Canadian Memorial Chiropractic College

RESEARCH POLICY MANUAL

Approved by Institutional Affairs Committee, April 2020

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INTRODUCTION

This manual describes the Canadian Memorial Chiropractic College's (hereafter called CMCC) policy governing the conduct of research. It also describes the procedural protocols to be followed in research conducted at CMCC.

These policies incorporate elements of and have been developed to comply with the **Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS)**[1]. This policy has been developed by revision from previous existing policies[2]. Other sources, e.g. CIHR or NIH guidelines and regulations among others, 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 2018.
[2] Canadian Memorial Chiropractic College. Research Policies and Procedures Manual 1996 (with 1999 and 2002 amendments).

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 Vice President (VP), Academic.

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**[3] (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. The REB operations are consistent with the policies of the Office of Human Subjects Research of the US National Institutes of Health (NIH). 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. review ethical policies and procedures and to provide feedback and recommendation to the VP, Academic upon request.

[3] 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 2018.

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 VP, Academic 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[4], 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**.

[4] *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 the guiding principles of ethical research: beneficence, non-maleficence, respect, and justice[5].

B.1.1. Beneficence and non-maleficence

Beneficence and non-maleficence can be understood as an obligation to minimize harm and to maximize possible benefits while minimizing harm[6].

B.1.2. 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[7]. An autonomous person is capable of deliberating about personal goals and acting under the direction of such deliberation[7]. 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.

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].

B.2. Conflict of Interest

Specific attention must always be paid to the motives that researchers 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. A conflict of interest is described by the Department of Health and Human Services (HHS) as work that is "compromised by financial interests of investigators

[5] 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 2018.
[6] Levine RJ. Ethics and regulation of clinical research 2nd ed. Baltimore, Urban and Schwarzenberg, 1986.
[7] 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.

that could reasonably be expected to bias the design, conduct or reporting of the research"[8]. This definition is mirrored in Chapter 7 of the **Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans**[9].

B.3. Authorship

CMCC refers, as a guideline, to the definition of "author" posted on the International Committee of Medical Journal Editors' (ICMJE) web site. The ICMJE, per the Council of Science Editors (CSE) Task Force on Authorship, states that "[a]n "author" is generally considered to be someone who has made substantive intellectual contributions to a published study, and biomedical authorship continues to have important academic, social, and financial implications". According to these standards, 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"[10].

Specifically, the following three ICMJE criteria should be considered when determining whether an investigator should be included as an author on a publication:

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 [10].

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[10].

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[8] Department of Health and Human Services, *Federal Register: Tuesday, July 11, 1995 (Volume 60, Number 132)*. The Department of Health and Human Services defines "Financial Conflict of Interest", and a revised definition of "Significant Financial Interest", as well as guidance on disclosure at http://grants.nih.gov/grants/policy/coi/coi_faqs.htm#3181 (last revised July 8, 2015).

[9] 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 2018

[10] 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**[11], the **Personal Information Privacy and Electronic Documents Act (PIPEDA)**[12] and the **Personal Health Information Protection Act (PHIPA)**[13]. 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.

[11] Privacy Act (R.S., 1985, c. P-21). Queens Printer for Ontario (Act current to August 4, 2015, last amended on July 30, 2015).
[12] Personal Information Protection and Electronic Documents Act (2000, c. 5). Queens Printer for Ontario (Act current to August 4, 2015, last amended on June 23, 2015).
[13] Personal Health Information Protection Act (2004). Queens Printer for Ontario (last amended in 2010).

SECTION C: INSTITUTIONAL 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[14].

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, animals or human or animal remains that is conducted under the auspices of CMCC, in whole or in part, on campus or off campus, must undergo institutional review by the REB consistent with the **Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans**[15]. 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.

[14] Levine RJ. Ethics and regulation of clinical research 2nd ed. Baltimore, Urban and Schwarzenberg, 1986.
[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 2018.

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[16].

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.

[16] 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 2018.

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 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 institutional 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 is research under CMCC policy, must be registered with the RA 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.

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[17].

[17] 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 2018.

C.5. Review of Collaborative Studies

Collaborative studies that involve human subjects, regardless if such studies have been approved by the collaborating institution/organisations, must be submitted for institutional ethical review according to the appropriate level as defined earlier in this policy. The REB, on consideration of the submission, may elect to accept the conclusions of external review or impose additional requirements consistent with Tri-Council Policy as it deems necessary. Such approval will ensure that all projects that are associated with CMCC fulfil the requirements contained herein.

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.**

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[18,19]. 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[18-20].

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[18].

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

[18] 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 2018.
[19] Levine RJ. Ethics and regulation of clinical research 2nd ed. Baltimore, Urban and Schwarzenberg, 1986.
[20] 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"[21]

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.

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

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

may be regarded as within the range of minimal risk[22]. 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[23]:

		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.

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

[22] 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 2018.
[23] BC Ethics Harmonization Initiative, Determining if a study is minimal risk – Common criteria guideline, May, 2013.

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[24](**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]:

- there is no standard treatment;
- standard treatment has been shown to be no better than placebo;
- evidence has arisen creating substantial doubt of the therapeutic advantage of standard therapy;
- effective treatment is not available due to cost constraints or short supply;
- a population of patients are refractory to standard therapy, and no standard second line therapy exists;
- testing of "add-on" treatments to standard therapy when all subjects in the trial receive all therapies they would normally receive; or
- patients have provided an informed refusal of standard therapy for a minor condition for which patients commonly refuse treatment and, when withholding such therapy, will not lead to undue suffering or the possibility of irreversible harm of any magnitude.

Patients must be fully informed about any therapy that will be withheld for purposes of the research, the anticipated consequences of the withdrawing or withholding of the therapy, and the reasons why the researchers deem a placebo-controlled trial necessary (**D.6.5.**).

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

[24] 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 2018.

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).

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[25].

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

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

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[26].

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[27]. 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.

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

[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 2018.
[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.

maintained throughout their participation in the research[28]. 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[29]. 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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[28] 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 2018.

[29] Health Care Consent Act, 1996. Statutes of Ontario 1996 Chapter 2, Schedule A. Feb 4, 1998. Queens Printer for Ontario.

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[30]. 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[31,32]:

- 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;

[30] 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 2018.
[31] 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.
[32] 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[33] and the Substitute Decisions Act 1992[34].

D.6.7.1. 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.6.7.2. 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 1996[31] and the Substitute Decisions Act 1992[32]. 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.

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[33] Health Care Consent Act, 1996. Statutes of Ontario 1996 Chapter 2, Schedule A. Feb 4, 1998. Queens Printer for Ontario (last amended July, 2010).

[34] Substitute Decisions Act, 1992. Statutes of Ontario, 1992, Chapter 30. July 1996. Queen's Printer for Ontario (current to January, 2011, last amended 2009).

Subject to applicable legal requirements, individuals who are not legally competent shall only be asked to become research subjects when[35]:

- 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[33]:

- 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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[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 2018.

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 a signed Access to Student Records form 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. Working with Animals

D.10.1. Animal Care Committee (ACC)

"It is the responsibility of the ACC to ensure that no research or testing project or teaching program (including field studies) involving animals be commenced without prior ACC approval of a written use protocol [consistent with Canadian Council on Animal Care (CCAC) guidelines]; further to this, that no animals be acquired or used before such approval. This includes internally funded projects."[36] The sections below (**D.10.1.1-6**) will be referred to as the ACC's Terms of Reference.

The senior administrator to whom the committee reports is the VP, Academic. Per CCAC guidelines, the senior administrator must not be a member of the ACC, but there can be a representative of the senior administration on the committee. The senior administrator is responsible for ensuring that:

- there are mechanisms in place to ensure that the proposed animal-based work has merit,
- there is an appropriately composed and structured, and well-functioning ACC in place for CMCC,

[36] Canadian Council on Animal Care, *Guide to the Care and Use of Experimental Animals, v. 1*, 1993 – addition between square parentheses added

- there are sufficient and well-structured veterinary and animal care staff resources,
- animal users are well-informed with regard to all aspects of the animal care and use program,
- a sound structure is in place to support a solid program and foster good communication between the animal users, ACC and veterinary and animal care staff,
- institutional measures are in place to protect all those who may be exposed to animals from related hazards, and
- the institution prepares appropriately for every CCAC assessment visit. [37]

Terms of Reference

D.10.1.1. ACC Membership

The ACC consists of a minimum of six (6) members and should be appointed for three year terms. The initial appointment will be staggered with appointments, other than the ORA support coordinator (see bullets below), randomly assigned to a minimum of 2 at 2 years, 2 at 3 years and 2 at 4 years, and appointment is renewable. With the exception of ex-officio ACC members whose membership has no term limit, positions are renewable up to a maximum of 8 consecutive years of service. The complement of the committee should include:

- scientists and/or teachers experienced in animal care and use, who may or may not be actively using animals during their term on the ACC; there should be a minimum of two such members, and representation of all the major animal-using divisions of the institution must be ensured;
- a veterinarian, normally experienced in Laboratory animal care and use;
- an institutional member whose normal activities, past or present, do not depend on or involve animal use for research, teaching or testing;
- at least one, and preferably two or more, person(s) representing community interests and concerns, who has (have) had no affiliation with the institution, and who has (have) not been involved in animal use for research, teaching or testing; community representation must be ensured for all ACC activities throughout the year;
- technical staff representation (either an animal care, an animal facility or an animal research technician) if there is (are) (a) technical staff member(s) actively involved in animal care and/or use within the institution;
- student representation (graduate and/ or undergraduate), and;
- the coordinator (the institutional employee who provides support to the ACC) as assigned through the Office of Research Administration.

The chair of the committee will be appointed by the senior administrator to whom the ACC reports. The ACC chair should not be an animal health or veterinary personnel member charged with ensuring compliance with CCAC guidelines, nor be involved in the preparation of a significant number of the protocols to be reviewed by the committee, in order to avoid potential conflicts of interest. Provision is made to temporarily appoint ad-hoc members to the ACC, following the bullets above, for individual meetings as the need arises to accommodate conflict of interest on the part of regular members and maintain quorum. A quorum shall be

[37] Canadian Council on Animal Care, policy statement for: senior administrators responsible for animal care and use programs, 2008

defined as a majority of the members for ACC meetings, and it must include at least one community member and one veterinarian.

D.10.1.2. Authority

The ACC has the authority, on behalf of the senior administrator responsible for animal care and use for CMCC, to:

- Stop any objectionable procedure if it considers that unnecessary distress or pain is being experienced by an animal;
- Stop immediately any use of animals which deviates from the approved use, any non approved procedure, or any procedure causing unforeseen pain or distress to animals; and
- Have an animal killed humanely if pain or distress caused to the animal is not part of the approved protocol and cannot be alleviated.

The ACC will delegate to the veterinarian(s) the authority to treat, remove from a study or euthanize, if necessary, an animal according to the veterinarian's professional judgment. The veterinarian will attempt to contact the animal user whose animal is in poor condition before beginning any treatment that has not previously been agreed upon, and will also attempt to contact the ACC Chair, but the veterinarian will have the authority to proceed with any necessary emergency measures, whether or not the animal user and ACC Chair are available. A written report should be sent by the veterinarian to the animal user and to the ACC following any such event.

The Chair of the ACC and the veterinarian(s) will have access at all times to all areas where animals are or may be held or used.

The Research Procedure Manual held in the ORA contains procedures, post-approval, for the monitoring of animal use protocols, and defines the roles and responsibilities of the members of the animal care and use program in the monitoring process. The ACC is responsible for determining and working to correct breaches of compliance with approved animal use protocols and standard operating procedures (SOPs). Breaches of compliance that cannot be corrected by the ACC working with the concerned animal users and veterinary/animal care staff will be referred to the senior administration, which will inform all members of the animal care and use program about sanctions that will be taken by the administration in the event of serious breaches of compliance.

D.10.1.3. Responsibility

It is the responsibility of the ACC to:

1. Ensure that no research or testing project or teaching program (including field studies) involving animals be commenced without prior ACC approval of a written use protocol; further to this, that no animals be acquired or used before such approval. This includes internally funded projects;
2. Ensure that no animals be held for display or breeding purposes, or for eventual use in research, teaching or testing projects, without prior ACC approval of a written animal use protocol, except where current CCAC guidelines provide for exemptions. The ACC

should also be aware of other animal-based activities, such as commercial or recreational activities, within the institution, and should work with the persons responsible for these activities to ensure that animal care and use is undertaken according to appropriate procedures;

3. Require all animal users to complete the CMCC Animal Use Protocol form and ensure that the information therein includes the information as outlined in the CMCC Research Procedure Manual. To facilitate the work of both protocol authors and ACC members, appropriate SOPs should be referred to as much as possible. Approved protocols and SOPs should be readily available in the areas where animal-based work is taking place.
4. Ensure that each research project has been found to have scientific merit through independent peer review before approving the project; if the review is not carried out by an external, peer review agency, the ORA will obtain it according to the *CCAC policy statement on: scientific merit and ethical review of animal-based research*, 2013. Refer to the Research Procedure Manual for the mechanism through which peer-reviewed projects are reviewed for their scientific merit;
5. Review and assess all animal use protocols, with particular emphasis on the *CCAC policy statement on: ethics of animal investigation* and *CCAC guidelines on: animal use protocol review* as well as on all other relevant CCAC guidelines and policy statements and, where necessary, require further supportive information from the investigator or meet with the investigator to ensure that all members of the committee understand the procedures to be used on the animal. Protocol authors and members of their teams will not be allowed to remain in the room for the duration ACC decision-making on their protocols.
   The committee will also ensure that all procedures comply with CCAC guidelines, and, if at variance with those guidelines, require justification for the variance on scientific grounds.
   The ACC may delegate the responsibility of interim approvals to an interim approval subcommittee, which will include at least one scientific member, one veterinarian and one community representative, one of which should be the chair of the ACC. However, such interim approvals will be used infrequently, and the interim review process, including exchanges between the ACC and protocol authors, will be documented and subject to discussion and final approval at a full meeting of the committee. The ACC defines its protocol review process in the Research Procedure Manual;
6. Ensure that animal users update their protocols with any modifications they intend to make, and approve any modifications to a protocol before they are implemented. Amendments to a project will be considered minor, and can be approved by the Chair of the ACC or a delegate, if they meet the following criteria:

   - There is no change in level of pain/discomfort (e.g., changing from no pain, or minimal pain, to moderate or severe pain);
   - There is no change in anaesthetic protocol (e.g., switching from injectable anaesthetic to inhaled anaesthetic);
   - There is no change from terminal to recovery experiments (i.e. in keeping with our license, all animals must be sacrificed under anaesthesia at the end of the experiment);
   - There is no change in surgical approach (e.g., opening abdomen versus opening back to expose spine);

- There is no change in the objectives of the study;
- There is no significant change in animal numbers, a significant change being a variation of greater than 10% in the number of animals proposed to be used;
- There is no change in species, age or gender of experimental animals.

An amendment entailing any of the above changes will be considered a major change. Major changes to a protocol will require a new submission to the ACC for full review. The ACC shall also ensure that animal users report any unanticipated problems or complications, as well as on the steps they have taken to address the problem(s), to the ACC;

7. Review all protocols annually, i.e., within a year of commencement of the project; annual renewals should be approved by at least a scientist, a veterinarian and a community representative and will be brought to the attention of the full ACC for its information. All protocol renewals must emphasize:
    a. the number of animals used in the preceding year;
    b. the number of animals needed for the year to come, with a justification;
    c. a brief progress report, describing any complications encountered relative to animal use (unpredicted outcomes, and any animal pain, distress or mortality), any amendments to the original protocol, and any progress made with respect to the Three Rs of replacement, reduction and refinement of animal use;
    d. a brief report on the adequacy of the endpoints for the protocol, and on any complications encountered or refinements made relative to protecting animals from pain, distress or mortality; and
    e. any other changes from the original protocol.

