**COURSE-BASED RESEARCH AND SENIOR UNDERGRADUATE   
STUDENT ETHICS PROTOCOL**

**APPLICATION FORM**

This form can be used by an undergraduate student that is seeking to obtain ethics approval for an independent or honours-based thesis or a course-based project at the graduate or undergraduate level involving interaction with human participants in research activities as part of course-work (whether involving actual research or pedagogical activities). After completion, this form should be reviewed by the thesis supervisor or course instructor before submitting to the Departmental Ethics Committee for review.

This form can also be used by an instructor that wishes to assign research activities within a course (whether actual research or pedagogical research exercises) that would be assigned to more than one student. The instructor should attach a list of all participating students, if available, and submit to their Department Ethics Committee for review.

Any research activities that are more than minimal risk must be reviewed by the University Human Research Ethics Board.

1. **Project Information** *Please key in your responses. Text spaces will expand as needed.*

|  |  |
| --- | --- |
| **Applicant Information** | |
| **1.1 Name:** | **1.2 Department:** |
| Click here to enter text. | Click here to enter text. |
| **1.3** **Phone:** | **1.4 E-mail:** |
| Click here to enter text. | Click here to enter text. |
| **1.5 For Undergraduate Student Researchers Only:** | |
| **1.5(a) Primary Supervisor Name:** | **Department/Institutional Affiliation (if not UW):** |
| Click here to enter text. | Click here to enter text. |
| |  |  | | --- | --- | | **1.5(b) Secondary Supervisor Name:** | **Department/Institutional Affiliation (if not UW):** | | **Click here to enter text.** | **Click here to enter text.** | | |
| **1.6** **Name(s) of Co-Investigator(s):** | |
| Click here to enter text. | |
| **Project Details** | |
| **1.7** **Title of Proposal:** | |
| Click here to enter text. | |
| **1.8** **Funding Status:** | |
| unfunded  funding applied for from Click here to enter text.(funder)  funding received from \* Click here to enter text.(funder)  contract research for Click here to enter text. (client)  **\*if internally funded, please provide grant number** | |
| **1.9** Anticipated Commencement Date (month/year): | **1.10**. Anticipated Completion Date (month/year): |
| Click here to enter text. | Click here to enter text. |
| **1.11** **List all research instruments**.  Please include questionnaires and reproductions or descriptions of visual or other sensory or   electronic stimuli.    **For observational research**, list documents describing Observation Protocols and/or Coding   Categories. All listed items must be attached to submission.  **For interviews**, list either Interview Questions or Interview Protocol (detailed description of   interview parameters). Include self-constructed, standardized, and/or commercial research   instruments. All listed items must be attached to submission. | |
| Click here to enter text. | |
| **1.12.** **Please check the category to which your proposed project belongs**.   (For further clarification and for categories of research/scholarship exempted from ethics   review, see *Policies and Procedures*.) | |
| **Senior/Undergraduate Honours Thesis Research/Scholarship:**  Theses, independent studies courses, or other undertakings in which the student takes substantial responsibility for the design and conduct of a full-scale project | **Course Projects:**  **Instructor-designed:**  **Student-designed:  Fully**  **Partially**  Course labs, assignments, demonstrations, papers and projects, including senior undergraduate research. |
| **Project Objectives and Design** | |
| **1.13 Provide a summary of the proposed research project.**  The summary of your research project should clearly indicate the problem or issue to be addressed, the potential contribution of the research to the advancement of knowledge and (where relevant) the wider social benefit. For pedagogical projects, highlight the pedagogical benefits of the project. Use language that is understandable to the general public. | |
| **Project Summary (150 words max.):** Click here to enter text. | |
| **1.14** **For Biomedical research**  Please indicate the type of study (i.e., Clinical, Database/Registry, Drug): | |
| **Type of Study:** Click here to enter text. | |
| **1.15 Provide a description of the proposed research project including study objectives,   context, methodology, procedures, etc. in the spaces provided below.**   Footnotes and references are not required and best not included here. Please focus on   those aspects of your procedures that relate to interaction with human participants. | |
| **Objectives (100 words max):** Click here to enter text. | |
| **Context/Literature (250 words max.):** Click here to enter text. | |
| **Methods (250 words max.):** Click here to enter text. | |
| **Knowledge Mobilization/Dissemination**  (i.e., publication, conferences, MB archives) (250 words max.):  Click here to enter text. | |
| **1.16 Review**  Please indicate the type of review you are requesting.  Note: Departmental Reviews are available only for **minimal-risk** projects. Full URHEB review   is required for all greater-than-minimal risk projects. See *Policies and Procedures* for  definitions and criteria. | |
| **Departmental Review:  Full UHREB Review:** | |
| **1.17 Other Approvals**  Please refer to Chapter 8 – Multi-Jurisdictional Research of the TCPS2 for further information.  Indicate if all or part of the proposed research has or will receive ethics approval from other   Canadian Research Ethics Boards or Canadian Institutions. | |
| **Yes:  No:** | |
| If **Yes** to the above, please specify below and attach letters of institutional approval (PDF format  preferred) or confirm that these will be submitted to the Research Office prior to initiating your  research. | |
| **Institutional Approval**  (e.g., school division, university, Winnipeg Regional Health Authority)  Click here to enter text. | |
| |  |  |  |  | | --- | --- | --- | --- | | **1.18 Research Team**  Please list all co-investigators, collaborators and community partners associated with this  project who will interact with human participants or have access to the data, including the course instructor or thesis supervisor. For pedagogical projects designed by a course instructor, please also attach a listing of all students that will be engaging in this pedagogical research. | | | | | **NAME**  Click here to enter text. | **Organization**  **(if not University of Winnipeg)**  Click here to enter text. | **Role**  **(i.e., collaborator)**  Click here to enter text. | **Position**  **(i.e., graduate student, research associate)**  Click here to enter text. | | |

