**CMCC RESEARCH ETHICS BOARD**

**APPLICATION TO INVOLVE HUMAN PARTICIPANTS IN RESEARCH**

**ORIGINAL RESEARCH**

**GENERAL INSTRUCTIONS**

* This application form follows the most recent Tri-Council Policy Statement – Ethical Conduct for Research Involving Humans (TCPS 2 2022). Several of the questions and/or guidance on the application form will refer to specific articles of the TCPS 2 document. The entire TCPS 2 document can be accessed online for more information at <https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2022.html>.
* All sections of this application MUST be completed before it will be considered for REB review.
* All research must comply with:
	+ The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (2022)
	+ The Ontario Personal Health Information Protection Act (2004) available at: <https://www.ontario.ca/laws/statute/04p03>
* The following is a key to the different font colours and formatting in this document:
	+ **GREEN** – Section headings
	+ Blue/Teal – Questions and prompts to be addressed by applicants
	+ *Orange* – Tips and notes for applicants to consider
	+ Black – Applicant responses to questions and prompts
* For checkboxes, double-click on the box and select Checked for the Default Value
* PLEASE DO NOT:
	+ Edit either the questions/prompts or tips/notes
	+ Change the font colours

**PROJECT INFORMATION**

REB File #:

Project title:

Principal investigator:

Application status:

[ ]  New

[ ]  Resubmission

[ ]  Addendum

[ ]  Renewal

Anticipated study start date:

Anticipated study end date:

**PERSONNEL**

**Principal investigator:**

Name:

Primary Institution/Affiliation:

Email:

**Co-investigator(s) (add as necessary):**

Name:

Primary Institution/Affiliation:

Email:

**Contact investigator (if not principal investigator):**

Name:

Primary Institution/Affiliation:

Email:

**Student projects**

Is the principal investigator for this project a student?

[ ]  Yes

Name of supervisor:

Email of supervisor:

[ ]  No

**Declaration**

[ ]  Each member of the investigative team named above has completed ethical training and has provided the Office of Research Administration with a certificate of completion proving that they have successfully finished the TCPS2: Course on Research Ethics (CORE) – 2022 or equivalent (e.g., CITI – USA).

**FUNDING**

Is the study in this application funded or will it be funded by a grant that is pending?

[ ]  Yes

Funder:

Status of funding: [ ]  Obtained

[ ]  Funding applied for. Expected date of decision:

[ ]  No

Will you be using any other sources of funding for the study in this application (e.g., Internal Research Support Fund)?

[ ]  Yes

Source:

[ ]  No

If funding is not awarded (in full or in part), do you plan to proceed with the study?

[ ]  Yes

[ ]  No

[ ]  Not Applicable

**1. CONFLICT OF INTEREST**

*According to Article 7.4 of the TCPS 2 (2022), researchers shall disclose in research proposals they submit to the REB any real, potential or perceived individual conflicts of interest, as well as any institutional conflicts of interest or community conflicts of interest of which they are aware that may have an impact on their research.*

1.1 – Are there any conflicts of interest in the conduct of this study? Conflicts of interest can be real, potential or perceived individual conflicts, interpersonal relationships, financial partnerships, multiple roles/competing interests. Please err on the side of declaring any potentially relevant conflicts.

[ ]  Yes

Describe how you plan to manage the conflict(s) of interest:

[ ]  No

**2. GENERAL QUESTIONS**

*There are certain types of research that may either be exempt from review or be eligible for expedited review. Questions in this section are intended to gather basic information about the nature of the proposed study and to determine if it qualifies for either an exemption from review or is eligible for expedited review. Please consult with the Office of Research Administration and the Chair of the Research Ethics Board if you have questions and/or are unsure how to respond to any of the questions in this section.*

2.1 – Does your application involve an investigation of a research question that involves human subjects?

[ ]  Yes

[ ]  No *If no, this study may not require REB review. Please refer to Chapter 2: Scope and Approach of the TCPS 2 (2022) and/or consult with the Office of Research Administration*.

2.2 – Is this application directly related to a previously approved study at CMCC?

[ ]  Yes

Name of principal investigator:

REB File #:

[ ]  No

2.3 – Does your application involve secondary use of existing human participant data only, with no interaction with the original study participants?

