**CMCC RESEARCH ETHICS BOARD**

**APPLICATION TO INVOLVE HUMAN PARTICIPANTS IN RESEARCH**

**SECONDARY USE OF DATA**

**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
* 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

**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 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

2.4 – 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

2.5 – 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

2.6 – 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

2.7 – 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 the following question.*

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

[ ]  Yes

[ ]  No

*An Access to CMCC Students form is required if you answer Yes to the following question.*

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

[ ]  Yes

[ ]  No

*An Access to CMCC Employees form is required if you answer Yes to the following question.*

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

[ ]  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:

[ ]  Experimental

[ ]  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

[ ]  Educational (*Approvals from the Registrar, Dean of Undergraduate 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. SUMMARY OF ORIGINAL DATA OR SAMPLE COLLECTION**

6.1 – Select all types of data and/or materials that will be used in the study.

[ ]  Administrative

[ ]  Clinical files

[ ]  Transcripts (interview, focus group)

[ ]  School records (course grades)

[ ]  Biological samples

[ ]  Images

[ ]  Biophysical (kinematics, EMG, EEG, ECG, heart rate)

[ ]  Recordings (audio, video)

[ ]  Other:

6.2 – Describe who is providing the data that is specified above? Provide proof of research ethics board approval and information letter/consent form if the proposed study will use data that was previously obtained for research purposes. Please explain if these documents are not available.

6.3 – Does the study involve transfer of data from an institution or organization outside of CMCC?

[ ]  Yes *Speak to the Office of Research Administration 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 from:

Describe how the data will be transferred and kept secure:

[ ]  No

**7. PARTICIPANTS**

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

[ ]  Yes

[ ]  Faculty/employees

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

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

[ ]  Other

[ ]  No

7.2 – Will data be used for all available participants?

[ ]  Yes

[ ]  No

List the inclusion criteria.

List the exclusion criteria.

7.3 – Does the data pertain to 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:

Justify and describe the possible implications of this analysis on this population:

[ ]  No

7.4 – Will your research use data collected from Canadian Indigenous communities and/or does 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

**8. DATA ANALYSIS**

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

**9. PRIVACY AND CONFIDENTIALITY**

9.1 – 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).*

9.2 – Will this study use 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:

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, if applicable:

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

Describe who will have access to the identifiable information or knowledge of who participated:

How long do you plan to retain the identifiable data?

[ ]  No

9.3 – Provide a rationale if personal identifiers will be retained.

9.4 – How long do you plan to retain research data (e.g., deidentified data)?

9.5 – 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** | **Storage location** | **Who has access** | **Retention period** |
| Linking code |  |  |  |
| Audio recording |  |  |  |
| Transcription |  |  |  |
| Intake form |  |  |  |
| Data collection form |  |  |  |
| Raw data |  |  |  |
| Processed data |  |  |  |
| *Add rows as necessary* |  |  |  |

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

**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: