|  |  |
| --- | --- |
| **OFFICE USE ONLY:** REB.MA.R.10.01.2017[ ]  **Incomplete** [ ]  **Conditional Clearance**  [ ]  **Cleared** [ ]  **Withhold Clearance**  **Review leve**l: [ ]  **Full** [ ]  **Delegated** [ ]  **Executive** [ ]  **Clinical Trials** [ ]  **SoTL** | **Protocol Reference Numbers**:REB#: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ERSO#:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |



***APPLICATION FORM FOR RESEARCH ETHICS REVIEW***

*RESEARCH INVOLVING HUMAN PARTICIPANTS*

Research Ethics Board

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

**Title of Research Project:**

|  |
| --- |
|       |

Please indicate the 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:        | Fax:       | Email:       |

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

|  |
| --- |
| Title:       Name:       |
| Phone:        | Fax:       | 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):***

**! NOTE !**

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

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

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

**DETERMINATION OF LEVEL OF REVIEW**

Based on your risk assessment in sections 17 and 18 of the application:

Indicate the highest level of group risk associated with this research: [ ]  Low [ ]  Medium [ ]  High

Indicate the highest level of method risk associated with this research: [ ]  Low [ ]  Medium [ ]  High

Does your application include any of the following:

[ ]  Use of deception or other departures from general informed consent

[ ]  Vulnerable population or limited capacity in exercising autonomy (children, cognitively impaired individuals, prisoners)

[ ]  First Nations, Metis, Inuit individuals

[ ]  Use of biological elements or clinical trials

[ ]  Other elements in protocol raise risks to greater than minimal level

# Checklist

**Please attach the following items, if applicable. All materials should be submitted in a single electronic file.**

**! NOTE !**

Please ensure ALL fields in the application are completed.

**Incomplete forms will not be accepted for review.**

[ ]  Letters of permission allowing research to take place on site

[ ]  Approval/Clearance decisions from other Research Ethics Boards

[ ]  Research contracts or other agreements

[ ]  Questionnaires, Instruments or other measures

[ ]  Permission letters for obtaining personal information

[ ]  Recruitment materials: Posters/flyers, social media posts, e-mail or verbal scripts, Participant Pool ads, etc.

[ ]  Consent Form

[ ]  Letters of Information

[ ]  Consent for Audio/Visual Taping Form

[ ]  Parental/Guardian Information and Consent Form

[ ]  Assent Form

[ ]  Debriefing Script or Letter: Needed only if deception is used in the study.

**Please also check**

[ ]  All signatures have been included for all investigators

[ ]  TCPS2 Core certificates for the Principle Investigator and all Co-Investigators have been included

[ ]  An On-line checklist (Any online data collection requires the on-line checklist) have been included

[ ]  Relevant certifications such as Health and Safety have been included

**Please submit**

[ ]  **One** complete paper copy with original signatures to the Research Ethics Board office

[ ]  Anelectronic version of the application and all supplementary documents and appendix in a **single file (.pdf)**

 to ETHICS@uwindsor.ca

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| **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:        | Fax:       | Email:       |

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

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

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

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

*\*Please append additional sections if necessary.*

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

**! NOTE !**

 If the research is to be conducted at a site requiring administrative clearance/ or permission (e.g. school, community agency, other university campus, etc.), please include documentation with the application that permission/clearance has been received. It is the responsibility of the researcher to determine whether additional approvals are required prior to initiating the research project.

*(Please indicate all that apply; provide the address for any site*

*that is not located at the University of Windsor or H*ô*tel Dieu-Grace Health Care)*

[ ]  University of Windsor

[ ]  *H*ô*tel* Dieu-Grace Health Care

[ ]  Band Council

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

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

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

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

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

 \*Please complete 4.0 below

**4. OTHER APPROVALS**

Do any of the other institutions/sites require permission for the research to take place on site? [ ]  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 protocols, 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? [ ]  No [ ]  Yes

**! NOTE !**

 UWindsor Researchers/Principal Investigators should seek UWindsor REB clearance prior to clearance from other REBs/institutions.

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), and when will clearance be sought?

|  |
| --- |
|  |

**5. FUNDING OF THE PROJECT**

This section refers to any funding received to conduct 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:      **! NOTE !** Please ensure that the grant application information is accurate. This includes having the ***proper and exact*** ‘title’ as it appears on your grant application. |
| Title of project associated with funding:       |
| Finance Grant Acct # (6 digits):       |
| 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 protocol is to cover more than one grant, please include all fund/grant numbers.*

(b) For funded research, will more than one protocol 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.*

**! NOTE !**

An annual Progress **Report** must be submitted to the Research Ethics Coordinator if your research project extends beyond one year.

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

Failure to submit reports could result in research funds being withheld and/or REB review of subsequent protocols delayed.

**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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**8. PRIOR SCHOLARLY REVIEW**

*(Please check one of the following)*

[ ]  The research has been formally reviewed by a thesis/dissertation committee

[ ]  The research has undergone scholarly review prior to this submission for ethical review (e.g., grant application)

Please specify):

[ ]  The research will undergo scholarly review prior to funding (Please specify the review committee):

[ ]  The research will not undergo scholarly review apart from this ethics review

[ ]  Other (Please specify):

**9. CONFLICT OF INTEREST/DUAL ROLES**

(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 researched (e.g. instructor-student; manager-employee; minister-congregant; co-investigators; organization-client; principal-teacher; doctor-patient; academic supervisor-participant; participant-participant)

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*All relationships identified in 9c must be described and addressed under 18b (risks) and 18c (management of risks) in the application.*

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

*\*Please include a list of appendices for all additional materials submitted***.**

**10. RATIONALE**

Describe the purpose and background rationale for the proposed project, and the hypotheses or research questions to be examined in this study. This background should be succinct, but include all information that an educated layperson needs to understand the purpose of the proposed project and the need for the project. Please place the study within a relevant scholarly literature and context.

|  |
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|  |

**11. METHODS**

*(See the companion document for issues relevant to types of research available at www.uwindsor.ca/reb)*

Please indicate all the research methods that apply:

[ ]  Action Research [ ]  Ethnography

[ ]  Observation [ ]  Survey

[ ]  Documentary/Filmmaking [ ]  Focus Group

[ ]  Experimental lab study [ ]  Interview

[ ]  Oral/Life history [ ]  Human Tissues

[ ]  Experimental behavioral study

[ ]  Online Research (complete online research checklist)

[ ]  Other

**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. Please include the number of points of contact and the total time required to complete the procedures.

|  |
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|  |

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 and address issues related to confidentiality and data security for recorded information in Section 24 of this application. Please note the specific recording devices to be used. (e.g. digital recorder, cellphone etc.)

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Please describe each of the distinct methods used in the research protocol including the corresponding data collection procedures and tools. Provide figures, diagrams, or pictures as required to completely describe the method to an educated layperson. Please describe any measures and attach all materials and measures in an appendix just as they will appear to the participants. If online, please provide a printout or a link to the survey.

Method #1:

|  |
| --- |
|       |

Method #2 (if applicable):

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| --- |
|       |

*Add additional methods as relevant*

Please provide 6-8 key words to identify this project.

|  |
| --- |
|       |

**12. DECEPTION**

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

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 recruited for the study and about whom personal information will be collected (i.e., numbers, age, special characteristics, etc.). Describe the size of the group from which participants will be recruited, the total number needed for the research, and the minimum needed for the research to succeed. Please describe inclusion and exclusion criteria. Where the research involves extraction or collection of personal information, please describe what type of information will be obtained and from whom and if permissions are necessary.

[ ]  This study will be using the UWindsor Psychology Participant Pool [ ]  Participant Pool screener form attached

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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, etc.). Where participant observation is to be used, please explain the form of “insertion of the researcher into the setting” that will be used (e.g. living in a community, visiting on a bi-weekly basis, attending organized functions). If applicable, attach letter(s) of permission from organizations where research is to take place.

[ ]  All recruitment materials have been included.

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**15. EXPERIENCE**

Please provide a brief description of the researcher’s/research team’s experience **with each method/type of applicable research**. Include all members of the team, including faculty supervisors. How will requisite research skills be obtained for research team members new to this type of research? (Note: This section asks for a description of the experience specific to the research methods described in this protocol and does not require additional details regarding professional qualifications outside of these methods or evidence of publication or citations)

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**16. COMPENSATION/INCENTIVE**

**! NOTE !**

Researchers should consider some form of token compensation in appreciation for participation. However, compensation should not create undue influence or the disregard of risks related to the research.

(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:

|  |
| --- |
|       |

(c) If there is a cost to participants such as parking, materials or transportation please justify why these are not compensated:

|  |
| --- |
|       |

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

|  |
| --- |
|       |

(e) 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.

Method #1:

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

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

**! NOTE !**

A **separate** risk assessment is required for **each method** described in SECTION C (11). Please append additional sections as necessary.

(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 matrixes for methods as needed.*

**18. RISK ANALYSIS**

*\*Please consult the Instructions for Ethics Review Protocol Submission Form.*

(a) Please fill in the following:

|  |
| --- |
| Method #1:       |
|  | **Research Risk** |
|  | **Low** | **Medium** | **High** |
| **Group Vulnerability** |  |  |  |
| **Low** | [ ]  **1** | [ ]  **2** | [ ]  **2** |
| **Medium** | [ ]  **2** | [ ]  **2** | [ ]  **3** |
| **High** | [ ]  **2** | [ ]  **3** | [ ]  **3** |

|  |
| --- |
| Method #2:       |
|  | **Research Risk** |
|  | **Low** | **Medium** | **High** |
| **Group Vulnerability** |  |  |  |
| **Low** | [ ]  **1** | [ ]  **2** | [ ]  **2** |
| **Medium** | [ ]  **2** | [ ]  **2** | [ ]  **3** |
| **High** | [ ]  **2** | [ ]  **3** | [ ]  **3** |

List each risk associated with the methods as described above in 18(b). Please describe how each risk is managed separately in 18(c).

(b) Briefly describe each risk associated with group vulnerability and 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 17.0.

Method #1:

|  |
| --- |
|       |

Method #2:

|  |
| --- |
|       |

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

Method #1:

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| --- |
|       |

Method #2:

|  |
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**19. POSSIBLE BENEFITS**

Discuss any potential direct benefits to the participants from their involvement in the project; these might include education about research methods, useful knowledge gained about self, etc.

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Comment on 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:**

*Indicate and 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:

|  |
| --- |
|  |

(b) Describe the process that the investigator(s) will be using 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 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. If the research involves extraction or collection of personal information as secondary data, please describe how consent from the individuals or authorization from the custodian will be obtained and documented. Address how participants can ask questions or have their questions answered before they provide consent, and how much time they will be given to review the information before being asked to provide consent.

**! NOTE !**

For information about the required elements in the consent form, please refer to [**http://www.uwindsor.ca/reb**](http://www.uwindsor.ca/reb)

|  |
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*\*Where applicable, please attach a copy of the Information Letter/Consent Form, Audio/Video Recording Consent Form, the content of any telephone script, letters of administrative consent or authorization and/or any other material that will be used in the informed consent process.*

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

|  |
| --- |
|       |

(d) Please provide the rationale for difference in Title:

|  |
| --- |
|       |

(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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**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.

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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.

|  |
| --- |
|       |

*\*Please attach any relevant documentation.*

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

(a) For studies that are not deceptive, briefly describe the process and nature of any information that that will be given to participants immediately upon completing the study and the rationale for providing this information (e.g. resource list, links, more information about the study, etc.).

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(b) How will participants be informed of study results?

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(c) **(Only for researchers who have completed SECTION C (12)).** If deception will be used in the research study, please explain the debriefing process and what information or feedback will be provided to participants to remedy the use of the deception.

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*\*Please attach a copy of the written debriefing form (if applicable).*

(d) **(Only for researchers who have completed SECTION C (12)).** Please provide the process by which participants will be provided a debriefing or description of the deception that meets the TCPS2 criteria of informed, sensitive, and tailored to participants. Describe how consent to retain the data obtained, or how participants can withdraw their data following the debriefing. How will the participants and/or communities be informed, unambiguously, that deception has terminated?

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**! NOTE !**

Information about participant withdrawal **must** be provided on the Consent Form or in the consent process.

**23. PARTICIPANT WITHDRAWAL**

(a) Please describe how the participants will be informed of their right to withdraw from the research. Outline the procedures which participants will follow to withdraw from the study or withdraw their data.

Method #1:

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| --- |
|       |

Method #2:

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 (b) Indicate what will be done with the participant’s data and any consequences which withdrawal may have on the participant.

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|       |

(c) Please describe if participants will not have a right to withdraw from the study or cannot withdraw beyond a certain point.

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(d) Please describe when or at what point, participants will no longer be able to request to withdraw their data. 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.)

|  |
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**! NOTE !**

**Confidentiality**: The safeguarding of information from unauthorized access, use, disclosure, modification, loss or theft.

**Anonymity**: Individuals cannot be identified by the researchers, research team or anyone in the research project at any point, nor can they be identified with any of the information. No identifiers are associated with any of the data.

**Anonymization:** Any process by which identifiable information is rendered unidentifiable.

Please review the companion document and the TCPS2 for information on distinguishing anonymity and confidentiality.

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

**24. CONFIDENTIALITY/ANONYMITY**

(a) Will the data be treated as confidential? [ ]  No [ ]  Yes

(b) Will the participant be anonymous to the researcher or anyone associated with the research? [ ]  No [ ]  Yes

(c) Describe the procedures to be used to ensure anonymity/confidentiality of participants or informants (where applicable) -or- the confidentiality of 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 how they will be destroyed. Describe how identifiable data will be de-identified or anonymized. Describe the standard data security measures for your discipline and how data will be stored or archived.

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(e) If participant anonymity or confidentiality is not appropriate to this research project, please explain.

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(f) Describe any limitations to protecting the confidentiality of 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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(g) Identify all parties who will have access to the data. Describe who has custodianship of the data once the study is completed (who will take responsibility for the current and future uses).

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(h) Please describe all forms of output that are anticipated to result from this research (e.g., presentations, written papers, placing data in an archive, creative works, documentary films, etc.). Describe how any potentially identifying information will be handled in each form of output.

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(i) Subsequent use of data beyond current study. Will the data potentially be used for other secondary purposes in the future (e.g., teaching, future analysis, publishing of dataset, archiving in an institutional repository, etc.)?
[ ]  No [ ]  Yes

*If “No”, the data will be solely used for the purposes describe in this application and will not be used for other purposes in the future.*

If “Yes”, *participants must be informed of this possibility during the consent process as subsequent use of the data. Also not that new purposes may require additional review by the REB.*

**25. PRIVACY REGULATIONS AND APPLICABLE LAWS**

For research involving extraction or collection of personal information, provincial, national and/or international laws may apply. **My signature as Principal Investigator or other named researcher listed in section B2 in this application, in Section G of this protocol form, confirms that I (We) understand and will comply with all relevant laws governing the collection and use of personal information in research.**

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| **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 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.

**! NOTE !**

**Faculty Investigators**: One complete hard copy application with original signatures of the Principle Investigator and all Co-investigators must be provided to the REB. One electronic version (.pdf) must be submitted by e-mail.

**Student Investigators**: One complete hard copy application with original signatures of the Student Principle Investigator and the Faculty Supervisor/Sponsor must be provided to the REB. One electronic version (.pdf) must be submitted by e-mail.

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 protocol;
* no changes to the REB cleared protocol 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 a minimum, a progress report is submitted annually or in accordance with the terms of certification.

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| Signature of Principal Investigator:       Date:       Signature of Student Principal Investigator:       Date:       Signature of Co-Investigator (s):       Date:       Signature of Co-Investigator (s):       Date:       (Add additional fields as needed) |

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| **SECTION H – FACULTY SPONSORS** |

**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 protocol;
* no changes to the REB cleared protocol 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.

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|  Signature of Faculty Supervisor / Sponsor (circle one):       Date:        |



[Sample Consent Form – *Revise to suit study*]

*[General guidelines: Consent forms should be written so as to be easily understood by potential participants. The reading level of those being recruited should be considered. The use of jargon and complex language should be avoided. The information provided on consent materials should be neither too brief nor too long. 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.*]**

**TIP:** Corresponds to SECTION C (10) of application.

PROCEDURES

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

**[*Describe the procedures chronologically using simple language, short sentences and short paragraphs. The use of subheadings helps to organize this section and increases readability. Medical and scientific terms should be defined and explained. Identify any procedures which are experimental.*]**

**TIP:** Corresponds to SECTION C (11) of application.

**[*Specify the participant’s assignment to study groups, 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 or subsequent related study.]***

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.*]**

**TIP:** Corresponds to SECTION D (18) of application.

**[*If there are significant physical or psychological risks to participants that might cause the researcher to terminate the study, please describe them.*]**

POTENTIAL BENEFITS TO PARTICIPANTS AND/OR TO SOCIETY

**[*Describe benefits to participants expected from the research. If the participant will not benefit from participation, clearly state this fact.* *State the potential benefits, if any, to science or society expected from the research.*]**

**TIP:** Corresponds to SECTION D (19) of application.

COMPENSATION FOR PARTICIPATION

**[*State whether the participant will receive payment. If not, state so. If participant will receive payment, describe remuneration amount.*]**

**TIP:** Corresponds to SECTION C (16) of application.

CONFIDENTIALITY

Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission.

**[*Describe procedures to ensure confidentiality of data and anonymity of participants. 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.*]**

**TIP:** Corresponds to SECTION E (20) and SECTION F (24) of application.

**[*If activities are to be audio- or videotaped, describe the participant’s right to review/edit the tapes, who will have access, if they will be used for educational purposes, and when they will be erased.*]**

PARTICIPATION AND WITHDRAWAL

**[*Indicate any conditions and participant’s withdrawal rights*]**. 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. Indicate whether or not the participant has the option of removing the data from the study. If participant will receive payment, describe remuneration amount.***

**TIP:** Corresponds to SECTION E (23) of application.

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.*]**

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: Research Ethics Coordinator, 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



[Sample Letter of Information – *Revise to suit study*]

 **LETTER OF INFORMATION FOR CONSENT TO PARTICIPATE IN RESEARCH**

*[General guidelines: Letters of Information should be written so as to be easily understood by potential participants. The reading level of those being recruited should be considered. The use of jargon and complex language should be avoided. The information provided on consent materials should be neither too brief nor too long. All information provided on consent materials should be reflected in the appropriate area of the application.]*

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**[*Indicate any conditions and participant’s withdrawal rights*]**. 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. Indicate whether or not the participant has the option of removing the data from the study.*]**

**TIP:** Corresponds to SECTION E (23) of application.

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.*]**

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

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

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These are the terms under which I will conduct research.

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

Signature of Investigator Date