Office of Research Administration 416-482-2340 X267 ora@cmcc.ca

# APPLICATION TO INVOLVE HUMAN PARTICIPANTS IN RESEARCH

(Please complete and submit this application in electronic form via email to the ORA at the above email address.)

This document will not perform Spell Check. If special formatting or Spell Check are required, sections may be completed separately, and pasted to the corresponding section on this form. Proper spelling and grammar reflect professionalism and integrity. Poor spelling and grammar may ultimately affect either a reviewer’s or a participant’s ability to understand a study. This would subsequently result in a ruling to delay approval.

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **D****ate** | **10/05/2018** | | | **Application Status:** |  | **New** | |  | **Resubmission** | |  |
|  |  | | |  |  | **Addendum** | |  | **Renewal** | | **REB #** |
| **Project Title:** | |  | | | | | | | | | |
| **PERSONNEL** | | | **NAME** | | | | **PHONE/EXT** | | | **E - MAIL** | |
| **Contact Investigator** | | |  | | | |  | | |  | |
| **Co-Investigators** | | |  | | | |  | | |  | |

Attachments

*(check ‘x’ for those appended)*

|  |  |  |  |
| --- | --- | --- | --- |
|  | Project Information Letter and Consent form |  | Advertising used in the study |
|  | Letters of permission for access to facilities/resources |  | Questionnaire |

# Ethics Training

# *(per CMCC Research Policy, ethics training is mandatory for all investigators conducting research involving human participants)*

# Each of the members of the investigative team named above have completed ethical training, and have attached a certificate of completion proving that they have successfully finished the [TCPS 2 Tutorial Course on Research Ethics (CORE)](https://tcps2core.ca/login). A certificate of completion from the National Institutes of Health’s Office of Extramural Health, [Protecting Human Research Participants](https://phrp.nihtraining.com/users/login.php), is an acceptable proxy to the TCPS certificate.I. CLINICS

## A. APPROVAL IN PRINCIPLE

*Answer the following questions to determine whether an Access to Clinics Form is necessary:*

|  |  |
| --- | --- |
|  |  |
| Does the project require the involvement of personnel (e.g., clinicians, interns) during their assigned hours in CMCC clinics, either on site at CMCC’s main campus, or external clinics? | Yes  No |
| Does the project involve the use of CMCC clinical equipment, or space, such as the treatment rooms or rehabilitation area? | Yes  No |
| Does the project require the involvement of patients attending CMCC clinics? | Yes  No |
| Does the project require access to patient files (physical or electronic)? | Yes  No |

If the answer to any of the above questions is “Yes”, you must download a copy of the [**Access to Clinics Form**](https://courses.cmcc.ca/access/content/group/41d16697-5a9e-430d-be8c-bfc89c288293/Access%20to%20Clinic%20updated.docx).

## B. FINAL APPROVAL

*Applicants answering ‘Yes’ to any of the above questions in Section A will require a signed Access to Clinics Form. Furthermore, once Part II of this application (see below) is completed, a second phase of consultation will be necessary with the appropriate party in Clinics. An itemized list of Clinics resources must be provided. Include your reason for access, steps that will be taken to anonymize and safeguard personal health information once extracted, and the duration of access that is required. Name all members of the investigative team who will have access to this data. Once this application has proof of final approval from Clinics, it will be considered complete.*

# II. PROPOSAL

## A. ABSTRACT

**1. Scientific Abstract**

*The Scientific Abstract is the protocol summary, using 500 words or less. It must include an introduction, and methods. For the introduction, a study objective is required. For methods, include study design, location, facilities used, sample, research methods, outcome measures, and analysis method.*

**2. Lay Abstract**

*A Lay Abstract is a lay language description of the expected impact of the project. It is intended to inform the public, and audiences at CMCC about researching that is happening on site. This Lay Abstract may be used on the CMCC website (100 words max).*

**3. Research Stream Classification for Internal CMCC Applicants**

*The 2017-2021 Strategic Plan for CMCC highlighted 5 research streams in which our faculty were engaged in research. 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 |

B. RESEARCH QUESTION AND HYPOTHESIS(ES)

*Develop the hypothesis or question, incorporating the following:*

*A sentence in the form of a question. Where applicable, include terms of clinical significance/administrative importance that will be used to answer the question. (e.g. 25% decrease in pain as a result of intervention).*

*Population being investigated.*

*Exposure or intervention being studied.*

*Endpoint of interest in quantifiable terms where appropriate. (e.g. Method to measure decrease in pain)*

C. INTRODUCTION

*Discuss whether the objective is primarily one of identification of a need, efficacy, effectiveness, efficiency, quality of care, or diagnosis. If it is either efficiency or quality of care, then effectiveness/efficacy is a prerequisite and the evidence for this should be indicated. Explain why the idea is good (scientific rationale). Demonstrate current knowledge of field, awareness aware of previous attempts to test hypothesis being studied. Indicate implications of the idea outside the population being studied.*

D. METHODS AND PROCEDURES

**1. Study Design**

*Will it be a quantitative design: e.g., Randomized Clinical Trial (RCT), cohort study, case-control study, case report or survey investigation? Or will it be a qualitative design: e.g., key informant interviews, a focus groups? Justify the design choice.*

**2. Sample Specification**

*The sample must be generalizable, or able to extend to the population of people to whom the study pertains. The audience must be convinced that the study is reproducible; that if another sample with similar characteristics would exhibit similar results. To do this:*

* *Define the target population.*
* *Describe sample selection (e.g., random selection, haphazard, snow-ball etc.)*
* *Provide sample demographics (e.g., middle-class elderly, young adult students, etc.) Will this limit study generalizability?*
* *Identify the proportion of subjects thought to be willing to participate. (e.g. What would happens if only 50% of those approached agree to take part? Do the other 50% have characteristics that would have changed results had they participated? How do you know?)*
* *What sample size was reached? (Insert this from Section D.5.)*
* *What steps have been taken to minimize sampling bias?*

*- See Sackett, D.L.: Bias in Analytic Research, J. Chron. Dis. (32): 51-63, 1979*

**3. Description of Experimental Manoeuvre**

**3.1 Overall Description of Protocol**

*Place an overall description of the experimental protocol here. As a guide, it might be helpful to place yourself in the shoes of the participant, and explain each of the steps that will be undertaken, from start to finish. Be sure to include instrumentation where applicable.*

**3.2 Recruitment Process and Compensation**

*Describe how and where the participants will be recruited from (e.g., direct recruitment, advertising, notice via e-mail, class announcements etc.)*

**3.3 Allocation and Minimization of Bias**

*Specify how allocation will occur, and how codebreaking will be avoided*

*Specify how the experimental and control group differ, direction of intervention*

* *the manoeuvre must be defined with sufficient precision to be reproducible by others (i.e. who does what to whom, when, why and how)*
* *if innovative, therapeutic manoeuvre/method of delivering health care is involved, this is even more crucial*

*Specify who, if anyone, will be ‘blinded’.*

*Specify how co-intervention and contamination will be avoided.*

*Specify how compliance, if applicable, will be assessed.*

*Specify how you will minimize bias in administering the manoeuvre.*

**3.4 Feedback to Participants**

*Whenever possible, upon completion of the study, participants should be informed of the results. Describe the arrangements for provision of this feedback.*

**4. Description of Outcome Measurement**

*Specify the outcome attribute(s) being measured. Consider which of the following should be measured: Symptoms, Death, Physical Function, Emotional Function, Social Function, Patient Satisfaction, Family Function.*

*Specify the method(s)/instrument(s)/questionnaire to be used to measure the attribute(s).*

*Specify the evidence for, or the plans for pretesting that will ensure the following:*

* *The Credibility and the Sensitivity of the instrument/questionnaire to change in the attribute and any other components of validity felt to be relevant.*
* *Precision.*
* *Feasibility.*

*Specify whether assessment will be blinded.*

*Specify how harmful side-effects will be detected.*

*Specify how you will minimize bias in measuring exposures and outcomes.*

**5. Analysis and Justification of Sample Size**

*To justify your sample size you must consider the following:*

* *Expected frequency of endpoint events in control/non-exposed groups.*
* *Clinical/Administrative significance of interest.*
* *The Type I and II error used in the calculation.*
* *The source of the estimate of the Standard Deviation where applicable.*

*For the Analysis you must consider the following:*

* *What are the criteria for substantive and statistical success?*
* *Reproducible details of statistical strategy to be used.*
* *Specification of data handling and collation and computer use.*

**6. Time Schedule and Duties of Research Personnel**

*Outline the duties of each of the investigators and propose a timeline for duration of each of the sections necessary to complete the work (e.g. Time and personnel assigned to subject intake, write up, etc.)*

**E. PILOT STUDIES**

*Specify any pretesting that was completed for such things as:*

* *Identification of eligible subjects*
* *Estimation of sample size*
* *Development of outcome measures*
* *Overall feasibility and logistics of study*

**F. ETHICS**

*The Research Ethics Board will weigh coverage of the following when reviewing this protocol:*

* *Discussion of the benefits of conducting the research versus risk of harm to participants. What harms might exist, and how will they be mitigated?*
* *How will the investigators ensure that the participants freely provide their informed consent?*
* *Procedures to ensure confidentiality which demonstrate, in detail, how it will be maintained.*
* *Describe possible relationship(s) between the investigator(s) and participant(s) (e.g., instructor-student relationship; manager-employee relationship).*
* *Will deception be used in this study? If so, justification must be present in the protocol. Include a debriefing protocol.*

*For CMCC Faculty, the Budget Justification Form can be found on KIRO, at* [***Application for Ethical Review***](https://courses.cmcc.ca/access/content/group/41d16697-5a9e-430d-be8c-bfc89c288293/Application%20for%20Ethical%20Review.pdf)*. This form is meant to act as a guide, in order to provide industry-wide examples of grant expense types, and information required.*

**Project Title:**

**EQUIPMENT**

**SUPPLIES**

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| **Item** | **Justification** | **Amount** |
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**TRAVEL**

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**OTHER** (*itemize by category*)

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**TOTAL**: $

*Attach appendices here, ordered by intended appearance. This part of the document will not re-format pasted items.*