[ ]  Yes *If yes, complete the Secondary Use form*.

[ ]  No

2.4 – Does your application involve quality assurance, quality improvement studies, program evaluation activities, and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes?

[ ]  Yes *If yes, consult with the Office of Research Administration and Chair of the Research Ethics Board since your project may be exempt from review under Article 2.5 of the TCPS 2 (2022)*.

[ ]  No

2.5 – Does your application involve research that relies exclusively on publicly available information such as information that is legally accessible to the public and appropriately protected by law, or the information is publicly accessible and there is no reasonable expectation of privacy?

[ ]  Yes *If yes, consult with the Office of Research Administration and Chair of the Research Ethics Board since your project may be exempt from review under Article 2.2 of the TCPS 2 (2022)*.

[ ]  No

2.6 – Does your application involve research that observes people in public places where: a) it does not involve any intervention staged by the researcher, or direct interaction with the individuals or groups; b) individuals or groups targeted for observation have no reasonable expectation of privacy; and c) any dissemination of research results does not allow identification of specific individuals?

[ ]  Yes *If yes, consult with the Office of Research Administration and Chair of the Research Ethics Board since your project may be exempt from review under Article 2.3 of the TCPS2 (2022)*.

[ ]  No

2.7 – Does your application involve research activities at another institution?

[ ]  Yes *If yes, either a complete application must be submitted to each site where this research will take place or formal confirmation that the project is exempt from review is required*.

 Location of primary site:

[ ]  No

2.8 – Has this study been approved by another non-CMCC Research Ethics Board or Institutional Review Board?

[ ]  Yes *Attach a copy of the approval to this application*. *This project may be eligible for expedited review.*

[ ]  No

**3. CHECKLIST FOR ADDITIONAL APPROVALS**

*An Access to Clinics form is required if you answer Yes to any of the following three questions.*

3.1 – Do you need access to CMCC clinic facilities?

[ ]  Yes

[ ]  No

3.2 – Do you need access to patient data (e.g., demographics, health records)?

[ ]  Yes

[ ]  No

3.3 – Does your study recruit patients from any of the CMCC clinics?

[ ]  Yes

[ ]  No

*An Access to CMCC Students form is required if you answer Yes to any of the following three questions.*

3.4 – Do you need access to student data (e.g., demographics, course grades)?

[ ]  Yes

[ ]  No

3.5 – Do you need direct access to students for recruitment?

[ ]  Yes

[ ]  No

3.6 – Do you need direct access to students for data collection during class time?

[ ]  Yes

[ ]  No

*An Access to CMCC Employees form is required if you answer Yes to any of the following three questions.*

3.7 – Do you need access to employee data (e.g., demographics, employment records)?

[ ]  Yes

[ ]  No

3.8 – Do you need direct access to employees for recruitment?

[ ]  Yes

[ ]  No

3.9 – Do you need direct access to employees for data collection during working hours?

[ ]  Yes

[ ]  No

**4.** **STUDY OVERVIEW**

*Please consider consulting the following page from the Oxford University’s Centre for Evidence-Based Medicine if you are not sure about your study’s design (*[*https://www.cebm.ox.ac.uk/resources/ebm-tools/study-designs*](https://www.cebm.ox.ac.uk/resources/ebm-tools/study-designs)*). The EQUATOR Network also provides a comprehensive database of reporting guidelines for specific study designs (*[*https://www.equator-network.org/*](https://www.equator-network.org/)*). These reporting guidelines outline methodological aspects that should be considered when planning your study.*

4.1 – Specify the nature of the study (select all that apply):

[ ]  Clinical trial (specify): *There are additional registration requirements for clinical trials. Please consult with the Office of Research Administration for guidance on registering a clinical trial*.

[ ]  This study involves an investigation with participants that evaluates the effects of one or more health-related interventions on health outcomes. *The following link provides a definition of “health outcome” (*[*https://uwaterloo.ca/research/office-research-ethics/research-human-participants/pre-submission-and-training/human-research-guidelines-policies-and-resources/definition-health-outcome*](https://uwaterloo.ca/research/office-research-ethics/research-human-participants/pre-submission-and-training/human-research-guidelines-policies-and-resources/definition-health-outcome)*).*

[ ]  This study involves an intervention or experimental therapy, by comparing two or more approaches.