**2.0 Conflict of Interest**   
 *Please key in your responses. The text spaces will expand as needed.*   
 Please refer to Chapter 7 – Conflicts of Interest of the TCPS2 for further information.

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| **2.1 Are any of the investigators or their family receiving any personal remuneration from   the funding of this study that is not accounted for in the study budget?**  (Including investigator payments and recruitment incentives but excluding trainee  remuneration or graduate student stipends.) |
| **Yes:  No:** |
| **2.2 Do any of the investigators or their immediate family have any proprietary interests in   the product under study or the outcome of the research?**  (Including patents, trademarks, copyrights and licensing agreements.) |
| **Yes:  No:  N/A:** |
| |  | | --- | | **2.3 Is there any compensation for this study that is affected by the study outcome?** | | **Yes:  No:  N/A:** | |
| **2.4 Do any of the investigators or their immediate family have equity interest in the   sponsoring company?**  (This does not include mutual funds.) |
| **Yes:  No:  N/A:** |
| **2.5 Do any of the investigators or their immediate family receive payments of other sorts   from this sponsor?**  (e.g., grants, compensation in the form of equipment or supplies, retainers for ongoing  consultation and honoraria) |
| **Yes:  No:  N/A:** |
| |  | | --- | | **2.6. Are any of the investigators or their immediate family members of the sponsor’s board   of Directors, Scientific Advisory Panel or comparable body?** | | **Yes:  No:  N/A:** | |
| **2.7. Is there any other relationship, financial or non-financial, that could be construed as a   conflict of interest?** |
| **Yes:  No:** |
| |  | | --- | | **2.8. If the answer to any of the above questions is Yes, please provide further explanation   and evidence of ethical acceptability.** | | **Summary:** Click here to enter text. | |

1. **Participants** **Information**   
   *Please key in your responses .Text spaces will expand as needed.*Please refer to Chapter 4 – Fairness and Equity in Research Participation of the TCPS2 for   
   further information.

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| **3.1** **Does your research involve contact with a living person or persons?** |
| **Yes:  No:**  Note: If **Yes**, you must answer all questions in this section. If no, go to section 4. |
| |  | | --- | | **3.2 Describe the participant(s) to be recruited or population about whom personally   identifiable information will be collected.** | | **Description:** Click here to enter text. | |
| **3.3 Describe and justify the inclusion criteria for participants.** (e.g., Criteria: age range, health status, gender; Justification: safety, uniformity, research   methodology, statistical requirement) |
| **Inclusion criteria:** Click here to enter text. |
| **3.4 Describe and justify the exclusion criteria for participants.** |
| **Exclusion criteria:** Click here to enter text. |
| |  | | --- | | **3.5 Will this study involve any group(s) where non-participants are present?** (e.g., classroom research) | | **Yes:  No:** | |
| **If YES, please answer the following; if no please go to section 4:** |
| **3.6 What measures will be taken to ensure that non-participants and their data are not   included in the study?** |
| **Measures:** Click here to enter text. |
| **3.7 Describe how appropriate activities for non-participants will be provided.** |
| **Activities:** Click here to enter text. |
| |  | | --- | | **3.8. What measures will be taken to address discomfort or disadvantages, if any, arising   out of non-participation?** | | **Measures:** Click here to enter text. | |

1. **Aboriginal Community**

*Please key in your responses. Text spaces will expand as needed.*   
 Please refer to Chapter 9 “Research Involving the First Nations, Inuit and Métis Peoples of   
 Canada” of the TCPS2 document for further information.

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| **4.1 Does your research fall into any of the following categories? If any of (a) to (e) apply,**  **answer Yes.**  **(a) research conducted on First Nations, Inuit or Métis lands;**  **(b) recruitment criteria that include Aboriginal identity as a factor for the entire study or for a subgroup in the study;**  **(c) research that seeks input from participants regarding a community’s cultural heritage, artefacts, traditional knowledge or unique characteristics;**  **(d) research in which Aboriginal identity or membership in an Aboriginal community is used as a variable for the purpose of analysis of the research data;**  **(e) interpretation of research results that will refer to Aboriginal communities, peoples, language, history or culture.** |
| **Yes:  No:  N/A:**  Note: If **Yes**, you must answer all questions in this section. If no, proceed to section 5. Mark N/A  if not applicable, and provide an explanation in 4.2. |
| **4.2 Provide details about any of the above criteria that apply to this research.** |
| **Criteria details:** Click here to enter text. |
| **4.3 Provide a plan for engagement with the relevant community or stakeholders. For example, researchers might consult, seek consent from, or make an agreement with elders, leaders, or other community representatives. Community engagement is a process that could take many forms, but should occur prior to recruiting participants and be maintained over the course of the research. Or, provide an explanation for why engagement is not required for this research.** |
| **Engagement Plan:** Click here to enter text. |
| **4.4 Is there is a plan for compliance with other relevant frameworks for research involving Aboriginal groups or communities (e.g., OCAP)? Provide details below.** |
| **Framework:** Click here to enter text. |
| **4.5 Provide information on how final results of the study will be shared with the   participating community.** |
| **Sharing Results:** Click here to enter text. |

