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| **OFFICE USE ONLY:** REB.2022.04.04 Version[ ]  **Incomplete** [ ]  **Conditional Clearance**  [ ]  **Cleared** [ ]  **Withhold Clearance**  **Review leve**l: [ ]  **Delegated** [ ]  **Full Socio-behavioral** [ ]   **Full Biomedical** [ ]  **Executive** [ ]  **Education**  | **Application Reference Numbers**:REB#: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ERSO#: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Application Review Process and Checklist**

1. Applicant(s) submit a complete application for ethical review which includes:
* The application form with all applicable questions answered and checklist completed and certified;
* Copies of TCPS2 Certificates for all members of the research team;
* All applicable appendices such as participant recruitment instruments (e.g., posters, scripts, and emails, participant pool screener), consent forms, interview questions/scripts, focus group scripts, and online survey URL, etc.
1. The REB completes a preliminary screening of the application for completeness and coherence. Incomplete or incoherent applications are not reviewed by the REB and are returned to the applicant with a request for more information.
2. Once a complete application is received, the REB completes a Proportional Review Assessment that determines whether the application will be reviewed at a monthly REB meeting or on a Delegated basis by a subcommittee of the REB. The level of Proportional Review Assessment evaluates the degree of risk and vulnerability of participants associated with the proposed research. Applications involving a higher degree of risk and vulnerability are reviewed at a monthly REB meeting. Applications involving a lower degree of risk and vulnerability are reviewed on an ongoing basis by a Delegated subcommittee of the REB.
3. Once an application has been reviewed, the REB provides the applicant with an email indicating that:
4. the application is cleared as submitted; or
5. the application contravenes the TCPS2 and/or requires additional information (in the latter case review minutes and REB queries are emailed to applicants.

The REB typically issues an initial decision in two to four weeks. Applications that are missing information critical to review may require re-review. Applications that are missing information or fail to recognize and account for risks to participants, sometimes require multiple resubmissions before being cleared.

1. A clearance email is issued to the Principal Investigator once the REB is satisfied that the application is compliant with the TCPS2. Once cleared, the application becomes the ethical protocol with which researchers must adhere; any planned deviations from the protocol must first be cleared with a request to revise before they can be undertaken; any unanticipated or adverse events must be reported immediately to the REB.

**REB Checklist:**

* **Either the Principal Investigator, or if there is one this defaults to the Faculty Supervisor or Faculty Sponsor, should complete the checklist to inform the REB of available documents and to confirm that the application is complete, coherent and ready for REB review. All materials should be submitted in a single electronic file.**
* **Faculty Supervisors are required to read and endorse the applications of those under their supervision.**
* **Student researchers are expected to develop their REB application with support of their Faculty Supervisor.**

**There are eight (8) sections in this application form. Please take note of the following sections:**

1. **Section A: PROJECT OVERVIEW**
2. **Section B: GENERAL INFORMATION**
3. **Section C: SUMMARY OF THE PROPOSED RESEARCH**
4. **Section D: DESCRIPTION OF THE RISKS AND BENEFITS OF THE PROPOSED RESEARCH**
5. **Section E: THE INFORMED CONSENT PROCESS**
6. **Section F: SAFEGUARDS FOR PROTECTING PARTICIPANTS AND DATA**
7. **Section G: SIGNATURES**
8. **Section H: STUDENT PRINCIPAL INVESTIGATORS AND FACULTY SUPERVISOR**

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| --- | --- | --- | --- |
| **SECTION** |  | **COMPLETED** | **NOTES FROM RESEARCHER(S)** |
| **A** | * Title
* Level of Research
* Principal Investigator
* Alternate Contact
* Co-Investigators
* Project start and end dates
 | [ ]  |  |
| **B** | * Faculty Supervisor or Faculty Sponsor
* Co-Investigators
* Locations
* Additional Approvals (e.g., permissions)
* Funding of the Project
* Contracts (e.g., funding agreements, etc.)
* REB Review of Ongoing Research
* Prior Scholarly Review (e.g., thesis, etc.)
* Conflict of Interest (e.g., dual roles, etc.)
 | [ ]  |  |
| **C** | * Rationale
* Methods
* Deception
* Participants/Informants
* Recruitment (e.g., posters, scripts, etc.)
* Experience
* Compensation/Incentive
 | [ ]  |  |
| **D** | * Possible Risks (e.g., physical, social, etc.)
* Risk Analysis
* Possible Benefits
 | [ ]  |  |
| **E** | * Description of the Consent Process
* Consent by an Authorized 3rd Party
* Post-Study
* Information/Feedback/Debriefing
 | [ ]  |  |
| **F** | * Anonymity/Confidentiality
* Data Management (e.g., storage, etc.)
* Privacy Regulations and Application

Laws | [ ]  |  |
| **G** | * Signatures
* Principal Investigator(s)
* Co-Investigator(s)
 | [ ]  |  |
| **H** | * Signatures
* Student Principal Investigator
* Faculty Supervisor or Sponsor
 | [ ]  |  |
| **RELEVANT DOCUMENTS****(APPENDICES)** | * Consent Form
* Consent Form (Audio/Video)
* Parental/Guardian Information and

Consent* Form/Assent Form
* Debriefing Script or Letter
* Recruitment materials (Posters/flyers, social media posts, e-mail or verbal scripts, Participant Pool ads, etc.)
* Permissions/Approvals
* Previous Approval Letters
* Questionnaires/Instruments
 | [ ]  |  |
| **ETHICS TRAINING****(APPENDICES)** | * TCPS2 Core certificates for the Principal Investigators, Co-Investigators and any other members of the research team
* Other relevant Ethics Training
 | [ ]  |  |
| **REB APPLICATION** | * An electronic version of the application

and all supplementary documents and appendix in a **single file (.pdf)** | [ ]  |  |

[ ]  **I certify that I have read all of the above, that this application is complete and coherent, and I understand that all applications that are not, may not be reviewed by the REB, and could be returned to the applicant(s) with a request for more information.**

Date:

**Signature of Principal Investigator:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**-OR-**

Date:

**Signature of Student Principal Investigator:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date:

**Signature of Faculty Supervisor or Sponsor:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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***NEW PROTOCOL APPLICATION FOR RESEARCH ETHICS REVIEW***

 *RESEARCH INVOLVING HUMAN PARTICIPANTS*

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| --- |
|  **SECTION A – PROJECT OVERVIEW** |

**Title of Research Project:**

|  |
| --- |
|       |

Level of research: [ ]  Faculty [ ]  Post-Doctoral [ ]  Doctoral [ ]  Master’s [ ]  Undergraduate

[ ]  Other (Describe):

**Principal Investigator:**All applications require a single primary investigator with whom the REB will communicate

|  |  |
| --- | --- |
| Title:        | Name:       |
| Department:       | Institution/Agency/Organization:       |
| Mailing address:       |
| Phone:        | Email:       |

***Alternate Contact*** *(e.g., Research Coordinator)****:***

|  |
| --- |
| Title:       Name:       |
| Phone:        | Email:       |

**\*Co-Investigators:**

Are co-investigators involved? [ ]  No [ ]  Yes *\*If YES, please fill out additional information in SECTION B (2).*

***Project start and end dates (Year/Month/Day):***

Data collection **SHALL NOT** begin until REB clearance is granted.

Estimated start date for data collection: YY/MM/DD

Estimated completion date for this project: YY/MM/DD

Estimated date for feedback to participants: YY/MM/DD

|  |
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| **SECTION B – GENERAL INFORMATION**Please ensure ALL fields in the application are completed.**Incomplete forms will not be accepted for review.**  |

**1. FACULTY SUPERVISOR -or- FACULTY SPONSOR** (if applicable)

|  |
| --- |
| **SECTION B – GENERAL INFORMATION** |

**1. FACULTY SUPERVISOR -or- FACULTY SPONSOR** (if applicable)

All student research must identify a single primary faculty supervisor, to whom all correspondence will be copied.

|  |  |
| --- | --- |
| Title:        | Name:       |
| Department/Agency:       |
| Mailing address:       |
| Phone:        | Email:       |

**2. CO-INVESTIGATORS** (if applicable)

|  |  |
| --- | --- |
| Title:        | Name:       |
| Department/Agency:       |
| Mailing address:       |
| Phone:        | Email:       |

|  |  |
| --- | --- |
| Title:        | Name:       |
| Department/Agency:       |
| Mailing address:       |
| Phone:        | Email:       |

|  |  |
| --- | --- |
| Title:        | Name:       |
| Department/Agency:       |
| Mailing address:       |
| Phone:        | Email:       |

*\*Please append additional sections if necessary.*

**3. LOCATIONS WHERE THE RESEARCH WILL BE CONDUCTED**

*(Please check all that apply)*

[ ]  University of Windsor

[ ]  *H*ô*tel* Dieu-Grace Health Care

[ ]  Hospital - (*specify site[s])*

[ ]  School board/community agency - (*specify site[s])*

[ ]  Community within the Windsor-Essex County - (*specify site[s])*

[ ]  First Nations, Métis, Inuit community

[ ]  International - (*specify site[s])*

[ ]  Other - (*specify site[s])*

**4. ADDITIONAL APPROVALS**

Do any of the other institutions/sites require permission for the research to be conducted? [ ]  No [ ]  Yes

*If yes, please attach documentation of approvals/permissions obtained.*

Do any of the institution(s)/site(s) require administrative approval? [ ]  No [ ]  Yes

*(for H*ô*tel Dieu-Grace application, check “Yes” for both and include the HDGH letter of no-objection)*

Do any of the institution(s)/site(s) have an ethics review board? If so, answer below. [ ]  No [ ]  Yes

Has any other REB cleared this project? [ ]  No [ ]  Yes

*If* ***Yes****, submit the original application and provide a copy of the clearance letter.*

If **No**, will any other REB be asked for clearance? [ ]  No [ ]  Yes

If **Yes**, from which REB(s):

|  |
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**5. FUNDING OF THE PROJECT**

This section refers to any funding received to conduct the research. Scholarships typically support students rather than projects and should not be indicated here (unless the scholarship comes with a specific research funding component).

**(a)**  Please select from the following:

|  |  |
| --- | --- |
| [ ]  Funded  | Agency:      **Please ensure that the grant application information is accurate. This includes having the *exact* ‘title’ as it appears on your grant application. This will facilitate connecting REB clearance with the appropriate funding.**  |
| Title of project associated with funding:       |
| Finance Grant Acct #:       |
| Funding Dates:       |
| [ ]  Applied for funding \*Please note you must contact the REB once funding has been received.  | Agency:       |
| Title of project associated with funding:       |
| Submission date:       |
| [ ]  Unfunded  |  |

***\*If one application is to cover more than one grant, please include all fund/grant numbers.***

**(b)**  For funded research, will more than one application be submitted to cover all research funded by the respective grant?

 [ ]  No [ ]  Yes

**6. CONTRACTS**

Is there a funding agreement or research contract associated with the research? [ ]  No [ ]  Yes

***\*If ‘Yes’, please include a copy of the agreement/contract with this application.***

**A Progress Report/Annual Report must be submitted to the Office of Research Ethics.**

**A Final Report must be submitted when the project is completed.**

**7. REB REVIEW OF ONGOING RESEARCH**

**(a)**  Are there any specific characteristics of this research that require additional

 review by the REB while the research is ongoing? [ ]  No [ ]  Yes

If **Yes**, please explain:

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**(b)** Is this part of a larger cleared Standard Operating Procedure (SOP)? [ ]  No [ ]  Yes

If **Yes**, please provide the corresponding REB Application Number xx-xxx

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**8. PRIOR SCHOLARLY REVIEW**

**(a)** Has this project been formally reviewed by a thesis/dissertation committee?

[ ]  No [ ]  Yes

If yes, please list the names of the thesis/dissertation committee:

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**9. CONFLICT OF INTEREST/DUAL ROLES (If not applicable, please answer ‘none’ in a, b, or c)**

**(a)** Will the researcher(s), members of the research team, and/or their partners or immediate family members receive any personal benefits (e.g. financial benefit such as remuneration, intellectual property rights, rights of employment, consultancies, board membership, share ownership, stock options, etc.) as a result of or in connection to this study?

 [ ]  No [ ]  Yes

If **Yes**, please describe the benefits (do not include conference and travel expense coverage or other benefits which are standard to the conduct of research):

|  |
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**(b)** Describe any restrictions regarding access to or disclosure of information (during or at the end of the study) that has been placed on the investigator(s). These include controls placed by sponsors, funding sources, advisory or steering committees.

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**(c)** Please describe any dual roles that may influence--or may be perceived as having an influence--on the research, researchers or participants. Describe any preceding, current, or anticipated relationship between the researcher(s) and those individuals/groups being recruited for the project (e.g. instructor-student; manager-employee; minister-congregant; co-investigators; organization-client; principal-teacher; doctor-patient; academic supervisor-participant; participant-participant, researcher-community member).

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***\*\*\*All relationships identified in 9c must be described and addressed under 18a (risks) and 18b (management of risks) in the application. Information from 9c may also be relevant in Section 20 Consent.***

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| **SECTION C – SUMMARY OF THE PROPOSED RESEARCH** |

**10. RATIONALE**

Describe the purpose, rationale, and justification for the proposed project. Please include research questions and hypotheses where relevant. The background should be concise but include all information that an educated layperson would need to understand the rationale for the proposed project. Please provide a brief scholarly background and relevant literature. References for the citations can be provided as an appendix.

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**11. METHODS**

**(a)** Please check **all** the research methods that apply:

[ ]  Action Research

[ ]  Case Study

[ ]  Documentary/Filmmaking

[ ]  Ethnography

[ ]  Experimental Design or RCT

[ ]  Focus Group

[ ]  Interview online/in-person

[ ]  Observation

[ ]  Online/Internet Research

[ ]  Oral/Life history

[ ]  Survey online/in-person

[ ]  Other:

Will the research make use of human biological materials or tissues? If **No**, please proceed to **(b)**.

[ ]  No [ ]  Yes

If **Yes**, please complete the remainder of **(a)**.

Please check the source from where the biological materials or tissues are coming.

 **[ ]** Archived Fixed Tissue

 [ ]  Frozen Tumor Bank

 [ ]  Autopsy

 [ ]  Fresh Tissue obtained from a Surgical Specimen

 [ ]  Fresh Tissue obtained from Excess Bodily Fluid (e.g., urine, saliva, etc.)

 [ ]  Fresh Tissue obtained from Excess Blood Sample (e.g., blood, plasma or serum)

 [ ]  Human DNA/RNA/proteins

 [ ]  Material related to Human Reproduction (e.g., embryos, fetuses, fetal tissue, cord

 blood)

 [ ]  Other (e.g., skin, hair, finger/toenails, bones, etc.) please specify:

Please indicate the type of human tissue sample or biological materials being requested and state what location the biologic materials will be from (e.g., hospital names or site names and geographical location if outside of Canada, etc.).

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If the specimen was obtained from an organization other than the University of Windsor, has that organization granted approval for it to be used for this research? If **Yes**, please attach a copy of that approval.

[ ]  No [ ]  Yes

Is approval required and/or has it been sought from the Research Safety Committee?

[ ]  Yes [ ]  No

If **Yes**, please indicate the Date of Approval: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Certificate Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If **No,** or approval is conditional, please explain:

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**(b)** Does this study include the use of an internet survey service (e.g., Qualtrics, LimeSurvey, etc.) or the University of Windsor’s REDCap to collect data?

**If you are using REDCap for E-Consent, Data Management, and/or Data collection, please see all the relevant policies and procedures highlighted on the WE-SPARK Health Institute** [**REDCap Resources**](https://www.wesparkhealth.com/redcap-documents-188/we-spark-redcap-policy-and-procedures) **page. These documents highlight proper REDCap usage and have been created in collaboration with the REB.**

[ ]  No [ ]  Yes

If **Yes**, please provide the following information:

What is the name of the internet survey service?

What is the URL for the survey (s)?

**(c)**  **Procedural Overview**

Provide a **step-by-step** description of all procedures that will occur between the point of first contact with participants until the completion of the study.

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|  |

**(d)** Do any of the methods involve:

 Audio Recording? [ ]  No [ ]  Yes

 Still Recording? [ ]  No [ ]  Yes

 Video Recording? [ ]  No [ ]  Yes

 Digital recording (in any form)? [ ]  No [ ]  Yes

If **Yes** to any of the above, please describe their use in the project. Please note the specific recording devices to be used (e.g. digital recorder, video recorder, etc.). Please note any online platforms that will be used (e.g. Teams, Zoom, etc.)

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**(e)**  Please describe each of the distinct methods used in the research and any corresponding data collection procedures and tools. Please provide standardized instruments, survey questions, interview questions in appendices. Please provide any figures, diagrams, or pictures as required to completely describe the method to an educated layperson. If using an online survey platform, please provide a printout of the survey in addition to the URL provided above.

Method #1:

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Method #2 (if applicable):

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*Add additional methods as relevant*

**(f)** Please provide 6-8 key words to identify this project.

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**12. DECEPTION**

*\*Researchers who complete this section are also required to complete SECTION 22 (c)*

Will deception be used in this study? [ ]  No [ ]  Yes

If **Yes,** please describe and justify the need for deception.

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**13. PARTICIPANTS/INFORMANTS**

Describe the participants who will be identified and recruited for the study. Indicate the size of the population from which participants will be recruited. Please provide the total number needed for the research, and the minimum needed for the research to succeed. Please describe any inclusion and exclusion criteria.

[ ]  This study will be using the UWindsor Psychology Participant Pool. Please attach the Participant Pool screener form.

[ ]  This study will be using an Internet Recruitment Service (e.g., Qualtrics, RSearch, Prolific, etc.)

Please describe the participants:

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**14. RECRUITMENT**

Please describe how and from where the participants will be recruited. Describe all steps from the point of first contact with the participant until the beginning of the consent process. Attach copies of all materials used for recruitment purposes (e.g., posters, advertisements, Participant Pool ad, letters, emails, oral scripts, telephone scripts, listserv postings, social networking site postings, website/Internet advertising, etc.). Please indicate if REDCap or WE-Spark Research Registry will be used.

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**15. EXPERIENCE**

Please provide a brief description of the researcher’s/research team’s experience **with each method used in this project.** Include all members of the team, including faculty supervisors. (Note: This section asks for a description of the experience specific to the research methods described in this application and does not require additional details regarding professional qualifications outside of these methods or a list of publications or citations).

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**16. COMPENSATION/INCENTIVE**

**(a)** Will participants receive compensation for participation? [ ]  No [ ]  Yes

*(Please check all that apply)*

Financial[ ]

In-kind [ ]

Draw [ ]

Psychology Participant Pool Bonus Points [ ]

Other:

**(b)** If compensation is provided, please provide the source of funding for the compensation/incentive:

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**(c)** If there is a cost to participants such as parking, materials or transportation please indicate if these will be covered or justify why these costs are not compensated:

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**(d)** If compensation is provided, please provide details and justification for the amount/value of the compensation offered:

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| --- |
|       |

**(e)** If using an Online/internet method describe how participant data and compensation data will be managed:

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**(f)** Where there is a withdrawal clause in the research procedure and a participant chooses to withdraw, how will compensation be handled?

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| **SECTION D – DESCRIPTION OF THE RISKS AND BENEFITS OF THE PROPOSED RESEARCH** |

**17. POSSIBLE RISKS**

Please indicate potential risks that the participants as individuals or as part of an identifiable group or community might experience by being part of this research project. Checking ‘Not Present’ indicates that there are no such risks associated with the methods. ‘Low’ meets the definition of minimal risk as set out in the TCPS2. Please indicate which method is being assessed; the ordering of the list should correspond with the methods as outlined in Section 11.

Please also indicate whether there are any potential bystander risks to those who have not consented to be participants in the research, but who may still incur risks as a result of the research. These can include risks to individual persons, groups, institutions etc. Many research projects will not involve bystander risks, but those that do must rate them here, and later describe and mitigate these potential risks in Section 18.

Note: If there are different participant groups, and the risks differ between or among those groups, then the researchers can use this section to indicate the risks for Participant Group 1, Participant Group 2, etc.

Method #1:

**(a)** Physical risks (including any bodily contact or administration of any substance)?

 [ ]  Not Present [ ]  Low [ ]  Medium [ ]  High

**(b)** Psychological/emotional risks (feeling uncomfortable, embarrassed, anxious or upset)?

 [ ]  Not Present [ ]  Low [ ]  Medium [ ]  High

**(c)** Social risks (including possible loss of status, privacy and/or reputation)?

 [ ]  Not Present [ ]  Low [ ]  Medium [ ]  High

**(d)** Economic risks (including possible costs, loss of job, money, fees)?

 [ ]  Not Present [ ]  Low [ ]  Medium [ ]  High

**(e)** Dual/multiple relationship with study participants?

 [ ]  Not Present [ ]  Low [ ]  Medium [ ]  High

**(f)** Data security (i.e., risk to participant from data exposure)?

 [ ]  Not Present [ ]  Low [ ]  Medium [ ]  High

**(g)** Tied to deception involved in the study? (See DEBRIEFING section below)

 [ ]  Not Present [ ]  Low [ ]  Medium [ ]  High

Method #2 (if applicable):

**(a)** Physical risks (including any bodily contact or administration of any substance)?

 [ ]  Not Present [ ]  Low [ ]  Medium [ ]  High

**(b)** Psychological/emotional risks (feeling uncomfortable, embarrassed, anxious or upset)?

 [ ]  Not Present [ ]  Low [ ]  Medium [ ]  High

**(c)** Social risks (including possible loss of status, privacy and/or reputation)?

 [ ]  Not Present [ ]  Low [ ]  Medium [ ]  High

**(d)** Economic risks (including possible costs, loss of job, money, fees)?

 [ ]  Not Present [ ]  Low [ ]  Medium [ ]  High

**(e)** Dual/multiple relationship with study participants?

 [ ]  Not Present [ ]  Low [ ]  Medium [ ]  High

**(f)** Data security (i.e., risk to participant from data exposure)?

 [ ]  Not Present [ ]  Low [ ]  Medium [ ]  High

**(g)** Tied to deception involved in the study? (See DEBRIEFING section below)

 [ ]  Not Present [ ]  Low [ ]  Medium [ ]  High

*\*Add additional risk matrices for methods or participant groups as needed.*

**18. RISK ANALYSIS**

For each method listed above, describe the associated risks and their level in 18 (a) below. Please describe how each risk is managed separately in 18(b).

**(a)** Briefly describe each risk associated with the methods used in this research. Address any actual known risks associated with the research, and any risks that might be reasonably perceived by the participant. Please refer back to Section 17.

Method #1:

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| --- |
|       |

Method #2:

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**(b)** Please describe how each of the potential risks described in 18a will be managed and/or minimized.

Method #1:

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| --- |
|       |

Method #2:

|  |
| --- |
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**Researchers are required to report to the REB any unanticipated issue or event that may increase the level of risk to participants or has other ethical implications that may affect participants’ welfare. Below are the timelines within which unanticipated events should be reported to the REB with a description of the event and the researchers’ response.**

**Unanticipated events:** These are events which may not directly affect participants but do have a negative affect on application procedures or other study processes. These should be reported to the REB within 10 business days of occurrence.

**Adverse events:** These are events which affect participants’ welfare or raise risks to the participants which

may or may not be directly related to the research. These should be reported to the REB within 3 business days of occurrence. Researcher may want to suspend the research until discussing the event with the REB.

**Serious adverse events:** These are events which result in harm to a participant, which may or may not be directly related to

the research or raise physical or mental health risks within the research study. These should be reported to the REB

within 24 hours of occurrence. Researchers must suspend the research until the event is cleared by the REB.

**19. POSSIBLE BENEFITS**

Discuss any direct benefits to the **participants** from their involvement in the project.

|  |
| --- |
|       |

Describe the potential benefits to the scientific/scholarly community or society that would justify involvement of participants in this study.

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| **SECTION E – THE INFORMED CONSENT PROCESS** |

**20. DESCRIPTION OF THE CONSENT PROCESS**

**Participants Capacity to Provide Informed Consent:**

*Check the box(s) which best apply to your participants:*

|  |  |
| --- | --- |
| **Competent** | **Non-Competent** |
| [ ]  **Competent Adult** [ ]  **Vulnerable Population (See TCPS2 criteria)** | [ ]  **Non-Competent Adult** [ ]  **Consent from authorized party will be obtained**[ ]  **Assent from the participant will be obtained**  |
| [ ]  **Competent Youth**[ ]  **Consent of both youth and parent/guardian required** [ ]  **Consent of youth required and parents informed**[ ]  C**onsent of youth required and parent/guardian not**  **informed**  | [ ]  **Non-Competent Youth**[ ]  **Consent from parent/guardian**[ ]  **Assent from the youth will be obtained** |
| [ ]  **Competent Children**[ ]  **Consent of parent and child**[ ]  **Other:**       | [ ]  **Non-Competent Children**[ ]  **Consent from parent/guardian**[ ]  **Assent from the child will be obtained** |

**(a)** Indicate if there is a relationship between participants and either of the following:

Person obtaining consent: [ ]  No [ ]  Yes

Investigator(s): [ ]  No [ ]  Yes

If YES, what steps will be taken to avoid the perception of undue influence:

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**(b)** Describe the process that the investigator(s) will use to obtain informed consent from the point of first contact with the potential participant. Obtaining consent involves more than providing a form to read. If a written consent will not be used, or if signed consent will not be obtained, please explain (e.g. discipline, cultural appropriateness, enhanced risk etc.) and describe how consent will be ***documented***. Please note it is the quality of the informed consent, not the format, that is important. Address how participants can ask questions or have their questions answered before they provide consent.

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**(c)** If the title of the project that is to be communicated to participants (e.g. on Consent Form) is different from the title of the project indicated in this application, please provide the alternate project title here:

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**(d)** Please provide the rationale for modifying the title:

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**(e)** **Ongoing Consent** is required if the research occurs over multiple occasions or over an extended period of time.

Does the research occur over multiple occasions and/or over an extended period of time? [ ]  No [ ]  Yes

If “Yes”, please describe the process of how you intend to obtain *ongoing* consent (e.g. verbal assent, additional form, etc.)

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**(f) This Question is Related to Human Biological Material and/or Tissues ONLY:** Is the donor identifiable by any member of the research team?

 **[ ]  Yes [ ]  No**

If **Yes**, please include a copy of the consents given for the tissue to be used in subsequent research.

If **No**,

1. Has the donor given consent for the tissue to be used in original research?

 [ ]  Yes [ ]  No

1. Has the donor given consent for tissue to be used in subsequent research?

 [ ]  Yes [ ]  No

**21. CONSENT BY AN AUTHORIZED 3rd PARTY**

**(a)** If the participants are children, or are not competent to consent, describe the proposed alternate source of consent.

*If not applicable, please write ‘none’.*

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*\*Please attach a copy of any permission/information letters to be provided to the person(s) providing the alternate consent as well as the assent process for the actual participants.*

**(b)** If the research is taking place within a recognized community or an organization that requires that formal consent be sought prior to the involvement of individual participants, explain how the researcher will document how consent has been obtained. Describe this consent process and attach any relevant documentation. If consent will not be sought, please provide a justification and describe any alternative forms of consultation that may take place.

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*\*Please attach any relevant documentation.*

**22. POST-STUDY INFORMATION/FEEDBACK/DEBRIEFING**

1. Will participants receive any information either during or immediately after they have completed their involvement in data collection, such as at the end of an interview or survey completion? (e.g. resource list, links to further information, more information about the study, etc.).

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**(b)**  How will participants be informed of study results? (Note: The REB and Leddy Library have a collaborative site where

study results can be posted as an option for researchers <https://scholar.uwindsor.ca/research-result-summaries/>)

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**(c)** **(Only for researchers who have completed SECTION C (12)).** Please provide the process by which participants will be debriefed or provided a description of the deception that meets the TCPS2 criteria of informed, sensitive, and tailored to participants. Describe how consent will be acquired to retain the data obtained, or how participants can withdraw their data following the debriefing if relevant. How will the participants be informed, unambiguously, that deception has terminated? *\*Please attach a copy of the written debriefing form (if applicable).*

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**23. PARTICIPANT WITHDRAWAL**

**(a)** Please describe how the participants will be informed about their withdrawal rights. Outline the procedures which participants will follow to withdraw from the study or withdraw their data. If On-line/internet research is a component of this study describe the procedures(s) through which participants will be able to exercise their withdrawal rights (e.g., close browser before submitting, click on a ‘Withdraw’ or ‘Exit Survey’ button, etc.).

Method #1:

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Method #2:

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 **(b)** Indicate how the researchers will handle any data provided up to the point of withdrawal.

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**(c)** Please describe when or at what point, participants will no longer be able to request to withdraw their data or withdraw from the study. This should be defined by a specific date, or by the occurrence of a particular event (e.g., upon submission of survey data, after completion of the interview, date at which participants’ data are anonymized, etc.)

**Anonymity**: Participants cannot be identified by the researchers, research team or anyone in the research project at any point.

**Confidentiality**: The protection of the identity of participants or information from unauthorized access, use, disclosure, modification, loss or theft.

**De-identified:** Any process by which identifiable information is rendered unidentifiable. Please review the TCPS2 for information on distinguishing anonymity and confidentiality.

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| **SECTION F – SAFEGUARDS FOR PROTECTING PARTICIPANTS AND DATA** |

**24. ANONYMITY/ CONFIDENTIALITY**

**(a)** Will identifying data be collected, such as names, contact information, other personal identifiers? [ ]  No [ ]  Yes

**(b)** Will the participants be anonymous to the researcher? [ ]  No [ ]  Yes

**(c)** Describe the procedures to be used to ensure anonymity and confidentiality of participants or their data during the conduct of research and dissemination of results.

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**(d)** Explain how identifiers or identifiable information including written records, video/audio recordings, contact information, triangulated identifiers, linking codes or master lists will be secured, how long they will be retained, and when they will be destroyed. Describe how identifiable data will be de-identified or anonymized.

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**(e)** If there are limitations to confidentiality or if confidentiality is not provided, please explain. Also describe any limitations to protect the confidentiality of the participants whether due to the law, the methods used, the nature of the sample population, or other reasons (e.g., duty to report, contract obligations, etc.).

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**25. DATA MANAGEMENT**

1. Describe how the data will be securely stored during data collection and analysis.

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1. Identify all parties who will have access to the data during the course of the study.

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**(c)** If you are sharing data amongst the research team or with others outside of the research team, please describe the procedures you will use to share the data.

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**(d)** Describe who has custodianship of the data and corresponding documentation once the study is complete. Please indicate who will take responsibility for providing permission for the subsequent use of the data or archiving.

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**(e)** If collecting data on-line, please describe the length of time the data will be kept on the server and the process of downloading, storage and disposal of identifying information or sensitive data.

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**(f)** Do you anticipate depositing the data or archiving the data with a Tri-Council compatible academic data repository?

[ ]  No [ ]  Yes

**For further support managing your research data and for complying with the most recent** [**Tri-Agency Research Data Management Policy**](https://www.ic.gc.ca/eic/site/063.nsf/eng/h_97610.html)**, please contact the Leddy Library:** **libdata@uwindsor.ca**

**If you have a Research Data Management Plan, submit the plan as an appendix.**

**(g) These Questions are Related to Human Biological Material and/or Tissues ONLY:**

Will the researchers collect additional personal health information or data directly from the patient charts?

 [ ]  Yes [ ]  No

If Yes, please specify the data to be collected:

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Is the donor of the sample still identifiable or is the tissue de-identified with a unique study code identifier or anonymized with no code identifier? Please explain:

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Could there be any leftover tissue or biological material upon completion of the research?

 [ ]  Yes [ ]  No

If Yes, please describe the plan for the leftover tissue or its destruction:

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**26. PRIVACY REGULATIONS AND APPLICABLE LAWS**

For research involving extraction or collection of personal information, provincial, national and/or international laws may apply. In section G below, my signature as Principal Investigator and/or signatures of other named researchers identified in section B(2), confirms that I (We) understand and will comply with all relevant laws governing the collection and use of personal information in research.

**SECTION G - SIGNATURES**

**All researchers must sign below in order for this application to be processed and reviewed.**

As the **Principal Investigator** on this project, my signature confirms that I will ensure that all procedures performed under the project will be conducted in accordance with all relevant

**Faculty or Staff Principal Investigators**: Please complete the signatures below in Section G.

**Student Principal Investigators**: Please complete the signatures in Section H.

University, provincial, national and international policies and regulations that govern research involving human participants. Any deviation from the project as originally cleared will be submitted to the Research Ethics Board for clearance prior to its implementation.

As an **Affiliated Researcher** or **Co-Investigator** listed in Section B2 on this project, my signature confirms that I will ensure that all procedures performed under the project will be conducted in accordance with all relevant University, provincial, national and international policies and regulations that govern research involving human participants. Any deviation from the project as originally cleared will be submitted to the Research Ethics Board for clearance prior to its implementation

For **student researchers,** my signature confirms that I am a registered student in good standing with the University of Windsor. My project has been reviewed and cleared by my advisory committee (where applicable). If my status as a student changes, I will inform the REB.

I agree to comply with the Tri-Council Policy Statement and all University of Windsor policies and procedures, governing the protection of human participants in research, including, but not limited to, ensuring that:

* the project is performed by qualified and appropriately trained personnel in accordance with REB application;
* no changes to the REB cleared application or consent form/statement are implemented without notification to the REB of the proposed changes and receipt of the subsequent REB clearance;
* significant adverse effects are promptly reported to the REB within 5 working days of occurrence; and
* at minimum, a progress report is submitted annually or in accordance with the terms of certification.

**\*This cannot be signed in READ ONLY – it must be saved first.**

Date:

**Signature of Principal Investigator:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signature of Co-Investigator (s):** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date:

Date:

**Signature of Co-Investigator (s):** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date:

**Signature of Co-Investigator (s):** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***(\*Add additional fields as needed)***

**For Student Principal Investigators and Faculty Advisors, see Signature Section H below.**

**SECTION H – STUDENT PRINCIPAL INVESTIGATORS AND FACULTY SUPERVISORS**

**For Undergraduate or Graduate Students, the signature of the Faculty Supervisor is required. For Post-Doctoral Fellows, the signature of a Faculty Sponsor is required.**

**For Visiting Professors or Researchers, the signature of a Faculty Sponsor may be required; please check with the REB.**

I certify that the application has been completed in full, that the information provided in this application is complete and correct and approve the scientific merit of the research project and this Ethics Review application.

I understand that as principal **Faculty Supervisor**, I have ultimate responsibility for the conduct of the study, the ethical performance of the project and the protection of the rights and welfare of human participants. I will supervise the student(s) in all correspondence with the REB throughout the application and clearance process, during the conduct of the research, and in the management of the resulting data following the completion of the research.

I understand that as **Faculty Sponsor**, I have responsibility, as the University of Windsor representative, for the conduct of the study, the ethical performance of the project and the protection of the rights and welfare of human participants.

I agree to comply with the Tri-Council Policy Statement and all University of Windsor policies and procedures, governing the protection of human participants in research, including, but not limited to, ensuring that:

* the project is performed by qualified and appropriately trained personnel in accordance with REB application;
* no changes to the REB cleared application or consent form/statement are implemented without notification to the REB of the proposed changes and receipt of the subsequent REB clearance;
* significant adverse effects are promptly reported
* at a minimum, a progress report is submitted annually or in accordance with the terms of certification.

[ ]  I certify that I have read and approved the student’s application as submitted here.

**Signature of Student Principal Investigator:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date:

**Signature of Faculty Supervisor or Sponsor:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date:



[Sample Consent Form containing all elements of consent – *Revise as necessary to be relevant to the study*]

*[General guidelines: Consent forms should be written to the participant, for example ‘you will be asked to or you will receive’, and they should be easily understood by potential participants. The reading level of those being recruited should be considered. The use of jargon and complex or technical language should be avoided. All information provided on consent materials should be reflected in the appropriate area of the application.]*

 **CONSENT TO PARTICIPATE IN RESEARCH**

Title of Study:[*Insert title of study.]* ***[If the study involves using different consent forms for different populations, identify the population group as the subtitle of the study.*]**

You are asked to participate in a research study conducted by **[*insert names and identify all investigators - faculty, student and other*]**, from the **[*insert department affiliation*]** at the University of Windsor **[*If student, indicate that results will be contributed to senior project, thesis or dissertation*]. [*Identify sponsoring agency(ies)/organization(s).*]**

If you have any questions or concerns about the research, please feel to contact **[*identify contact person: Faculty Investigator(s)/Faculty Supervisor(s). Include daytime phone numbers for all listed individuals. For greater than minimal risk, include night/emergency phone numbers.*]**

PURPOSE OF THE STUDY

**[*State what the study is designed to assess or establish.*]**

PROCEDURES

If you volunteer to participate in this study, you will be asked to:

**[*Describe the procedures chronologically from the perspective of the participant using simple language. Medical and scientific terms or procedures should be explained.*]**

**[*Specify the participant’s assignment to different groups in the study, such as experimental arms, length of time for participation in each procedure, the total length of time for participation, frequency of procedures, location of the procedures to be done, etc. Provide details about any plan to contact participants for follow-up sessions.]***

POTENTIAL RISKS AND DISCOMFORTS

**[*Describe any reasonably foreseeable risks, discomforts, inconveniences (including for example, physical, psychological, emotional, financial and social), and how these will be managed.*]**

POTENTIAL BENEFITS TO PARTICIPANTS AND/OR TO SOCIETY

**[*Describe any direct potential benefits to participants expected from the research. If the participants will not directly benefit from engagement in the research, clearly state this.* *State the potential benefits, if any, to science or society expected from the research.*]**

COMPENSATION FOR PARTICIPATION

**[*State whether the participant will receive any compensation. If not, indicate that participants receive no compensation. If participants will receive compensation, describe the type and remuneration amount.*]**

CONFIDENTIALITY

**[*Describe procedures to ensure confidentiality of the data and participants. Please provide information on length of retention and security of data. If information will be released to any other party for any reason, state the person/agency to which the information will be furnished, the nature of the information, and the purpose of the disclosure.*]**

PARTICIPATION AND WITHDRAWAL

**[*Indicate how participants can withdraw their data or withdraw from the study. Indicate a date or event by which participants cannot withdraw their data or withdraw from the study.*]** The investigator may withdraw you from this research if circumstances arise which warrant doing so. **[*If appropriate, describe the anticipated circumstances under which the participant’s involvement may be terminated by the investigator without regard to the participant’s consent.]***

FEEDBACK OF THE RESULTS OF THIS STUDY TO THE PARTICIPANTS

***[Include a statement of whether or not a summary of the research findings will be available to participants and how/where/when they will be made available to participants.*]** **\*If the researcher chooses to use the REB/Leddy Library’s Summary for Participants platform here is the link:** <https://scholar.uwindsor.ca/research-result-summaries/>

Web address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date when results are available: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

SUBSEQUENT USE OF DATA

These data may be used in subsequent studies, in publications and in presentations.

RIGHTS OF RESEARCH PARTICIPANTS

If you have questions regarding your rights as a research participant, contact: The Office of Research Ethics, University of Windsor, Windsor, Ontario, N9B 3P4; Telephone: 519-253-3000, ext. 3948; e‑mail: ethics@uwindsor.ca

SIGNATURE OF RESEARCH PARTICIPANT/LEGAL REPRESENTATIVE

I understand the information provided for the study **[*insert title*]** as described herein. My questions have been answered to my satisfaction, and I agree to participate in this study. I have been given a copy of this form.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Participant

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Participant Date

SIGNATURE OF INVESTIGATOR

These are the terms under which I will conduct research.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Investigator Date