[ ]  This study involves the use or administration of any health products, drugs, medical devices, or biological matter.

[ ]  Experimental (Non-clinical)

[ ]  Observational (specify):

[ ]  Lab-based

[ ]  Cross-sectional

[ ]  Cohort

[ ]  Case-control

[ ]  Epidemiologic

[ ]  Clinical (*An Access to Clinics form may be required*)

[ ]  Other:

[ ]  Qualitative (specify):

[ ]  Focus groups

[ ]  Interviews

[ ]  Observational (naturalistic, field)

[ ]  Chart review: (*An Access to Clinics form may be required*)

 Source:

[ ]  Database:

 Source:

[ ]  Human tissue and biological specimens (specify):

[ ]  Biomarker

[ ]  Genetic

[ ]  Radioactive material or radiation treatment devices

[ ]  Case study/report/series (*Please use the CMCC REB Form for Retrospective Case Reports for retrospective case reports*)

[ ]  Educational (*Approvals from the Registrar, Dean of Undergraduate and Graduate Education, and//or Dean of Clinics may be required*)

[ ]  Other (specify):

**5. PROJECT DETAILS**

5.1 – In 500 words or less, provide a summary of the study’s rationale and methodology. Include a short background followed by stating the study’s objective(s) and methods. Ensure that the following information is provided in the methods: study design, setting, population/participants involved, sample size, protocol, data collection methods/instruments, outcome measures, and analysis plan.

5.2 – In 100 words or less, provide a lay language description of the expected impact of the study. This is intended to inform the public and audiences at CMCC about research that is happening at the institution. The lay abstract may be used on the CMCC website.

5.3 – The 2021-2025 Strategic Plan for CMCC highlighted 5 research streams in which our faculty were engaged in. Please indicate which stream you believe this application should fit under. Identify **only 1** stream in which this research is most prominent.

[ ]  Biological basis of musculoskeletal injury and manual therapies

[ ]  Clinical and health services research

[ ]  Education in healthcare

[ ]  Health and wellness

[ ]  Knowledge translation and health policy

5.4 – What is/are the specific research question(s)?

5.5 – If applicable, what are the study hypotheses?

5.6 – Provide background information, with reference to relevant literature, and describe the purpose and scholarly rationale for the study. *Provide references using* [*Vancouver formatting*](https://www.cmcc.ca/library/documents/VCS-CMCC.pdf) *as an appendix to this application (*[*https://www.cmcc.ca/library/documents/VCS-CMCC.pdf*](https://www.cmcc.ca/library/documents/VCS-CMCC.pdf)*).*

**6. PARTICIPANTS**

6.1 – Will the study involve participants from CMCC? (Select all that apply)

[ ]  Yes

[ ]  Faculty/employees (*Approvals from the Director of Human Resources, and/or Manager of Institutional Effectiveness and Accreditation*)

[ ]  Students (*Approvals from the Registrar, Dean of Undergraduate and Graduate Education, and//or Dean of Clinics may be required*)

[ ]  Patients (*An Access to Clinics form may be required*)

[ ]  Other

[ ]  No

6.2 – Will the study involve participants from outside of CMCC?

[ ]  Yes

Specify target population(s):

[ ]  No

6.3 – What is the approximate (targeted) number of participants for this study? *Please consult with one of CMCC’s biostatisticians if you need help determining an appropriate sample size.*

6.4 – Provide a rationale for the choice in sample size and/or the sample size calculation.

6.5 – List the inclusion criteria.

6.6 – List the exclusion criteria.

6.7 – Does your study involve individuals from vulnerable populations (i.e., those with limited access to social goods, may be marginalized, or have diminished/altered capacity to consent)?

[ ]  Yes

 Specify population:

For populations with altered capacity to consent, describe by whom and how capacity to consent will be assessed and how a substitute decision-maker will be identified:

[ ]  No

6.8 – Will your research involve collecting data from Canadian Indigenous communities and/or will the data pertain to Indigenous identity or knowledge?

[ ]  Yes

Describe and provide a copy of any formal agreements, written decisions, or summary of advice received from the community:

[ ]  No

**7. RECRUITMENT**

7.1 – Is there recruitment of participants?

[ ]  Yes

[ ]  No *Skip to next section*

7.2 – Please select all applicable methods for recruitment from the following list. Provide documents and scripts for all materials that will be used to recruit study participants as appendices to this application.

[ ]  Recruitment poster (paper or digital), Appendix:

[ ]  Study information sheet/pamphlet, Appendix:

[ ]  Script for video/audio recording, Appendix:

[ ]  Social media/online advertisement, Appendix:

[ ]  Website content, Appendix:

[ ]  Verbal script, Appendix:

[ ]  Telephone script, Appendix:

[ ]  Email script (sent directly to participant by an investigator), Appendix:

[ ]  Email script (sent by holder of participant contact and who is not an investigator), Appendix:

[ ]  Recruitment for follow up (e.g., follow up interviews), Appendix:

[ ]  Snowball recruitment script, Appendix:

[ ]  Reminder email/script, Appendix:

[ ]  Other (specify):      , Appendix:

7.3 – Describe where and how you will identify potential participants for recruitment into the study.

7.4 – Who will identify potential study participants?

[ ]  Investigator/study personnel

[ ]  Non-study personnel (e.g., other healthcare professionals)

[ ]  Self-referral (e.g., respond to advertisement)

[ ]  Other (specify):

7.5 – Provide the role(s) and name(s), if known, of those who will contact potential participants.

7.6 – Are there any already-existing relationships between people who will be responsible for recruitment and potential participants that may possibly contribute to feelings of obligation or undue influence to take part in the study?

[ ]  Yes

Describe these relationships and mitigation strategies:

[ ]  No

7.7 – Will you require permission to conduct any of the described recruitment strategies (e.g., Registrar, Dean of Clinics, Director of Human Resources, Dean of Undergraduate and Graduate Studies, Manager of Accreditation and Institutional Effectiveness, Association Authority, Event Organizer)? *Please consult with either the Office of Research Administration or Chair of the Research Ethics Board if unsure.*

[ ]  Yes *Include any relevant documentation to demonstrate that permission has been granted*

[ ]  No

**8. CONSENT**

*Guidance related to the consent process can be found in Chapter 3 of the TCPS 2 (2022) manual.*

8.1 – Will you obtain individual participant consent/assent prior to starting the study?

[ ]  Yes

[ ]  No

Provide justification and describe alternative consent process, which includes partial disclosure and deception:

8.2 – Does your study include participants who cannot consent on their own behalf? *Please refer to Articles 3.3, 3.9 and 3.10 of the TCPS 2 (2022) for guidance on people who can provide consent and/or assent.*

[ ]  Yes

Describe assent and consent process:

[ ]  No

8.3 – Who will obtain consent from potential participants?

8.4 – Describe the entire consent process, from start to end, that will be used to explain the study and obtain informed consent. Explain the method (e.g., written, verbal, online, etc.) and why the method was chosen. Please also indicate how participants will be able to ask questions.

8.5 – Are there any already-existing relationships between the people obtaining consent and potential participants that may possibly contribute to feelings of obligation or undue influence to consent to the study?

[ ]  Yes

Describe these relationships and mitigation strategies:

[ ]  No

**9. WITHDRAWAL PROCESS**

9.1 – Describe how the participants will be informed of their right to withdraw from the study before, during, and/or after data collection. If there is a point where withdrawing from the study will no longer be possible (e.g., after deidentification of data without a linking key), describe and justify.

9.2 – Describe the procedures for participants to withdraw from the study. Please ensure to describe procedures for withdrawing from the study before, during and after data collection.

Before:

During:

After:

9.3 – Describe any consequences for participants who withdraw from the study.

9.4 – Describe what you will do with any collected data after a participant withdraws from the study. Provide justification for not removing a participant’s data if they withdraw from the study.

**10. REIMBURSEMENT/INCENTIVE**

10.1 – Will participants be reimbursed for expenses related to participating in the study (e.g., transportation, parking, childcare, etc.)?

[ ]  Yes

 Specify:

[ ]  No

10.2 – Will participants receive any incentives for their participation in the study (e.g., gift card, monetary gift, refreshment, course credit, etc.)?