1. **Other Communities**

*Please key in your responses. Text spaces will expand as needed.*

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| **5.1 Does this research project involve other self-governed communities or groups?** |
| **Yes:  No:  N/A:**  Note: If **Yes**, you must answer all questions in this section. Mark N/A if not applicable**.** |
| **5.2 Is there a formal research agreement with the community?** |
| **Yes:  No:** |
| **5.3 Provide details about the agreement or why an agreement is not in place, not required,   etc.**  *Please attach any supporting documentation in the attachment section at the end of this   application.* |
| **Agreement details:** Click here to enter text. |
| **5.4 Does this research project involve obtaining consent from leaders or other community   representatives?** |
| **Yes:  No:** |
| If **YES**, provide details explaining how consent will be obtained and from whom. If no, explain   why consent will not be sought. |
| **Leadership consent details:** Click here to enter text. |
| **5.5. If leaders of the group will be involved in the identification of potential participants,   provide details.** |
| **Leadership involvement:** Click here to enter text. |
| **5.6 If property or private information belonging to the group as a whole is studied or used,   please provide details.** |
| **Group data:** Click here to enter text. |
| **5.7 If the research is designed to analyze or describe characteristics of the group, please   provide details.** |
| **Group analysis:** Click here to enter text. |
| **5.8 If individuals are selected to speak on behalf of, or otherwise represent the group,   please provide details.** |
| **Group representation:** Click here to enter text. |
| **5.9 Please provide information on how final results of the study will be shared with the   participating community. (e.g., special presentation, deposit in community school)** |
| **Sharing results:** Click here to enter text. |

1. **Risk/Benefit Analysis**

*Please key in your responses. Text spaces will expand as needed.*   
 Please refer to Chapter 2 – Scope and Approach of the TCPS2 document for further   
 information.

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| **6.1 Please indicate the level of risk associated with this research.**  Greater-than-minimal risk would include risks that will be greater than those encountered by   the participants in those aspects of their everyday lives related to the research. | |
| **Level: Minimal:** | **Greater Than Minimal Risk:** |
| **6.2 Does this research project involve any potential risks or discomforts listed below?  Potential Physical Risks and Discomforts:** | |
| **Fatigue (Participants might feel physical fatigue, e.g., sleep deprivation):**  **Yes:  No:  Possibly:** | |
| **Stress (Participants might feel physical stress, e.g., cardiovascular stress tests):**  **Yes:  No:  Possibly:** | |
| **Injury (Participants might sustain injury, infection, side-effects or complications):**  **Yes:  No:  Possibly:** | |
| **Potential Psychological, Emotional, Social and other Risks and Discomforts.**  **Stress (Participants might feel psychologically or emotionally stressed, demeaned,   embarrassed, worried, anxious, scared, or distressed, e.g., description of painful or   traumatic events):** | |
| **Yes:  No:  Possibly:** | |
| **Fatigue (Participants might feel psychological or mental fatigue, e.g., intense concentration required):**  **Yes:  No:  Possibly:** | |
| **Social (Participants might experience cultural or social risk, e.g., loss of privacy or status or damage to reputation):**  **Yes:  No:  Possibly:** | |
| **Economic (Participants might be exposed to economic or legal risk, e.g., non-anonymized workplace surveys):**  **Yes:  No:  Possibly:** | |
| **6.3 Provide details of the risks and discomforts associated with the research, e.g., health,   cognitive or emotional factors, socio-economic status, physiological or health   conditions. If you did not identify any risks in section 6.2, then go to section 6.5.** | |
| **Risk Description:** Click here to enter text. | |
| **6.4 Describe how you will manage and minimize the risks and discomforts, as well as   mitigate harm, e.g. provide a list of resources you will provide for participants.** | |
| **Risk Management:** Click here to enter text. | |
| **6.5 If your study has the potential to incidentally identify conditions warranting medical   attention, describe the arrangements made to try to assist these individuals. Explain if   no arrangements have been made.** | |
| **Risk Mitigation:** Click here to enter text. | |
| **6.6 If any data were released, could it reasonably be expected to place participants at risk   of criminal or civil law suits?** | |
| **Yes:  No:** | |
| **Benefit Analysis**  **6.7 Describe the benefits (direct or indirect) to the participants and/or the participant’s   community from their involvement in the project. If using human biomaterials,   describe the benefit to society.** | |
| **Benefit description:** Click here to enter text. | |
| **6.8 Describe the benefits to the scientific/scholarly community or society that would justify   involvement of participants or human research models in this study.** | |
| **Academic benefit:** Click here to enter text. | |
| **6.9 Benefits/risk analysis: Describe the relationship of benefits to risk of participation in   the research.** | |
| **Benefit/Risk analysis:** Click here to enter text. | |

1. **Recruitment**

*Please key in your responses. Text spaces will expand as needed.*   
 Please refer to Chapter 1 – Ethics Framework of the TCPS2 document for further   
 information.

