Canadian Memorial Chiropractic College

RESEARCH MANUAL

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DEFINITIONS

INTRODUCTION

This manual describes the Canadian Memorial Chiropractic College's (hereafter called CMCC) practices, including procedural protocols to be followed, in the conduct of research.

These pracitces incorporate elements of and have been developed to comply with the **Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS)**[1]. This manual has been developed by revision from previous practices at CMCC. Other sources, e.g. CIHR or NIH guidelines and regulations, have also been used and will be referenced in the appropriate areas.

[1] Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, December 2022.

SECTION A: THE DIVISION OF RESEARCH AND INNOVATION

A.1. Mission and Goals

Research at CMCC is administered by the Division of Research and Innovation. The mission of the Division of Research and Innovation is to support faculty, create and maintain the research environment to enhance the conducting of research, and to promote scientific and philosophical inquiry.

In support of this mission, the Division of Research and Innovation:

1. provides ethics review of research via the Research Ethics Board (REB) to ensure high ethical standards and the protection of research subjects;
2. provides administrative support and seed funding resources for faculty research;
3. recruits and develops researchers;
4. acts as a resource to assist in the development of the research skills of faculty and students;
5. promotes and acts as a resource for collaborative research with other health care and academic disciplines and institutions;
6. promotes the dissemination of faculty research; and
7. provides administrative support and funding for student investigative projects in cooperation with the Dean, Research & Assessment.

A.2. The Research Ethics Board (REB)

The procedures of the REB are described in more detail in **Section H**.

The REB operates under the **Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans**[2] (TCPS) of the Canadian Institutes of Health Research (CIHR), the Belmont Report, the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC) as well as the Privacy Act. CMCC's research ethics policies are guided by national and/or international guidelines and policies, such as the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2022) and the Office of Research Integrity (ORI) governed by the United States' Department of Health and Human Services (HHS). For purposes of reference within this policy all sources guiding the REB management are grouped under the term (TCPS). The functions of the REB are to:

1. perform both expedited and full ethical reviews of research proposals, as appropriate under the TCPS to ensure the ethical and dignified treatment of research volunteers and human remains;
2. facilitate content-expert peer review and consultative feedback to investigators through the Office of Research Administration (ORA) and the REB Chair for investigators who request this service;
3. CMCC's REB reports to CMCC's President. CMCC's REB operates at arm's length from the institution and is independent in its decision making. The President is responsible

[2] Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2022.

for maintaining an appropriate reporting relationship with the REB and ensuring the REB is provided sufficient financial and administrative resources.

A.3. Office of Research Administration (ORA)

The Office of Research Administration (ORA) consists of the Research Administrator (RA) of CMCC and support staff.

The responsibilities of the RA are to:

1. administer the policies and procedures of the Division of Research and Innovation;
2. distribute the policies and procedures of the Division of Research and Innovation;
3. provide information on funding sources available to researchers and assist faculty in the completion of research grant applications;
4. register, catalogue, and distribute information related to all CMCC research projects and related policy, including declarations of conflict of interest, internally, to government, industry, and other academic institutions;
5. assist with submission of faculty research proposals/grant applications;
6. assist the accounting office in setting up and administering grant accounts;
7. assist in the coordination of research among departments and assist in developing collaborations with other chiropractic programs, universities, the government, and private sector;
8. assist in the protection of significant innovations and intellectual property arising out of research activities, in a manner consistent with both the public interest and the role and image of CMCC, and consistent with CMCC policy;
9. administer policy and coordinate with the accounting office and the Dean, Research & Assessment in management of faculty research and student project supervisory units, and research project budgets;
10. act as liaison officer with collaborating institution research administration offices in the implementation of collaborative and consortial grants.

The duties of the RA shall also include liaising with the Canadian Institutes of Health Research (CIHR) as per the **Agreement on the Administration of Agency Grants and Awards by Research Institutions** signed between CMCC and CIHR[3], as well as with the Office of Research Integrity (ORI) in any and all matters pertaining to the governance of grants provided through NIH, in particular with regard to instances of misconduct as detailed in **Section G**.

[3] *Agreement on the Administration of Agency Grants and Awards by Research Institutions*. As signed between the Canadian Institutes of Health Research and the Canadian Memorial Chiropractic College.

SECTION B: GUIDING ETHICAL PRINCIPLES

B.1. Guiding Principles

Researchers who are conducting research involving human subjects have a fundamental moral obligation to advance knowledge and understanding as well as to conduct their research in the interests of human welfare. Ethical research uses morally acceptable means to achieve morally acceptable ends. The research must embrace three core principles of ethical research: respect for persons, concern for welfare, and justice[4].

B.1.1. Respect

Respect for persons requires that individuals are treated as autonomous agents and that persons with diminished autonomy are entitled to have their interests protected[5]. An autonomous person is capable of deliberating about personal goals and acting under the direction of such deliberation. This view includes respect for the subject's physical, psychological, and cultural integrity. It includes the assurance of the autonomous individual's rights to an informed and uncoerced decision by ensuring the dialogue, process, rights, duties, and requirements for free and informed consent. It requires special consideration for vulnerable subjects with a diminished decision making capacity (e.g. children, people with diminished competence). It includes the respect for privacy, anonymity, and confidentiality. Respect for a subject also requires an appreciation for differences that may exist between individuals, groups, and cultures and how research issues or protocols may affect them[5].

B.1.2. Concern for Welfare

Welfare, and personal welfare, refer to the quality of a person's experience of life in all its aspects[4]. Personal welfare pertains to physical, mental and spiritual health as well as physical, economic and social circumstances. Therefore, determinants of personal welfare include housing, employment, security, family life, community membership and social participation. Researchers and REBs must concern themselves with protecting participant welfare when considering potential risks involved in the research being reviewed. In ensuring that participants are not exposed to unnecessary risks, researchers and REBs provide the necessary groundwork in achieving the most favourable balance of risks and potential benefits. In this way, participants and third parties can make a judgment about the acceptability of this balance when deciding to take part in research.

B.1.3. Justice

Justice in the context of conducting research refers to distributive justice. No segment of the population should be unfairly burdened with the harms of research or excluded from sharing in the benefits of research[6].

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[4] Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2022.

[5] The Belmont Report. Ethical principles and guidelines for the protection of human subjects of research. National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, 1979.

B.2. Conflict of Interest

Conflict of interest is defined in Chapter 7 of the **Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans** as when an activity or situation place an individual or institution in a real, potential, or perceived conflict between the duties or responsibilities related to research, and personal, institutional or other interests [6]. Specific attention must always be paid to the motives that researchers or institutions could have, or could be construed as having, when conducting, publishing or presenting their work. It is expected of all investigators at CMCC that any potential conflicts of interest are reported in the research proposal form, which is subject to the scrutiny of the REB and the Division of Research and Innovation. Conflicts of interest that are reported or perceived will be addressed according to the discretion of those bodies.

B.3. Authorship

CMCC refers, as a guideline, to the four criteria on authorship posted on the International Committee of Medical Journal Editors' (ICMJE) web site:

1. substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work;
2. drafting the work or revising it critically for important intellectual content; and
3. final approval of the version to be published; and
4. agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved [7].

In order to be considered an author, it is necessary to be responsible for at least one component of the work, and furthermore, an author should be able to identify who is responsible for each other component, and should ideally be confident in their co-authors' ability and integrity[7].

In keeping with these guidelines, all members of an investigative team who do not meet these criteria, including those who have helped to collaborate on a project, may be listed in the Acknowledgements section. An investigative team should be clear amongst themselves, by consensus, who will be considered an 'author', and who will be considered a 'contributor', before a manuscript has been submitted for publication, so that the designated corresponding author is able to offer explanation as to the roles of the individuals listed as involved. The ICMJE also considers the titles of "clinical investigators" and "participating investigators" who meet fewer than the above 4 criteria to be ineligible for authorship, but eligible for the acknowledgement section, so long as the authors comply with journal guidelines concerning obtainment of written permission from those parties to be acknowledged.

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[6] Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2022

[7] International Committee of Medical Journal Authors. *Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Ethical Considerations in the Conduct and Reporting of Research: Authorship and Contributorship*. [online at: http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html]

B.4. Privacy

CMCC conducts research in accordance with the **Privacy Act**[8], the **Personal Information Privacy and Electronic Documents Act (PIPEDA)**[9] and the **Personal Health Information Protection Act (PHIPA)**[10]. The accumulation of documents pertaining to the identities of the human participants used in research conducted at this institution, as well as the safe-keeping and eventual disposal of that information, is subject to the procedures as described in the abovementioned laws.

[8] Privacy Act (R.S., 1985, c. P-21). Queens Printer for Ontario (Act current to February 4, 2025, last amended on January 31, 2025).
[9] Personal Information Protection and Electronic Documents Act (2000, c. 5). Queens Printer for Ontario (Act current to February 4, 2025, last amended on August 19, 2024).
[10] Personal Health Information Protection Act (2004). Queens Printer for Ontario (Act current to December 1, 2024).

SECTION C: ETHICS REVIEW

C.1. Preamble

Research is defined as the processes, done with conscious effort, to develop or acquire generalizable knowledge. Generalizable knowledge includes the theories, principles, or relationships that can be corroborated by accepted scientific observation and inference as well as the collection of data on which they can be based[11].

All research conducted under the auspices of CMCC, in whole or in part, on campus or off campus, must be registered with the Office of Research Administration (ORA) following procedures as published by CMCC and updated from time to time, as necessary.

Any and all research that involves humans, or human remains that is conducted under the auspices of CMCC, in whole or in part, on campus or off campus, must undergo ethics review by the REB consistent with the **Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans**[12]. Research that does not involve humans may require scholarly review, depending on the research (**C.2.3.**).

C.2. Scope of Projects Requiring Review

All research must undergo institutional REB review, except where exempted in Section **C.2.4.**, whether:

1. research is funded or not;
2. funding is internal or external;
3. subjects are from inside or outside CMCC;
4. subjects are paid or unpaid;
5. research is conducted inside or outside of Canada;
6. research is conducted inside or outside CMCC;
7. research is conducted by or includes faculty, staff, and/or students;
8. research is collected in person or remotely (e.g., by mail, electronic mail, fax, telephone)
9. information is collected directly from subjects or from existing records not in the public domain;
10. research is to be published or not;
11. research is observational, experimental, correlational, or descriptive;
12. focus of the research is the subject;
13. project has been approved elsewhere or not;
14. research is a pilot study or a fully developed protocol;
15. research is to acquire basic or applied knowledge; or
16. research is primarily for teaching or training purposes or whether the primary purpose is the acquisition of knowledge.

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[11] Levine RJ. Ethics and regulation of clinical research 2nd ed. Baltimore, Urban and Schwarzenberg, 1986.
[12] Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2022.

The level of review, (e.g. full, expedited, scholarly or exempt) necessary for any research activity will be determined from written registration of the research activity with the REB through the Office of Research Administration using procedures determined by the ORA and approved by the REB, from time to time[13].

C.2.1. Full review

Research involving human subjects must undergo either expedited or full review with the exceptions for expedited review as per section **C.2.2.** Research requires full review if it meets any of the following criteria:

1. Projects that present greater than minimal risk;
2. Projects that are invasive (e.g. venipuncture) or involve administration of therapeutic interventions or medical devices;
3. Research that involves vulnerable populations (e.g. children, mentally incompetent, prisoners) or:
    a. Proposes to gather sensitive information (e.g. sexual history)
    b. Could be stressful beyond that expected from normal life activities under the Tri-council Policy for determining minimal risk.
4. Projects that do not meet the requirements for expedited review (**C.2.2.**)

C.2.2. Expedited review

Expedited reviews are reserved for those categories of research that are confidently expected to involve minimal risk to research subjects. Examples of such categories might include:

1. retrospective studies such as chart reviews, or reviews of patient records by clinical personnel;
2. studies involving no direct subject contact or reporting only aggregate data;
3. studies using previously-collected tissue or other biological samples;
4. annual renewals of approved projects in which there has been little or no change in ongoing research;
5. research protocols that have been previously reviewed and approved by an external REB. Studies that have been approved at an external REB will require relevant documentation (REB review letter, reply to any REB concerns and approval letter) in order to be considered; or
6. any minor protocol amendment, e.g. administrative changes such as deleting the name of a co-investigator or a change in sponsorship/study budget (however, any amendments likely to affect the rights, safety and/or well-being of the research subjects will always require full REB review).

The principal investigator must include the justification for requesting expedited review, if such a review is desired. Projects requiring use of Clinics resources will require a completed Access to Clinics form. The decision of whether a study qualifies for expedited review rests with the REB Chair.

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[13] Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2022.

C.2.3. Scholarly peer review

Research not involving human subjects (i.e. does not meet the requirement in **C.2.1.**) may undergo scholarly peer review, and is facilitated by the ORA. Scholarly review may be requested by the researcher or may be required by:

- the funder (e.g. Division of Research and Innovation, CIHR, etc.),
- CMCC in the case where the research is being submitted for external funding, or
- the Research Ethics Board during the course of evaluating risk to human subjects.

Scholarly peer review may be conducted during the course of Faculty Research Hours applications, Internal Research Support Fund applications, and external funding applications. It may also be used to review projects in conceptual phases, before a methodology involving human participants is employed. Scholarly peer review provides consultative feedback to researchers and assists in the quality improvement of research done under the auspices of CMCC.

C.2.4. Exempt works

Certain works that could be construed to be research do not require ethics review. These include performance reviews, quality assurance studies, testing within a normal educational requirement, evaluation of regular or special instruction strategies, and evaluation of instructional techniques, curricula, or classroom management methods. However, these works become research if the intent changes from quality assurance or performance evaluation to the production of generalizable knowledge. One useful way to determine if a work should be considered research is to determine if the results of the work are intended for publication or public presentation. If so, it must be registered with the ORA and may require REB review.

C.3. Scholarly Review as Part of the Ethics Review

Scholarly review examines the scientific rigour underlying the thesis and the proposed methods of research to ensure they meet sound scientific standards. Controversial works, or those that challenge scientific ideas, are evaluated on their rigour and methods and may not be discriminated against on a conceptual basis. This helps ensure the academic freedom of the researcher. It also ensures that with academic freedom comes a responsibility for scholarly excellence in the formulation of ideas and the processes of research. Research that is not in the interest of CMCC must not be discriminated against, but evaluated on its scientific merit. Similarly, a research proposal will not be given special consideration or allowed to proceed before a complete ethics review has been conducted according to REB procedures.

REB reviewers conduct a scholarly review for any project that is reviewed. Projects that undergo expedited review may not undergo a scholarly review, under the discretion of the REB Chair.

C.4. Proportionate Review

The REB has adopted a proportionate approach to review consistent with Tri-council Policy, such that the more invasive the research, the greater should be the care in assessing the research. All research must be reviewed adequately, but proportionate review reserves the most intensive scrutiny and protection for the most ethically challenging research. Proportionate review applies to setting criteria for required level of review (exempt, minimal,

full) as well as intensity of scrutiny applied within full review as based on level of risk perceived for individual projects[14].

C.5. Review of Collaborative Studies

All collaborative studies that involve human subjects, regardless of whether the study has been approved by a collaborating institution/organization, must be submitted for ethics review at CMCC. CMCC's REB may elect to accept the conclusions of the collaborating institution/organization's ethics review or impose additional requirements.

C.6. Consultation on Proposals from External Sources

Chiropractic practitioners who are members of CMCC may submit research proposals for consultative review and feedback, that may be reviewed by the REB. Consultations to non-CMCC members will be on a fee-for-service basis and/or at the discretion of the RA. This administrative fee will be commensurate with the needs and requirements of the practitioner.

C.7. Access to CMCC Populations

Any research proposing to access any CMCC clinic populations must undergo REB review under the procedures defined earlier within this policy. CMCC usually requires works done using non-patient populations (e.g. students, faculty, or staff) to undergo REB review. The requirement for review includes works that require access to confidential documents such as student grades, employee records, etc. Exceptions to this review are discussed in **C.2.4.**

[14] Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2022.

SECTION D: ETHICAL NORMS IN RESEARCH

D.1. Preamble

The following are the ethical norms that are used in the review of all research projects meeting the criteria for full review[15,16]. These norms incorporate the ethical principles listed in **Section B**.

D.2. Research Methods

Research must be sufficiently well designed to achieve its purpose (e.g. educational and/or scientific) or it is not justified. Subjects are entitled to expect that their participation is meaningful. If the research cannot achieve its purpose, then no benefit can arise from it[18-17].

D.3. Competence of the Investigators

The investigator must have sufficient training and expertise or, in the case of student research for the purpose of completing educational requirements, must have adequate supervision/consultation by experienced mentors to accomplish the research.

The investigator must also provide evidence of an appropriate level of competence for care in cases where treatment is being rendered, a condition is being observed or tested, or the subject is at physical risk. At least one member of the research team must be able to monitor subjects for adverse effects of participation.

All investigators interacting with human subjects or data extracted from human subjects, bodily tissues or personal information, shall have completed certification regarding the protection of human subjects consistent with Tri-Council policy.

D.4. Distribution of risks and benefits

The researchers must ensure that the benefits of participation in research are maximized and the risks are minimized. They must also ensure that the benefits of participation are greater than the possibility of harm. The magnitude and duration of both benefits and risks must be considered. In all cases, the Principal Investigator (PI) is unequivocally responsible for the proper conduct of the entire research team and the safety of the subjects[18].

The researcher should consider the following when assessing risks and benefits:

1. Is the proposed question and the research protocol scientifically valid?
2. Are human subjects necessary? The use of human beings in the study must be essential for scientific reasons, and should be based on data from appropriate preliminary research on animal or other models, wherever possible. The study should

[15] Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2022.
[16] Levine RJ. Ethics and regulation of clinical research 2nd ed. Baltimore, Urban and Schwarzenberg, 1986.
[17] World Medical Association Declaration of Helsinki. Recommendations guiding physicians in biomedical research involving human subjects. JAMA 1997;277(11):925-6.

not repeat work already done, unless the new work makes a contribution to the existing body of knowledge.

3. What are the identifiable and potential risks of the research? This includes risks that are present during the research as well as risks that may occur in the future as a result of research participation.

D.4.1. Classification of risks

Risks of participation in research to subjects may be:

- physical;
- psychological;
- legal;
- social; or
- economic.

The BC Ethics Harmonization Initiative report stated that "vulnerability exists along a continuum and is influenced by many factors. The presence of these factors (including but not limited to those listed below) in combination with the research design can influence the level of risk and ultimately the designation of risk for the research study:

- Participant capacity (mental, emotional, cognitive)
- Age
- Wellness or health status
- Institutionalization
- Power relationships
- Gender and gender identity
- Setting and recruitment
- Dependency
- Socio-economic status"[18]

The risk to society may be social, legal or economic. In all cases, the researcher must take a subject-centred perspective when assessing risk. This perspective recognizes that the researcher and the subject may not see the risks of harm and benefits of participation in the same way. The researcher must understand the views of the potential or actual research subjects[21].

The investigator must determine, as completely as possible, both the known and the potential risks involved in the research regimen. The risk involved in any procedure, the numbers of human subjects required, and the number of times the procedure will be performed should be minimized without jeopardizing the integrity of the research.

D.4.1.1. Minimal risk

No special consideration or review is provided for research that is within the range of minimal risk.

[18] BC Ethics Harmonization Initiative, Determining if a study is minimal risk – Common criteria guideline, May, 2013.

The standard of minimal risk is commonly defined in the Tri-Council Policy Statement, Chapter 2, Article 2.8 as follows: if "the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research" [emphasis added], then the research may be regarded as within the range of minimal risk[19]. The BC Ethics Harmonization Intitiative risk assessment matrix provides an example of criteria for determining whether a study should be classified as employing minimal risk[20]:

		Research Risk		
		Low	**Medium**	**High**
Group Vulnerability	**High**	Full Board	Full Board	Full Board
	Medium	Minimal Risk (Delegated Review)	Full Board	Full Board
	Low	Minimal Risk (Delegated Review)	Minimal Risk (Delegated Review)	Full Board

Minimal risk is relative and serves as a reference to assess the allowable risk (or relative safety) of research. For instance; a therapeutic procedure (e.g. undergoing a diagnostic test or treatment) may not exceed the range of minimal risk for a subject already undergoing these procedures. These same procedures may exceed the range of minimal risk for a subject who does not usually experience these procedures. As well, evaluating minimal risk must also consider the frequency or duration of exposure to a procedure. An investigative procedure (for example, venipuncture) may be within the range of minimal risk, but multiple or serial venipunctures may not be.

Non-therapeutic risks that are undertaken solely for the purpose of research still require review relative to the threshold of minimal risk, regardless if the therapeutic risks are within the range of minimal risk.

Minimal risks may include such events such as:
- completing a survey or questionnaire;
- answering questions in an interview;
- mild exercise in healthy individuals;
- routine physical or psychological tests or examinations; or
- inconvenience.

[19] Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2022.
[20] BC Ethics Harmonization Initiative, Determining if a study is minimal risk – Common criteria guideline, May, 2013.

While these events may generally be considered within the range of minimal risks, they are context specific and instances may arise in which they cannot be considered within the range of minimal risk. For example, surveying sensitive information, such as substance abuse or sexual disease exposure, may present greater than minimal risk. These events are presented only as a guideline to aid in the proportionate review of research. It is the REB reviewers' responsibility to determine the basis for evaluating if a procedure is within the range of minimal risk.

D.4.1.2. Physical risks to subjects

Physical risks to subjects are often the easiest risks to identify and describe. The issues in the following sections are those noted in regulations such as the Tri-Council Policy Statement.

D.4.1.2.1. Variability in the subjects

Investigators and the REB should be aware that procedures may pose additional risks because of the predisposition of certain individuals or groups to adverse reactions. Precautions should be provided in the research protocol that anticipate and take into account such risks. These precautions include such procedures as inclusion screening and providing evidence of competence for care.

D.4.1.2.2. Placebos and withholding of treatment

A subject is always entitled to the best clinical judgement and delivery of care. Research considerations must never displace this. Placebo or no-treatment control groups should only be used in the presence of clinical equipoise; a genuine uncertainty about the therapeutic benefits of each arm of a clinical trial[21](**D.4.3.**).

Placebo or no-treatment controls are generally unacceptable when standard therapies or interventions are available, but may be used under the following circumstances[24]:

- its use is scientifically and methodologically sound in establishing the efficacy or safety of the test therapy or intervention;
- it does not compromise the safety or health of participants;
- the researcher articulates to the REB a compelling scientific justification for the use of the placebo control; and
- the general principles of consent are respected and participants or their authorized third parties are specifically informed (**D.6.5**) about any:
    - intervention or therapy that will be withdrawn or withheld for purposes of the research;
      and
    - of the anticipated consequences of withdrawing or withholding the intervention or therapy.