    The ACC shall require the submission of a new protocol after a maximum of three consecutive renewals;
8. Document all ACC discussions and decisions in the committee minutes and on attachments to the protocol forms;
9. Refer to the Standing Research Appeals Board (SRAB) institutional appeal mechanism described in section **H.8.** of this policy manual, which can be used by the author of a protocol in the event that animal use is not approved by the ACC. In the case of a protocol which has not been approved by the ACC, the SRAB will include appropriate expertise and ensure a separate, fair and impartial process. The CCAC may be called upon for information purposes; however, appeals cannot be directed to the CCAC;
10. Ensure that all ACC members and animal users have the opportunity to become familiar with the CCAC Guide and CCAC policy statement on: ethics of animal investigation and all other CCAC guidelines and policy statements, federal, provincial or municipal statutes that may apply, as well as institutional requirements;
11. Ensure appropriate care of animals in all stages of their life and in all experimental situations. Veterinary care must be available. Formal arrangements must be made to obtain the services of a veterinarian, at least on a consultative basis, if they are not readily available within the institution. These formal arrangements must be based on the elements contained in the CALAM/ACMAL Standards of Veterinary Care of the Canadian Association for Laboratory Animal Medicine (2007), which define the roles and responsibilities of veterinarians involved in scientific animal care and use programs;
12. Establish procedures, commensurate with current veterinary standards, to ensure that:

a. unnecessary pain or distress is avoided, and animal stress and injuries are avoided, whether during transfers of animals or in their normal quarters;
b. anaesthesia and analgesia are properly and effectively used; the only exception to this may be when agents must be withheld as a scientifically justified requirement of the study, and that this has been approved by the ACC. Painful studies requiring exemption from the use of either anaesthetics or analgesia will be subject to scrutiny prior to approval and during the experiment;
c. appropriate post-operative care is provided;
d. all due consideration is given to animal welfare, including environmental enrichment;

13. Ensure that policies to provide for a system of animal care that will meet the needs of the institution are established and implemented, and include:
    a. the requirement that all animal care and animal experimentation are conducted according to CCAC guidelines and policies, and to any federal, provincial and institutional regulations that may be in effect;
    b. ensuring adequate animal care and management of the animal facilities, in particular by verifying that a member of the ACC is designated to be in charge of animal care and management of the animal facilities, who will update ACC members on activities within the animal facilities;
    c. the training and qualifications of animal users and animal care personnel; veterinarians and animal care staff must receive continuing education in their field, and animal users (scientists/study directors, post-doctoral fellows, graduate students and research technicians) must receive appropriate training according to the *CCAC guidelines on: institutional animal user training*, 1999, either within the institution or through the programs of other institutions;
    d. an occupational health and safety program for those involved in animal care and use, in collaboration with CMCC's Occupational Health and Safety officer, that will appropriately protect all those who may be affected by animal-based work, according to CCAC guidelines (see Chapter VIII of Volume 1 (2nd Edn, 1993) of the CCAC Guide or the most recent CCAC guidance on occupational health and safety);
    e. standards of husbandry, facilities and equipment;
    f. standard operating procedures for all activities and procedures that involve animals, including animal care and facility management SOPs, and animal use SOPs; the ACC will receive all SOPs and ensure they are produced and regularly reviewed;
    g. procedures for euthanasia;
14. Encourage the use of pilot studies with few animals when new approaches, methods or products are being tried, before approving new, large scale protocols. Ensure that animal users report on the results of any pilot studies, no matter whether they wish to pursue the study immediately or not, in order to preserve important data on various approaches to animal-based studies, whether they work well or not; and
15. In the case of projects involving proprietary or patentable research or testing, ensure that as much information as possible is provided to the ACC in terms of what effects to expect on animal health and welfare, and insist on close monitoring of animals in order to respect the elements outlined in section D.10.1.3.12.

16. The Animal Care Committee is responsible for carrying out Post Approval monitoring program.

D.10.1.4. Meetings

The ACC will meet at least twice per year and as often as necessary to fulfil their Terms of Reference and be satisfied that all animal use within their jurisdiction is in compliance with institutional, municipal, federal and provincial regulations, and CCAC guidelines. Minutes detailing ACC discussions, decisions and modifications to protocols will be produced for each meeting, and forwarded to the VP, Academic.

In addition, members of the ACC will regularly visit all animal care facilities and areas in which animals are used, in order to better understand the work being conducted within the institution, to meet with those working in the animal facilities and animal use areas and discuss their needs, to monitor animal-based work according to approved protocols and SOPs, to assess any weaknesses in the facilities (ageing facilities, overcrowding, insufficient staffing and any other concerns) and to forward any recommendations or commendations to the person(s) responsible for the facilities and for animal use.

Visits of the animal facilities should be conducted at least once a year, and should be documented through the ACC minutes or written reports. Those responsible for the animal facilities should respond to any ACC recommendations in writing, and site visit reports should always be followed up on jointly by the senior administration and the ACC. The full ACC may tour the facilities as a group. No matter what the process employed, each member of the ACC should participate in some of the facility visit(s) on an annual basis.

More frequent ACC site visits will be made as necessary to follow up on any protocols that have raised significant concern during the protocol review process, or where problems have been encountered with a protocol being carried out in practice or with other aspects of animal facility operations; these visits may be carried out by the Chair of the ACC or delegate, accompanied or not by other members or animal care staff.

D.10.1.5 Animal-Based Projects Involving Two or More Institutions

Most animal use at CMCC is undertaken by investigators working on site, and overseen by CMCC's ACC. However, in certain cases, CMCC faculty may undertake animal use in more than one 'host' institution(s). In other cases, various parts of an animal-based project are carried out by several institutions.

D.10.1.5.1. Investigators and teachers carrying out animal-based work in host institutions.

