

Title: Regulatory framework for research involving humans at the Centre intégré universitaire en santé et services sociaux du Centre-Ouest-de-l'Île-de-Montréal		
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SUMMARY

The CIUSSS du Centre-Ouest-de-l'Île-de-Montréal and the institutions it administers ("CCOMTL") place strong value on research and wish to continue overseeing it in a manner that meets the highest standards of research ethics, quality, efficacy, and effectiveness, with a view to protecting the safety, dignity, and confidentiality of research subjects.

The regulatory framework for research involving humans at the CCOMTL (the "Regulatory Framework") replaces the research framework policies or the research regulatory frameworks that were previously in effect at the merged or consolidated institutions under administration by the CIUSSS du Centre-Ouest-de-l'Île-de-Montréal since 2015. It applies to all actors involved in activities that, regardless of the type of research or funding:

- are conducted in whole or in part at the CCOMTL or for which the CCOMTL is responsible;
- involve users or their loved ones, employees or physicians of the CCOMTL;
- use information contained in user records held by the institution;
- use human biological material stored at or obtained from the CCOMTL, or information derived from it;
- use the human, material, or financial resources of the CCOMTL;
- include the creation or use of a database or biobank created for research purposes.

All institutions in the health and social services network (HSSN) whose activities include conducting research under their auspices or their responsibility must implement a research regulatory framework, adopted by the Board of Directors (*Cadre de référence ministériel pour la recherche avec des participants humains*, MSSS, October 2020, hereinafter called *Cadre MSSS 2020*).

The objectives of the Regulatory Framework are to:

- establish the roles and responsibilities of the actors involved in the research process;
- establish the expected conduct of the actors involved in the research process;
- specify the approval process needed to: ensure that research meets recognized scientific and ethical standards; protect and ensure the dignity, welfare and rights of research participants; and ensure the local feasibility of the research;

present the management mechanisms and major guidelines governing research at the CCOMTL and, where applicable, reference the policies, procedures, regulations, and standard operating procedures (SOPs) associated with them

INTRODUCTION

The **Centre intégré universitaire de santé et de services sociaux du Centre-Ouest-de-l'Île-de-Montréal**, resulting from the merger of the CSSS Cavendish and the CSSS de la Montagne, is a health and social services institution under the meaning of Section 4 of the *Act to modify the organization and governance of the health and social services network, in particular by abolishing the regional agencies* (CQLR, c. O-7.2). In accordance with the same section, it is designated as an integrated **university** health and social services centre (IUHSSC) because it is located in a health region where a university offers a complete undergraduate program in medicine and operates a centre designated as a university institute in the social sector. The Centre intégré universitaire de santé et de services sociaux du Centre-Ouest-de-l'Île-de-Montréal administers the following grouped institutions: the Sir Mortimer B. Davis - Jewish General Hospital (JGH), the Lethbridge-Layton-Mackay Rehabilitation Centre, the Centre Miriam intellectual deficiencies rehabilitation centre, the Jewish Eldercare Centre, Mount Sinai Hospital, and the Maimonides Geriatric Centre.

For the purposes of this Regulatory Framework, the term “CCOMTL” refers to the Centre intégré universitaire de santé et de services sociaux du Centre-Ouest-de-l'Île-de-Montréal and the grouped institutions it administers.

The CCOMTL’s mission is to:

- Provide a continuum of high-quality health and social services at all its facilities;
- Provide compassionate, user-centered care and services and create an exceptional patient-user experience;
- Establish and promote leadership and excellence in health and social sciences education;
- Advance knowledge and practice in the health and social sciences through research and innovation.

The CCOMTL has three important university designations, in accordance with sections 88 to 91 of the *Act respecting health services and social services* (AHSSS) because, in addition to carrying on the activities inherent to its mission, it also participates in medical education, conducts research, evaluates technologies or methods of intervention, develops leading-edge practices, and offers specialized or highly specialized services. The CCOMTL is affiliated with several Montreal universities.

By virtue of its university designations, the CCOMTL is committed to providing the highest quality care and services, in partnership with its users and their loved ones, and to supporting the advancement of health and social sciences knowledge and practice. It does so through excellence in research, teaching and innovation, which ultimately enhances the care and services provided by the institution.

The CCOMTL’s university designations also mean it is equipped with high-quality, efficient research infrastructures, recognized by the Fonds de recherche du Québec, in both the health and social services sectors. The CCOMTL’s university mission is backed by expertise and research areas that cover studies related to biomedical, psychosocial and rehabilitation aspects. This is unique to the CCOMTL and allows it to integrate the practice of various disciplines across all its clinical programs, promoting a comprehensive approach to the diverse needs of the population.

The research component of the CCOMTL’s university mission is supported by the following components, which are affiliated or integrated with its university designations:

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The Lady Davis Institute for Medical Research is the main research branch of the JGH and is one of the biggest medical and biomedical research institutes in Canada. It is a world leader in several research fields including cancer, clinical epidemiology, and molecular and regenerative medicine. It also has a psychosocial research axis that focuses on cultural psychiatry, the psychosocial factors of illness, and the etiology and treatment of mental disorders.

- The University Institute for Ethnocultural Communities, and its SHERPA research infrastructure, is the only Quebec institute that specializes in the intercultural field. It has developed expertise in the cultural adaptation of frontline health and social services practices for people from ethnocultural communities, the development of training and practices for intervening in situations of intercultural interventions or social polarization, and the field of migration and settlement support policies.
- The University-affiliated centre in social gerontology, and its research infrastructure and Expertise in Social Gerontology (CREGÉS), is the only university-affiliated social gerontology centre in Quebec. Among other things, it focuses on seniors as actors in their own aging process, on the public policies that concern them and—in the area of interventions with seniors and their loved ones— on practices to counter abuse, with the goal of supporting informal caregivers, as well as people in palliative care and their loved ones, and of promoting diversity, inclusion and social participation among seniors.
- The CCOMTL also has a research team at the Maimonides Geriatric Centre, which specializes in research on the long-term care of seniors, in particular as it relates to medical and nursing practices for seniors with dementia.
- The CCOMTL also has a research team at Mount Sinai Hospital that carries out research related to pulmonary and sleep medicine.
- Finally, the CCOMTL is also a partner of the Pôle universitaire en réadaptation, and a proud founding member of the Centre for Interdisciplinary Research in Rehabilitation (CRIR). As such, it hosts a rehabilitation research support team and supervises several research and knowledge transfer activities in the areas of sensory, motor and cognitive functions and activities, participation, social inclusion and rehabilitation services.

The CCOMTL upholds its mission by combining all of its integrated or affiliated research components described above, representing more than 500 researchers of various statuses: university researchers and clinician-scientists, associate researchers, research fellows, and institutional researchers. The CCOMTL's managers, professionals and stakeholders also engage in or support research activities. The CCOMTL's various research infrastructures and components are a source of pride and wealth, because the research of today represents the care and services of tomorrow.

The CCOMTL also hosts many researchers from other institutions or research institutes that are integrated or affiliated with the CCOMTL. Year after year, these individuals come to conduct research at one of its facilities, according to a multicenter review process.

The CCOMTL places strong emphasis on research and wishes to continue ensuring that it meets the highest standards of research ethics, quality, efficacy, and effectiveness, with a view to protecting the safety, dignity, and confidentiality of research subjects.

1. GENERAL PROVISIONS

1.1. Scope

This Regulatory Framework applies to all actors involved in Research Activities (as defined below) that, regardless of the type of research or funding:

- are conducted in whole or in part at the CCOMTL or for which the CCOMTL is responsible;
- involve users or their loved ones, employees or physicians of the CCOMTL;
- use information contained in user records held by the institution;
- use human biological material stored at or obtained from the CCOMTL, or information derived from it;
- use the human, material, or financial resources of the CCOMTL;
- include the creation or use of a database or biobank created for research purposes.