[ ]  Yes

Specify type of incentive and monetary value if applicable:

[ ]  No

10.3. – Is the reimbursement/incentive affected when a participant withdraws?

[ ]  Yes

Justify:

[ ]  No

**11. DATA COLLECTION METHODS**

11.1 – Check all the procedures and/or methods that are involved in this study. *Upload copies of all questionnaires, interview guides, tests, data collection instruments, standardized measurement protocols, etc. used in the study*.

[ ]  Survey/questionnaire – postal, Appendix:

[ ]  Survey/questionnaire – in person, Appendix:

[ ]  Survey/questionnaire – online, Appendix:

[ ]  Survey/questionnaire – telephone, Appendix:

[ ]  Interview – in person, Appendix:

[ ]  Interview – telephone, Appendix:

[ ]  Interview – video/online, Appendix:

[ ]  Focus group – in person, Appendix:

[ ]  Focus group – video/online, Appendix:

[ ]  Secondary use of data (public records and datasets)

[ ]  Secondary use of data (non-public records and datasets)

[ ]  Chart reviews (e.g., of medical records with personal health information)

[ ]  Audio recording

[ ]  Video recording

[ ]  Participant observation, Appendix:

[ ]  EEG/EMG/ECG

[ ]  Invasive physiological measurements (e.g., venipuncture, muscle biopsies) (specify):

[ ]  Non-invasive physical/physiological measurements (e.g., heart rate, blood pressure, range of motion, movement, forces, physical performance test) (specify):

[ ]  Other (specify):

11.2 – Provide a detailed description of all data collection procedures for all stages that occur following informed consent, and in which the research participants will be involved. Include detailed information about who will conduct the research tasks, how long it will take, where data collection will take place, and the ways in which data will be collected.

11.3 – Describe your methods for data processing/handling, outcome/dependent measure derivation and analysis (e.g., statistical analysis, textual analysis).

**12. RISKS AND BENEFITS**

12.1 – Select any possible risks that participants may experience by participating in the study that are beyond risks encountered during their daily living. If any are selected, describe the risks that may occur and how they will be mitigated and managed.

[ ]  Physical risks (e.g., bodily contact, SMT-related, administration of any substance, injury)

[ ]  Psychological risks (e.g., feeling demeaned, embarrassed)

[ ]  Social risks (e.g., loss of status, marginalization)

[ ]  Legal risks (e.g., lawsuit, discovery of illegal activities)

[ ]  Other risks (specify):

[ ]  No risks identified

12.2 – Are there any risks to the research team?

[ ]  Yes:

Specify:

[ ]  No

12.3 – Describe any direct benefits to the participants from their involvement in the study (e.g., treatment, monetary).

12.4 – Is there a potential of material incidental findings resulting from your research (e.g., tumour, blood cell count)? *Please see Article 3.4 of TCPS 2 (2022) for a definition of “material incidental finding”*.

[ ]  Yes

Describe possible incidental findings and how this will be managed:

[ ]  No

**13. DECEPTION**

13.1 – Will deception or partial disclosure be used? *Please see Article 3.7 of TCPS 2 (2022) for definitions of “deception” and “partial disclosure”.*

[ ]  Yes

[ ]  No *Skip to next section*

13.2 – Describe the nature of the deception and/or partial disclosure and how they will be carried out. Justify why they must be used. Include why no alternative methodology can be used to answer the research question.

13.3 – Describe the process you will use to debrief participants. Explain and justify whether participants will be given the option to withdraw their data after debriefing. Include the second consent form required for full disclosure.

**14. PROVIDING PARTICIPANTS WITH STUDY RESULTS**

14.1 – Describe what feedback and/or information will be provided to the participants after their participation. Describe how the feedback and/or information will be provided to participants.

**15. PRIVACY AND CONFIDENTIALITY**

15.1 – What level of confidentiality and data protection will be used in this study? Select all that apply. Ensure to consider any identifying information that will be collected to provide feedback to participants.