An institutional ACC is responsible for overseeing the work carried out by all members of the institution who use animals for research, teaching or testing. Therefore, a member of CMCC faculty who wishes to carry out animal-based work within a host institution's facilities must first submit a written animal use protocol describing the project to the ACC at CMCC. The ACC at CMCC must review the project to ensure that it meets the committee's normal standards and does not contravene any institutional policies on animal care and use. The ACC at CMCC can

then approve the protocol in principle, conditional to the approval of the protocol by the host institution's ACC.

The host institution's ACC, having received the approval in principle of the protocol from CMCC's ACC, can then review the protocol focussing primarily on whether the animals can be housed, cared for and used appropriately according to CCAC guidelines and policies, given the host institution's facilities and resources. The host institution's ACC must approve the protocol before the protocol can begin, and normally before animals are acquired. It must also take responsibility, with the collaboration of the animal care and veterinary staff of the host institution, for oversight of the protocol and of the welfare of the animals to be used. The host institution's ACC must inform the ACC at CMCC of its decision and of any relevant conditions or details accompanying the decision.

Where possible, and to facilitate this process for all of those involved, the investigator will use a single protocol form agreed upon by the ACCs and the investigator. The chairs of each ACC must communicate directly with each other to discuss any questions that either committee may have. This will minimize delays in the review process while ensuring that each committee is clearly informed and that each can make the most appropriate decision in light of this information.

D.10.1.5.2. Animal-based projects undertaken in two or more institutions.

Investigators from two or more institutions may choose to undertake a collaborative project in which the animal-based work is to be divided between the animal facilities of the various institutions. For these projects, the ACC of each institution involved must receive a written animal use protocol detailing the animal-based work to be undertaken within the facilities for which it is responsible. This protocol must also provide a brief description of the project as a whole. Any interactions between the institutions relative to the animal-based work (e.g., transfer of animals from one institution to another, special requirements to ensure the health and welfare of the transferred animals, etc.) must be understood and accepted by the ACCs of each of the institutions involved.

Once again, clear and direct communication between ACCs is strongly recommended to facilitate the process and to ensure that CCAC guidelines and policies are applied, and animal care and use is appropriately overseen throughout all phases of a collaborative project. The ACC at CMCC should normally take the lead in providing an ethical review of the most comprehensive protocol, and should coordinate and address questions and comments from the other ACCs involved.

D.10.1.6. General

The ACC:

1. Will review, at least every three years:
    a. its Terms of Reference to meet new CCAC guidelines or policies and changing needs within the institution, the scientific community, the animal welfare community and society as a whole, and expand its Terms of Reference to meet the requirements of each institution;
    b. the security of the animals and research facilities;

c. standard operating procedures and institutional animal care and use policies; SOP review may be delegated to ACC members with the appropriate expertise, but SOPs should be accessible to all ACC members, and the full ACC should review all SOPs that involve procedures that may result in deleterious effects to animal health or welfare; and
d. policies and procedures for monitoring animal care and experimental procedures within the institution, including the identification of the persons responsible for monitoring animal health and welfare, and the procedures carried out by the ACC to conduct monitoring;

2. Will maintain liaison through the ORA with the CCAC Secretariat, and inform the Secretariat of any changes to their program: to the senior administrator responsible for animal care and use, the chairperson of the ACC, or the veterinary or senior animal care personnel;
3. Will submit complete and accurate animal use information in the CCAC Animal Use Data Form (AUDF) format for all protocols annually (animal use information for each calendar year must be submitted by March 31 of the following year) and also in pre-assessment documentation;
4. Will develop and maintain a crisis management program for the animal facilities and for the animal care and use program, in conjunction with any general institutional crisis management plan(s). This program must detail plans in the event of power outages (short and prolonged), work stoppages, fires, natural disasters, large chemical spills and other similar crises, and must include a communications plan for addressing public and media inquiries on concerns related to animal use;
5. Should, from time to time, sponsor seminars or workshops on the use of animals in science and the ethics of animal experimentation, and encourage as many animal users, animal caregivers, students, ACC members and other interested parties to attend as much as possible;
6. Should try to achieve and maintain a high profile within the institution and in the community in order to demonstrate the institution's efforts in promoting animal welfare and to allay some of the public concerns regarding animal experimentation; and
7. Should be open to developing and maintaining communication with animal welfare organizations.

The ACC will report to the VP, Academic, and the oversight and storage of the minutes and all other procedures will be handled through the Office of Research Administration.

D.10.2. Animals in Research

With regard to the review of protocols that may propose animal experimentation, CMCC subscribes to the following principles of the CCAC:

D.10.2.1. General Principles

The following are general guiding principles for protocol review. Each ACC has an ethical, scientific, and social responsibility to apply protocol review and approval criteria in a fair, equitable and consistent manner. This requires the provision of complete and appropriate information by the investigator. Not all protocols, however, require the same level of review: the intensity of the review should vary directly with the level of invasiveness of the procedures. Protocols involving physical and/or psychological distress (pain, fear) must be fully reviewed

and require strong scientific justification that is clearly supported by current knowledge. All aspects of the review process, including protocol approval status, amendments, clarifications, modifications, and renewals must be documented, regardless of the category of invasiveness.

A summary of the primary aims and proposed use of animals must be provided in a language understandable to a layperson. This lay summary will be provided in a self-labelled portion of all animal research applications, and will provide an overview of the entire experiment. It will include a description of procedures designed to assure that animal suffering will be prevented or at least minimized. The submission of sections of grant proposals containing excessive detail of procedures not related to the use of animals is inappropriate, but may be helpful if related to scientific merit or statistical analysis. The ACC members should request investigators to provide all descriptions in this section with a minimum of technical jargon: the ACC is primarily interested in the responsible, humane use of animals. Further information pertaining to the protocol review process and the Post Approval Monitoring (PAM) Program can be found in Section D of the Research Procedure Manual, under *Annual Renewal of Animal Use Protocols*, *Post Approval Monitoring Program*, and *Ongoing Review of Research Involving Animals*.

Each protocol must be reviewed annually and must take into consideration changes in standards and guidelines, and developments in the replacement, reduction, and refinement of experimental animal use. Renewal applications should permit ACCs to review proposed modifications to the original protocol, if any, and the justification for the changes. Major modifications, including changes in animal species, category of invasiveness, the nature of the invasive procedure(s), or significant changes in the use of anesthetics/analgesics must be subjected to the same level of review and information requirements as a new application. All modifications must be approved and documented by the ACC before being initiated by the investigator. An ACC should not renew a protocol more than three times; after three renewals, a complete, new protocol should be submitted.

A faculty and/or staff member must accept responsibility for the project. In addition, a knowledgeable member of the research project must be available for contact at all times. Requirements for permits for wildlife studies, use of radioactive compounds, biohazards, and other special circumstances must be reported in the protocol. Generally, copies of permits/licences should be filed with the ACC before the project begins. When the acquisition of a Provincial Wildlife Permit is directly relevant to issues of animal use, a copy of the Permit should accompany the protocol.

D.10.2.2. Potential Benefit of Research

Clear statements on the purpose (specific scientific objectives) and potential value of the study (originality and importance of the new information) are required. Information provided within the protocol review form will provide the ACC with a clear sense of the need for the experimental project, and of the relationship between the proposed experiment and the overall objective. The ORA will ensure that all approved proposals have been peer reviewed for scientific merit. Proposals associated with competitive funding applications to agencies with adequate peer review processes generally do not require review for scientific merit by the ACC. The requirement for scientific merit will normally be satisfied if the application is funded. Where ACC approval is required by the funding agency before it will review the application,

ACC approval will be provisional, pending assurance from the funding agency that the application has high scientific merit. Further discussion of the ORA procedures to determine the scientific merit of a project can be found in Section D of the Research Procedure Manual, under ACC Peer Review Process: Scientific Merit.

Projects approved and funded by some agencies or organizations, or from internal funds may have been subjected to little or no peer review. Some funding agencies award 'Program Grants' which, unlike their 'Project Grants', may include animal use that is not subjected to a focused peer review for scientific merit. When evidence of good peer review is absent, the ORA will solicit two reviews of the objectives, hypotheses, methods and contributions of the project by knowledgeable scientists who do not collaborate with the investigator. Both referees must be external to the Committee. The reviews must be documented and must contain sufficient information to support the reviewers' conclusion(s).

D.10.2.3. Replacement Alternatives to Animal Use

If the scientific objectives of the study can be achieved by using available non-animal models or animals of low sentience, the ACC must require consideration by the investigator of the alternative to live and/or more sentient animals and justification for its rejection. The absence of replacement alternatives is to be supported by a brief description of the methods and sources used to determine that alternatives were not available, and/or an explanation of the aspects of the protocol that preclude using non-animal models or animals of lower sentience. A simple statement that there is no replacement alternative is insufficient.

D.10.2.4. Animal Model Selection

The characteristics of the animal model that make the species/strain appropriate for the study are to be described. This might include structural, behavioural, physiological, biochemical or other features or considerations (e.g., data from previous studies) which make the model compatible with the research objectives. Ordinarily, cost should not be a primary consideration.

D.10.2.5. Reduction of Animal Use/Numbers

The information provided must include a clear description of the experimental design along with the statistical rationale which supports the size of the control and test group(s). A pilot study may be recommended by the ACC, particularly when large numbers of animals are requested for a new study, to provide data for a more accurate assessment of the invasiveness of the procedure and number of animals required. Overall, the number of animals to be used must be optimized to the greatest extent possible consistent with sound scientific and statistical standards, i.e., not below or in excess of the number required to produce statistically valid experimental data.

D.10.2.6. Refinement of Experimental Technique

Once it has been determined that the use of animals is necessary and there is appropriate justification for the number requested, the ACC and the investigator have a shared responsibility to ensure that the husbandry practices and experimental procedures employed minimize or eliminate physical and/or psychological distress within the limitations imposed by the objectives of the research.

All members of ACC's and all investigators have the responsibility to continuously refine procedures. Some examples of potential areas of refinement include: increased training and expertise of personnel; environmental enrichment for captive animals; well planned, pre-, intra-, and post-procedure care management; proper anaesthesia/analgesia; selection of more humane endpoints; proper methods of euthanasia; less invasive surgery; less toxic adjuvants; and appropriate transportation/transfer methods.

D.10.2.7. Setting Endpoints

The lack of a well-defined, humane endpoint is often a key issue in protocol review. When morbidity is anticipated, its time course and severity, monitoring frequency, training and expertise of the monitors, care and treatment, and provision for unexpected complications are all important considerations for the ACC. If the expected frequency, severity, and signs of morbidity are unknown, a pilot study under close veterinary observation must attempt to answer these questions. Death or moribundity as endpoints must be avoided. Animals must be euthanized at the earliest possible endpoint consistent with the scientific objective(s) of the proposal, and in accordance with acceptable criteria for determining the endpoint.

Procedures that involve sustained and/or inescapable severe pain or deprivation in conscious animals, i.e., Category E experiments, are considered highly questionable or unacceptable, irrespective of the significance of anticipated results. The CCAC's Ethics of Animal Investigation document states: 'An animal observed to be experiencing severe, unrelievable pain or discomfort should immediately be humanely killed, using a method providing initial rapid unconsciousness' and 'Studies such as toxicological and biological testing, cancer research and infectious disease investigation may, in the past, have required continuation until the death of the animal. However, in the face of distinct signs that such processes are causing irreversible pain or distress, alternative endpoints should be sought to satisfy both the requirements of the study and the needs of the animal'.

D.10.2.8. Invasive/Stressful Procedures

A description of the preparative regimen is to be provided which includes, as applicable, a description of the animal preparation and procedures, specification of any antibiotic or tranquillizers to be administered, ventilation procedures, instrumentation (i.v. lines, catheters, etc.). The dose (e.g., mg/kg) and route (e.g., i.m., i.v.) of any compound to be administered must be stated. When repetitive use of a particular methodology is anticipated, the ACC is to require the investigator to develop a detailed Standard Operating Procedure for submission to the ACC. The type of monitoring and the criteria used to assess the level of anaesthesia/analgesia, e.g., respiration/heart rate, EKG, toe pinch, corneal reflex, colour of mucus membrane, muscular relaxation, is to be provided, as well as a brief technical description of the procedure. Other information is to include the source, method, volume and frequency of sampling when blood or tissue recovery is employed. There is to be a clear relationship between each procedure and the objective(s) of the research. Estimation in advance of any potential adverse effects on the animal will assist in developing plans to prevent, monitor and relieve as much suffering as possible during the post-procedure period. All animals must be monitored at appropriate intervals which are dictated by the nature of the procedure(s), the degree and duration of potential post-procedure physical and/or psychological distress, and possibility of complications. For example, monitoring may be required at more frequent intervals during the immediate post-surgical period (e.g., first 24

hours post-operatively) and during the latter stages of tumour induction or toxicology experiments that have associated morbidity and mortality. Criteria are to be established to assess the presence and severity of post-procedure distress, and to provide a basis for analgesic administration or other procedures to minimize or eliminate the distress. In evaluating distress in animals, species-specific behavioural changes, e.g., in vocalization, appearance/posture, locomotion, temperament and physiological signs, e.g., weight, heart rate, respiration, appearance of urine and feces, weakness/paralysis, must be looked for. It is important to note that many sources of distress may be unrelated to the procedures performed. These include: variable or inappropriate temperature, humidity, illumination or ventilation; inappropriate cage or enclosure space; inappropriate intensity or type of noise; unsatisfactory species-specific sanitation practices; and negative social conditions (e.g., overcrowding, isolation, incompatibility, maternal deprivation).

The administration of analgesics or use of other distress-reducing measures is to be based on the premise that where physical and/or psychological distress is a concern, the animal is to be given the benefit of the doubt. Conversely, the active withholding of these measures, where their use is indicated, must be based on scientific fact or experimental data, as documented by pertinent literature, or data from pilot studies. Multiple surgical or other repetitive highly stressful procedures on a single animal are generally unacceptable and are not adequately justified by cost savings. These protocols must undergo stringent ethical and welfare review for justification.

D.10.2.9. Euthanasia

In addition to the selection of an appropriate method of euthanasia, the training and competence of the individual(s) performing euthanasia is to be specific for the species and method used (*CCAC guidelines on: euthanasia of animals used in science*, 2010). The criteria for euthanasia, in terms of species-specific behavioural changes and physiological signs, or in relation to the experimental design, must be clearly described.

If surviving animals are not to be euthanized during, or upon completion of the study, a description of their future disposition must be included. Euthanasia will be performed in accordance with the guidelines set out in the CCAC guidelines on: euthanasia of animals used in science.

The ACC will delegate to the veterinarian(s) the authority to treat, remove from a study or euthanize, if necessary, an animal according to the veterinarian's professional judgment. The veterinarian will attempt to contact the animal user whose animal is in poor condition before beginning any treatment that has not previously been agreed upon, and will also attempt to contact the ACC Chair, but the veterinarian will have the authority to proceed with any necessary emergency measures, whether or not the animal user and ACC Chair are available. A written report should be sent by the veterinarian to the animal user and to the ACC following any such event.

D.10.2.10. Hazardous Materials

Appropriate approval for the use of hazardous agents (radioactive materials, recombinant DNA/RNA, human/plant/animal pathogens, acute toxins, chemical carcinogens, ethers) must be filed with the ACC before the project begins. Brief descriptions of the potential health risks

to humans or animals, special animal care required, precautions for personnel, special containment requirements, specific storage, waste, and animal disposal requirements, and emergency procedures must be provided as part of the protocol form or in an appended copy of the approval application.

D.10.2.11. Disposal of Animal Remains

The Division of Research and Innovation at CMCC will provide an appropriate remains disposal mechanism using licensed service contractors consistent with CMCC policy on disposal of hazardous waste and/cadaveric materials. The remains will be disposed of in a way that conforms to CCAC standards, with due regard to a sanitary and ethical means of removing the remains from the site and destroying them. This will include bagging and freezing the remains, and transferring them to special bins provided by the contracted disposal company designed to contain the remains at the time of pickup. Procedures outlining disposal consistent with this policy must be posted in each laboratory that is used for animal experimentation.

D.10.2.12. Conclusion

The ACC attempts to reconcile public demands for medical, scientific and economic progress with demands for reduction in animal use, pain, and suffering. The cost, in terms of animal welfare and integrity must be measured against the expectation of a proportional contribution to the understanding of fundamental biological principles, or to improvement of human or animal health and welfare. Protocol review by the institutional ACC provides a mechanism for achieving this 'cost/benefit assessment' which involves consideration of relevant ethical, scientific, and social issues. Approval of a protocol does not guarantee that a benefit will be realized, but does mean that there will be a cost imposed on the animals. The ACC must be convinced therefore of the need for animal use, and that the expected benefit will outweigh the cost.

D.11. 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)[38].

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

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[39].

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.

[38] Anatomy Act, R.S.O. 1990, c. A.21. Queen's Printer for Ontario (current to July, 2012, last amended 2006).
[39] 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 2018.

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 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. The REB review process is discussed in detail in CMCC's Research Procedures Manual, which can be found in the ORA. 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 by courier to the agency. Covering forms must be signed by the VP, Academic, 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. Calls inviting applications are issued once the institutional budget has been approved, in the early summer. IRSF support may be requested for research projects. 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 VP, Academic. 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, PI's, 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 policy must be reviewed and approved by the VP, Academic.

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, then 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, fax and telephone 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 VP, Academic. 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 VP, Academic. 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 VP, Academic. 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

PI's will be given printed statements of their project-accounts, revenues and expenses upon request. PI's 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.

PI's 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 CMCC Research Development Fund 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 VP, Academic and approved by the President, the amounts will be credited to the Research Development Account.

F.1.4. Research Development Account

Funds recovered from grants and contracts for indirect costs and salaried faculty time will be credited to the Research Development Account. 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 VP, Academic.

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 VP, Academic. 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 VP, Academic. 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.1.6.3. Advance payments

If an up-front cash or cheque payment has to be made for an item/service, then the PI should notify the RA of the exact amount, the nature of the item/service, the name, etc. of the vendor, and the name of the individual picking up the cheque/cash from the accounting office. The RA will prepare a cheque requisition/cash requisition and arrange for the funds to be made ready for the individual indicated on the requisition. Five working days should be allowed for this procedure. The PI must submit a receipt for the purchase within 2 weeks of receiving the cheque/cash.

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 PI's 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 PI's with timely detailed grant accounts summaries from the Accounting Department. These will be available anytime upon request.

PI's 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 VP, Academic. 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 the Research Development Fund.

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 Medical Research Council of Canada, the Social Sciences and Humanities Research Council and the Natural Sciences and Engineering Research Council, as well as their Tri-council Policy Statement[40]. Furthermore, the institution adopts, and is compliant with, the policies and procedures as outlined by the Canadian Institutes of Health Research (CIHR) and the Office of Research Integrity (ORI), an entity 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.** A full discussion of the processes CMCC has in place for allegations of misconduct and the subsequent proceedings can be found in the Research Procedure Manual.

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 VP, Academic 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.

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[40] 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 2018.

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 VP, Academic 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. These procedures are detailed in full in CMCC's Research Procedure Manual.

Further information on the ORI and the HHS can be found in the **Definitions Section**.

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. 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 VP, Academic, 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 CIHR'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 CIHR and the ORI as needed, to carry out any administrative actions that CIHR 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 ORI during its oversight reviews of this institution and its research misconduct proceedings and during the process under which the respondent may contest ORI findings of research misconduct and proposed HHS 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 ORI 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

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[41]); 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 VP, Academic. The basic membership is to provide the broad range of experience and knowledge required to provide competent ethics review. Substitute members (defined in Article 6.4 of the Tri-Council Policy Statement) and/or ad hoc advisors (Article 6.5) 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[42]. 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.

H.2. REB Meetings and Records

The REB meetings are generally scheduled to be on the third Friday of every month. Meetings may be called to deal with specific issues at the discretion of the VP, Academic.

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 VP, Academic.

H.3. REB Decision-making

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 Research Administrator and the VP, Academic.

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[41] Interagency Panel on Research Ethics. REB Membership—Individuals Knowledgeable in Ethics. Government of Canada; December, 2004. Available from: http://www.pre.ethics.gc.ca/archives/tcps-eptc/interpretations/docs/REB_Membership_Individuals_Knowledgeable_in_Ethics_Dec_2004.pdf

[42] 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 2018.

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 using the Proposal Evaluation Form 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 VP, Academic 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 rebut reviewer comments rather than modify their application. If the reviewer declines to modify their decision, the applicant must modify their proposal before it may commence.

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 VP, Academic.

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. The format for such submissions is outlined in the procedure manual.

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[43]. The REB may elect to review individual 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.12.**). 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 REB should communicate with other REB's to facilitate the review of multi-centred research as necessary.

H.7. REB Conflicts of Interest

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 PI's 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 PI's or Co-Investigators on projects being reviewed. The PI must leave the room at

[43] 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 2018.

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 leave the room for this reason shall still be counted towards quorum during this time, until the vote is taken and they have been asked to return.

H.8. Research Appeals Board

Proposals that are rejected by the REB or by the ACC 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 or ACC 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 or ACC 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.

Containment Level 2 (CL2) Facility
A laboratory containing organisms which pose risk to personnel by exposure through ingestion, inoculation or mucous membrane routes, and care must be taken to prevent the creation of harmful aerosols.

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[44]. 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.

[44] Ministry of Health and Long Term Care. Personal Health Information Protection Act, 2004: An Overview for Health Information Custodians. Ottawa: Ministry of Health and Long Term Care; 2004.

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)

Research at CMCC is governed by the Research Policy and Procedure manuals. CMCC personnel involved in research must be familiar with this policy.