PROTOCOLS

#88 - Demonstration Application

Protocol Information

Submission Type	Status
New	**In Progress**

General Information

Are any of the research team members affiliated with any of the Research Ethics BC (REBC) institutions, other than SFU? Please check the up to date list of REBC institutions here.

No

Will any recruitment of participants or conduct of research occur at any of the Research Ethics BC (REBC) institutions, other than SFU? Please check the up to date list of REBC institutions here.

No

Principal Investigator

Kim Lajoie

Department/School

Biomedical Physiology Kinesiology

Title of Research Project

Demonstration Application

General Questionnaire

Select the type of submission you are completing

New Application

Indicate what type of study you are applying for

Clinical

Has this study received ethics approval from a research ethics board that is Tri-Council Policy Statement (TCPS2) compliant, such as another Canadian University or Health Authority? Please note: Institutions outside of Canada are not TCPS2 compliant. Please note that approval from a Canadian federal funding agency does not apply to this question.

No

Personnel

study and designate the type of online access you would like them to have. Study personnel you grant the Full Access permission to will be able to complete the initial application, or initiate amendments, but the PI must submit all applications.

Instructions to add or update personnel.

- Click "+ Add Info" below to add your first person.
- Click "+ Add Line" to insert additional persons.
- Select the Edit Pencil next to a person to edit or update.

SFU Affiliated Personnel

Person

Kim Lajoie

Home Unit

No Item Selected

Email Address

klajoie@sfu.ca

Phone

Researcher Role

Principal Investigator

Appointment Status

Permissions

Full Access

People Attachments

Contact Roles

Admin

Does this project include personnel that are external to SFU?

Yes

Team Members External to SFU

Add all co-investigators and other study team members associated with this study who are not affiliated with SFU. The co-investigators will be listed on the REB Approval Letters, but will not have online access to the study application.

Instructions to add or update personnel.

- **Click "+ Add Info" below to add your first person.**
- **Click "+ Add Line" to insert additional persons.**
- **Select the Edit Pencil next to a person to edit or update.**

All SFU affiliated study team members (including but not limited to faculty, undergraduate and graduate students, and research staff) are required to complete either the TCPS2 (CORE) tutorial or the Social and Behavioral Research Ethics course or Biomedical Research Ethics course offered through the CITI Program before submission. Please confirm that all SFU affiliated study team members have completed one of the TCPS2 (CORE) tutorial or either of the CITI Program courses.

All SFU affiliated study team members have completed either the TCPS2 (CORE) Tutorial or a CITI Program course.

In-Person Research Activities

Will your study involve in-person research activities?

Yes

Effective July 21, 2021, SFU has adopted a university-wide Communicable Disease Plan. All SFU affiliated study team members (including but not limited to faculty, undergraduate and graduate students, and research staff) are required to follow this plan when conducting in-person research activities. Researchers are reminded that they will need to follow local site safety information made available to them by their research site(s).

I will ensure that all study team members are aware of their obligation to follow the prevention measures outlined in the SFU Communicable Diseases Plan

I confirm that all SFU affiliated research team members are fully vaccinated against COVID-19.

will abide by the latest provincial health guidelines in relation to the COVID19 pandemic and will be fully vaccinated against COVID-19."

Please describe what the in-person research activities are.

Will participants be required to be vaccinated in order to participate in the study?

Yes

Please add the following statement to the study recruitment materials and consent form:

"Participants will be required to be fully vaccinated in order to participate in the study and will be required to show proof of vaccination at the start of the study."

Please also include fully vaccinated status as an inclusion criteria in the application form.

Funding

Types of Funding

Grant

Please enter the details for the research funding application/award associated with this study.

Instructions to add or update funding source.

- Click "+ Add Info" below to add your first funding source.
- Click "+ Add Line" to insert additional funding sources.
- Select the Edit Pencil next to a funding source to edit or update.

Is this a U.S. Department of Health and Human Services grant?

Yes

DHHS Funding Source

Please enter any applicable information about your funding which is not already shown above.