[ ]  Anonymous *The information never had identifiers associated with it (e.g., anonymous surveys) and risk of identification of individuals is low or very low.*

[ ]  Anonymized *The information is irrevocably stripped of direct identifiers, a code is not kept to allow future re-linkage, and risk of reidentification of individuals from remaining indirect identifiers is low or very low.*

[ ]  Coded (Deidentified) *Direct identifiers are removed from the information and replaced with a code. Depending on access to the code, it may be possible to re-identify specific participants (e.g., the principal investigator retains a list that links the participants’ code names with their actual names so data can be re-linked if necessary).*

[ ]  Indirectly Identifying *The information can reasonably be expected to identify an individual through a combination of indirect identifiers (e.g., date of birth, place of residence or unique personal characteristic).*

[ ]  Directly Identifying *The information identifies a specific individual through direct identifiers (e.g., name, social insurance number, personal health number).*

15.2 – Are you collecting personal information and/or data that directly identifies participants (e.g., names, email addresses, video recordings, etc.) or information that could indirectly identify participants (e.g., combination of postal code & direct quotes)?

[ ]  Yes

List all identifiable data:

Explain why each type is necessary to conduct the study:

[ ]  No

15.3 – Will there be a unique code linking the participant name/contact information to the data?

[ ]  Yes

Describe the linking code and how it will be kept secure, who will have access to it, and how long it will be retained for:

[ ]  No

15.4 – Describe the procedures that will be used to deidentify/anonymize data and to keep the information confidential and secure during data collection and analysis.

15.5 – Describe who will have access to the identifiable information or knowledge of who participated.

15.6 – How long do you plan to retain study-related documents that identify participants (e.g., consent form, feedback form, intake form)? Also describe the process for destroying study-related documents that identify participants. If personal identifiers are retained, provide a rationale.

15.7 – How long do you plan to retain research data (e.g., deidentified data)? Also describe the process for destroying research data.

15.8 – Complete the following table that describes where information will be stored and how the storage procedures will keep the data and other study records secure. Please add/remove rows as necessary.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Information source** | **Level of Confidentiality** | **Storage location** | **Who has access** | **Retained until** |
| Consent form |  |  |  |  |
| Linking code |  |  |  |  |
| Audio recording |  |  |  |  |
| Transcription |  |  |  |  |
| Intake form |  |  |  |  |
| Data collection form |  |  |  |  |
| Raw data |  |  |  |  |
| Processed data |  |  |  |  |
| *Add rows as necessary* |  |  |  |  |

15.9 – How will study participants’ data be reported in the dissemination of results (e.g., aggregated data, identifiable descriptors, deidentified descriptors, etc.)?

15.10 – Will study-related documents or research data be made open-access (e.g., repository)?

[ ]  Yes

State the location (e.g., CMCC repository, Open Science Framework, GitHub, etc.):

Describe how consent will be obtained from participants for open-access availability:

Describe the process to ensure research data is deidentified prior to being made open-access (if different from above):

[ ]  No

15.11 – Will study-related documents or research data be available for use in the future (i.e., secondary use)? *Secondary use refers to the use in research of information or human biological materials originally collected for a purpose other than the current research purpose.*

[ ]  Yes

Describe how consent will be obtained from participants for secondary use:

[ ]  No

15.12 – Will you be transferring or electronically transmitting any study records, data, personal information, personal health information, materials or human resources outside of CMCC?

[ ]  Yes *Speak to the Office of Research Administration, and possibly the Privacy Officer, regarding the requirement for a Data Transfer Agreement*

Describe the information/resources that will be transferred:

Provide rationale for why data must be transferred:

Provide details on who the data will be transferred to:

Describe how the data will be transferred and kept secure:

[ ]  No

**BUDGET**

*Attach an itemized budget which reflects all costs required to complete the study.*

**APPLICANT UNDERTAKING**

As the principal investigator of this study, I assume full responsibility for the scientific and ethical conduct of the study as described in this application and agree to conduct this study in compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2022) and any other relevant laws, regulations or guidelines. I also agree that if I receive any personally identifiable information (including but not limited to personal health information and biological samples), I will only use or disclose the information as set out in the application, the conditions of the REB, the research participant's consent (unless consent is waived), and the conditions and restrictions imposed by the relevant information guardian who supplies the information. I certify that all researchers and other personnel involved in this project at this institution are appropriately qualified or will undergo appropriate training to fulfill their role in this project.

I have read and agree to the above conditions.

Name:

Signature:

Date: