but exceeding them. The CAE collaborates with the DQEPE on continuing improvement projects in a variety of areas including risk management, employee safety, management and protection of personal health information, etc.

Accountability: the CAE works in collaboration with other MUHC Departments, and is accountable to the DQEPE and the Board of Directors. It does so through attendance at statutory meetings, production of reports, presentations, etc. The CAE regularly updates its website with information to better inform the MUHC community about its activities. The completion of this first annual report also testifies to the CAE's strong commitment to accountability, **transparency** and **good governance**. The Centre also systematically prepares annual reports on research ethics review as required by government authorities.

ANNEX A

ORGANIZATIONAL STRUCTURE



“The MUHC’s CAE represents the next, innovative phase in the evolution of the field of applied ethics in health care.”

EUGENE BEREZA MD CM
PRESIDENT,
CANADIAN BIOETHICS SOCIETY, 2015-2016



PRIME MINISTER · PREMIER MINISTRE

The 28th Annual Canadian Bioethics Society Conference

It is with great honour that I welcome you to the 28th Annual Canadian Bioethics Society Conference, hosted by the Centre for Applied Ethics at the McGill University Health Centre.

This year's theme, *Falling Through the Cracks*, addresses an issue that Canadian society has struggled with for the entirety of our 150-year existence. We are, at our core, a nation built on helping our neighbours, but there are countless examples of groups and individuals that we have let down throughout our history. Though we have made progress in helping our most vulnerable, it is clear that we still have work to do.

As Canadians concerned with bioethics, you have outsized roles in ensuring that that our marginalized populations have access to equal services and care. Through the free exchange of ideas at this conference, you have the potential to change many lives for the better, a truly laudable goal that speaks to the humanitarian values that rest at the core of our Canadian identity.

Thank you to the organizers of this amazing event and to all of you who are in attendance to participate in this important discourse. Please accept my best wishes for a productive conference.

Ottawa
2017

Centre universitaire
de santé McGill



McGill University
Health Centre

**Centre d'éthique appliquée
Centre for Applied Ethics**

muhc.ca/cae

2155 Guy Street, 2nd floor
Montréal (Québec) H3H 2R9

cae@muhc.mcgill.ca

514 934-1934

