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Description generated with very high confidence**

**This form is for researchers who are planning to conduct research at Fleming College only.**

**Application to Involve Human Participants in Research**

**SECTION A – GENERAL INFORMATION**

1. Title of the Research Project:

2. Investigator Information

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Name & position | Dept./Address | Phone No. | E-Mail |
| Principal Investigator (PI) \*: |  |  |  |  |
| Faculty:  Co-Investigator(s) |  |  |  |  |
| Student: Investigator(s) |  |  |  |  |
| Other:  Investigator(s) |  |  |  |  |

\* **The advisor must be listed as PI for any student investigators. Student investigators are faculty /staff who are completing research for educational purposes.**

3. **Proposed Date** a) of commencement:      b) of completion:

**Note: The commencement date should be the date the principal investigator (PI) expects to actually begin interacting with human participants (including recruitment). The completion date should be the date that the PI expects that interaction with human participants, including any feedback or follow-up, will be complete.**

4. **Indicate the location(s) where the research will be conducted:**

5. **Other Research Ethics Board Approval**

* + 1. Has any other institutional Ethics Board approved this project?  Yes  No  N/A
  1. If **Yes**, please provide the following information:

Title of the project approved elsewhere:

Name of the Other Institution:

Name of the Other Ethics Board:

Date of the Decision:

A contact name and phone number for the other Board:

**OR**

A copy of the clearance certificate/approval **AND**

final copies of all supporting documentation already approved

6. **Project Funding**

* + 1. Is this project currently funded?  Yes  No  N/A

1. If **YES,** please indicate:

Period of Funding: From       To:

Agency or Sponsor (funded or applied for)

CIHR:

NSERC:

SSHRC:

Please specify the complete title of the funding source. For example, ‘NSERC Discovery Grant”

Other:

**Note: If the funding source changes, or if a previously unfunded project receives funding, you must submit a change/amendment form to each Research Ethics Board that has approved your project.**

8. **Conflict of Interest**

1. Will the researcher(s), members of the research team, and/or their partners or immediate family members:
2. Receive any personal benefits (for example a financial benefit such as remuneration, intellectual property rights, rights of employment, consultancies, board membership, share ownership, stock options etc.) as a result of or connected to this study?

YesNo  N/A

1. If **YES**, please describe the personal benefits below. (Do not include conference and travel expense coverage, possible academic promotion, or other benefits which are integral to the general conduct of research.)

|  |
| --- |
| If **yes**, please explain. |

* + 1. Are there any real, perceived or potential [conflicts of interest](http://www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf) of which you are aware (for example, researchers who will benefit financially from the research, research which may be in conflict with institutional roles and responsibilities, faculty members who may be responsible for awarding participant grades)?  Yes  No  N/A

|  |
| --- |
| If **yes**, please explain. |

* + 1. Are there any restrictions regarding access to or disclosure of information

(during or at the end of the study) that the sponsor or institution has placed

on the investigator(s)?  Yes  No  N/A

|  |
| --- |
| If **yes**, please explain. |

* + 1. Is there the possibility of commercialization of the research findings?  Yes  No  N/A

|  |
| --- |
| If **yes**, please explain. |

**SECTION B – SUMMARY OF THE PROPOSED RESEARCH**

9. **Rationale**

* + 1. Describe the purpose and background rationale for the proposed project, as well as the hypothesis(es)/research question(s) to be examined.

|  |
| --- |
| Please explain purpose and background. |

10. **Methodology**

1. Describe sequentially, and in detail, all procedures in which the research participants will be involved (e.g., paper and pencil tasks, interviews, surveys, questionnaires, physical assessments, physiological tests, time requirements etc.)

**Note: Attach a copy of all questionnaire(s), interview guides or other test instruments. Check with the individual REB re letterhead requirements if they are intended for public dispersal.**

|  |
| --- |
| Please explain the methodology. |

1. Does the nature of the research create vulnerability for any

of the groups listed below?  Yes  No  N/A

* 1. If **YES**, check all that apply:

People with relevant health issues Children

People in medical emergencies  Elderly people

Aboriginal people  People in poverty

People in long-term care  People in prison

People with mental-health issues  People who are unable to consent

Other

If **OTHER**, please specify:

* + 1. If **YES in 10b) above**, please explain your screening process (maximum 5 lines):

Please explain your screening process:

**Note**: **Researchers must destroy all information collected during screening in a secure**

**manner as soon as screening is complete.**

Please explain how you will destroy your screening data securely:

1. **Recruitment**
2. How do you plan to recruit participants (please check all that apply):

Investigators will approach their own students/patients

Investigators will receive referrals from other faculty

Indirect advertising (e.g. poster, e-mail, web-based). .

Database of people who consented to future contact.

Direct approach (e.g. random digit dialing, blogs and chat room)

Educational records (e.g. academic performance information, Student Information System)

Other

If **OTHER**, please specify:

1. Do you screen personal health information to identify  Yes  No N/A

potential participants?

1. Does your recruitment plan require you to contact potential participants by:
   * 1. Telephone  Yes  No  N/A
     2. Personal E-mail  Yes  No  N/A
     3. Anonymous Email  Yes  No  N/A
     4. Letter  Yes  No  N/A

**Note: If you answered YES to any category above, please attach a copy of all telephone**

**scripts and recruitment correspondence.**

1. **Informed Consent**
   * 1. Will you be seeking *written* consent from participants?  Yes  No  N/A
        1. If **YES**, please attach a copy of the Information Letter and Consent form for Participants.

**Note:**

* **Participants should *actively* choose whether or not to participate. A lack of response (i.e. a statement such as “you will be assumed to want to participate unless you indicate otherwise to the researchers”) should not be construed to imply consent.**
* **Written consent is not required in all circumstances. For example, you could require participants to click a box in an online survey or provide verbal consent.**

1. If consent will not be written, please provide details of how you will obtain consent in the box below.

If **OTHER**, please specify:

1. Will any participants be minors (i.e. age 0-15)?  Yes  No N/A
2. Will all participants be competent to consent?  Yes  No N/A
3. If the participants are minors, or are not competent to consent, describe the proposed alternate source of consent. Please include any permission/information letter to be provided to the person(s) providing the alternate consent.

|  |
| --- |
| Please explain. |

1. Who will obtain consent to participate for minors or those not competent to consent?

Please explain:

1. When and where will this be done?

Please explain:

1. Do you need to request a waiver of consent?  Yes No N/A
2. If **YES**, please explain:

Please explain:

1. Will any of the investigators have a position of power or authority

over the participants? Yes No N/A

* 1. If **YES**, how will you manage and minimize any undue influence?

Please explain:

1. Will [continuing consent](http://www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf) (for example, research which may continue beyond

an academic year) be required during the study? Yes No N/A

1. If **YES**:

Please explain:

1. Will participants have the option to withdraw from this study? Yes No N/A
   1. If **YES**, what do they have to do to withdraw?

Please explain:

1. Indicate what will be done with the participant’s data and any consequences for the participant withdrawing from the study.

Please explain:

1. If the participants will not have the right to withdraw from the project, please explain the rationale:

Please explain:

1. Will you be using [deception](http://www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf) in your research? Yes No N/A
2. If **YES**:

Please explain.

1. **Collection of Personal Information**
2. Please check all types of data which you intend to collect:

* Identifying information which identifies a participant through direct identifiers (e.g. full name, medical record number)
* Identifiable information which could identify a participant through a combination of indirect identifiers (e.g. DOB plus address)
* De-identified/coded information in which identifiers are removed and replaced with a code; the code can be used to re-identify participants
* Anonymized information in which all identifiers are removed and no code is kept
* Anonymous information in which no identifiers are collected

1. Will all data be treated as confidential? Yes No N/A
2. If **NO**:

Please explain.

1. Will you collect any Personal Health Information (PHI)?

Yes  No  N/A

**Note:**

* **The collection, use and disclosure of Personal Health Information (PHI) are regulated by the Personal Health Information Protection Act (PHIPA). Researchers must comply with this legislation**
* **Collection of participant SIN (social insurance number) is prohibited, unless payments to participant exceed $500/year (required for tax purposes)**
* **PHI should be collected at the lowest level of identifiability possible (e.g. initials instead of a name, age instead of DOB)**

Please detail the specific identifiers required for this study:

|  |  |
| --- | --- |
| Identifier (check all which apply) | Why is this necessary? |
| Full name |  |
| Initials |  |
| Student/Employee number |  |
| Social Insurance Number |  |
| Health card number |  |
| Medical record number |  |
| Address |  |
| Full postal code |  |
| Partial postal code |  |
| Telephone number |  |
| Email |  |
| Physician |  |
| Date of birth |  |
| Age |  |
| Other: (Specify) |  |

1. How will you record study data?

Case report form.