D.4.1.2.3. Modalities of care and assessment

Some modalities of care and assessment (e.g. therapeutic ultrasound or x-rays) carry specific risks. Consideration must be given to whether the use of these modalities is within the range

[21] Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2022.

of minimal risk. Consideration must also be given to a competency for care standard (**D.3.**) to ensure that the modalities are used by qualified individuals and adequate precautions are taken for the safety of the subjects.

D.4.1.2.4. X-ray in research

In any research involving the use of x-rays, the following criteria must be fulfilled in order to obtain ethical approval:

- all imaging equipment used on research subjects must meet generally accepted imaging standards, so that all research subjects are exposed to the lowest possible x-ray dosages;
- an x-ray dosage protocol must be clearly stated in the protocol;
- subject exposure to ionising radiation must not exceed generally accepted safe limits. This also requires completion of the standard clinic documentation that is used to help ensure a female subject is not pregnant;
- if subject exposure exceeds what could be expected during the normal course of health care, and yet does not exceed generally accepted safe limits, then the informed consent form must thoroughly disclose this to the subject in an understandable fashion; and
- study subjects undergoing x-ray procedures should be informed in practical terms of the acceptable limit of elective diagnostic x-ray exposure for the following 12 months (e.g., number of combined chest and lumbar series).
- A medical imaging and radiation technologist in radiography registered/licensed with the College of Medical Radiation and Imaging Technologists of Ontario will be responsible for performing all x-ray taking procedures in the research study.

D.4.1.2.5. Safety in the Research Environment

CMCC is responsible for providing a safe working environment to all investigators and research assistants. Similarly, a safe environment must be provided to all research subjects participating in a study. This environment should be in a private space to ensure confidentiality and to protect against psychological risks. The ensuring of this safe environment is the responsibility of the PI.

D.4.1.3. Psychological Risks

Psychological risks may be more difficult to identify and communicate. Consideration to psychological risks to subjects from the subject's perspective must be given.

D.4.1.3.1. Detection of a disorder

Whether for the purposes of exclusion or inclusion screening, a condition may be detected of which the patient may be unaware or not understand. For instance, screening may detect osteoporosis, depression, or another clinical condition. The informed consent should include this possibility and the research protocol should specify how these situations will be handled. This may include notification of the patient's health care provider, etc. All actions should be planned with the patient's perspective in mind.

D.4.1.3.2. Declaration of "fit versus unfit" for inclusion

Consideration should be given for a subject's interpretation of being refused entry into a study or of being excluded during the research. For instance, a subject may become concerned if

they are refused entry into a trial that is advertising for “healthy volunteers”. Careful explanation as to the basis for refusal of entry should be given.

D.4.1.3.3. Anxiety

Subjects or potential subjects may undergo anxiety when involved in, or when invited to, participate in research. Assessment tools that deal with sensitive topics may cause anxiety. A potential subject may be anxious if he or she believes that declining to participate in research will offend a care giver/researcher. A subject centred perspective must be taken when inviting subjects to participate in research and a means of minimizing this risk must be used wherever possible.

D.4.1.4. Social risks

Involvement in research may put subjects at social risk that affect their social interaction. For instance, labelling subjects as "malingering", "deconditioned" or rendering an incorrect diagnosis in the early stages of researching a diagnostic test may have effects not only on a subject’s psychological well-being, but on his/her ability to interact socially.

Participation in research that is contrary to the interests of an employer or institution may have an impact on subjects if his/her participation is not confidential.

D.4.1.5. Risks to society

Risks to society may be physical, psychological, social or economic. Clinical research ordinarily poses little physical risk to society, unlike some biological research. Providing premature or inappropriate dissemination of findings may present psychological risks. Studies that compare ethnic, social, or economic features may present risk of stigmatization to certain groups. Researchers should be cognizant of these risks by ensuring the scientific rigour of their work, the validity of their conclusions, and a responsible means of dissemination.

D.4.2. Classification of benefits

Direct health care benefits of participation are often relatively easy to describe. Other benefits are less easy to describe and include psychosocial benefits and kinship benefits. Psychosocial benefits may be an increased feeling of personal worth, hope with new treatment, or as a diversion from boredom. Kinship means that a subject is contributing out of a sense of kinship in the hopes that their contribution will benefit others like them or society at large.

D.4.3. Clinical equipoise

Clinical equipoise refers to the presumption that the experimental treatment does not differ from standard therapy in terms of its balance of risk and benefit. This requirement is satisfied if there is a genuine uncertainty on the part of the clinical and research community, as elaborated in section **D.4.1.2.2.**, not necessarily the individual investigator[22].

[22] Freedman, B. Equipoise and the ethics of clinical research. N Engl J Med 1987; 317:141-5.

D.5. Selection of Subjects

The risk and benefit should be distributed to all potential subjects to whom the research applies. Members of society or a group should not bear an unfair direct burden of participating in research or be unfairly excluded from the potential benefits of participation. Subjects shall not be automatically excluded solely on the basis of sex or reproductive capacity (e.g. research which fails to include women of child-bearing age because of challenges in clinical trial design, although the results would be applicable to them). Subjects who are not competent to consent for themselves (**D.6.6.**) shall not automatically be excluded from research which is potentially beneficial to them as individuals, or to the group that they represent[23].

Research that is designed to survey or investigate a number of living human subjects because of involvements in generic activities, that are not specific to identifiable groups, shall not exclude prospective or actual research subjects on the basis of attributes such as culture, religion, race, mental or physical disability, economic status, sexual orientation, ethnicity, sex, or age, unless there is a valid reason for doing so.

Similarly, subjects should not be included in research that does not apply to them or to any group to which they belong.

Selecting subjects solely for availability, compromised position or manipulability rather than reasons directly related to the research problem being studied is not acceptable.

D.5.1. Children as Research Subjects

Children differ from adults in their psychology, biology, and pathology. They also differ in their level of competence and experience, not only from adults, but from other children as well. These differences must be considered when involving children in research[24]. The term “children” refers to individuals who have not reached the age of majority in the Province of Ontario.

The range of minimal risk for children is not the same as for adults. The ranges of risk may also vary between children as well. Risks for some children may be well within their daily encountered experiences, but not within that of other children.

In dealing with children, specific attention must be given to differences in the concept of minimal risk in research design (**D.4.1.1.**) as well as issues of competence (**D.6.6.**).

Parental consent for a child’s participation does not replace or mitigate the scrutiny of the REB in the evaluation of the ethics of research involving children.

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[23] Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2022.
[24] Freedman B, Fuks A, Weijer C. In loco parentis. Minimal risk as an ethical threshold for research upon children. Hastings Center Report 1993;23(2):13-9.

D.6. Informed Consent

D.6.1. Preamble

Research may only begin if prospective subjects, or authorized third parties, have had the opportunity to give free and informed consent about participation and that consent is maintained throughout their participation in the research[23]. Informed consent ensures that subjects are respected as self-determining and autonomous individuals.

Consent for care in Ontario is governed by the Health Care Consent Act, 1996[25]. Researchers involved in health care intervention studies must ensure conformity with this document.

D.6.2. Documentation of informed consent

Evidence of free and informed consent should ordinarily be documented in writing. Not all circumstances will allow the use of written consent forms (e.g., secondary use of data, case reports). If free and informed consent is not documented in writing, the procedures used to seek free and informed consent must be documented.

D.6.3. Deception and informed consent

Deception or partial disclosure may be required if full disclosure would likely alter a subject's responses and invalidate the research. Partial disclosure is only acceptable to ensure the quality of collected data rather than to ensure participation. If a prospective subject is unlikely to participate in the research if given full disclosure, partial disclosure is not acceptable.

D.6.4. Voluntariness

Free and informed consent must be given voluntarily, without manipulation, undue influence, or coercion. The subject also has the right to withdraw consent at any time, and must be given the opportunity to do so during the course of their participation in the research.

Attention must be given to specific instances where voluntariness may be compromised.

D.6.4.1. Remuneration of subjects

Subjects may be remunerated for participation to the point that it compensates for their time or inconvenience. Remuneration must not be used as an incentive to participate.

D.6.4.2. Trust relationships

Subjects may be influenced in their decision making by a relationship of trust, e.g. a physician-patient relationship or a professor-student relationship. Such trust may be coercive if relied upon as a venue to induce participation.

D.6.4.3. Authority relationships

Authority relationships, such as employee-employer or institution-student, may influence the voluntariness of consent and be coercive to participation.

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[25] Health Care Consent Act, 1996. Statutes of Ontario 1996 Chapter 2, Schedule A. Feb 4, 1998. Queens Printer for Ontario. (Act current to May 18, 2023)

D.6.4.4. Naturalistic observation

Naturalistic observation, by its nature, requires the lack of awareness of observation on the part of the subject. The REB and researchers should be aware of the context-specific implications of such research, both personal, social, and legal.

D.6.5. Informing potential subjects

Researchers shall provide, to prospective subjects or authorized third parties, full and frank disclosure of all information relevant to free and informed consent[26]. Throughout this consent process, the prospective subject must be given opportunity to discuss and contemplate their participation. Subject to the exceptions in **D.6.3.**, the researchers or their designated representatives shall provide prospective subjects with:

- information that the prospective subject is being invited to participate in a research project;
- a statement that is comprehensible to all potential participants of the research purpose, the identity of the researchers, the expected duration and nature of the participation, and a description of the research procedures, as well as the potential methods by which the researchers may disseminate their work;
- a description that is comprehensible to all potential participants of the foreseeable harms and benefits that may arise from participation in research, as well as the likely consequences of non-participation (particularly as relates to treatment) where there is a potential for psychological or physical harm;
- an assurance that prospective subjects are free not to participate and have the right to withdraw at any time with no penalty or consequence to pre-existing entitlements (such as health care) and that they will be given continuing and meaningful opportunities for deciding whether or not to continue to participate; and
- the possibility of commercialization of research findings and any potential or existing conflict of interest on the part of the researchers, CMCC or sponsors.

Informed consent may not include any statement that waives any of the subject's legal rights.

At the discretion of the REB, additional requirements may include[27,28]:

- an assurance that new information that may affect a participant's decision to participate will be made available in a timely manner;
- the basis for the subjects' selection as potential participants;
- the identity of a qualified, designated representative who can explain scientific or scholarly aspects of the research. In the case of risks above the range of minimal risk, it may be advisable to have a representative independent of the research team in this role;
- an individual outside the research team to contact regarding potential ethical issues in research;

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[26] Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2022.
[27] Freedman B, Fuks A, Weijer C. In loco parentis. Minimal risk as an ethical threshold for research upon children. Hastings Center Report 1993;23(2):13-9.
[28] Levine RJ. Ethics and regulation of clinical research 2nd ed. Baltimore, Urban and Schwarzenberg,1986.

- an indication of who will have access to information collected on the identity of subjects, descriptions of how confidentiality will be protected, and anticipated uses of the data;
- an explanation of the responsibilities of the subjects;
- consent to partial disclosure. In some instances it may be necessary to inform subjects that some information is being withheld deliberately. There may be an offer to share this information at points or at the end of the trial;
- information of the circumstances under which the subject's participation may be terminated by the researcher;
- information on any costs, payments, reimbursement for expenses or compensation for injury;
- the probability of assignment to treatment arms, in the case of randomized trials;
- in the case of health care research, information of
  (a) alternative procedures that may be advantageous to the subject,
  (b) which aspects of the procedures are not generally recognized or accepted,
  (c) the care that will be provided if the potential subject declines to participate; and/or
- the ways in which the research results will be published and how the participants will be informed of the results of the research.

D.6.6. Competence

The subject must be able to understand the information presented, to appreciate the potential consequences of a decision, and to provide free and informed consent. Those with diminished competence must be protected. Competence to consent for health care is governed in Ontario by the Health Care Consent Act 1996[29] and the Substitute Decisions Act 1992[30].

D.6.6.1. Ability to comprehend

The information that is given to the patient, both oral and written, must be within the ability of the prospective subjects or their representative to understand. This requires attention to the complexity of the language used, as well as consideration of the potential subject's ability to comprehend, which may be diminished by subject-specific circumstances such as first language.

D.6.6.2. Capacity

Subjects with diminished capacity, such as children or those who are not legally competent, are not able to give free and informed consent under any circumstances. This diminished capacity may not be global or permanent. Researchers must comply with the legal definitions of diminished capacity as defined by the Health Care Consent Act[36] and the Substitute Decisions Act[37]. Consideration must be given to the wishes of the potential subject even in the presence of authorized third party consent. A potential subject's dissent will preclude his or her participation.

[29] Health Care Consent Act, 1996. Statutes of Ontario 1996 Chapter 2, Schedule A. Feb 4, 1998. Queens Printer for Ontario. (Act current to May 18, 2023)
[30] Substitute Decisions Act, 1992. Statutes of Ontario, 1992, Chapter 30. July 1996. Queen's Printer for Ontario (current to Apil 1, 2024)

Subject to applicable legal requirements, individuals who are not legally competent shall only be asked to become research subjects when[31]:

- the research question can only be addressed using individuals within the identified group(s);
- free and informed consent will be sought from their authorized representative(s); and
- the research does not expose them to more than minimal risks without the potential for direct benefits for them. Attention should be made to the differences, for instance, between risks in children and adults. Harm in children may have longer term consequences.

For research involving incompetent individuals, the REB shall ensure that, as a minimum, the following conditions are met:

- the research describes how the free and informed consent will be sought from the authorized third party, and how the subject's best interests will be protected.;
- the authorized third party may not be the researcher or any other member of the research team;
- the continued free and informed consent of an authorized third party will be required to continue the participation of a legally incompetent subject in research, so long as the subject remains incompetent; and
- when a subject who was entered into a research project by an authorized third party becomes competent during the project, his or her informed consent will be sought as a condition of continuing participation.

D.7. Confidentiality

The best protection for confidentiality is to use methods employing anonymity. This may not be practical at all stages of research, but every attempt should be made to code or otherwise conceal subjects' identities.

Information that is disclosed in the context of a professional or research relationship must be held as confidential. With the exception of those cases where a court order is issued, or there is a prevailing legal requirement, this confidentiality cannot be breached without the subject's free and informed consent. This includes a potential subject's presence in a health care setting. Researchers may not make direct contact with subjects in such settings unless the health care provider or health information custodian has acted as an intermediary in such contacts.

Confidentiality applies to information obtained directly from the subjects or from other sources that have a legal obligation to maintain the confidentiality of records.

Personal information means information relating to a reasonably identifiable person who has a reasonable expectation of privacy. This includes personal characteristics as well as their life experience, educational, medical or employment histories. It does not include information that is in the public domain.

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[31] Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2022.

D.7.1. Interviews

Researchers who intend to interview a subject to secure personal information require approval for the interview procedure and the method of securing the personal information arising from it. Free and informed consent is required (**D.6.**).

D.7.2. Data collection, surveys, and questionnaires

REB approval is required for obtaining data and shall include considerations such as:

- the type of data collected;
- the purpose for which data will be used;
- limits on use, disclosure, retention or destruction of the data;
- safeguards for security and confidentiality of the data;
- modes of observation (e.g. photographs or videos) or access to information (e.g. sound recordings) that allow identification of subjects;
- anticipated secondary uses of identifiable data;
- anticipated data linkage with other data about the subjects, whether public or personal; and
- provisions for confidentiality of data resulting from the research.

D.7.3. Secondary use of data

Secondary use of data includes research on data that was not collected for the purpose of research (e.g. patient health records, student records) or research on data that was collected for the purposes of other research. The researcher must ensure that:

- the identifying information is essential to the research, data and analysis;
- appropriate measures are taken to protect the privacy of the individuals, ensure confidentiality, and minimize harm to subjects;
- individuals to whom the data refer have not documented their objection to secondary use; and
- where applicable, the legal custodian of the information (e.g. health care provider) has agreed to its use and a contract for its use has been agreed upon. At CMCC, each clinician is a health record custodian and the chief health records custodian is the Dean, Clinics. The REB requires the chief health record custodian's documented approval in principle for any research involving health records. See the RA for the appropriate forms. Additionally, the custodian of student academic records is the Registrar. Permission for access to and use of these files may only be achieved with documented permission from the Registrar.

When secondary use of data occurs, the REB may require:

- purpose for which the data is being used;
- informed consent from those who contributed the data (or an authorized third party);
- an appropriate strategy for informing the subjects;
- consultation with representatives of those who contributed the data; or
- limits on use, disclosure, retention or destruction of the data.

Researchers who wish to contact individuals to whom the data refer require REB authorization prior to contact. In general, the researcher is not allowed to make direct contact. An

intermediary, who is a representative of the means for which the data was collected (e.g. the health care custodian), must make the initial contact.

D.8. Pilot Studies

Pilot studies are valuable to guide more detailed investigations. Pilot studies explore an idea (e.g. an innovative therapy, a potential correlation or association, a search for certain descriptive information), determine if the logistics of the proposed research protocol will function, or train researchers in a new technique.

Pilot studies, however, do not usually answer scientific questions unless the results are unquestionably definitive. The benefit of a pilot study is the guidance it gives on the design or implementation of a full study. The REB must ensure that the reasons for the proposed pilot study are well defined, the design is sound, the study will produce scientifically sound data and the balance of the risks and benefits are in accordance with Section **D.4.**

A pilot study is a prelude to subsequent research, so there must be a reasonable expectation that subsequent research will be conducted.

D.9. Case Reports

Case reports are a form of research involving human subjects. Case reports undergo an expedited review process. Review of case reports on data collected from CMCC clinics requires a signed Access to Clinics form, per Section **D.7.3.** All submissions for approval, whether accepted or rejected, are reported to the REB at the next meeting. Rejected applications will undergo full REB review. If the rejection is upheld, the researcher may request full REB review as per the procedures section.

D.10. Research Involving Human Remains, Cadavers, Tissues, or Biological Fluids

Research protocols involving the use of human tissue, in whole or in part, must have written permission from the Anatomy Department Chair prior to submitting the proposal for ethical review. The Chair may:

- grant permission directly;
- grant permission directly and notify the Coroner's Office in writing (as a courtesy to the Coroner's Office);
- if in doubt, yet favourable towards the request, send a letter to the Coroner's Office requesting permission to comply with the request; or
- in more complicated cases, the Coroner may distribute the request to a standing committee (consisting of representatives from Anatomy Departments of qualified universities and colleges) for further consideration.

In all cases, CMCC adheres to the Anatomy Act Revised Statutes of Ontario Ch. 21 & Regulation 15 (see ORA for further information)[32].

[32] Anatomy Act, R.S.O. 1990, c. A.21. Queen's Printer for Ontario (current to December 5, 2016).

The permission granted by the Anatomy Department Chair is not an exemption from REB review.

D.11. Clinical Trials

All studies meeting the definition of a clinical trial according to TCPS2 2022 – Chapter 11: Clinical Trials and International Committee of Medical Journal Editors (ICMJE) must be registered on a publicly accessible clinical trial registration site.

All clinical trials must be conducted in accordance with Chapter 11: Clinical Trials of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2022). Researchers conducting a Phase I, II, or III clinical trial involving a drug or natural health product or a biologic or genetic therapy must contact the Office of Research Administration (ORA) prior to submitting a clinical trial application to Health Canada. The Health Canada application includes: (1) a protocol which details the objectives, benefits, risks, methods, and conditions for the trial to function, (2) Clinical Trial Site Information Form, (3) Clinical Trial Application, and (4) Qualified Investigator Undertaking.

D.12. Review Procedures for Ongoing Research

All ongoing research, whether involving human subjects or not, will provide an annual report to the RA summarizing status of the work being undertaken according to procedures as published by the ORA from time to time. The timeline currently established for this annual report is each year on the official anniversary date of REB approval, as set out on the REB Certificate of Approval, until the project's completion. Ongoing research involving human subjects will be subject to continuing ethics review by the REB. The rigour of this review will be proportionate to the ethical considerations of the research (**C.4.**) and follow procedures as determined by the REB and administered by the RA. The RA must be notified at the conclusion of research and will in turn notify the REB as necessary[33].

For research that is above the threshold of minimal risk, the REB may require:

- a formal review of the free and informed consent process;
- establishment of a safety monitoring committee;
- periodic review by a third party of the documents generated by the study;
- review of reports of adverse events;
- review of patient health records; or
- a random audit of the free and informed consent process.

[33] Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2022.

SECTION E: GRANT APPLICATIONS

E.1. Preamble

Research projects, conferences, presentations, training, capital purchases, and infrastructure development can all be funded by grants from a variety of sources, both external and internal.

E.1.1. Scope of external funding

External funding is provided by independent entities (e.g. individuals, corporations, foundations, provincial or federal granting agencies) outside of CMCC and is limited only by the individual entity.

E.1.2. Scope of internal funding

Internal funding for research activity is available through application to the Office of Research Administration for the following items:

- Research project seed funding;
- travel and presentation expenses for the purposes of presentation scientific or scholarly conferences;
- open access publication costs;
- training; or
- research release time.

E.2. Funding Research Projects

Funding for research may be sought externally or internally. Researchers are reminded that CMCC requires that projects involving human subjects receive ethics approval through the REB prior to the implementation of any funding (**E.2.1.1.**). It is imperative that researchers consider the time required for the review process (**H.3.1.**) and be aware of external funder's deadlines in order to adequately plan their application.

E.2.1. External funding

Faculty are strongly encouraged to secure external funding whenever possible. Some agencies are very specific with regard to their funding priorities, while others are quite general.

Investigators are encouraged to consider applying to one of the major chiropractic funding agencies in North America which make grants available for chiropractic research. These are financially supported by the profession and are peer-reviewed, with specific deadlines, requirements and procedures for submissions. These organizations include the:

- the Canadian Institutes of Health Research (CIHR);
- the National Sciences and Engineering Research Council of Canada (NSERC);
- the Social Sciences and Humanities Research Council of Canada (SSHRC);
- the Canadian Chiropractic Research Foundation (CCRF);
- the US National Institutes of Health (NIH) including the National Center for Complementary and Integrative Health (NCCIH), and other centres;
- provincial Ministries of Health;

- other not-for-profit Foundations; and
- for-profit corporations willing to meet ethical research standards.

Names of additional funding agencies and their specific funding priorities are filed with the RA. The RA can assist faculty investigators in their search for those agencies most likely and most appropriate to fund their areas of interest. Potential sources include Canadian municipal, provincial and federal governments, and foundation grants as well as federal and foundation sources in the United States (**E.3.**).

Once the PI decides which granting agency to target for submission, the RA is available to assist in the preparation of the submission. Copies of all external applications must be filed with the RA, regardless of whether or not the grant is held at CMCC.

E.2.1.1. Proposals to be submitted to external funders

Granting agencies may or may not require ethical approval from the sponsoring institutions before reviewing a proposal for funding or before releasing any project funding. Once a proposal has received approval from the REB, the PI will be issued a Certificate of Approval. The certificate must be provided to the granting agency. Investigators are encouraged to discuss the application and planned research with the ORA and, when practicable, to submit for necessary REB approval prior to agency submission to avoid undue delay in implementation should funding be granted.

The number of proposal copies required by the granting agency should be made and forwarded to the agency. Covering forms must be signed by the Dean, Research & Assessment, and/or designates, as required by the funding agencies.

Some funders require a notice or letter of intent rather than a complete proposal. This is usually done to ensure that the proposed research is within the funding scope of the agency. If approved, a funder may request a full application. The time given for this submission may be quite short.

E.2.1.2. Contract research

Funding opportunities for specific and targeted research may take the form of contracts with outside parties. Contract research is research work that is commissioned and funded by outside clients (usually commercial enterprises), which typically approach CMCC or researchers to do specific research work for them. Any contracts that arise as part of a research project are subject to CMCC's Contract Management, Review and Approval policy.

E.2.2. Internal Funding

Internal funding for research is intended to help support works for novice researchers to help develop a granting record and to assist researchers who may have few external grant sources for their field of endeavour.

Investigators receiving internal funding support are expected to engage in solicitation for funding support from external agencies, foundations, corporations or other philanthropic sources within 36 months of being granted internal funding. Investigators may also form collaborations with researchers at other academic institutions, with the intention of engaging in

solicitation for external funding. Failure to engage in timely applications for external funding may result in withdrawal of internal support.

E.2.2.1. Internal Research Support Fund

Internal funding is offered through the Internal Research Support Fund (IRSF), which considers applications once per year. This funding is prioritized for new researchers without a grant record, researchers who are unable to access or locate appropriate external funding sources and projects considered particularly important to the mission of CMCC. Both faculty and staff at CMCC may apply to this opportunity. This includes students in the CMCC Graduate Residency Program. The intent of the IRSF is to encourage investigators to pursue projects which will eventually evolve into protocols that may be submitted to competitive calls from funding agencies. Proposals for reviews (systematic, scoping, narrative) are not considered for this opportunity. Secondary analysis of an existing dataset is eligible. Applications involving research for a Masters thesis or Doctoral thesis at another institution (i.e. not CMCC) are not eligible.

E.2.2.2. Open Access Publication

Open access publication must be considered as a line item in all applications for external funding, especially in those cases where it is a requirement listed by the funding agency – as for example, with grant applications to CIHR. In cases where external funds are not available for open access publication, CMCC will fund applications according to the criteria below.

Requests for approval to fund publication costs to an open source journal must be made prior to submission of the article to the Office of Research Administration. The RA will then forward the request for consideration to the Directors, Lifes Sciences Laboratories, Partnerships and Health Policy, Human Performance Research, and the Dean, Research & Assessment. Consideration will include:

- Track record of the applicant, including their level of involvement in research at CMCC;
- Access to external funding, especially in those cases where publication costs have been budgeted;
- An internal peer review of the manuscript;
- Quality of the journal at which the manuscript has been accepted.

E.2.3. Research Budget Line Items

Different external funders allow different expenses (line items) to be included in the grant request. Researchers must ensure that their grant request includes only allowable line items. The ORA can assist the researcher in ensuring all line items are allowed by the funder.

E.2.3.1. Overhead charges for indirect costs

When allowed by the granting agency or institution, overhead charges should be factored into external grant requests in an attempt to recover the indirect costs incurred in conducting research under the auspices of CMCC (administrative costs, heat, hydro, repairs, insurance, salaries of personnel who manage the grants, PIs, grant management personnel, technicians, software rentals, books/journals for the library, phones, legal opinions on contracts, ethics reviews, use of equipment etc.).

Final indirect cost rates are negotiated with the funding agency by the RA once funding has been awarded. It is CMCC policy to request indirect cost payment in projects done under any contract or application. The current rate is calculated at 50% of personnel costs, however, in the case of United States National Institutes of Health applications, it is necessary to review the regulations of each funding vehicle. In general, non-US applicants are limited to 8% calculated on the entire budget. The PI should include the maximum overhead allowable by a granting agency on all research grants and contracts. Deviations from this practice must be reviewed and approved by the Dean, Research & Assessment.

E.2.3.2. Equipment

When allowed by the granting agency or institution, external grant applications should include budgetary provisions for purchasing all equipment needed to run the project. If the granting agency does not provide for capital purchases, then the proposal should include provisions for rentals/leasing maintenance of the equipment, other supplies for the equipment, software licensing fee etc. if eligible.

All equipment acquired through research grants and/or contracts is the property of CMCC, unless otherwise stipulated in writing and approved by the appropriate CMCC and granting agency authorities.

E.2.3.3. Equipment and liability insurance for externally funded projects

Equipment acquired through external research grants, whereby CMCC becomes the owner, shall be covered by CMCC's insurance policies. Equipment borrowed by or loaned to CMCC is also covered by CMCC's insurance policy. CMCC’s insurance policy may not cover all types of equipment. Researchers should consult with the VP of Administration and Finance to ensure the equipment will be covered under existing finance and insurance policies.

The researcher must include liability insurance in the budget to cover the equipment that is not covered under CMCC policy.

E.2.3.4. Maintenance contracts

When allowed by the granting agency or institution and the project is utilizing equipment, the external grant application must include provision for equipment maintenance whether the equipment is owned by CMCC, or is being acquired through a grant or otherwise.

E.2.3.5. Office supplies

When allowed by the granting agency or institution, office supplies should be included in the external grant application budget. This would include such items as: paper, envelopes, photocopier rental, long distance charges, postage, pens, markers, pencils, staplers, staples, paper clips, tape, post-its, etc.

E.2.3.6. Cost of treatment procedures in research projects

The payment, or lack thereof, for care must be considered at the time of proposal submission. Adequate funding should be requested to cover all expenses directly related to the research, such as additional hospital or office visits, laboratory analyses, devices or therapies that are ordered for research purposes and that would not normally be ordered for the patient.

E.2.3.7. Publication and presentation of research

When allowed by the granting agency or institution, publication and presentation costs should be included in the grant budget. The RA may assist in this regard, upon request.

E.2.3.8. Proposal development costs

Few funders allow for costs incurred in developing a proposal. Costs for proposal development, for example funder searches, may be funded internally.

E.2.3.9. Salaries

When allowed by the granting agency or institution, salaries for all research investigators, personnel, and staff should be included in the funding application. Those portions of the grant allocated toward research assistants and support staff should be clearly delineated in the proposal budget. For submissions for internal funding, research personnel or support staff who are students or employees at CMCC must be clearly identified in the grant request.

Budget calculation should take into consideration legislated requirements regarding pay equity, statutory obligations, etc. CMCC has salary ranges for specific job descriptions and payroll benefits to which the employee is entitled. Payroll benefits rates on application budgets must be established in collaboration with the Division of Human Resources.

Salaries for personnel who are CMCC employees on the grant should be calculated based upon the percentage of the employee's time that will be devoted to the work of the project on an FTE basis. The full dedication of the employee to all professional activity including that of the application in question may not exceed 100% FTE. A method of accounting for the use of time allocated for the participation of each employee on the work of the application is required.

Consultation with the Division of Human Resources is required prior to finalizing salaries. Consultation with the ORA is recommended prior to finalizing the budget. A copy of the budget approved by the granting agency is required to be filed with the ORA which will work with the Division of Human Resources in maintaining appropriate records of the income and expenditures related to the grant.

E.2.3.9.1. Benefits and vacation time

When salaries are paid from a grant -- be it an external or internal grant -- CMCC is the employer, not the grant holder; therefore, researchers must pay the current benefits rate for workers. These rates must be factored into the requested salary. The calculation for benefits and vacation time to be allocated for all full and part-time staff and faculty must be consistent with the policies contained in the Collective Bargaining Agreement between CMCC and CUPE Local 4773. This information can be obtained from the Division of Human Resources.

Note also, that the sharing of personnel amongst researchers, such that full-time status results for that person, or the support of a portion of an already full-time employee, will require that full-time benefits be included. The maximum combined commitment of an employee to one or more research project(s) may not exceed 100% FTE, per **F.1.3.1.2.**

E.2.4. Foreign Currency

If a grant application is to be submitted to a foreign agency and the research budget is to be detailed in a foreign currency, a separate budget page translated into Canadian dollars must be attached to the copy provided for the ORA. The type of currency and the exchange rate being used must be clearly marked on the budget sheets.

Researchers are required to use the current exchange rates at the time of budget submission to the granting entity. The exchange rate in effect at the time the award money is received, however, will be the rate used to convert the funds.

E.3. Funding Source Searches

Applications for internal grants to fund external funding source searches are approved at the discretion of the Dean, Research & Assessment. Approval for funding must be in place prior to the commencement of the search.

E.4. Travel Assistance Policy for Research Presentations

Researchers are required to include travel and presentation costs in external grant applications when allowed by the granting agency or institution. However, CMCC is committed to assisting its faculty in the dissemination of their research if this expense is not allowed by the funder. The RA must be notified of intent to submit for presentation to any meeting requiring expenditure for travel expenses.

To help ensure that funding is available, it is suggested that faculty anticipate probable submissions three months in advance. Requests for travel to present at a conference must be received no sooner than 90 days before the abstract or poster submission deadline, as posted by the organizers on the conference web site, or on releases of requests for abstract or poster submissions. Proposals for support must be submitted to the ORA. In order to accommodate as many requests for travel for conference presentations as possible, faculty members will be expected to exercise prudence concerning the duration of their stay at a venue. Accommodation may include expenses from the night before the event begins until the last night of the conference, and need to be approved by the direct report and ORA to ensure workload isn't disrupted.

For further information related to travel and research, please refer to the Collective Bargaining Agreement between CMCC and CUPE Local 4773.

Applicants who submit work accomplished as a member of CMCC faculty, or with support from CMCC including travel assistance, are required to acknowledge this support in presentations and print materials.

E.5. Training

The issue of reimbursement for costs incurred for training in research (e.g. seminars, cross training apprenticeships, etc.) is also discussed in the Collective Bargaining Agreement between CMCC and CUPE Local 4773.

Development grants may assist in the training or education of faculty that is not necessarily related to research. The RA can assist faculty in their search for those agencies or institutions most likely and most appropriate to fund career development.

E.6. Research Hours

The Division of Research and Innovation is committed to providing opportunities for professional growth and development and in support of faculty who wish to pursue scholarly work and seek academic advancement. Funds are available through an annual application process whereby faculty may apply for hours related to research activities. A call for applications are circulated late each calendar year, to permit adequate time for review and decision in advance of workload negotiations with Human Resources each April. Applications require a letter of support from the applicant's direct report.

Research hours are not intended as a substitution for existing workloads, but instead will be added to the workload of successful applicants for the fiscal year for which the applications are approved. The receipt of funds to support research hours does not imply or presume to meet eligibility criteria for faculty promotion, as this is evaluated independently and through a separate process. All faculty, excluding Teaching Assistants, may apply to this opportunity. Faculty are able to apply either as individual investigators (i.e. sole primary investigator) or as part of a team of investigators. This implies that faculty can be named as investigators on multiple submissions. If the proposed project involves a team of faculty, then all members of the team must be named on the application. The primary investigator must be identified and the role of each faculty member in the research activity must be clearly described within each proposal as justification for the requested research workload.

The applications are reviewed by a team consisting of the RA, the Directors, Lifes Sciences Laboratories, Partnerships and Health Policy, Human Performance Research, and the Dean, Research & Assessment. The review team may also include other members of the CMCC community who are subject matter experts (e.g., a member of the Clinic Management Team will be invited to review applications for clinical research, or the Research Methodologist might be invited as a reviewer on research project methodologies).

SECTION F: GRANT MANAGEMENT

F.1. Research Grant Management

CMCC is responsible to the granting agency for completing the project on-time and within the approved budget, for financial record keeping, and for ensuring regular progress reporting. The primary responsible party for meeting CMCC's commitments to completion and accountability reside in the PI. The PI is responsible for making every effort to complete the project as stated in the approved proposal, and preparing progress reports as required.

F.1.1. Arranging for and Administration of a Research Grant Account

F.1.1.1. External awards

When a granting agency awards all or part of the funds requested in the budget portion of the grant application, the PI and ORA will be notified of this by the granting agency. The agency might forward a cheque for part of the award (i.e., in instalments), pursuant to its contract with CMCC, at the beginning of the funding period. The funding agency, having approved the proposed budget, entrusts CMCC with overseeing the proper allocation of expenses.

In order to ensure that all expenses are clearly documented, the following procedure must be followed:

- Upon the awarding of an external grant, all funds received must be first forwarded to the ORA.
- The ORA staff, working with the PI, then will coordinate with CMCC's accounting office to set up a new Research Grant Account (project account) outlining the name of the study, CMCC account number, the PI, and the amount of the approved grant with appropriate line items via a New Research Grant Form.

The New Research Grant Form must be signed by the Dean, Research & Assessment. This form will then be submitted with the attached grant cheque to the Accounting Department for deposit to the new project account.

F.1.1.2. Internal awards

In order to ensure that all expenses are clearly documented, the following procedure must be observed:

- Upon the awarding of an internal grant, the PI will be notified by the RA and the procedures for establishing a new project account listed under section **F.1.1.1.** will be followed.

F.1.2. Accountability of Funds

PIs will be given printed statements of their project-accounts, revenues and expenses upon request. PIs are expected to check these statements for accuracy. Any discrepancies should be reported immediately by the PI in writing to CMCC Controller, with a copy to the ORA.

PIs will be held personally, financially accountable for any over-spending on research accounts. The PI must monitor the project's budget and immediately report to the ORA if there are any anticipated deviations from the approved budget.

If supplementary funds are required to complete the project as approved, it is incumbent upon the PI to contact the funding agency and determine if such funds are available. It is the responsibility of the PI to ensure that all possible steps have been taken to make up any anticipated shortfalls.

Unless timely arrangements to deal with any project overspending have been made with the RA, the PI will be personally responsible for such deficits.

F.1.3. Recovery of Salary, Overhead and Research Expenses

Expenses incurred by CMCC in the execution of a research proposal, if recoverable by grants, must be clearly accounted for. The two principal expenses to CMCC are those for personnel and overhead costs. Each must be appropriately expensed to the grant in question and credited to one of CMCC's research development funds to reflect the recovery of such funds.

F.1.3.1. Salaries

Salaries may be disbursed directly or via CMCC payroll. The payroll method is usually used for full- and part-time personnel who will be working at CMCC for several months. See the RA to determine the most appropriate arrangement.

If the payroll method is used, then the PI must notify the RA for whom this arrangement applies, the number of payments involved, and the amount of each payment. It should be noted that employee salary is paid every two weeks. The RA will then make the appropriate arrangements with CMCC Payroll Administrator.

With this method, all statutory withholdings (EI, Canada Pension Planincome tax, etc.) and any other benefits are automatically deducted from each pay. These amounts must be budgeted into the grant (**E.2.3.9.**), and be determined by a rate established in collaboration with the Human Resources Division.

F.1.3.1.1. Salaries and fees to students and non-CMCC personnel

Payment made to an assistant for time spent on research work will be made after the assistant has submitted a time sheet to the PI, who in turn initials it to signify his/her approval. The completed form is then forwarded to the RA for processing. See the RA for required forms and standard recommended RA hourly rates.

F.1.3.1.2. Salaries & consulting fees to CMCC faculty with Assigned Research Hours

An external salary or consulting fee received by a CMCC faculty member who has assigned research hours, for time spent on research work which falls within a faculty member's assigned research hours, will be credited to the Division of Research and Innovation.

F.1.3.1.3. Remuneration for contract researchers

In cases where researchers are contracted using monies received from research and/or special contract grants, the RA will determine, based on the language of the contract, whether to process remuneration through Payroll, or Accounting. The contract must define the researcher's role in the study, the amount of remuneration, allowable expenses and frequency of payment.

In cases where the RA has determined that the contracted researcher is to be remunerated through Accounting, that researcher will be required to invoice CMCC, according to the terms of the contract, addressing the invoice to the attention of the ORA. The RA will then process these invoices through Accounting.

In cases where the RA has determined that the remuneration should be processed through Payroll, the contracted researcher is to keep Timesheets, which must be submitted to the ORA. The RA will work with Payroll to ensure that the funds are released according to the terms of the contract.

In all cases, the RA will work with Accounting to determine which forms should be issued per Canada Revenue Agency guidelines.

F.1.3.2. Indirect costs

External awards which permit the inclusion of indirect costs (**E.2.3.1.**) will be debited to reflect the recovery of funds for administrative expenses. Unless otherwise negotiated through the Dean, Research & Assessment and approved by the President, the amounts will be credited to one of CMCC's research development accounts.

F.1.4. Research Development Accounts

Funds recovered from grants and contracts for indirect costs and salaried faculty time will be credited to one of CMCC's research development accounts. The funds will be used to support programs related to fostering continued growth and development of research initiatives in CMCC. Expenditures from this account are approved by the Institutional Affairs Committee with recommendation from Dean, Research & Assessment.

F.1.5. Budget Modifications

Specific procedures for expensing/accessing funds from a project grant account must be adhered to as allocated in the proposal.

If the proposed budget allocation is determined by the PI to be inappropriate or inconsistent with the anticipated expenses, it is incumbent upon the PI to obtain written approval from the funding agency to make any modification to the submitted budget, and notify the ORA of such a change.

F.1.6. Procedure for Expensing/Accessing Funds from a Grant Account

All expenses must be approved by the PI, the ORA, and the Dean, Research & Assessment. There are several methods for accessing project accounts but using a Purchase Order is the preferred method. Other methods may be used when time or circumstances do not allow for

use of the Purchase Order method; however, procedures selected must be consistent with current policies set forth by the Finance Division. The researcher shall notify the ORA of any equipment purchases that will be covered under CMCC's liability insurance. The ORA will then notify the Office of the Vice President of Administration and Finance to ensure that such coverage is enforced.

F.1.6.1. Purchase orders

Using this method, the vendor sends an invoice to CMCC which includes the Purchase Order Number (PO#) of the expense, and CMCC's accounting department issues a cheque directly to the vendor. This way, none of the project personnel has to personally assume any temporary financial burden, as is the case in the "Reimbursement" method.

Before the purchase is made, the PI must prepare a PO# requisition, which includes the exact amount, the nature of the expense, and the name and address, etc. of the vendor. The PO# requisition is submitted to the RA and must be signed by the PI and the Dean, Research & Assessment. The Accounting Department then issues a PO# to the RA, and the RA subsequently forwards this PO# to the PI, who can then proceed to order the item/service and give the PO# to the vendor (who includes it on the invoice). When the CMCC Accounting department receives the invoice, the payment is already authorized, and the vendor will receive payment.

F.1.6.2. Reimbursements

When supplies and services are purchased with "out of the pocket" funds of project personnel, the original receipt must be signed by the PI and submitted to the ORA. Provided that the expense is one approved by the granting agency, the RA will forward an Expense Form with the attached receipt(s) to Finance. An electronic payment (or petty cash if the amount is $20 or less) will be issued to the individual named on the form.

F.1.7. Progress Reporting

The PI is responsible for submitting progress reports to the RA (annually or as otherwise stipulated by the RA) and to the granting agency as per the agency's requirements. This report should contain, at a minimum, a summary of debits to the research account, a description of remaining funds, and an overall status report on the project. Additionally, the RA must receive a copy of all reports made to the granting agencies.

The RA will attempt to remind PIs of upcoming progress report deadlines, in order to avoid any conflict with the granting agency.

The RA will provide the Budget Accounting portion of the Progress Report to the PI. The RA is responsible for making sure that project expenses match those in the agency-approved (proposal) budget. The RA is responsible for providing PIs with timely detailed grant accounts summaries from the Accounting Department. These will be available anytime upon request.

PIs will be required to submit annual internal progress reports and to reconcile their project accounts on a quarterly basis.

F.1.8. Refunds to Granting Entities

Refunds to funding agents are based on the policies of the granting entity. Given that the terms set out in the agreement between CMCC and the funding agent are met, refunds would be considered when the data-gathering and data-analysis portions of the study are completed, all outstanding debts have been paid, and all expenses other than conference-presentation and publishing costs have been debited from the grant account. At that point, the ORA will arrange that the monies budgeted for presentations and publishing be set aside. The course of action concerning the remaining/residual funds will be determined by CMCC, in consultation with the funder.

If the granting entity forgives return of residual unspent funds within their policies or if funds are awarded by contract not requiring return, the disposition of residuals will be made based on review of the project by the RA and the PI. The RA will make one of three recommendations on use of the funds to the Dean, Research & Assessment. The recommendation will be either a) to reimburse the Research Division for uncompensated expenses related to the PI's research, b) distribution to CMCC's general fund or c) transfer the remaining monies to one of CMCC's research development funds.

F.1.9. Closing a Grant Account

At the conclusion of the project and filing of a final report to the ORA, after the account funds have been appropriately spent, the balance of funds returned to the granting entity or transfer of residuals per section **F.1.8.** as may be appropriate (such that the account balance is "0"), the RA will arrange that the project account be closed-out.

SECTION G: SCHOLARLY MISCONDUCT

G.1. Preamble

CMCC affirms that all members of CMCC have the responsibility to maintain the highest standards of academic conduct. It is the responsibility of the faculty to follow acceptable standards of conduct in their scholarly pursuits and to foster this responsibility in others, and to ensure compliance with the standards by students involved in research (c.f., CMCC's Academic Honesty Policy). Students must also be aware of and abide by these standards (CMCC Academic Calendar, section on Academic Honesty Policy).

CMCC incorporates by reference the regulations on scholarly conduct which have been established by national or international funding agencies including, but not limited to, the Canadian Institutes of Health Research, the Social Sciences and Humanities Research Council and the Natural Sciences and Engineering Research Council, as well as their Tri-council Policy Statement[34]. CMCC's research ethics policies are guided by national and/or international guidelines and policies, such as the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2022) and the Office of Research Integrity (ORI) governed by the United States' Department of Health and Human Services (HHS). Specific policies related to the ORI's misconduct process, and CMCC's adherence to this process, are listed in section **G.5.**

The official responsible for communicating allegations of, and assisting in all investigations of misconduct in the domain of research, shall be the Research Administrator from the Office of Research Administration (ORA) at CMCC. The RA will report to the Dean, Research & Assessment and the President.

G.2. Research Integrity

There are two overriding principles which underlie the integrity of research in CMCC setting:

- a researcher must be honest in proposing, seeking support for, conducting and reporting research; and
- a researcher must respect the rights of others in the pursuit of these activities and any departure from these principles will diminish the stature of CMCC and may lead to administrative or disciplinary action.

G.3. Definitions

"Scholarly misconduct" means any conscious act of fabrication, falsification, plagiarism, or other behaviour that seriously deviates from commonly accepted practice in institutes of higher learning and scholarly communities in the proposing, conducting and reporting of research activities. This definition does not include differences of opinion or honest differences in the interpretation of research results.

[34] Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2022.

G.4. Improper Research Practices

Improper research practices, which include, but are not limited to the following, constitute scholarly misconduct, namely:

1. misrepresentation, fabrication or falsification of data;
2. plagiarism, including plagiarism of one's own work;
3. misrepresentation of the methods used in research;
4. unacknowledged, selective reporting or omission of conflicting information or data to support a particular thesis or hypothesis;
5. abuse of confidentiality with regard to the information and ideas taken from manuscripts, grant applications or discussion held in confidence;
6. failure to comply with guidelines for review of or conducting of research involving human or animal subjects as described in CMCC Research Policy Manual or the policies of funding agencies;
7. abuse of confidentiality related to the data obtained during the course of a study;
8. obstruction of the academic activities of others, including interference or tampering with experimental data, substances or subjects;
9. knowingly aiding and abetting scholarly misconduct; or
10. failure to reveal any material conflict of interest which might arise in the conduct of research.

G.5. Dealing With Charges of Scholarly Misconduct

Allegations of scholarly misconduct relating to research must be reported to the ORA. The RA will then inform the Dean, Research & Assessment and the response of CMCC in investigating these allegations will have the following three properties:

1. before any determination is made, the person against whom the allegations have been made shall have full disclosure of the allegations and evidence and an opportunity to respond fully;
2. the process of disclosure and due process will occur in a timely manner; and
3. the proceedings will remain strictly confidential to the extent possible to protect the identity of the persons making the allegations and the person against whom the allegations are made from persons not party to or witnessing the proceedings.

The policies by which CMCC will respond to allegations of scholarly misconduct are outlined below. When verified, a finding of scholarly misconduct will lead to appropriate sanction. In the instance of an allegation of misconduct processes relevant to the appropriate funding source will be followed. The processes shall be guided by applicable Ontario statutes and the provisos drawn up in the Memorandum of Understanding between CMCC and CIHR, and the guidance of the United States' Department of Health and Human Services (HHS), in the body of the Office of Research Integrity (ORI), as may apply.

G.5.1. Confidentiality

To the extent allowed by law, CMCC shall maintain the identity of respondents and complainants securely and confidentially and shall not disclose any identifying information, except to:

1. those who need to know in order to carry out a thorough, competent, objective and fair research misconduct proceeding; and
2. external funding oversight organization (e.g., The Secretariat on Responsible Conduct of Research, or the ORI) as it conducts its review of the research misconduct proceeding and any subsequent proceedings.

To the extent allowed by law, any information obtained during the research misconduct proceeding that might identify the subjects of research shall be maintained securely and confidentially and shall not be disclosed, except to those who need to know in order to carry out the research misconduct proceeding.

G.5.2. Ensuring a Fair Research Misconduct Proceeding

CMCC shall take all reasonable steps to ensure an impartial and unbiased research misconduct proceeding to the maximum extent practicable. The President of CMCC, with recommendation by the Dean, Research & Assessment, shall appoint an Ad Hoc investigating board of 3 to 7 persons. Those conducting the inquiry or investigation will be selected on the basis of scientific expertise that is pertinent to the matter and, prior to selection, the institution shall screen them for any unresolved personal, professional, or financial conflicts of interest with the respondent, complainant, potential witnesses, or others involved in the matter. Any such conflict which a reasonable person would consider to demonstrate potential bias shall disqualify the individual from selection.

G.5.3. Interim Protective Actions

At any time during a research misconduct proceeding, CMCC shall take appropriate and reasonable interim actions to protect public health, federal funds and equipment, and the integrity of Tri-Council's and the ORI supported research process. The necessary actions will vary according to the circumstances of each case, but examples of actions that may be necessary include, but are not limited to:

- delaying the publication of research results;
- providing for closer supervision of one or more researchers;
- requiring approvals for actions relating to the research that did not previously require approval;
- auditing pertinent records; or
- taking steps to contact other institutions that may be affected by an allegation of research misconduct.

G.5.4. Institutional Actions in Response to Final Findings of Research Misconduct

CMCC will cooperate with and assist The Secretariat on Responsible Conduct of Research and the ORI as needed, to carry out any administrative actions that the Canadian government or HHS may impose as a result of a final finding of research misconduct.

G.5.5. Restoring Reputations

CMCC shall undertake all reasonable, practical, and appropriate efforts to protect and restore the reputation of any person alleged to have engaged in research misconduct, but against

whom no finding of research misconduct was made, if that person or his/her legal counsel or other authorized representative requests.

CMCC shall also undertake all reasonable and practical efforts to protect and restore the position and reputation of any complainant, witness, or committee member who has acted in good faith and to counter potential or actual retaliation against those complainants, witnesses and committee members.

G.5.6. Cooperation with Office of Research Integrity (ORI)

CMCC shall cooperate fully and on a continuing basis with The Secretariat on Responsible Conduct of Research and/or the ORI during its oversight reviews of this institution and its research misconduct proceedings and during the process under which the respondent may contest the oversight body's findings of research misconduct and proposed administrative actions. This includes providing - as necessary to develop a complete record of relevant evidence - all witnesses, research records, and other evidence under CMCC's control or custody, or in the possession of, or accessible to, all persons that are subject to CMCC's authority.

G.5.7. Reporting to ORI

CMCC will report to the applicable oversight body any proposed settlements, admissions of research misconduct, or institutional findings of misconduct that arise at any stage of a misconduct proceeding, including the allegation and inquiry stages.

G.6. Allegations Involving Externally Funded Research

Where an investigation of alleged scholarly misconduct involves an ongoing, externally funded project, CMCC is responsible for taking whatever steps are necessary to:

- protect the scientific integrity of the project;
- protect human or animal subjects;
- provide reports to granting agencies;
- ensure that awarded funds are properly expended and ensure the continuation of the project to the extent that such continuation is consistent with the overall objectives of the project and the need to ensure prompt, fair investigation and resolution of the allegations.

SECTION H: RESEARCH ETHICS BOARD POLICY

The content in this section serves as the Terms of Reference for the Research Ethics Board at CMCC.

H.1. Research Ethics Board (REB)

The REB consists of at least five (5) members: at least 2 members must have expertise in research disciplines, fields and methodologies in chiropractic; 1 member must be knowledgeable in ethics (Tri-Council Policy Statement training certified, unless specialized ethical concerns demand additional expertise); 1 member must be knowledgeable in the law (not currently retained by, or representing CMCC); 1 member who represents the community, and has no affiliation with CMCC and; 1 member who is knowledgeable in privacy legislation. The REB is chaired by an individual nominated by the RA and the Dean, Research & Assessment. The basic membership is to provide the broad range of experience and knowledge required to provide competent ethics review. Substitute members and/or ad hoc advisors may be invited to the REB from time-to-time. Substitute members may be nominated to allow the REB to continue its function in the event of illness or other unforeseen eventualities, without altering membership composition set out in this section. Substitute members will have appropriate knowledge, expertise and training to fulfil their duties. Ad hoc advisors may be invited to provide content expertise with respect to proposed research according to the policies of the REB[35]. Substitute members are to be distinguished from ad hoc advisors by their ability to be present for in camera discussions and to take part in voting. REB members and ad hoc advisors shall maintain confidentiality of the documents submitted for ethics review and of the REB discussions.

The REB Chair is responsible for ensuring that the REB review process conforms to all applicable regulatory requirements, including institutional requirements and the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2022). The REB Chair provides leadership for the REB, monitors the REB's decision for consistency, and ensures that these decisions are recorded accurately and communicated clearly to applicants (i.e., researchers) in writing as soon as possible.

REB members receive initial and continuing training when appropriate. All REB members are required to complete the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2022) Course on Research Ethics prior to becoming a member. The onboarding process for new REB members involves: (1) initial meetings with the ORA and REB Chair to discuss roles, responsibilities, and procedures; (2) attending REB meetings in a non-voting capacity; (3) conducting an ethics review of a project as a secondary reviewer, paired with an experienced primary reviewer; and (4) debrief meetings with the ORA and REB Chair to review the process and their experience.

[35] Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2022.

H.2. REB Meetings and Records

The REB meetings are generally scheduled to provide assigned reviewers two weeks to review submissions circulated by the ORA every month. Meetings may be called to deal with specific issues at the discretion of the Chair of the REB or the Dean, Research & Assessment.

Minutes are kept and maintained on behalf of the REB by the RA. These minutes are not generally available but may be accessed for the purposes of internal and external audits, research monitoring, and to facilitate reconsideration and appeals. The release of this information is mediated by the Dean, Research & Assessment.

H.3. REB Decision-making

The REB is mandated to review ethically acceptable research on behalf of CMCC and in accordance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2022). The REB's mandate includes approving, rejecting, proposing, modifying, or terminating any proposed or ongoing research involving humans (as per TCPS2, Article 6.3). This mandate shall apply to research conducted under the auspices or within the jurisdiction of CMCC. CMCC's REB decision-making for research involving humans is independent, free of undue influence, including situations of real, potential, or perceived conflicts of interest (as per TCPS2, Article 6.2). No project involving human subjects or data from human subjects (including cadaver materials) may proceed without a determination of REB acceptance based on policies and procedures set out by the REB from time-to-time and published through the ORA.

The REB may establish rules under which preliminary data on a limited number of subjects, using procedures previously determined by the REB as posing very minimal or no risk, may qualify for approval based solely on those grounds, subject to the discretion of the RA and the Dean, Research & Assessment.

H.3.1. Full Review

Proposals submitted to the REB are reviewed by two to three members, selected on the basis of availability. These reviewers assess the proposal and render a recommendation to provisionally accept, revise and resubmit, or reject. The reviewers present a summary of the project at the monthly meeting, including a discussion of its strengths and weaknesses to the REB with particular focus on the issues for protection of human subjects. The proposal is then open for discussion by the full REB, after which a vote is taken. Voting for acceptance is by majority with a quorum (6 members) of REB members present. If provisional acceptance is given, the PI may demonstrate compliance with provisional requirements to the Dean, Research & Assessment and receive expedited acceptance and begin the project.

REB questions with respect to research methodology may result in:

a) recommendations to the PI;
b) requirement for review (**C.2.3.**) by content experts external to the REB; and
c) rejection based on unnecessary risk to human subjects for methodology unlikely to yield meaningful results.

If an external review is required, the REB may permit expedited acceptance if the report indicates that methods are acceptable within the discipline for the state of the art or may require full review.

If the proposal is not accepted, it is returned to the applicant for modification. An applicant may: (1) rebut ethics review feedback in the form of a written response or (2) modify their proposal. If the REB declines to modify their decision, the applicant must modify their proposal before the project may commence. The REB and the applicant must make every effort to resolve disagreements with the ethics review feedback or decision through deliberation, consultation or advice.

The REB shall accommodate reasonable requests from researchers to participate in discussions about their proposals. They may not be present at the meeting during the voting on their proposal or during discussions not pertaining to their proposal.

If a proposal is rejected, the applicant has the opportunity to proceed to a standing appeals board (**H.8.**).

The applicant should allow at least eight weeks for REB review and to allow adequate time if resubmission is required.

H.3.2. Expedited Review

A project may proceed through expedited review if it is one of the following;

- a case report;
- uses instrumentation and standard procedures, consistent with normal activities in the subject's daily life, previously reviewed and listed by the REB as minimal risk;
- an annual report of an ongoing project;
- an ongoing review of a project, where allowed by the REB;
- approval of minor variations to a research protocol that has received REB approval; or
- has received provisional REB approval and has met the provisional requirements as confirmed by the Dean, Research & Assessment.

Full details regarding the classification of projects that qualify for expedited review are listed in section **C.2.2.**

H.3.3. Scholarly Review

Projects meeting the requirement for scholarly review only (**C.2.3.**) may be reviewed by the REB.

H.4. REB Authority

The REB establishes the standards for and policies of review of research involving human subjects guided by and consistent with the Canadian Tri-council policy statement: Ethical conduct for research involving human subjects[36]. The REB may elect to review individual

[36] Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2022.

proposals and is the final authority on routine ethics review. REB decisions, notwithstanding appeals to the appeals board, are final. No research that requires REB review may be conducted in the absence of REB approval. Although CMCC may refuse to allow research to proceed within its jurisdiction, this does not influence the REB's decision that the proposal is ethically acceptable. The REB has the authority to halt research that is not in compliance with these policies. The REB has the authority to terminate research that is unethical.

H.5. REB and Ongoing Review of Research

The REB reviews ongoing research (**D.11.**). The REB may halt research that is not complying with this review process or that, based on the review or independent information, may be in undeclared conflict of interest or of sufficient conflict of interest to be considered scholarly misconduct.

H.6. REB and Multi-Centred Research

The REB dictates the level of its involvement in proposals that are multi-centred in nature. It may 1) review and accept the decision of another institution's REB, 2) elect to review all elements of the research, or 3) only elements that may be require modification due to local requirements. The President of CMCC may make a decision to allow the REB to recognize research ethics decisions made by another qualified REB. The REB should communicate with other REBs to facilitate the review of multi-centred research as necessary.

H.7. REB Conflicts of Interest

All REB members are responsible for disclosing any real, potential, or perceived conflicts of interest. When the REB meeting agenda is distributed, REB members are expected to disclose (orally or in writing) as soon as possible, any conflicting interest(s) for any of the meeting items/projects on the agenda. If the REB Chair declares a conflict of interest, an alternate REB member will assume the REB Chair's responsibilities. All declared conflicts of interest will be recorded in the REB meeting minutes.

REB members may find themselves in conflict of interest if their own research is under review or they have been in direct academic conflict or collaboration with the applicant whose research is under review.

All PIs whose projects are being reviewed by the REB may attend the REB monthly meeting for initial discussion of their project, in order to answer questions and provide further clarification to the REB regarding its concerns. This provision extends to REB members who are also PIs or Co-Investigators on projects being reviewed. The PI must leave the room at the time during which the final ethical deliberations are being made, and when the vote is being cast. REB members who are Co-Investigators on a project being reviewed must also leave the room for the final deliberation and vote period, with their votes being counted as abstentions. Members who recuse themselves due to a conflict of interest shall not be counted toward quorum during their absence. Quorum will only be maintained if the remaining members possess the specific expertise, relevant competence, and knowledge necessary to proceed with decision-making.

The REB Chair is responsible for ensuring that these criteria are met when reviewing projects involving identified conflicts of interest.

H.8. Research Appeals Board

Proposals that are rejected by the REB may proceed to an appeals review by the Standing Research Appeals Board (SRAB). The SRAB consists of five members: three faculty members, one legal counsel (not representing CMCC) and one member external to CMCC. The SRAB will review the proposal in the same manner as the REB. They will have access to prior REB reviews and any correspondence or records relevant to the case in order to reach a decision. The SRAB's decision is final and is reported by a representative to the REB at a regular meeting.

DEFINITIONS

Case Report

Case reports are divided into three types 1) Retrospective, 2) Prospective or mixed report that is observational only and 3) Prospective or mixed report with altered case management. These represent a type of descriptive research in which one individual or unit (case series) is studied in depth.

A retrospective case study is one where the case report will be completed using a clinic file. The patient is no longer attending the clinic and there is no intent to contact the patient to provide additional data.

A Prospective or mixed time frame case report may take advantage of observations using combined retrospective and prospective information from a case in progress. Like the retrospective case report, a key feature to this type of case report is that no changes will be made to the clinical protocol (evaluation, management/treatment) experienced by the patient.

A Prospective or mixed time frame case report is a case report whereby either observations for case study will be made at the time of initial presentation or will begin at some point in the clinical course, during the treatment phase. A key feature to the altered case management case report is that the clinical protocol may be altered to include typical clinical options such as questionnaires and examination procedures that may ordinarily be applied to the case, but which have been included particularly for data collection. NOTE: This type of case study should not include atypical treatment or novel questionnaires or examination procedures.

CMCC

The Canadian Memorial Chiropractic College as represented by its duly appointed officers and officials and their designates.

CMCC Research Project

A research project is considered a CMCC research project if:

- the research is sponsored by CMCC;
- the research is conducted by or under the direction of any employee or agent (faculty or staff) of CMCC in connection with institutional responsibilities either on campus or off-campus or in collaboration with other institutions;
- the research is conducted by or under the direction of any employee or agent of CMCC using any property or facility of CMCC; or
- the research involves the use of CMCC's non-public information to identify or contact human research subjects or prospective subjects.

Co-investigators

Members of the research team, exclusive of the principal investigator, who bear responsibility for the research. Co-investigators typically have made a significant contribution to the development or execution of the research.

Collaborative research
Works done by CMCC faculty are considered collaborative if the criteria for a CMCC research project apply to the employee or agent of another institution.

College facilities
Any physical space, area, supplies or non-consumable equipment to which CMCC has title.

College personnel
All members of CMCC's faculty (professional, technical, and administrative), staff, students registered in CMCC's undergraduate and graduate programs, and any other persons employed in CMCC's academic or research programs.

College support
Any non-facility provision by CMCC (e.g. secretarial services, release time, library support, consumable material) that is provided to CMCC personnel pursuant to their institutional responsibilities.

Contract Research
Research in a particular subject or field which is done under specific stipulations and conditions set in an agreement between CMCC and a client providing financial support for the project.

Computer program
Any sequence of coded instructions and data for a computer including any hardware modifications required for a sequence of instructions to be executed by or made available to the computer in order to bring about a specific result.

Copyright
Copyright shall have that definition as set out in the Copyright Act and Regulations RSC 1985, c.C-42 (the Act) and, except where the following is contradictory to the definition as set out in the Act, "Copyright" meant that only the individual who has produced the work has the right to copy or permit others to copy their work. It generally includes the right to publish, produce, reproduce, and to perform a work in public. Copyright does not protect mere ideas, procedures, discoveries or facts. Copyright, in relation to work, applies to every original literary, dramatic, musical and artistic work, including but not limited to books, compilations, pamhplets and other writings, translations, lectures, musical, dramatical or dramatico-musical works, sculptures, cinematographic works, photographs, engravings, sound recordings, and computer programs.

Creator/Author
A member of CMCC's personnel who has made a significant contribution to the development or creation of a work (as defined in the Copyright Act) or product (as defined in the Patent Act).
Custodian: See Health Information Custodian

Development costs
Those resources specifically allocated to College personnel, department or division for the purposes of, either directly or indirectly, creating and/or developing a product and/or software.

Faculty
The teaching and administrative staff and those members of the administration having academic rank in an educational institution (Merriam-Webster). Embraced within this definition are the competencies associated with scholarship and expertise within a domain of knowledge and practice. Faculty, in general, may choose to participate in research activity.

Health Information Custodian
The term health information custodian is defined extensively by Ontario's Ministry of Health and Long Term Care. At CMCC, each clinician is a health record custodian and the chief health records custodian is the Dean, Clinics.

HHS: See Office of Research Integrity (ORI).

Net Revenues
The gross income received from the sale or licensing of a product and/or software less all expenses paid or incurred directly or indirectly in connection with the development, creation, marketing and promotion, licensing and maintenance of a product and/or software.

Office of Research Integrity (ORI)
The Office of Research Integrity (ORI) oversees and directs Public Health Service (PHS) research integrity activities on behalf of the Secretary of Health and Human Services with the exception of the regulatory research integrity activities of the Food and Drug Administration. Organizationally, ORI is located within the Office of the Assistant Secretary for Health (OASH) within Office of the Secretary of Health and Human Services (OS) in the Department of Health and Human Services (HHS). More information is available about the ORI at its **website**.

Patent
An exclusive right to an invention or process granted to a person. A patentable product (invention) refers to any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in art, process, machine, manufacture, or composition of matter (s.2, Patent Act, R.S.C. 1985, c. P-4) and includes related computer software, know-how and new life forms.

Principal Investigator (PI)
The member of the investigative team who is identified as the individual ultimately responsible for the research, the conduct of the research team, and the funding associated with the research.

Product
Any new and useful art, process, machine, manufacture, or composition of matter, or any new and useful improvement in art, process, machine, manufacture, or composition of matter (s.2, Patent Act, R.S.C. 1985, c. P-4).

Public Health Service (PHS): See Office of Research Integrity (ORI)

Research
The processes done with conscious effort to develop or acquire generalizable new knowledge.

As defined in U.S. federal policy [45CFR46.102(l)], research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Research Faculty
Those personnel whose assignments are made for the purpose of directing and/or conducting research and service to CMCC and profession as a principal activity or activities. Research faculty possess the capacity to oversee the systematic effort of research and perform as principal investigators (PIs) or co-PIs and supervise technical support staff, students or other professional level assistants who are collaborating on or assisting with such research. In addition to general scholarship within a topical discipline, they possesses specific competencies; including but not limited to

- Identifying, following, and applying a defined body of literature and knowledge to accomplish investigations
- Identifying and assembling the necessary team and infrastructure to carry out investigations.
- Designing, coordinating, supervising, and conducting the technical implementation of an investigation involving the use of technical knowledge, skills and equipment.
- Analyzing, interpreting, and generalizing the results in context of the body of knowledge and in communication to interested stakeholders including to other scholars, commerce, industry, and to the public and voluntary sectors.

Research Grant
Financial support of an investigator(s) conducting research in a particular subject area or field with stipulations as described in the grant application protocol approved by a granting entity.

Research Infrastructure
Research infrastructure is defined as “the physical, informational and human resources essential for researchers to conduct high-quality research.” It includes: tools, equipment, instrumentation, computer platforms, and facilities; software and information resources, including enabling (i.e., used for more than one project) computer systems, databases, data analysis and interpretation systems, and communication networks; technical support (human or automated) and services needed to operate infrastructure and keep it working effectively; and special environments and installations (e.g., buildings and research space) necessary to effectively create, deploy, access and use research tools. Such infrastructure may be used for an individual research project or as a common resource available to many research undertakings (SSHRCC, *Highlights from the March 2004 Council meeting in Victoria*).

Research Team
All individuals - including researchers, employees and support staff - associated with a research project.

Research Technical support
Technical support consists of human or automated resources and services needed to operate infrastructure and keep it working effectively (SSHRCC, ibid.). Technical support includes but is not limited to routine testing and routine analysis of materials, components and processes including the maintenance of equipment standards of safety, as distinct from the development of new theory, applications or analytical techniques.

Research Technicians
Research technicians are members of CMCC's administrative staff who assist in conduct of elements or phases of research during performance of projects, providing technical support and maintaining infrastructure under the supervision and direction of research faculty. Technicians are valuable assets to the research team and usually possess specialized technical skills and knowledge related to equipment, procedures or techniques of research and infrastructure management.

Scholarship
Scholarship may be defined as the creation, development, and maintenance of the intellectual infrastructure of subjects and disciplines, in forms such as dictionaries, text volumes, catalogues, scientific and professional journals, and contributions to major research databases.

Subject
A human being who is participating in research and bears the risks or benefits of involvement.

Work:
"Work" includes the title thereof when such title is original and distinctive (Copyright Act 1994/5. P.924)