Conflict of Interest

Conflicts of Interest (COIs) can arise naturally from an Investigator's engagement inside and outside the University, and the mere existence of a COI or the perception of a COI does not necessarily imply wrongdoing on anyone's part. Nonetheless, real and perceived COIs must be recognized, disclosed, and assessed.

Do the Principal Investigator, Co-Investigators and/or their related parties (defined in SFU Policy GP 37) have any personal interest(s) that could compromise or reasonably be perceived to compromise the objective conduct of the research or the integrity of the data generated by the study? Personal interests may include business, commercial or financial interests, as well as personal matters and career interests.

Yes

What is the status of your Conflict of Interest Form ?

Completed by the researcher

Please email the draft form to dore@sfu.ca. Do not sign the form or send it to the Dean before sending it to ORE.

Peer Review

Is this application closely linked to any other application previously/simultaneously submitted to this (or another) REB?

Yes

Please enter the Research Ethics Board number of that proposal.

Please describe the relationship between this proposal and the previously/simultaneously submitted proposal listed above.

Are you aware of any rejection of this study by any Research Ethics Board?

No

Will biological materials be collected or analyzed by researchers or a research lab?

Yes

Please provide the applicable Biosafety Permit Number(s).

Yes

Please provide the applicable Radiation Permit Number(s).

Will devices be used in this project?

No

Has this study received External Peer Review?

Yes

Please provide known details.

Has this study received Internal Peer Review?

No

Minimal Risk Matrix

Participant Vulnerability	Research Risk
High	Medium

Your project has an overall risk level of high and will likely be designated as "above minimal risk". This will be determined during initial review.

Above minimal risk research requires Full Board Review.

Explain/Justify the level of risk

Data Registry/Data Bank

In addition to other research activities, does this study involve the creation of a research database or registry for future unspecified research?

No

Is this an application for research requiring secondary use of data collected for a purpose other than the current research purpose?

No

Summary

In a sentence or two, provide a short summary of the project written in lay language.

Provide an overview of the research.

Describe research procedures that are going to occur. When applicable, outline or describe standard of care or standard procedure. This is particularly important for addressing what is incremental to standard of care.

Community Engagement

Does this project involve a group or community that requires specific considerations?

Yes

Does this research involve Indigenous peoples, communities, lands, cultural heritage, artefacts, knowledge, or organizations as a central theme to this project?

Yes

Will this project engage in any of the following activities:

Please provide details

Does the group, organization or Nation involved in this project have a research review process or ethics committee?

No

Have you initiated or do you intend to initiate an engagement process with the community or communities, organization(s) or Nation(s) for this study?

Yes

Describe the activities that you have undertaken to demonstrate meaningful community engagement as it applies to Chapter 9 of the TCPS2 policy document.

Recruitment

Specific communities may have processes for inclusion and involvement, or protocols for recruitment, that may need to be followed. Where applicable, include details below.

There may be protocols for recruitment for some Indigenous communities that may need to be followed. Please be aware of these protocols, where they exist, and elaborate on how they will be followed here and in the questions below.

Provide a detailed description of the method of recruitment.

Describe how prospective normal/control participants will be identified, contacted, and recruited, if the method differs from the above.

If existing records (e.g., course grade sheets, other records/databases, health records) will be used to IDENTIFY potential participants, please describe how permission to access this information, and to collect and use this information, will be obtained.

Consent

Are you altering the consent process or seeking a waiver of consent for all or some of the participants in this study?

No

Acknowledging the invitation above (i.e. recruitment), provide details on the consent process. Specify:

1. who will explain the consent form;
2. who will consent participants;
3. details of where the consent will be obtained and under what circumstances; and,
4. the relationship between the person obtaining consent and the participant.

How much time will a participant be asked to dedicate to the study?
If there are multiple sessions, please explain how long each session will take.

Please include this information in the Consent Form.

If applicable, how much time will a normal/control volunteer be asked to dedicate to the project?