The Regulatory Framework targets the managers and staff in all the clinical and administrative departments of the CCOMTL who supervise, support, or participate in Research projects, namely Researchers, physicians, pharmacists and dentists, Research staff, students, postdoctoral fellows, managers of research funds, Research Review Office staff, members of research ethics boards, staff from the Academic Affairs and Research Ethics Directorate and the Lady Davis Institute (LDI) who assist the Researchers with submitting research projects, and the Responsible Conduct of Research Officer (RCRO) at the CCOMTL.

1.2. Purpose

All institutions in the health and social services network (HSSN) whose activities include conducting research under their auspices, or their responsibility must implement a research regulatory framework, adopted by the Board of Directors (*Cadre de référence ministériel pour la recherche avec des participants humains*, MSSS, October 2020, hereinafter called *Cadre MSSS 2020*).

The objectives of the CCOMTL's Regulatory Framework are to:

- establish the roles and responsibilities of the actors involved in the research process;
- establish the expected conduct of the actors involved in the research process;
- specify the approval process needed to: ensure that research meets recognized scientific and ethical standards; protect and ensure the dignity, welfare and rights of research participants; and ensure the local feasibility of the research;
- present the management mechanisms and major guidelines governing research at the CCOMTL and, where applicable, reference the policies, procedures, regulations, and standard operating procedures (SOPs) associated with them.

Issues of management and the protection of intellectual property generated by the Research are beyond the scope of this Regulatory Framework and will be the subject of a separate procedure.

1.3. Definitions

Board of Directors: The CCOMTL's Board of Directors, as defined by sections 9 and 10 of the *Act to modify the organization and governance of the health and social services network, in particular by abolishing the regional agencies* (CQLR, c. O-7.2).

Conflict of interest: Circumstance of a person or organization in a real, perceived, or potential conflict between their duties or responsibilities related to the Research Activities and their personal, institutional or other interests.

Data: Data includes data from Research Activities, as well as health or social services data, regardless of its medium.

Institution: An institution is a legal entity with legal capacities and responsibilities that is licensed by the Ministère de la Santé et des Services sociaux (MSSS). According to Section 94 of the AHSSS, an institution is any person or partnership carrying on activities inherent in the mission of one or more of the following centres: residential and long-term care centre (CHSLD), local community service centre (CLSC), child and youth protection centre (CPEJ), rehabilitation centre (CR), and hospital centre (CH). An institution has a Board of Directors and is covered by the liability insurance plan of the Direction des assurances du RSSS (DARSSS).

Multicentre: Research taking place at more than one public institution within the HSSN having a board of directors. Multicentre research is subject to only one ethics review, by a research ethics board (REB) at an HSSN institution that will act as the reviewing REB. The terms and conditions are outlined in the *Cadre de référence des établissements publics du réseau de la santé et des services sociaux pour l'autorisation d'une recherche menée dans plus d'un établissement* (2016).

Nagano: Nagano is an online computer system used by most public institutions in Quebec's HSSN as a multifunctional planning and management platform for Research projects.

Research Activities or Research: All steps included in the life cycle of knowledge creation through rigorous methodologies that are—or are in the process of becoming—recognized by peers, spanning from the initial project proposal to the dissemination of results, including applications for research funding and peer review. These steps also include activities related to research management.

Research ethics: All Research Activities must be conducted in accordance with a set of ethical standards for research, such as those set out in the Tri-Council Policy Statement, the ethics standards of the FRQ (Fonds de recherche du Québec), or the *Politique d'éthique et d'intégrité scientifique* of the FRQNT (Fonds de recherche du Québec - Nature et technologie). These standards are primarily concerned with the deontological approach governing the behaviour of researchers, students and research personnel regarding the respect and protection of human participants and animals used in research. In Quebec, research ethics boards (REB) and animal protection committees ensure that all research involving human participants or animals (respectively) complies with these ethical standards.

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Research Ethics Board (REB): A group of individuals with specific expertise (e.g., in ethics or relevant research disciplines) established formed by an organization to review the ethical acceptability of all any research involving humans participants conducted within under the organization’s jurisdiction or under its auspices, in accordance with applicable standards and laws.

Research participant: An individual who directly participates in research, whose data, biological material, responses to interventions, stimuli, or questions by the Researcher are relevant to answering a research question; also referred to as “human participant” or, in other policies/guidanceguidelines, as “subject” or “research subject.”

Research personnel: Person employed by the CCOMTL or an academic institution to take part in Research Activities. This person may be a research professional or a support staff for the research activities being conducted at the CCOMTL. Research personnel may also include postdoctoral fellows or students in certain contexts.

Research Review Office (RRO): Office comprised of staff that coordinate and support the institutional feasibility and ethics review of Research conducted at the CCOMTL or that involves users of its care and services, under the authority of the person formally designated to authorize the research.

Researcher: A person to whom the CCOMTL has awarded research privileges, excluding research personnel or students.

Single-centre: Research taking place at a single public institution within the HSSN having a board of directors. In the case of this Regulatory Framework, a project is considered single-centre if it will be carried out at one of the merged or grouped institutions, one of the CCOMTL’s facilities or sites, or with the CCOMTL’s users or their loved ones.

Student: A person registered at an academic institution for the purpose of obtaining a degree, diploma or other academic recognition requiring that they engage in research activities. A student may be a college student, an undergraduate, graduate or postgraduate university student, or a postdoctoral fellow who receives a grant from one of the Fonds de recherche du Québec or other private or public funds.

The Research covered by this regulatory framework includes any research activity that involves living human participants or human biological material, embryos, fetuses, fetal tissue, human reproductive materials or stem cells and information derived therefrom, whether or not it identifies the person to whom it relates, and the creation or use of a database or biobank (Cadre MSSS 2020). To be more clear, fundamental research that does not require access to participant data or to human biological materials, embryos, fetuses, fetal tissue, reproductive materials, or stem cells is excluded from the application of the Regulatory Framework and will be the subject of a separate regulatory framework on fundamental research. Also, quality assurance and quality improvement studies, program review activities and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management, or improvement purposes, do not constitute Research.

1.4. Roles and responsibilities

Board of Directors

The responsibilities of the Board of Directors with respect to Research are as follows:

- Adopt the Regulatory Framework and policies related to research activities at the institution and ensure they comply with generally accepted standards governing REBs, including the *Cadre de référence ministériel pour la recherche avec des participants humains* (MSSS 2020);
- Establish and empower the REB to review Research involving human participants conducted under the auspices of the CCOMTL;
- Adopt the REB's operational guidelines (REB SOP);
- List the members of the Research Ethics Boards (REBs) that it has instituted;
- Annually acknowledge the activity reports produced by the CCOMTL's REB;
- Ensure that the REB fulfils its duties in accordance with this regulatory framework and the ethical standards in effect, and in accordance with the ministerial designation under Article 21 of the *Civil Code of Québec*;
- Ensure that the independence of the REB is protected and that it is afforded the conditions needed to properly carry out its duties;
- Ensure that REB members and, when needed, RRO staff that support the REB have access, on a regular basis, to research ethics training activities;
- Designate the person formally appointed to authorize Researchers to conduct their Research at the CCOMTL or under its auspices;
- Appoint the director of the LDI.
- Appoint the Director of the Research Infrastructure (SHERPA) at the University Institute with regard to ethnocultural communities.
- Appoint the Director of the Research Infrastructure (CREGÉS) at the University-affiliated Center in Social Gerontology.

Academic Affairs Committee of the Board of Directors

The Board of Directors has given this committee the responsibility and authority to make recommendations to the Board of Directors regarding the CCOMTL's academic affairs. The committee is responsible for ensuring that the CCOMTL's university mission is well integrated and that the institution incorporates the university mission into all decisions made by and services delivered through the CCOMTL. It also ensures that the user's perspective is considered in all matters related to academic affairs. It ensures, as needed, that the necessary plans are implemented and updated to address the various challenges, issues and opportunities. More specifically, the committee exercises an oversight role with respect to the performance of the CCOMTL's university mission in its various components: research; medical, university and college teaching; knowledge transfer; leading-edge practices; evaluation of technologies or methods of intervention; and outreach. The committee reports to the Board of Directors on any issues, problems, progress, and performance related to the university mission and makes recommendations to support the latter. The committee also plays an information/awareness role with respect to the criteria to be met for the CCOMTL's university designations.

Affiliated universities

The Affiliated universities fulfill their research responsibilities as stipulated in the university affiliation **Regulatory framework for research involving humans at the Centre intégré universitaire en santé et services sociaux du Centre-Ouest-de-l'Île-de-Montréal** 1100_01_01_01F 10

agreements with the CCOMTL. These agreements establish the joint responsibilities of the University and the Institution in terms of research and define undertakings regarding:

- Joint development of research programs for the various CCOMTL research infrastructures, taking into account the priorities of the CCOMTL and the University's research programs;
- Compliance with the policies, standards, and regulations of any organization funding their research activities, including granting organizations;
- Communications aimed at reporting to the other party any event, information, or project likely to affect research conditions within the CCOMTL;
- The joint procedure regarding any public announcement concerning the impact of research

- activities resulting from the collaboration between the University and the institution;
- Mention of the affiliation of University members and CCOMTL staff in communications related to Research and knowledge transfer or valorization;
 - Support from foundations, government and other organizations for research projects and programs jointly agreed upon by the parties;
 - Compliance with internal rules and policies, including those related to research administration and research data management, in accordance with applicable laws and regulations;
 - Need to inform each other of any information concerning a complaint or a breach of responsible conduct of research policies, related to the behaviour of a student, a Researcher or a Research staff member, or a faculty member carrying out their academic activities in facilities maintained by the institution, including those related to probity, ethics and conflict of interest management.

Specific agreements also set out certain responsibilities of McGill University toward the research mission of the LDI , which has close ties to McGill. Each Researcher is appointed to an academic position at McGill University, is a member of a department and teaches certain courses, and some Researchers have an employment relationship with the university. McGill University supports the need for student accommodations, and access to scientific libraries and the Technology Transfer Office.

President-CEO's (PCEO) office

The PCEO's office is responsible for the CCOMTL's university mission, promoting and spearheading it both internally and externally. It ensures that the university mission is given centre stage and treated as a joint responsibility of all components of the CCOMTL, and that each component actively supports the conduct of research activities. It ensures that the Research management and support structure has the necessary resources and receives adequate support to carry out its purpose. It signs affiliation contracts with the universities. It signs contracts and agreements related to research or academic affairs. It ensures that the institution avoids placing itself in conflict-of-interest situations related to research activities. It promotes research ethics and the responsible conduct of research within the CCOMTL. He is also responsible for the process of appointing a scientific directorate for research infrastructures.

Associate Chief Executive Officer's (A-CEO) office

The A-CEO chairs the Clinical Coordination Committee and must ensure that the directors under their responsibility ensure the integration of the university mission into their clinical programs and services, and support research activities, knowledge transfer, the development of leading-edge practices, and the evaluation of technologies and methods of intervention, in order to improve the accessibility, continuity, quality and safety of care and services.

Person designated by the institution to authorize the conduct of the Research activities

The CCOMTL must formally authorize the conduct of all Research activities taking place under its auspices or responsibility. To this end, the Board of Directors formally designates a person to authorize the conduct of Research at the institution or under its auspices, in accordance with Section 169 of the *Act respecting health services and social services*. Their mandate also includes authorizing a Researcher to create a database and/or biobank for Research purposes or to contribute to an existing bank, under the auspices of the CCOMTL.

Academic Affairs and Research Ethics Directorate (AAD): The vision of the AAD is to position the CCOMTL as a competitive leader in research, teaching, leading-edge practices, knowledge transfer, and the evaluation of technologies and methods of intervention in health and social services, and to contribute to the national and international visibility of the expertise developed by our various research components

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so that that latter can contribute to improving care and services. To this end, its role is to promote the development of a culture of learning and innovation throughout the CCOMTL, to attract top talent, and to support the integration of activities across all components of the CCOMTL's university mission.

For the research component, it promotes a culture of ethics and responsible conduct of research within the CCOMTL. The AAD is designated by the CCOMTL's CEO as the directorate responsible for implementing, applying, and regularly updating the Regulatory Framework adopted by the Board of Directors. The AAD is responsible for the Research Review Office (RRO), comprised of staff that coordinate and support the scientific review, the institutional feasibility review and the ethics review of Research conducted at the CCOMTL and at the facilities and sites it administers, or that involve users of its care and services, under the authority of the person formally designated to authorize the research.

The Board of Directors delegates to the AAD the responsibility for conducting formal performance evaluations of RRO staff, in accordance with the policies and procedures of the CCOMTL's Human Resources, Communications, Legal Affairs and Global Security department.

Council of Physicians, Dentists and Pharmacists

The Council of Physicians, Dentists and Pharmacists (CPDP) is responsible for monitoring and assessing the quality and relevance of the medical, dental and pharmaceutical care provided in the context of Research. It must inform its members who wish to conduct research of the need to have research privileges. It ensures that its members conducting research activities at the institution are informed of and comply with all policies, regulations and procedures of the granting organizations and those in effect at the CCOMTL, including this Regulatory Framework, the Research Ethics Board SOPs, and the procedure for managing allegations of breach of responsible conduct of research. The CPDP is responsible for reviewing these allegations when they relate to a medical, dental or pharmaceutical act performed in the context of Research.

Professional Services Directorate

The Professional Services Directorate (DPS) coordinates the professional and scientific activity of any centre operated by the institution, along with the other directors concerned. Moreover, the DPS is responsible for assessing the relevance of and authorizing access to user records and user clinical data for research purposes, in accordance with applicable legislation.

Financial Resources Directorate

The financial management of research funds is ensured by the CCOMTL's Financial Resources Directorate (FRD) in accordance with the guidelines of the granting organizations, governments, Universities, and CCOMTL policies (see Section 3.1).

Administrative and clinical directorates

The directors and their managers play a fundamental role in integrating and carrying out the various components of the university mission within the CCOMTL. They create favourable conditions for carrying out research activities in a way that aligns with the specific interests, capacities, issues and resources of their directorates, programs or services. They participate in certain governance bodies of the AAD or the LDI. They ensure the development of a research culture in their departments, promote the participation and involvement of professionals and stakeholders in Research projects, and support the recruitment of research participants, as needed.

Lady Davis Institute Management

The LDI management is responsible for the scientific organization of the research conducted by LDI researchers and for its proper functioning. It is responsible for fostering and promoting the scientific development of the LDI's clinical, fundamental, epidemiological and psychosocial research; ensuring sound management of the LDI's budget; recruiting Researchers; overseeing the development and training of graduate students and post-doctoral fellows; building bridges to harmonize the conduct of activities through research links between McGill University and the JGH; developing collaborations with other research centres and other institutions in the network; determining research priorities for the LDI, based on the recommendations of the assembly of Researchers; designing, implementing, monitoring and modifying the LDI's development plan and evaluating the results annually. Its mandate is for five years and is renewable. The director is appointed by the Board of Directors on the recommendation of a nominating committee. It performs its duties on a full-time basis.

Scientific directors (research infrastructures in university institutes and university affiliated centres in the social sector)

The scientific director is a person who has demonstrated scientific leadership in their field in the eyes of their peers, who has the status of university researcher or, in special circumstances, institution researcher, and who is released from some of their university or professional duties to provide scientific leadership to a research centre at an institution. Scientific directors are key players in the development of the CCOMTL's university mission. Their main purpose is to establish the orientations and plan the scientific programming of their research centre. They oversee the centre's research activities, including the design, implementation, monitoring and adaptation of the scientific programming. Moreover, they contribute to the positioning of the university mission and the areas of expertise of their university institute or university affiliated centre with external partners, including the MSSS, and participate in the various related bodies. They also oversee the six components of the university mission, for which they have scientific responsibility. His mandate and the conditions relating to his exercise are defined within the framework of an agreement established between the CCOMTL, the candidate and, where applicable, the university to which the scientific management is affiliated.

Researchers

Researchers conducting research at the CCOMTL or under its responsibility must ensure that they have research privileges (see Section 2.3) and conduct their research in compliance with the legislative and normative framework applicable to Research Activities, this Regulatory Framework, the related policies and procedures, as well as the general and specific guidelines and policies of the granting organizations and their programs. They must behave in accordance with the expected values and principles of the responsible conduct of research and ensure that their co-Researchers and research staff also behave in accordance with these policies, regulations and procedures as well as the values of honesty, reliability and rigour, objectivity, fairness and independence, justice (especially in recognizing the contributions of others), trust, accountability and benevolence, openness and transparency. They are committed to having the general research ethics knowledge required to carry out their projects and to regularly obtaining training to stay up to date on best practices. They must maintain their research files in accordance with regulatory requirements and REB decisions. They are accountable for the management of the research funds granted to them and must ensure, with the support of the FRD or the designated managers at the AAD or the LDI, that the rules of sound financial management are respected. They do not have the authority to sign contracts on their own behalf. Researchers must also ensure the transfer of knowledge about the results of their work, in particular to the teams that supported them and to the target clientele.

When they are employed by the university or have a university appointment, they must also follow all applicable research policies and regulations at their university, including those associated with intellectual property, conflict of interest, and integrity and the responsible conduct of research.

2. MANAGEMENT OF RESEARCH ACTIVITIES

2.1. Research activities management structure

As mentioned in Section 1.3, the responsibility for implementing, applying, and regularly updating the Regulatory Framework adopted by the Board of Directors was delegated by the CEO to the Academic Affairs and Research Ethics Directorate. The AAD is responsible for the Research Review Office (RRO) and ensures that any research covered by this Regulatory Framework taking place at our institution has been reported and has obtained all necessary approvals and authorizations as described in this Regulatory Framework. Under Section 4 of the *Act to modify the organization and governance of the health and social services network, in particular by abolishing the regional agencies* (CQLR, c. O-7.2), the CCOMTL is the institution responsible for implementing the Regulatory Framework.

The AAD reports directly to the CEO. The Academic Affairs director sits on the CCOMTL's committee of directors and co-chairs, with the Vice-Principal (Health Affairs) and Dean of the Faculty of Medicine and Health Sciences at McGill University, the academic affairs committee of the Board of Directors, which is authorized to make recommendations to the Board of Directors with respect to the CCOMTL's academic affairs. This academic affairs committee is comprised on the CEO, the Director of the Lady Davis Institute (LDI), a scientific director representing social research, as well as senior academic, clinical and scientific partners. The AAD is also represented on several strategic and operational committees related to the clinical mission (e.g., the clinical coordination committee, the Integrated practice units coordination committee, the Public health strategic and operational committee, etc.). The AAD has also established governance committees in relation to the university missions of social gerontology and ethnocultural communities, and related to the university's partnership in rehabilitation. These committees include the senior and associate directors of the AAD, middle managers of the AAD, who support the operational management of activities related to the university mission, scientific directors from the social sector, and the clinical program directors most concerned by these missions. The university mission and its research component are well positioned as a crucial mission of the CCOMTL. The various governance bodies under the responsibility of the AAD or in which it participates facilitate exchanges on potential issues or problems, make any necessary recommendations, and prioritize actions to be taken with respect to the various components of the university mission.

The AAD and the LDI have managers on their team who are responsible for developing and monitoring scientific programs, ensuring sound management of research funds in collaboration with the CCOMTL's Financial Resources Directorate, hiring and managing research staff, and meeting the quality and performance requirements of the research infrastructures and components, in collaboration with the Director of the LDI or the scientific directors of the Institutes and University affiliated centres.

Each research component, whether in the health or social sector, also has an internal research management structure and specific internal statutes and regulations. This structure is comprised of executive or steering committees, committees or groups of the various research programming axes, executive committees, research assemblies, and, in the case of the LDI, an animal welfare committee that oversees the ethical use of animals within the LDI.

Despite the specificities, the entire CCOMTL research community must abide by the Regulatory Framework, the policies and procedures associated with the framework, and the guidelines and procedures of the Research Ethics Board.

2.2. Mandatory declaration of Research Activities

All Research involving human participants in the HSSN must be declared, reviewed and approved by an HSSN REB. No intervention or interaction may be undertaken with human research participants, including recruitment, until an HSSN REB has reviewed and approved the research protocol, consent documents and recruitment materials. Similarly, no research may begin at our institution until all other necessary approvals described below have been obtained and until formal institutional approval has been obtained by the Person formally designated by the CCOMTL to authorize the conduct of Research activities.

2.3. Granting of research privileges

Research involving human participants must be conducted by individuals appropriately qualified by education, training, and experience to assume responsibility for the proper conduct of the research and for the protection of research participants.

The person responsible or jointly responsible for a Research project undertaken at a CCOMTL facility, involving users of its care and services, including home care services, or its staff, must have research privileges. This person guarantees the responsible conduct of this research. This rule applies to both single-centre and multicentre research projects for the portion conducted at the CCOMTL.

The Researcher must have CCOMTL research privileges before they can submit their Research on Nagano. If they do not have such privileges, they must follow the CCOMTL's granting procedure, which is designed to confirm their research qualifications.¹

The Director of the LDI and the scientific directors of the research infrastructures concerned must determine the criteria for granting the status of member Researcher, according to the guidelines of their respective FRQ programs. Privileges last for three years and are renewable at the end of that period if the Researcher's status within the research infrastructure remains unchanged and if they continue to meet the research qualification criteria. The register of Researchers with research privileges at the CCOMTL is updated annually by the persons designated for this purpose by the AAD and the LDI, so as to reflect new members and departures. The register is shared with the RRO staff.

Certain professionals at the CCOMTL who demonstrate their research qualifications may also be granted research privileges. Their CV must demonstrate quality research training (e.g., master's thesis or doctoral dissertation on a research topic, accepted by a jury of researchers; postdoctoral fellowship), authorship or co-authorship of scientific publications, and participation in Research studies. For psychosocial researchers, after review by the person designated by the AAD, research privileges may be granted for a period of two years, renewable on REB approval from the date of the last approval. If there is any doubt about the research qualifications of the professional, the opinion of a CCOMTL scientific director may be sought out.

If applicable, the Researcher must be a physician with qualifications in their specialty and with professional qualifications entitling them to provide health care under the applicable laws. The approval of the Council of Physicians, Dentists and Pharmacists (CPDP), the Director of Professional Services, and the Director of the LDI are required for a clinician-researcher to be granted research privileges at the CCOMTL.

¹ <https://www.ciussswestcentral.ca/about-us/academic-affairs/research-review-office/research-privileges/>

For external researchers (non-members of the CCOMTL's integrated or affiliated research infrastructures), the CCOMTL will recognize the researcher status or the research privileges granted by another public institution of the HSSN, however, the researcher must provide a formal letter with their application attesting that they have privileges or researcher status at another public institution of the HSSN.

Privilege requests are reviewed by two individuals: 1) the LDI research director, for medical, biomedical or psychosocial Research projects taking place at the JGH, the LDI, or Mount Sinai Hospital; or 2) the associate director of the AAD.

Status as a masters, doctoral or post-doctoral research student does not constitute eligibility for the granting of research privileges. Students require the scientific and/or clinical supervision of a Researcher or a professional with research privileges. The onus is on that Researcher or professional to take steps to obtain privileges or to demonstrate that they have privileges. To do so, the Researcher must provide the LDI research director or the director of academic affairs and research ethics their current CV and licence number (medical or other, as the case may be), as well as information about their relevant training and experience, in sufficient detail to make an objective judgment regarding the researcher's qualifications.

Researchers or professionals will receive written confirmation of the granting of their privileges, signed by the LDI research director or by the director of academic affairs and research ethics. This confirmation outlines certain roles and responsibilities of the research privilege holder and the scope of the privileges.

The granting of privileges is necessary for the Researcher and, where applicable, the co-Researcher, responsible for leading a project, supervising members of a research team, and vouching for all research activities conducted by other co-Researchers, as the case may be, including those involving access to participants or to their non-anonymized samples or data.

The granting of privileges is accompanied by obligations. All Researchers or professionals who are granted research privileges must agree to:

- Refer to the principles established by the "Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans," with respect to the ethics and professional conduct of research involving human participants;
- Complete training in research ethics²; university Researchers who are members of research infrastructures integrated or affiliated with the CCOMTL must demonstrate that they have completed such training at the time of renewal of their privileges, every 3 years.
- Comply with the standards for responsible conduct of research, as detailed in the FRQ's Policy for the Responsible Conduct of Research and the CCOMTL's procedure for handling allegations of breach of responsible conduct of research;
- Abide by the decisions of the REB that will have approved and that will monitor their Research; Ensure the competency of the co-Researchers and members of their research team, as well as the research students whose projects they supervise.

² Tutorial on the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, available in English and French: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans: https://ethics.gc.ca/fra/education_tutorial-didacticiel.html; https://ethics.gc.ca/eng/education_tutorial-didacticiel.html

Research privileges may be revoked by the granting authorities, i.e., the LDI management or the Academic Affairs and Research Ethics Directorate, for any breach of this Regulatory Framework, in accordance with the Policy and procedure for managing allegations of breach of responsible conduct of research.

2.4. Review of a Research project

Before authorizing the conduct of research involving human participants, the institution must ensure that the project has undergone each of the following reviews: **scientific review, ethical review, and feasibility review**. All of these reviews must be positive.

In order to limit delays, it is recommended to carry out the three reviews in parallel. However, the outcome of the scientific review must be available at the time of the ethics review.

2.4.1. Scientific review

Before approving research involving humans, the REB must determine whether the methodology is scientifically sound and capable of answering the research question. This methodology must be validated by a recognized peer review committee, failing which the REB must form a scientific review committee. Along with other administrative requirements related to the Research, the Researcher must submit to the REB the outcome of the scientific review by the recognized peer review committee. The following shall constitute a recognized peer review committee:

- the scientific committee formed by another institution in the HSSN;
- the scientific committee of a Quebec-based or federal funding agency or of an agency (national or international) recognized by one of the latter, whether or not the project is funded;
- the scientific committee of a University or College in Quebec or another Canadian province, or a scientific committee recognized by such an institution (e.g., program committee, thesis committee, departmental authority).

When the project has not undergone a scientific review by a recognized scientific committee, the CCOMTL's scientific review committee must carry out the review. The REB is designated by the institution to conduct the scientific review. The scientific members of the REB (Psychosocial and Medical-Biomedical components) have a dual mandate, as reviewers and members of the scientific review committee (SRC). The scientific review takes place only at the time of the initial Research review, prior to the full REB committee. The SRC has its own chair chosen from among the scientific members of the REB. The chair leads the SRC and the scientific review conducted by the members, and communicates the REB's decision to the Researcher.

Even if research is approved by a recognized scientific committee, the REB's mandate includes reviewing the ethical implications of the research methods and design (REB SOP-403.003).

2.4.2. Research ethics review

Research projects require an ethics review and approval by an REB before the research commences.

Certain Research is exempt from an ethics review. For example, Research based exclusively on information accessible to the public and adequately protected in accordance with the law and for which there is no reasonable expectation of privacy. REB SOP-102.001 describes the Research Activities that require REB review and those that do not. In case of doubt, the RRO, in support of the REB, may advise the Researcher.

The REB reviews and oversees the Research to ensure that it meets ethical principles and that it complies with all applicable regulations and guidelines pertaining to the protection of human participants.

The REB has full autonomy and independently reviews any Research within its jurisdiction. It ensures that all Research conducted under its oversight is designed and conducted in such a manner that it protects the rights, welfare, and privacy of research participants. Specifically, the REB has the authority to:

- establish the ethics review processes and provide research ethics oversight to ensure the ethical conduct of the research;
- approve, require modifications to, or disapprove any Research Activity that falls within its jurisdiction;
- with active follow-up, ensure that the Researcher follows policies and procedures aimed at protecting the rights, safety, and welfare of research participants;
- request, receive, and share any information involving research that the REB considers necessary to fulfill its purpose, while maintaining confidentiality and respecting privacy;
- conduct an ethical review to protect the rights, welfare, and privacy of research participants;
- suspend or terminate the ethics approval for the research;
- place restrictions on the research;
- take any actions considered reasonably necessary and consistent with policies and procedures, to protect the rights, safety, and welfare of participants in research conducted under the REB's jurisdiction.

The REB's work is guided by ethical principles regarding all research involving human participants, including:

- Respect for persons:
 - Recognize the intrinsic value of all human beings, and the respect and consideration they are due;
 - Incorporate the moral obligations to respect autonomy and to protect those with developing, impaired, or diminished autonomy.
- Concern for welfare:
 - Aim to protect the welfare of participants, and, in some circumstances, to promote their welfare in view of any foreseeable risks;
 - Provide participants with enough information to be able to adequately assess the risks and potential benefits associated with their participation;
 - Ensure that participants are not exposed to unnecessary risks.
- Justice:
 - Treat people fairly and equally;
 - Vulnerable or marginalized people may need to be afforded special attention.

REBs should adopt a proportionate approach to the ethics review, such that the level of review is determined by the level of risk associated with the Research: the lower the risk level, the looser the review

will be, and the higher the risk level, the greater should be the care in assessing the Research.³ In all cases, the proportionate approach is understood as taking into account the foreseeable risks, potential benefits, and ethical implications of the Research in question.

In practice, the proportionate approach implies different levels of REB review for different Research. The two levels typical used by REBs are full board review or delegated review by one or more experienced REB members, as determined by the REB Chair or designee.

Approval is effective as of the date of delegated REB approval (final or initial, depending on the site), for at most one year from this date. The letter of approval, however, is not issued until all the conditions for approval have been met.

2.4.3. Institutional feasibility review

The institutional feasibility review ensures that the CCOMTL can devote the necessary resources to a Research project to ensure its successful completion, with respect to all prerequisites specified in the Research protocol, regardless of the nature of the resources requested. It also ensures that the CCOMTL is adequately compensated for these complementary activities. The institutional feasibility review process applies to any Research project that requires the resources or services of different hospital departments or CCOMTL directorates. This review is carried out for all projects, whether single-centre or multicentre.

Depending on the nature of the Research, the review may cover various elements of a clinical, administrative, operational, legal and technological nature. In particular, it is important to ensure:

- availability of human resources to support the project;
- availability of facilities, beds, specific equipment required;
- safe and effective management of investigational drugs;
- coordination with the day-to-day operations and interactions in the service or department: Consideration must be given to the potential impact of the Research on other ongoing activities at the CCOMTL and to its demands on users or staff;
- information security or system architecture requirements;
- biosafety and the implications of the CCOMTL's contribution to a database and/or biobank established for research purposes;
- verification of the financial aspects of the project to support the study protocol and the contractual aspects of the project, including service agreements with the various hospital departments and services, when requested;
- coverage of the project by the CCOMTL's insurance policies;
- compliance of the transfer of data outside the CCOMTL or received from external sources;
- public relations elements, in some cases.

It is therefore necessary to conduct this feasibility review and to ensure approval by the authorities concerned. Each department or directorate of the CCOMTL has designated a contact person to confirm feasibility. These people are listed in the feasibility module on Nagano⁴ and on the RRO's website. As the

³ *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* – Interagency Advisory Panel on Research Ethics, 2014, art. 2.9 and 6.12, hereafter *TCPS2*.

⁴ Currently being implemented.

case may be, one or more departments or directorates will review the feasibility within 30 days of a project being submitted on Nagano.

Research projects covered by this Regulatory Framework must undergo a financial and legal review.

1.2. Institutional authorization

As stated in Article 2.2, the CCOMTL must formally authorize the conduct of all Research taking place under its auspices or responsibility and keep a register of authorized Research projects.

The Director of Academic Affairs and Research Ethics is the person formally designated by the Board of Directors to authorize Research at the CCOMTL. No Research, as defined in this Regulatory Framework (see Article 1.3), may begin without the formal approval of the person formally designated by the Board of Directors.

Before granting institutional authorization, the latter ensures the positive outcome of the three mandatory reviews: scientific, ethical and feasibility. They ensure that all required documents have been received:

- Positive REB letter of decision;
- Letter(s) of feasibility approval from all departments/services/programs involved;
- Public health authorization, if required;
- Letter of approval from the bank management committee (if applicable) guaranteeing access to a bank (for any project using data and samples held in a bank);
- Necessary signed contracts (e.g., contracts with the private sector, data or material transfer agreements, collaborative agreements, funding agreements);
- Research budget;
- Funding letter if the project is funded by a public body or certain non-profit organizations.

The authorization to carry out the Research at the CCOMTL or under its responsibility is communicated to the Researcher through an official correspondence via Nagano. The Researcher may then carry out their Research under the auspices of the CCOMTL for a defined period of time, according to the terms and conditions identified during the institutional feasibility review and the ethics review. Authorization requires the Researcher to comply with the following terms and conditions:

- Respect the Regulatory Framework, including the guidelines regarding respect for the dignity, privacy and confidentiality of research participants;
- Use the REB-approved versions of the research documents and do not make any changes other than administrative ones and, if so, clearly identify the change and communicate it to the REB;
- Comply with the terms and conditions determined by the REB required for the annual ethics approval review;
- Respect the procedures determined by the MSSS for multicentre research, specifically with regard to respecting the dignity, privacy and confidentiality of research participants, by creating and updating a list of CCOMTL participants recruited to participate in a multicentre Research project approved by an REB other than the CCOMTL's;
- Keep research records for the period prescribed by any applicable regulations or by the REB.

2.5.1. Register of authorized projects

The register of Research projects can be found on the Nagano platform. This platform centralizes the information and documents used to conduct the scientific, ethical and feasibility reviews for Research projects and to ensure their follow-up during their post-authorization conduct. It contains the necessary information on Research projects (project title, name of principal investigator, name of REB that performed the ethical review, date of REB letter stating the positive outcome of the ethical review, date of the institutional authorization letter, date on which the REB received notification of the end of the research, service agreements related to the research project), or the necessary information on the databases and biobanks (title, name of person in charge, date of ethical review of database/biobank creation, date of cessation of activities of database/biobank, type of content, name of REB(s) that performed the ethical review).

3. SPECIFIC MANAGEMENT MECHANISMS

3.1. Financial management

The CCOMTL's Financial Resources Directorate (FRD) is responsible for the financial management of the research funds administered at the CCOMTL, in accordance with the management standards and practices set out in the HSSN's Financial management manual. The administrative managers of the research infrastructures ensure that the Researchers make proper use of the funds allocated to them, in accordance with the guidelines of the granting organizations, the universities, and the management policies of the MSSS and the CCOMTL. Administrative managers must report to the FRD.

The following responsibilities are assigned to (1) the LDI, for the financial management of Research projects led by Researchers with privileges granted by the LDI; or (2) the FRD, for all other Research.

- Open a separate administrative unit for each research account, with proof of funding;
- Produce periodic financial reports to ensure expenses do not exceed revenues and to maintain a balanced budget;
- Produce the accounting reports required by the granting organizations and academic and industrial partners. The Researcher must approve the reports before they are submitted to the granting organization;
- Invoice any direct and indirect costs to private companies and other granting organizations indicated in the contracts;
- Close the research budget at the end of the grant.

3.1.1. Management of ethics review and project approval costs

The costs related to the scientific and ethics review and authorization of projects funded by private industry are determined according to the MSSS directive (*Facturation à l'entreprise privée des services fournis par les établissements publics de santé et de services sociaux lors de l'examen et de l'autorisation d'un projet de recherche*). This circular outlines the costs associated with the scientific review, ethics review, institutional approval, amendments, and annual renewal (including costs for annual monitoring of the research AUTHORIZATION). The CCOMTL has developed a procedure for managing the associated revenues. Moreover, as mentioned in the section on the feasibility review, the involvement of the clinical

and administrative departments is essential to the start-up and proper conduct of research. In exchange for their participation, which includes coordinating the entire feasibility process, reviewing research protocols, and analyzing the needs and resources required for the research activities, some clinical and administrative departments request compensation for the costs incurred. This makes it possible to determine responsibilities and the allocation of revenues among the various departments.

3.1.2. Management of indirect research costs

In accordance with MSSS directives and through the procedures in place, the FRD ensures that indirect costs related to Research Activities are collected.

3.1.3. Duplicate payments

No costs or fees reimbursed in relation to a Research project may be paid in duplicate. In particular, a physician may not claim from the Régie de l'assurance maladie du Québec (RAMQ), a research participant or an insurance company, fees for services rendered as part of a Research project for which they are being paid.

3.2. Management of conflicts of interest

A conflict of interest (COI) may arise when activities or situations place an individual or an institution in a real, potential, or perceived conflict between the duties or responsibilities related to research activities, and personal, institutional, or other interests. These may include the commercial, business, or financial interests of the institution or other persons involved, their family members, friends or former, current or prospective business associates. Such conflict could affect professional judgment, objectivity, and independence, not to mention the outcome of a decision motivated by a personal gain.

For example, conflicts of interest may occur when an individual's judgment or actions or an organization's actions in relation to research are, or could be, affected by personal, organizational, or other interests, including, but not limited to, business, commercial, or financial interests, whether of the individuals concerned, their family members, their friends, or their former, current or prospective professional associations, or of the organization itself.

The REB is independent and plays an important role in determining whether conflicts of interest affect the research conducted by the institution. Two REB SOPs (REB SOP 105A.001 and 105B.001) describe the procedure for managing conflicts of interest and the requirements and procedures regarding the disclosure and management of conflicts of interest 1) regarding Research Ethics Board members (including the REB Chair and any ad hoc advisors) and RRO staff that supports the REB; 2) regarding Researchers and research staff taking part in Research involving human participants.

Researchers must disclose, in the research application they submit on Nagano, any real, potential, or perceived personal or institutional COI that may affect their Research. The Researcher is additionally required to provide information on their Research budget when submitting a research application.

REBs must identify and manage conflicts of interest in order to maintain public confidence, protect participants, and maintain the independence and integrity of the ethics review. All possible efforts should be made to avoid COI. If a COI cannot be avoided, procedures should be in place to mitigate the conflict.

These include, for example, the assignment of REB reviewers, procedures during meetings, and documentation of conflicts of interest.

The Researcher must disclose any conflict to the REB during the initial request presented to the REB, at each of the project's ongoing reviews and whenever a conflict of interest arises, such as changes in responsibilities or financial circumstances. The Researcher shall comply with all the requirements of the REB and with COI policies to eliminate and/or to manage the conflict.

The REB has the final authority to determine whether a COI has been eliminated or managed appropriately. The REB may reject a Research project that involves a COI that has not been appropriately managed. Any COI management plan will be documented in the final project files. Any discussions at the REB meeting regarding COI and the management plan will be documented in the REB meeting minutes.

The REB must be fair and impartial, immune from pressure either by the sponsor, affiliated organizations, the CCOMTL, or the Researchers whose research is being reviewed.

The CCOMTL conflict of interest management policy also applies to all persons in a position of authority, or authorized to make decisions within the CCOMTL, who may be in a situation of personal conflict of interest and thus create possible institutional conflicts of interest. This policy states that no person covered by the regulation (employees, middle and senior management, non-management staff, members of the Council of Physicians, Dentists and Pharmacists (CPDP), volunteers, interns, or any service provider) may place themselves or someone close to them in a conflict of interest with the CIUSSS. It provides for the declaration of conflicts of interest and sanctions, and defines the roles and responsibilities, in particular of the Board of Directors, with respect to measures to prevent or eliminate conflicts of interest.

Furthermore, the CCOMTL's Policy and procedure on disclosure of wrongdoing by employees and physicians/dentists is designed to make it easier for employees, students, interns, physicians/dentists, and volunteers to disclose wrongdoing that is in the public interest and not in their personal interest, to describe the procedures to follow, and to provide a process for handling the disclosure. It covers any act by a staff member of a public body in the performance of their duties, or by any person, partnership, group or other entity in the preparation or execution of a contract, including the granting of financial assistance, entered into or about to be entered into with a public body, and that constitutes:

- A contravention of a law or regulation applicable in Quebec;
- A serious breach of the standards of ethics and professional conduct;
- A misuse of funds or property of a public body, including funds or property that it manages or holds for others;
- Gross mismanagement within a public body, including an abuse of authority;
- An act or omission that seriously compromises a person's health or safety or the environment;
- The fact of ordering or advising a person to commit one of these wrongdoings is also considered a wrongdoing.

3.3. Management of allegations of breach of responsible conduct of research

As described in more detail in the FRQ's Policy for the Responsible Conduct of Research, responsible conduct of research refers to the behaviour expected of the various actors targeted by the policy in the

conduct of research activities. This expected behaviour is based on values such as honesty, reliability and

rigour, objectivity, fairness and independence, justice (especially in recognizing the contributions of others), trust, accountability and benevolence, openness and transparency.

The expected elements of **responsible conduct** of research, detailed in the policy, are as follows:

- Conduct research in an honest search for knowledge;
- Foster an environment of research integrity, accountability and public trust;
- Maintain an appropriate level of knowledge and expertise, and act accordingly;
- Review the work of others with integrity;
- Avoid conflicts of interest, or if they cannot be avoided, address them in an ethical manner;
- Be transparent and honest in applying for and managing public funds;
- Use research funds and resources responsibly and provide accountability;
- Report on research in a responsible and timely fashion;
- Treat data with scholarly rigour;
- Acknowledge all contributors and contributions in research;
- Treat all research participants fairly and with respect and consider the environmental impact of research;
- Define the responsibilities of partners in the responsible conduct of research;
- Promote the responsible conduct of research and remain up to date with the development of best practices.

Furthermore, the CCOMTL adheres to the definitions of **breach of responsible conduct of research** as described in the FRQ's Policy for the Responsible Conduct of Research. They are as follows:

- **Fabrication:** Making up data, source material, methodologies or findings, including graphs and images.
- **Falsification:** Manipulating, changing, or omitting data, source material, methodologies or findings, including graphs and images, without acknowledgement and which results in inaccurate findings or conclusions.
- **Destruction of research records:** The destruction of one's own or another's research data or records to specifically avoid the detection of wrongdoing or a contravention of the applicable funding agreement, CCOMTL policies, laws, regulations, or professional or disciplinary standards.
- **Plagiarism:** Presenting and using another's published or unpublished work, including theories, concepts, data, source material, methodologies or findings, including graphs and images, as one's own, without appropriate referencing and, if required, without permission.
- **Redundant publications:** The re-publication of one's own previously published work or part thereof, or data, in the same or another language, without adequate acknowledgment of the source, or justification.
- **Invalid authorship:** Inaccurate attribution of authorship, including attribution of authorship to persons other than those who have contributed sufficiently to take responsibility for the intellectual content, or agreeing to be listed as author to a publication for which one made little or no material contribution.
- **Inadequate acknowledgement:** Failure to appropriately recognize contributions of others in a manner consistent with their respective contributions and authorship policies of relevant publications. Inadequate acknowledgement also includes failure to mention the source of funding of the research activities, as required by the funding agencies.

- **Mismanagement of conflict of interest:** Failure to appropriately manage any real, potential or perceived conflict of interest, in accordance with the CCOMTL's policies and procedures on conflict of interest and the REB's SOPs on conflict of interest.
- **Misrepresentation** in an agency application or related document:
 - a) Providing incomplete, inaccurate or false information in a grant or award application or in a related document, such as a letter of support or a progress report.
 - b) Applying for and/or holding funds from an agency when deemed ineligible to apply for or hold funds from such agency for reasons of breach of responsible conduct of research policies, such as ethics, integrity, or financial management policies.
 - c) Listing of collaborators or partners without their consent.
- **Mismanagement of grants or award funds:** Using grants or award funds for purposes inconsistent with the policies of the funding agency; misappropriating grants and award funds; contravening the CCOMTL's financial policies; destroying relevant documents in an untimely manner or providing incomplete, inaccurate or false information on documentation related to expenditures charge to grant or award accounts.
- **Breaches of policies or requirements for certain types of research:** Failing to meet agency policy requirements or to comply with relevant policies, laws or regulations providing clear and compulsory directives for the conduct of certain types of research activities; failing to obtain appropriate approvals, permits or certifications before conducting these research activities; failing to respect confidentiality agreements.
- **Infringement of the integrity of a scientific peer review process and the awarding of funding:** Collusion; failure to appropriately manage conflict of interest; appropriating the work of another following a scientific assessment; or failure to respect confidentiality.
- **False or misleading allegations:** Making malicious or knowingly false allegations of research misconduct or accusing a person of such a breach.

Each institution must designate a responsible conduct of research officer (RCRO) who will be responsible for reviewing the admissibility of any complaint or allegation of breach of responsible conduct of research involving a Research project under the responsibility of the CCOMTL. The RCRO must hold a position with a sufficient level of independence and decision-making autonomy, namely to appropriately address any conflicts of interest associated with the management of allegations of breach of responsible conduct of research. This person must ensure that the institution promotes the responsible conduct of research, in particular through training for its community members. They are supported by the personnel in the CCOMTL's RRO. As part of its educational component, the RRO is developing a training program to promote the responsible conduct of research.

RCRO

The RCRO is responsible for overseeing the management of allegations of breach of responsible conduct of research for the institution. They receive and handle allegations of breach of responsible conduct of research according to the terms and conditions established in the Policy and procedure for managing allegations of beach of responsible conduct of research at the CCOMTL (2022). The procedure specifies the various steps involved in the review of grounds, the review of admissibility of allegations, and the investigation. It also sets out when complaints are reviewed by the local service quality and complaints commissioner, and when the review is done jointly with the University's RCRO.

3.4. Management of research record:

The responsibilities of Researchers with respect to research records are presented in REB SOP-107.001, in particular with respect to the use and disclosure of personal information. The Researcher is responsible for submitting information to the REB and to the participant regarding the nature of the personal information (including personal health and social services information) that will be collected for the research. The REB reviews the measures taken by the Researcher to safeguard personal information for the full life cycle of the information, including the manner in which it is identified, collected, accessed, used, disclosed, retained, disposed of, and protected. The REB verifies the measures taken by the Researcher for meeting confidentiality obligations and any reasonably foreseeable disclosure requirements. The Researcher is responsible for complying with the decisions and SOPs set out by the REB, as well as with all applicable regulations.

The Researcher is responsible for compiling and updating the list of CCOMTL research participants, as outlined in Section 2.5 on research authorization. This obligation is formally indicated in the letter of authorization signed by the person formally designated to authorize the research.

An SOP (REB SOP-303-001) details the management of research records and REB administrative records, as well as procedures associated with their access, retention, archiving and destruction. The REB office must retain all relevant records (e.g., all documents related to research submitted, REB meeting minutes, correspondence with Researchers, SOPs, REB membership list, etc.), in order to provide a complete history of all actions related to REB activities. Such records will be kept for the period of time required by the applicable regulations and guidelines.

Relevant records must be made available to authorized regulatory authorities, representatives of the academic affairs committee of the CCOMTL's Board of Directors, Researchers, and funding agencies within a certain period of time following their request for access.

3.5. Control of investigational drugs

The administration of any drug used in anticipation of, during or following a clinical trial must meet the same controls as in the care setting (AHSSS, sections 116 and 117). The management of investigational drugs at the CCOMTL is the responsibility of the head of the CCOMTL Pharmacy Department. The Pharmacy Department has several procedures and guidelines in place for controlling investigational drugs at all facilities that may administer them. In particular, there are procedures in place to:

- assess the feasibility of supporting research protocols;
- establish the necessary training and search process in the oncology pharmacy;
- order commercially available drugs or supplies;
- record the information that must be included in prescriptions in order to dispense investigational products or drugs to participants in clinical trials;
- ensure that research staff are able to get an appointment to visit the pharmacy in the context of a research project;
- ensure the use of standardized accountability logs for investigational drugs in the pharmac

3.6. Management of databases and biobanks created for research purposes

Since 2004, the JGH has had a policy and procedure for managing databases and biobanks created for research purposes. McGill University and its Faculty of Medicine have also developed general guidelines for biobanks and associated databases used for medical research,⁵ intended for Researchers within the Faculty and at its affiliated institutions who collect and store human biological samples and/or associated data for medical research purposes. These guidelines define the general requirements for the creation, maintenance and access to biobanks and associated databases.

Ethically speaking, the JGH policy is based on the broad requirements of the *Guide d'élaboration des cadres de gestion des banques de données et de matériel biologique constituées à des fins de recherche* (MSSS 2012). The medical-biomedical REB is responsible for the ethics review of biobanks under the responsibility of the CCOMTL. Prior to the REB review, the RRO, in support of the REB, ensures that the Researcher has collected all the essential information for the review, using a standard grid (*Writing Biobank Policies Essential Elements*, revised November 2015) in keeping with MSSS and TCPS 2 (2018) guidelines.

When a Researcher wants to create such a database or biobank, they must submit an application to the REB, via Nagano, that includes the following elements:

- Identification: name of the biobank, Researcher in charge and other Researchers involved, source of funding, host institution of the biobank, purpose of the collection;
- Recruitment and data collection procedures; and
- Terms and conditions related to privacy and the protection of personal information, including the access mechanism.

Prior to the REB review, the designated person ensures that the application submitted is complete and compliant, and contacts the Researcher, if necessary.

No biobank may commence operations until the REB has given final approval and institutional approval has been granted. The REB must approve any changes or updates to a biobank's management framework or schedules. The REB is responsible for conducting annual reviews of biobank research activities.

Databases and biobanks created for research purposes at the CCOMTL must remain there for the duration stipulated in their management framework. Formal approval from the CCOMTL and its REB is required to transfer responsibility to another institution. Biobanks located at more than one institution must be subject, upon their creation, to contractual agreements aimed at providing a framework for the transfer of data or biological material, the roles and responsibilities of each party, and compliance with Quebec and Canadian legislation.

The CCOMTL will soon have an updated policy on these biobanks that will reflect the new guidelines.

3.7. Management of business creation and incorporation of persons covered by this Regulatory Framework

⁵ McGill University (2015) *General Guidelines for Biobanks and Associated Databases*
<https://muhc.ca/sites/default/files/docs/2.%20Guidelines%20for%20Biobanks%20and%20Associated%20Databases.March2015.pdf>

The Board of Directors encourages technology transfers, whether through licensing or through the creation of spin-offs, in order to maximize the public usefulness and benefits for Research.

A person covered by this Regulatory Framework who chooses the path of business creation or incorporation must comply with the applicable Research standards. In particular, they must fulfil all the obligations defined in this Regulatory Framework, in addition to giving the CCOMTL access to all the documents and information needed to demonstrate their compliance with the MSSS and CCOMTL standards governing the financial management of Research projects and all applicable standards, including those related to the management of investigational drugs or the rental of CCOMTL premises.

Due to the increased risk associated with Conflicts of Interest in this context, these persons covered by this Regulatory Framework must obtain authorization from the CCOMTL before conducting any activity related to their company or under their incorporated status, at a CCOMTL institution. These activities include:

- Providing services;
- Granting licences;
- Loaning equipment;
- Loaning premises; or
- Establishing a head office.

Following approval by the person formally designated by the CCOMTL to authorize the Research Activities, agreements will be put in place with the incorporated companies or Researchers.

3.8. Management of risks specifically related to research

The CCOMTL will set up a committee to manage the risks specifically related to Research and to this Regulatory Framework, such as risks related to biosecurity, cybersecurity, and artificial intelligence. The purpose of this committee, which will be made up of experts in these fields and representatives of the CCOMTL directorates concerned, and whose operation will be described in more detail in a specific procedure, is to identify, review, and rank the risks related to the Research Activities and to determine methods for mitigating them. These methods can take the form of specific management plans or even the rejection of certain Research projects.

4. HOW RESEARCH ETHICS BOARDS WORK

As an REB within the HSSN, the CCOMTL's REB is authorized by the MSSS to review Research projects, including those involving the participation of vulnerable persons (incapable adults and minors), and the application of Article 21 of the *Civil Code of Québec*. It is comprised of two operating committees: the medical/biomedical research ethics board (MBREB) and the psychosocial research ethics board (PREB). The CER is headed by a President and a Vice-President, both appointed by the Board of Directors (BOD). They chair one of the two operational committees, respectively, depending on their area of expertise.

On September 30, 2021, the Board of Directors adopted the ***Standard operating procedures (SOP) of the Research Ethics Board***; these SOPs apply to both of the CCOMTL's research ethics boards. The SOPs are **Regulatory framework for research involving humans at the Centre intégré universitaire en santé et services sociaux du Centre-Ouest-de-l'Île-de-Montréal** 1100_01_01_01F 32

based on federal and provincial laws, as well as regulatory requirements and Research standards. They

also adhere to the standards, norms and principles of research ethics, and the policies and procedures of the CCOMTL.

These SOPs outline the purpose, jurisdiction and authority of the REB, as recognized by the Board of Directors to which it is attached; the requirements regarding the composition of the REB and appointment of members; the roles and responsibilities of RRO staff that supports the REB; the REB's decision-making process and internal governance rules, including quorum requirements; rules for documentation and archiving of REB records; and the REB's reporting requirements.

These SOPs specifically address the following:

- **Authority and purpose**
- **Research that requires REB review**
- **Training and education**
- **Management of RRO staff that supports the REB**
- **Conflicts of interest – REB members and RRO staff that supports the REB**
- **Conflicts of interest – Researchers**
- **Conflicts of interest – CCOMTL’s Board of Directors**
- **Signing authority**
- **Use and disclosure of personal information**
- **Standard operating procedures maintenance**
- **Composition of the REB**
- **Management of REB membership**
- **Duties of REB members**
- **REB submission requirements and administrative review procedures**
- **REB meeting administration**
- **Document management**
- **REB review decisions**
- **Delegated review**
- **Initial review – criteria for REB approval**
- **Recruitment and informed consent requirements**
- **Ongoing REB review activities**
- **Annual review – renewal of REB approval**
- **Suspension or termination of REB approval**
- **Research completion**
- **Communication of REB decisions**
- **REB review during publicly declared emergencies**
- **Researcher qualifications and responsibilities**
- **Quality assurance**
- **Non-compliance with the responsible conduct of research**

All HSSN REBs authorized by the MSSS to review Research projects have a similar structure and operation and are subject to the same regulatory requirements and research standards. They can act as reviewing REBs, in particular in a multicentre process. Some REBs may also act as reviewing REBs under certain agreements. For example, under a partnership agreement with the CCOMTL, the CRIR REB reviews rehabilitation Research projects for the CCOMTL.

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