Other:

Please specify:

1. **Storage and Protection of Information**

**Note: PHIPA Requirements**

* **Paper files with identifiable information must be kept in a locked cabinet within a locked office (but not at home)**
* **Electronic files with identifiable information may be stored on a password-protected computer on a secure network (i.e. Virus protection, file backup, firewall) or they must be encrypted.**
* **Electronic files with identifiable information may be stored on mobile devices (e.g. laptop, CD, USB, PDA), but no alternative method of storage; these files must be encrypted.**
* **Identifying and/or identifiable PHI cannot be transmitted by email unless it is encrypted**

**Note: Coding**

* **Identifying and/or identifiable PHI should be protected by a coding system**
* **The code (study ID and identifiable PHI) must be isolated from study data and**

**stored in a secure manner**

* 1. Will you use a coding system to protect identifiable information?  Yes No  N/A
     1. If **NO**:

Please explain.

1. How will you store and protect the study code (or other data with identifiers)?

|  |  |  |
| --- | --- | --- |
| Type of record | Required protection | Location (i.e. building, room) |
| Paper file | Locked cabinet in locked institutional office |  |
|  | Password protected computer on a secure network |  |
|  | Encrypted (specify software used): |  |
|  | Identifiers and participant data are stored separately |  |

1. How will you store and protect data without identifiers?

Please explain.

1. Do you plan to anonymize the study data?  Yes  No  N/A
   * 1. If **YES**, when?

Please explain.

**Note: You are required to destroy identifiers or links at the earliest possible time.**

1. How long will you keep the study data?

**Note: If this study requires Health Canada approval, records must be retained for 25 years.**

**For all other studies, the REB recommends 7 years. Sponsors and institutions may set out**

**other requirements.**

1. Do you plan on physically moving the data?  Yes  No  N/A
   * 1. If **YES**, how will the data be secured while in motion?

Please explain.

1. What will you do with the study data after this period?

**Note: Use of data for** [**purposes other than those for which the data was originally collected**](file:///\\FLEMING0\jmcdonald\User\mnummelin\Local%20Settings\Temporary%20Internet%20Files\Content.Outlook\TCPS\TCPS_2_FINAL_Web.pdf) **is considered to be secondary use of data and requires participant’s permission.**

Please explain.

1. **Transmission of Data**
2. Will the research data be moved outside its original location of collection

(for example, sent for transcription or uploaded to a central data

repository?  Yes  No  N/A

1. If **YES**, does this data to be transmitted include identifiers?  Yes  No  N/A
   1. If **YES**, please provide details on the data transfer agreement:

Please explain.

* 1. If **YES**, where will the data be sent?

Please explain.

**Note: Data sent to the United States, or uploaded to American servers (e.g. Survey Monkey), is open to access by American regulatory bodies. Researchers must inform study participants of this possibility.**

1. Please list the names and affiliations of persons outside of your research team who will have access to the identifiable data.

**Note: If you require outside sources to have access to participant data, you need to ensure that mechanisms are in place to ensure data security, confidentiality and anonymity.**

|  |  |
| --- | --- |
| Name | Institutional Affiliation |
|  |  |
|  |  |
|  |  |

1. How will the data be transmitted?

Fax

Email **(Note: Encryption protocol must be attached)**

Private Courier **(Note: Delivery must be traceable)**

Canada Xpresspost **(Note: Regular mail may not be used)**

Other:

Please explain.

1. **Secondary Use of Data**
2. Will you combine your research data with any other data sets?  Yes  No  N/A
3. If **YES**, please specify:

Identify the dataset:

Explain how the linkage will occur:

Provide a list of data items contained in the dataset:

1. Will your data be entered into another database for future use?  Yes  No  N/A
2. If **YES**, please specify:

Where it will be stored?

Who will be the custodian?

Who will have access to the database?

What security measures will be in place?

**Note: Any** [**secondary use of data**](file:///\\FLEMING0\jmcdonald\User\mnummelin\Local%20Settings\Temporary%20Internet%20Files\Content.Outlook\TCPS\TCPS_2_FINAL_Web.pdf) **must be approved by the REB prior to its use.**

1. **Experience**
2. What is your experience with this kind of research?

Please explain.

**Note: It is strongly recommended that researchers complete** [**the free online TCPS training**](http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/)**, available at:** <http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/>

1. **Compensation**
2. Will participants receive compensation for participation?
   * 1. Financial   Yes  No  N/A
     2. Non-financial   Yes  No  N/A

1. If **Yes** to **either** i) or ii) above, please provide details.

Please explain.

1. If participants choose to withdraw, how will you deal with compensation?

Please explain.

**SECTION C – DESCRIPTION OF THE** [**RISKS**](file:///\\FLEMING0\jmcdonald\User\Local%20Settings\Final%20Guidelines%20Approved\G_18%20Level%20of%20Risk%20to%20Participants'%20Assessment%20Tool.doc) **AND** [**BENEFITS**](file:///\\FLEMING0\jmcdonald\User\Local%20Settings\Final%20Guidelines%20Approved\G_18%20Level%20of%20Risk%20to%20Participants'%20Assessment%20Tool.doc) **OF THE PROPOSED RESEARCH**

1. **Possible Risks to Participants**
2. Indicate if the participants might experience any of the following risks: Yes No N/A
   * 1. Physical risk (including any bodily contact or administration of any

substance)?

* + 1. Psychological risks (including feeling demeaned, embarrassed worried

or upset)?

* + 1. Social risks (including possible loss of status, privacy and/or reputation)?
    2. Economic risks (including incurring expenses, loss of incentive)?
    3. Academic risks (including loss of bonus marks or course standing)?
    4. Potential access to personal data
    5. Are any possible risks to participants greater than those the participants

might encounter in their everyday life?

1. If you answered **YES** to any of Points i) through vii) above, please explain the risk.

Please explain.

1. Please comment on the [magnitude](file:///\\FLEMING0\jmcdonald\User\mnummelin\Local%20Settings\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\Windows\Final%20Forms%20Approved\TCPS%20Definitions.doc)of harm participants are likely to encounter i.e. would you assess it as minimal, substantial, transient or longer lasting?
2. Please comment on the [probability](http://www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf) that participants will encounter harm, i.e. would you assess it as low, medium or high?

Please explain.

1. Describe how the risks will be managed (including an explanation as to why alternative approaches could not be used).

Please explain.

1. **Possible Risks to Researchers**

Please explain any risks to researchers which you anticipate.

1. **Possible Benefits to Participants**
2. Discuss any potential direct benefits to the participants from their involvement in the project. Comment on the (potential) benefits to the scientific community/society that would justify involvement of participants in this study.

Please explain.

**SECTION D – PARTICIPANT FEEDBACK**

1. Explain what feedback/ information will be provided to the participants after participation in the project. (For example, a more complete description of the purpose of the research, or access to the results of the research). Indicate when results will be available and, if they will be made available on the internet, the URL to be used to access the results:

**Note: Feedback should be provided in a way which is accessible to participants. For example, some participants may not have access to a computer so uploading results to a website may not be sufficient.**

Please explain.

**SECTION E – MONITORING ONGOING RESEARCH**

1. **Annual Review and Adverse Events**
2. Protocol review requires the completion of a “Renewal/Completed Status Report” at least annually. Indicate whether any additional monitoring or review would be appropriate for this project.

**Note: It is the principal investigator’s responsibility to notify the REB the project is completed, or if it is cancelled, using the appropriate form.**

Please explain.

1. **Adverse events** (i.e. unanticipated negative consequences or results affecting participants) must be reported to the Research Ethics Board and the Research Ethics Coordinator as soon as possible using the form available on this website.
2. **Additional Information**

Please explain

(Use an additioN/Al page if more space is required to complete any sections of the form, or if there is any other information relevant to the project that you wish to provide to the Research Ethics Board.)

**SECTION F – SIGNATURES**

**Principal Investigator (PI) Assurance:**

**I­­, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [PLEASE PRINT] have the ultimate responsibility for the conduct of the study described in this application including my responsibilities as an advisor to any students involved in this project. I have read and am responsible for the content of this application. The information provided is complete and accurate. I understand that, as Principal Investigator, I will be the primary link with the REB, other researchers involved with this project, and the research participants. I agree to conduct the research in accordance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, this individual college’s policies and procedures for ethical Conduct of Research, and the conditions of approval indicated by the ­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Research Ethics Board.**

**I also understand that if I make any changes whatsoever to the sample documents provided with this application (including, but not limited to, the recruitment scripts, information and consent letters, survey questions, interview or focus group questions), I need to complete a change request form and submit this to the REB for review. I further understand that these changes, if determined to be substantive by the REB, may require a new application if they constitute new research. If any changes are made in the above arrangements or procedures, or if adverse events are observed, I will bring these to the attention of the Research Ethics Coordinator immediately. I further understand that I may not start any research without receiving a Certificate/Letter of Ethical Acceptability. I further understand that ethical approval does not constitute institutional approval of this research.**

**I understand that if I fail to advise the REB of any changes or adverse events, or fail to comply with research protocols outlined in this application, or make any unauthorized changes to any document submitted with this application, the Certificate of Ethical Acceptability may be rescinded by the REB.**

**Name of Principal Investigator:**

**Signature of Principal Investigator:**

**Date:**

      (yyyy-mm-dd)

**Signature Date**

***Please submit this application together with all relevant attachments by email to*** [***research@flemingc.on.ca***](mailto:research@flemingc.on.ca) ***and the Office of Applied Research will contact you shortly after receipt to advise as to when the REB committee will review your application and next steps.***