Describe any potential benefits to the participant that could arise from their participation in the proposed research.

Please expand on how the community, specifically, will benefit from the project and the outcome.

How will the project support capacity building?

Describe what is known about the risks and potential harms of the proposed research for participants.

Describe the likely impacts of the research on the identified group or community.

Are there any costs participants can reasonably be expected to incur in order to participate?

Describe any payments, gifts, prizes, credits, etc. to be offered to participants.

Will every participant have the capacity to give fully informed consent on their own behalf?

Yes

Withdrawal process

Please describe the process the participants will need to follow in order to withdraw from the study and if they will be able to withdraw their data. Please explain if there are any restrictions and/or time limitations as to when their data can be withdrawn. Please include this information in the Consent Form.

Does this study have a reaffirmation or revival of consent and a formal re-consenting process?

No

What provisions are planned for participants, or those consenting on a participant's behalf, to have special assistance, if needed, during the consent process?

Describe any restrictions regarding the disclosure of information to research participants (during or at the end of the study) that the sponsor has placed on investigators, including those related to the publication of results.

Location

Does the research involve other organizations, institutions and other jurisdictions?

Yes

Please select "Add" to enter the name of the institution or organization and/or jurisdiction or country.

Please select "Add" to enter the name of the jurisdiction or country and if you have already received approval attach the approval letter.

Has a Request for Ethics Approval been submitted to the institution or responsible authority in the other jurisdiction or country?

No

If a Request for Approval has not been submitted, provide the reasons below.

Number of Participants

How many participants will take part in the study?

How many, out of the total number of participants, will be controls? If controls will be recruited at multiple institutions, please list the number of participants per institution.

Please enter any additional comments

Registered Trial

Is this study a clinical trial or investigational test requiring Health Canada regulatory approval?

Yes

Please check all that apply from the list below

This study is a clinical trial of a Natural Health Product pursuant to the Natural Health Product Regulations.

Name the sponsor/institution/investigator responsible for filing a Clinical Trial Application (CTA) or Investigational Testing Authorization (ITA) with Health Canada or Other.

If regulatory approval from a Health Canada directorate is required for this study, your certificate of ethical approval will not be released until the regulatory approval certificate, approval date and control number are received by REB administration.

I have read and understand the statement above

Click "Add" to complete the information for either the initial application or subsequent amendments.

Does this research fall within the categories of pluripotent stem cell research that need to be submitted to the CIHR Stem Cell Oversight Committee (SCOC)?

No

Does this clinical study fall within the definition of clinical trials stated in the guidelines?

Yes

Has it been registered?

Yes

Indicate the Authorized Registry used

Enter your Clinical Trial unique identifier

Is there a requirement for this research to comply with United States regulations for research ethics?

Yes

Please indicate whether or not an FDA (Investigational New Drug) number (drug studies) or an FDA Investigational Device Exception (IDE) is required for the research and provide documentation from the Sponsor or the FDA verifying the IND/IDE number, or explaining the study exemption status, in supporting documents.

Data Security & Confidentiality

situation, and indicate who has the code.

Describe data monitoring procedures while research is ongoing. Include details of planned interim analyses, Data and Safety Monitoring Board, or other monitoring systems.

Describe the circumstances under which the ENTIRE study could be stopped early. Should this occur, describe what provisions would be put in place to ensure that the participants are fully informed of the reasons for stopping the study.

Data Type

Are you collecting fully identifiable participant data?

Yes

Data Type Description

Please describe the type of identifiable data you will be collecting:

Where will the study data be stored?

Data Storage

What are the security arrangements in place to protect the data?

Data Storage

How long will the data be stored for?

Who will have access to the data, and will this differ across stages of the study? If yes, please explain:

Describe how the identity of research participants will be protected both during and after the research study, ie: will data be coded, anonymized, de-identified. Please refer to the TCPS2 definitions for data.

Identity Protection

If your study involves the use of data collection forms (ie: questionnaires), please describe how you will protect the identity of participants on the completed forms. For example, will you be using a participate code to identify the completed form, instead of the participant's name?

Identity Protection

If using participant codes, will you be retaining the master list / code-breaking file that links the code to the participant's name? If yes, please explain where the file will be stored, who will have access, how long the file will be retained for and the security arrangements in place to protect the file.

Will data be destroyed after study completion or maintained for future use in other research studies?

Maintained for Future Use

Please describe the plans for future use of the data, including who will have access to the data and for what purpose. If data will be stored for future use, please describe the storage and security arrangements.

Will any personal health information or personal identifiers be collected and retained as part of the dataset?

Yes

Please describe what personal identifying information will be collected, and justify the need for it to be collected.

For the use of biospecimens, please describe the following:
(A) describe what will happen to the study biospecimens at the end of the study, including
(B) how long the study biospecimens will be retained and
(C) if, where, when and how the biospecimens will be destroyed, and
(D) what plans there are for future use of the biospecimens, including who will have access to the biospecimen in the future and for what purpose.

Will data and/or biospecimens be sent outside of the Institution where it is being collected?

Yes

Please describe the following:
(A) the type of data and/or biospecimens to be transferred,
(B) who the data and/or biospecimens will be transferred to,
(C) where the data and/or biospecimens will be transferred, and
(D) how the data will be sent.

Will the researchers be receiving data and/or biospecimens from other sites?

Yes

Please describe

A) the type of data and/or biospecimens to be received,
B) who the data and/or biospecimens will be received from,
C) where the data and/or biospecimens will be received from, and
D) how the data and/or biospecimens will be received.

Will the data be linked to any other data source (including a biorepository)?

Yes

Please describe the following:
A) Identify the data set
B) how the linkage will occur, and
C) explain how confidentiality regarding the shared information will be preserved.

Are there any plans for feedback on the findings or results of the research to the participant? Provide detail.

Yes

Please elaborate on how feedback/findings/results will be shared with participants.

What is the dissemination plan for the study results? Will these be presented at a conference(s) or published, for example?

PI Confidentiality Declaration

I will ensure that all study team members are aware of their obligation to maintain the data security and confidentiality arrangements as described in this application.

Supporting Documentation

Please ensure that all study documents include the document title, eg: Consent Form, the ethics application number, a version number, a full document date (day/month/year), the SFU logo and page numbers.

If you are submitting multiple versions of the same document, eg: Interview Questions for different participant groups, please ensure to include a subheading to describe the participant group. For example, Consent Form (Teachers).

Please ensure the document file names reflect the document type, eg: Consent Form. Do not

label them as Appendix A, or with the investigator's name, or the study title, or the ethics application number.

When submitting revised document in response to the initial review, please use track changes to make the edits to your documents, or highlight the amended text.

Please review our Top Tips document for information on how to submit a valid ethics application.

Please provide approved COI Form

Depending on the method of consent, please provide one or more of the following:
• Participant consent form
• Verbal consent script

Please provide a copy of all recruitment materials that will be used to engage participants with the study, including email scripts, phone call scripts, flyers, radio/television scripts, posters, newspaper ads, internet messages, social media posts, letters of initial contact.

Please provide a copy of the biosfety permit.

Please provide a copy of the Radiation Permit.

Please provide copies of the internal or external peer review comments.

Please provide written evidence of community engagement. This may be a research agreement or a letter/email of approval/support.

Please attach approval letters from the other jurisdictions and/or institutions as applicable.

Please provide a copy of Health Canada approval, or a copy of the No Objection Letter (NOL), Investigational Testing Authorization (ITA), Notice of Allegation (NOA), as applicable.

Please provide provide documentation from the Sponsor or the FDA verifying the IND/IDE number, or explaining the study exemption status.

Website (Optional)

If a Web site is part of this study, enter the URL below. Since URL's may change over time or become non-existent, you must also attach a copy of the documentation contained on the

web site to this section or provide an explanation.

PI Declaration

Administrative Details Form

Determinations

Review Type

Study Status