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| **7.1 Are there any recruitment activities for this study?** |
| **Yes:  No:  N/A:**  Note: If **Yes**, you must answer all questions in this section. Mark N/A if not applicable. If no, go to section 8. |
| **If Yes, please describe the activities that will be used when recruiting individuals for this study.** |
| **Recruitment Activities:** Click here to enter text. |
| **Recruitment Method**  **7.2 How will potential participants be sought?** |
| **Approach:** Click here to enter text. |
| **7.3. Outline how individuals will be approached for participation or screened for eligibility.**  (e.g., response to advertising, websites, email, listserves, pre-existing records or  existing registries, physician or community organizations, referrals, longitudinal study) |
| **Approach:** Click here to enter text. |
| **7.4 Indicate the method by which individuals will obtain details about the research in order   to make a decision about participating.** |
| **Method:**  **Potential participant will contact researchers:**  **Researchers will contact participants:**  **Contact will be made through a third party or intermediary:** |
| **Please describe the above in more detail:** Click here to enter text. |
| **7.5 If contact will be made through an intermediary (including snowball sampling), select   one of the following:** |
| **Third Party Contact Method:**  **1) Intermediary provides information to potential participants who then contact**  **the researchers**  **2) Intermediary provides potential participants’ contact information to researchers with**  **participants’ informed consent for release of contact information** |
| **7.6 Explain why the intermediary is appropriate and describe what steps will be taken to**  **ensure participation is voluntary**  (e.g., if you are asking instructors to provide contact information for their students). |
| **Third Party Justification:** Click here to enter text. |
| **7.7 Provide the locations where recruitment will occur, if applicable.** (e.g., particular schools, shopping malls, clinics) |
| **Location:** Click here to enter text. |
| **7.8 If recruitment will take place in a group situation, describe what measures will be taken   to guard against peer pressure influencing an individual’s decision to participate or not.** |
| **Peer Pressure:** Click here to enter text. |
| **7.9 How many participants do you hope to recruit?** |
| **Recruitment number:** Click here to enter text. |
| **7.10 If this is a multi-site study, how many participants are expected to be enrolled by all   investigators at all sites in the entire study?** |
| **Total number:** Click here to enter text. |
| **7.11 Please justify your choice of sample size.** |
| **Justification:** Click here to enter text. |
| **Pre-existing relationships**  **7.12 Will potential participants be recruited through pre-existing relationships with**  **researchers?**  (e.g., students, employees, family members, clients) |
| **Yes:  No:** |
| **7.13 If yes, identify any relationship between the researchers and participants that could   compromise the freedom to decline** (e.g., professor-student). **Describe the measures   that will be taken to ensure that there is no undue pressure on the potential   participants to agree to the study.** |
| **Relationship Description:** Click here to enter text. |
| **7.14 For biomedical research involving therapies, procedures and interventions, describe   the standard of care in Manitoba for this patient population.** |
| **Standard of Care:** Click here to enter text. |

1. **Secondary Use of Data**

*Please key in your responses. Text spaces will expand as needed.*Please refer to Chapter 5 Section D – Consent and Secondary Uses of Identifiable Information for Research Purposes of the TCPS2 document for further information.

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| **8.1 Does this study involve secondary use of data?** |
| **Yes:  No  If no, go to Section 9** |
| **8.2 Please list all original sources of data, or anticipated plans to use this study data in another study.** |
| **Sources:** Click here to enter text. |

1. **Informed Consent Determination**

*Please key in your responses. Text spaces will expand as needed.*   
Please refer to Chapter 3 – The Consent Process of the TCPS2 document for further information.

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| **9.1 Indicate who will provide informed consent for this study (select all that apply).** |
| **1) All participants have capacity to give free and informed consent.**  **2) Not all participants will have capacity to give free and informed consent, therefore third-party consent will be sought.**  **3) Consent obtained by a third party (biobank, company or other research group) for the collection of human biomaterials.**  **4) All participants have capacity but consent is not required.**  **5) Not all participants have capacity but consent is not required.** |
| **9.2 If prior consent is not required or has been obtained by a third party, please provide   justification.** |
| **Justification:** Click here to enter text. |
| **9.3 How is participant consent to be indicated and documented?** |
| **Consent documentation:**  **1) Signed consent form (attach a copy on UW letterhead)**  **2) Explicit oral consent**  **3) Implied by overt action (i.e., completion of questionnaire)**  **4) Implied by inaction/non-objection**  **5) Assent (usually seen in conjunction with another consent process, most often**  **signed consent form)** |
| **Explain in more detail how the study information will be communicated, and how participant consent will be presented, obtained, documented, and stored. Provide details for EACH of the options selected above.** |
| Click here to enter text. |
| **9.4 If a participant wishes to withdraw, end, or modify their participation in the research or   certain aspects of the research, describe how their termination would be ended or   changed. Give specific dates if possible, or a general time frame.** |
| **Termination:** Click here to enter text. |
| **9.5 Describe the circumstances and limitations of data withdrawal from the study, including the last point at which it can be done. Give specific dates if possible, or a general time frame.** |
| **Data Withdrawal:** Click here to enter text. |
| **9.6 Indicate how participants or their authorized representatives may follow up with   researchers and/or UHREB to ask questions or obtain information about the study.** |
| **Follow up:** Click here to enter text. |
| **Will this study involved people that are not able to provide inform consent?**  **Yes:  No:  If no, then go to section 10.**  **9.7 Explain why participants lack capacity to give informed consent.**  (e.g., age, mental or physical condition) |
| **Consent Capacity:** Click here to enter text. |
| **9.8 Will participants who lack capacity to give full informed consent be asked to give   assent?**  If applicable, please ensure that a copy of assent form is attached to this application. |
| **Yes:  No:** |
| **If Yes, please provide details.** |
| **Assent details:** Click here to enter text. |
| **9.9 In cases where participants (re)gain capacity to give informed consent during the   study, how will they be asked to provide consent on their own behalf?** |
| **Method:** Click here to enter text. |
| **9.10 What assistance will be provided to participants, or those consenting on their behalf,   who have special requirements?**  (e.g., non-English speakers, visually impaired) |
| **Specific assistance:** Click here to enter text. |

1. **Deception or Partial Disclosure**

*Please key in your responses. Text spaces will expand as needed.*

Please refer to Chapter 3 – The Consent Process of the TCPS2 document for further information.

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| **10.1 Does this study include the use of deception or partial disclosure?** |
| **Yes:  No:  N/A:**  Note: If **Yes**, you must answer all questions in this section. Mark N/A if not applicable. If no go to section 11. |
| **10.2 Describe the information that will be withheld from, or the misinformation that will be   provided to, the participants.** |
| **Description:** Click here to enter text. |
| **10.3 Provide a rationale for withholding information or misinforming the participants.** |
| **Rationale:** Click here to enter text. |
| **10.4 Indicate how and when participants will be informed of the concealment and/or   deception. Describe the extent of the debriefing.** |
| **Disclosure:** Click here to enter text. |
| **10.5 Describe the procedure for giving the participants an opportunity to provide fully   informed consent after debriefing. Explain if debriefing and re-consent are not viable.** |
| **Consent:** Click here to enter text. |
| **10.6 If applicable, please indicate how participants may follow up with researchers for   further debriefing.** |
| **Follow-up:** Click here to enter text. |

1. **Reimbursements and Incentives**

*Please key in your responses. Text spaces will expand as needed.*    
 Please refer to Chapter 3 – The Consent Process “Incentives” of the TCPS2 document for   
 further information.

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| **11.1 Will any participant in this study receive reimbursement or incentive for their**  **participation?**  A reimbursement includes any reimbursement for costs associated with participating in this   study, e.g., meals or parking. An incentive would include prize draw, gift card, cash payment,  etc. |
| **Yes:  No:  N/A:**  Note: If **Yes**, you must answer all questions in this section. Mark N/A if not applicable. If no, go to section 12. |
| **11.2 Describe in detail the expenses for which participants will be reimbursed, the value of**  **the reimbursements, and the process, if applicable.**  (e.g., participants will receive a cash reimbursement for parking, at the rate of $12.00 per visit  for up to three visits for a total of $36.00). |
| **Reimbursement Description:** Click here to enter text. |
| **11.3 If personal information will be collected to reimburse or pay participants, describe the**  **information to be collected and how privacy will be maintained.** |
| **Reimbursement personal details:** Click here to enter text. |
| **11.4 Please select the incentive types that participants may receive. Select all that apply.** |
| **Incentive Type:**  **1) Not applicable**  **2) Cash payment**  **3) Gift card**  **4) Meals/Refreshments**  **5) Prize draw**  **6) Other** |
| **If “Other”, please specify** |
| **Other incentive:** Click here to enter text. |
| **11.5 Excluding prize draws, what is the maximum value of the incentives offered to an**  **individual throughout the research?** |
| **Incentive value:** Click here to enter text. |
| **11.6 Provide details of the value, including the likelihood (odds) of winning for prize draws**  **and lotteries.** |
| **Incentive details:** Click here to enter text. |
| **11.7 Justify the value of the incentives offered.**  If incentives are offered to participants, they should not be so large or attractive as to  constitute coercion. |
| **Incentive value:** Click here to enter text. |

1. **Anonymity and Confidentiality**

*Please key in your responses. Text spaces will expand as needed.*

**Researchers have the obligation not to misuse or wrongfully disclose the identity of**

**participants (maintain anonymity] or the information provided by them (maintain confidentiality).** Please refer to Chapter 5 – Privacy and Confidentiality of the TCPS2 document for further information.

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| **12.1 Will the identity of participants or human biomaterials be protected both during and**  **after research?** |
| **Yes:  No:** |
| **12.2 Please indicate how privacy will be maintained. Please indicate all that apply.** |
| **Data Privacy Method:**  **1) Anonymous – the information NEVER had identifiers associated with it and the risk of identification of individuals is low or very low**  **2) Directly Identifying Information – the information identifies a specific individual through direct identifiers, e.g., name, SIN, personal health number**  **3) Indirectly Identifying Information – individuals could be identified through a combination of indirect identifiers, e.g., date of birth, address, photo or description of event**  **4) Anonymized - personal Identifying Information removed**  **5) Made Public and Cited – including cases where participants have elected to be identified and/or allowed use of images, photos, etc.**  **6) Other**  Note: If you answered ‘other’ please provide details.  Click here to enter text. |
| **12.3 Will the researcher or study team be able to identify any of the participants at any**  **stage of the study?** |
| **Yes:  No:** |
| **12.4 If applicable, describe the extent of your confidentiality obligations, e.g., limits on**  **what can and cannot be disclosed.** |
| **Confidentiality:** Click here to enter text. |
| **12.5 How will the principal investigator ensure that any research collaborators are aware of**  **their responsibilities concerning participants’ privacy and the confidentiality of their**  **information?** |
| **Confidentiality Awareness:** Click here to enter text. |
| **12.6 What measures will be taken to protect the anonymity and/or confidentiality of**  **participants? Explain how participants will be informed about any limits on your**  **ability to protect this information.** |
| **Protection Measures:** Click here to enter text. |

1. **Interviews, Focus Groups, and Surveys**

*Please key in your responses. Text spaces will expand as needed.*    
 Copies of all protocols, question frameworks, and survey questionnaires must be attached   
 in the attachment section at the end of this application.

|  |
| --- |
| **13.1 Does this research involve an interview, focus group, and/or survey?** |
| **Yes:  No:  N/A:**  Note: If **Yes**, you must answer all questions in this section. If No or N/A, go to section 14. |
| **13.2 Are any of the questions potentially of a sensitive nature?** |
| **Yes:  No:** |
| **If Yes, please provide details.** |
| Click here to enter text. |
| **13.3 Will you be using audio/video recording equipment and/or capture of sound or images**  **for the study?** |
| **Yes:  No:** |
| **If Yes, please provide details.** |
| Click here to enter text. |

**14.0 Use or Production of Creative Works**

*Please key in your responses. Text spaces will expand as needed.*

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| **14.1 Does this research involve the use or creation of media or other works?** |
| **Yes:  No:  N/A:**  Note: If **Yes**, please complete Schedule A. |

**15.0 Internet-based Interaction**

*Please key in your responses. Text spaces will expand as needed.*   
 Please refer to Chapter 5 – Privacy and Confidentiality of the TCPS2 document for further   
 information.

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| **15.1 Does this research involve interaction with participants via the Internet?** |
| **Yes:  No:  N/A:**  Note: If **Yes**, you must answer all questions in this section. |
| **15.2 Will your interaction with participants occur in private spaces where there is a   reasonable expectation of privacy? (e.g., members-only chat rooms, social networking   sites, small discussions, private zoom meetings.)** |
| **Yes:  No:** |
| **15.3 Will these interactions occur in public space(s) where you will post questions   initiating and/or maintaining interaction with participants?** |
| **Yes:  No:** |
| **15.4 Describe how permission to use the site(s) as a research site will be obtained, if   applicable.** |
| **Site Permission:** Click here to enter text. |
| **15.5 If you are using a third-party research tool, website survey software, transaction log   tools, screen capturing software, or masked survey sites, how will you ensure the   security of the data gathered at the site?** |
| **Data Security:** Click here to enter text. |
| **15.6 If you do not plan to identify yourself and your position as a researcher to the  participants from the onset of the research study, or if you are using deception for research purposes, please explain why you are doing so and at what point you will disclose that you are a researcher or the true purposes of the study. Provide details of debriefing procedures, if any, and indicate if participants will be given a way to opt out, if applicable.** |
| **Disclosure:** Click here to enter text. |
| **15.7 How will you protect the privacy and confidentiality of participants who may be   identified by email addresses, IP addresses, and other identifying information that   may be captured by the system during your interactions with these participants?** |
| **Privacy:** Click here to enter text. |

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| **16.1 Please indicate which if any of the following Personal Identifiers will be collected**  **during the course of this study, including recruitment.** |
| **1) Not applicable**  **2) Address**  **3) Age**  **4) Birth Date - full**  **5) Birth Year**  **6) Email address**  **7) Employee ID Number**  **8) First and/or Last Name**  **9) Initials**  **10) Photograph**  **11) Postal Code – first 3 digits**  **12) Postal Code - full**  **13) Professional Certificate/License Number**  **14) Provincial Health Identifier**  **15) Recorded Image**  **16) Social Insurance Number**  **17) Student ID Number**  **18) Telephone Number**  **19) Vehicle Identifier**  **20) Other** |
| **If Other, please specify.** |
| Click here to enter text. |
| **16.2 If collecting personal identifiers, please explain why it is necessary to collect this**  **information.** |
| **Rationale:** Click here to enter text. |
| **16.3 If applicable, please explain when and how identifying information will be removed.** |
| **Removal:** Click here to enter text. |
| **16.4 If applicable, specify what identifiable information will be retained once data collection**  **is complete, and explain why retention is necessary. Include the retention of master**  **lists that link participant identifiers with anonymized data.** |
| **Retention:** Click here to enter text. |
| **16.5 If applicable, describe if the data in this study will be linked with data associated with**  **other studies or with data belonging to another organization (e.g., with a data**  **repository).** |
| **Data Association:** Click here to enter text. |

**16.0 Safeguarding Information**

*Please key in your responses. Text spaces will expand as needed.*   
 Please refer to Chapter 5 – Privacy and Confidentiality of the TCPS2 document for further

information.

**17.0 Data Storage**

*Please key in your responses. Text spaces will expand as needed.*   
 Please refer to Chapter 5 “Privacy and Confidentiality” of the TCPS2 document for further

information.

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| **17.1 Describe how research data will be stored, e.g., digital files, hard copies, audio**  **recordings. Specify the physical location and how it will be secured to protect  confidentiality and privacy.** (e.g., study documents are kept in a locked filing cabinet and computer files are password protected) |
| **Data Storage:** Click here to enter text. |
| **17.2 If you plan to destroy your data, describe when and how this will be done.** |
| **Data Disposal:** Click here to enter text. |
| **17.3 How long will the research data be retained?**  University policy requires that you keep your data for a minimum of 7 years following  completion of the study but there is no limit on data retention. |
| **Data Retention:** Click here to enter text.   |  | | --- | | **17.4 Will the research data become part of a data repository or involve the creation of a database or registry for future research use?** | | **Yes:  No:**  Note: If no, or the database will be located on the University’s Winnspace Repository, then go to Section 18. If yes, but the database will not be hosted on Winnspace, please complete each question in this section. | |
| **17.5 Specify where the database(s) will be located.**  Specify if the database will be under Canadian or foreign jurisdiction.  Note that data housed on U.S. servers fall under the U.S. Patriot Act. At a minimum,  participants should be informed of this potential breach of confidentiality. |
| **Location:** Click here to enter text. |
| **17.6 Describe who will have access to the database and how that access is determined.** |
| **Access:** Click here to enter text. |
| **17.7 Will identifying information be stored within the database?** |
| **Yes:  No:** |
| **17.8 If the database is to be maintained locally, what steps have been taken to ensure that**  **the security of the database is upheld?** |
| **Security:** Click here to enter text. |
| **17.9 Indicate who is responsible for the database(s).** |
| **Responsibility:** Click here to enter text. |
| **17.10 Are there any standard operating procedures for the database management, use, and**  **access? If Yes, please attach in the attachment section at the end of this application.** |
| **Yes:  No:** |

1. **Human Biological Material**

*Please refer to Schedule B*

**19.0 BioHazard Safety**

*Please refer to Schedule C*

**20.0 DECLARATION**

Please read the agreement text carefully and sign the form at the bottom of the page,   
 signifying your agreement to the terms and conditions.

**My signature below confirms that I (the applicant/Principal Investigator/Primary Supervisor):**

* **certify that the information provided in my ethics application and related documents is true, complete, and accurate;**
* **attest that others listed on the application have agreed to be included;**
* **am familiar with and accept the terms and conditions set out in the University of Winnipeg’s *Research Manual: Policies and Procedures*;**
* **am familiar with and accept the terms and conditions set out in the** [**University of Winnipeg University Human Research Ethics Board (UHREB) *Policies and Procedures***](file:///C:\Users\bayaraa-v\Downloads\june2017-uhreb-policyandprocedures%20(1).docx)**;**
* **am familiar with and accept the terms and conditions set out in the University of Winnipeg’s *Integrity in Research and Scholarship* policy;**
* **am familiar with and agree to comply with the policies described in the TCPS 2 – Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (2018);**
* **will follow guidelines and procedures which ensure compliance with all relevant professional, University, provincial, national or international policies and regulations governing research involving human participants;**
* **understand that if there is any deviation from the project as originally approved, I must submit an amendment or reapply to the appropriate ethics review body (Departmental Ethics Committee or UHREB) for approval before implementing any changes;**
* **will report to the UHREB, without delay, all adverse participant responses or other significant problems that exceed the levels anticipated and provided for in this application.**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of Applicant/Principal Investigator**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of Primary Supervisor**

**\_\_\_\_\_\_\_\_ \_\_\_**

**Date**

**21.0 LIST OF ATTACHMENTS/APPENDICES**

**CORE Certificate - mandatory**

**Signed DEC Approval Form(s) – mandatory for full review proposals submitted to UHREB**

**List of student participants (for pedagogical projects).**

**Appendix A – Use or Production of Creative Works**

**Appendix B – Human Biological Materials**

**Appendix C – Biohazard Safety and Biohazard Safety Approval**

**Recruitment Materials**

**Informed Consent Documents**

**Feedback Form**

**Interviews, Focus Groups, and Surveys - Protocols**

**Interviews, Focus Groups, and Surveys – Question Frameworks**

**Interviews, Focus Groups, and Surveys – Survey Questions**

**Other Attachment (Please specify:**Click here to enter text.

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**Schedule A - Use or Production of Creative Works**

*Please key in your responses. Text spaces will expand as needed.*

|  |
| --- |
| **14.1 Does this research involve the use or creation of media or other works?** |
| **Yes:  No:  N/A:**  Note: If **Yes**, you must answer all questions in this schedule. |
| **14.2 Who will have access to this material?** |
| **Access:** Click here to enter text. |
| **14.3 In cases where you will be sharing materials for verification or feedback, what steps   will you take to protect the dignity of those who may be represented or identified?** |
| **Interim Feedback:** Click here to enter text. |
| **14.4 When publicly reporting data or disseminating results of your study that include   materials you have collected, what steps will you take to protect the dignity of those   who may be represented or identified? (e.g., presentation, reports, articles, books,   curriculum material, performance)** |
| **Public Reporting:** Click here to enter text. |
| **14.5 Does this research involve the use of materials created by participants?** |
| **Yes:  No:** |
| **14.6 Explain if consent obtained at the beginning of the study will be sufficient, or if it will   be necessary to obtain consent at different times, for different stages of the study or   for different types of data. (e.g., obtaining consent from individuals who are depicted**  **in the materials created by participants)** |
| **Consent:** Click here to enter text. |
| **14.7 At what stage, if any, can a participant withdraw his/her material?** |
| **Withdrawal:** Click here to enter text. |
| **14.8 What opportunities are provided to participants to choose to be identified as the   author/creator of the materials created in situations where it makes sense to do so?** |
| **Identification:** Click here to enter text. |
| **14.9 If necessary, what arrangements will you make to return original material to   participants?** |
| **Return:** Click here to enter text. |

**Schedule B - Human Biological Material**

*Please key in your responses. Text spaces will expand as needed.*Please refer to Chapter 12 “Human Biological Materials Including Materials Related to

Human Reproduction” of the TCPS2 document for further information.

|  |
| --- |
| **18.1 Does this research project involve Human Biological Material?** |
| **Yes:  No:  N/A:**  Note: If **Yes**, you must answer all questions in this schedule. |
| **18.2 Please indicate if this study will involve any one of the following** (select all that apply)**:** |
| **Material Sample Type:**  **1) Not Applicable**  **2) Analysis of banked sample**  **3) Collection of sample for banking (future use)**  **4) Collection of sample for immediate use**  **5) Genetic analysis**  **6) Other** |
| **If Other, provide details.** |
| Click here to enter text. |
| **18.3 Indicate the biological material that will be studied.**  (e.g., body tissues, fluids – be specific) |
| **Description:** Click here to enter text. |
| **18.4 Describe how the material will be collected.** |
| **Collection Method:** Click here to enter text. |
| **18.5 Identify the person(s) or institution that collected the biological materials.** |
| **Collector:**Click here to enter text. |
| **18.6 Describe how the material will be stored.** |
| **Storage Method:** Click here to enter text. |
| **18.7 Indicate how long the material will be stored.** |
| **Length of Storage:** Click here to enter text. |
| **18.8 Describe where the material will be stored.**  Include information if the specimen will be sent out of the province. |
| **Storage Location:** Click here to enter text. |
| **18.9 Specify all intended uses of collected material.** |
| **Biological Material Use:** Click here to enter text. |
| **18.10 Indicate if there will be a code that allows linkage of the specimens back to the**  **original study and/or the patient’s clinical records.** |
| **Specimen Linkage:**  **Yes:  No:** |
| **If Yes, please specify how specimens will be coded to protect confidentiality and indicate who will maintain this link to identifying information.** |
| Click here to enter text. |

**Schedule C - Biohazard Safety**

*Please key in your responses. Text spaces will expand as needed.*

If you answer **YES** to any of these questions, you will need to apply for Biohazards Approval.

Send a copy of your grant application or experimental plan detailing the planned use of these

biohazards to the Safety Office. If you already have Biohazard approval, attach

documentation. Otherwise, please forward the documentation to the Research Office once

approval has been received.

|  |
| --- |
| **19.1 Does this research project involve Human Biological Material?** |
| **Yes:  No:  N/A:**  Note: If **Yes**, you must answer all questions in this schedule. |
| **19.2 Indicate if your research will involve the use of one or more of the following:** |
| **1) Risk group 2, 3, or 4 viruses, bacteria, fungi, parasites or eukaryotic cell lines**  **2) Environmental specimens suspected to contain risk group 2, 3, or 4 microbes**  **3) Large-scale single volume culture in excess of 10 litres for any microbe or eukaryotic cell line**  **4) Microbial toxins**  **5) Human clinical specimens, including blood or other body fluids, or primary culture of human cells**  **6) Xenotransplant studies involving vertebrate donors and/or recipients**  **7) Genetic manipulation involving virulence genes from risk group 2, 3, or 4 microbes, mammalian oncogenes, mammalian cytokine or interleukin genes or microcode resistance genes**  **8) Genetic manipulation involving the use of recombinant vector systems based on lentivirus, adenovirus, retrovirus, or herpes virus backbones** |
| **19.3 If you checked off any of the above, please describe in more detail.** |
| **Description:** Click here to enter text. |