Please submit completed form and all attachments to: appliedresearch@jibc.ca

**Outline of the Ethics Review Application Form**

**Section 1: Project information**

This section provides the foundational information on the project, researchers, and partners.

**Section 2: Scope**

This section has several parts.

* Part A helps the Review Board determine whether or not the project requires ethical review.
* Part B helps determine whether projects that require ethical approval may be exempt from the process (e.g., the project involves human participants and thus needs ethical review, but involves primarily program evaluation that will not be published and therefore is exempt from the need for ethical approval).

**Part 3: Project Description**

This section lays out key elements of the project’s goals, design, methodology, participants, and data collection procedures.

Section 4: Risks and Benefits

This section explore the key ethical implications of the proposal, including benefits, potential harm, potential risks to participants, ways of mitigating those risks, and identifying (and mitigating) potential conflicts of interest for researchers.

**Section 5: Consent**

This section outlines the requirements for and issues surrounding participants understanding and giving informed consent to participate in the study, including informing participants, identifying undue influence, providing incentives, identifying situations in which consent is not required, use of deception, obtaining consent in medical emergencies, and issues involving participants who lack capacity to give consent.

**Section 6: Criteria for Consent Letters**

This section outlines criteria that should be included in information letters and consent forms.

**Section 7: Expedited Review**

This section explores whether or not the study may be eligible for expedited review and information required to determine whether or not the study is considered minimal risk.

Please submit completed form and all attachments to: appliedresearch@jibc.ca

ADMINISTRATIVE INFORMATION (Not to be completed by applicant)

|  |  |
| --- | --- |
| Application # |  |
| Date Received |  |
| Date Reviewed |  |
| Date Approved |  |
| Certificate # |  |

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| **Section 1: Project Information** |
| The Project Information section is used to identify, describe, and track your project. |
| **Title of Project as it will appear on the certificate** |
|  |
| **Project Nickname or abbreviated name (if any)** |
|  |
| **Name of Applicant or Primary Contact** |
|  |
| **Phone of Applicant or Primary Contact** | **Email of Applicant or Primary Contact** |
|  |  |
| **Summary of project**NOTE: Maximum 250 words |
|  |
| **Principal Investigator** |
|  |
| **Co-Investigator(s)** |
|  |
| **Student/Other Investigator(s)** |
|  |
| **If Course-based: Course Name**  |
|  |
| **If Course-based: Instructor Name**  |
|  |
| **Sponsoring School/Division** |
|  |
| **Partner Agencies/Institutions** |
|  |
| **Funding Source(s)**NOTE: If no direct funding, please indicate “Internally funded” and department or division |
|  |
| **Project Start Date** | **Anticipated Project End Date** |
|  |  |
| **Date that Data Collection is anticipated to begin** |
|  |
|  |
| **Have the Principal Investigator and all Co-, Student, and other investigators completed the Tri Council Policy Statement 2 Tutorial?**  |
| **Yes** | **No** | **If “yes,” please provide names and certificate numbers in the space below.** |
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| **Section 2: Scope** |
| Complete this section to determine whether or not you are required to complete a full Ethics Approval application. Please read the instructions carefully and note that, even if you do NOT require Ethics Approval, you must complete this section, sign the bottom of the form, and submit to the Centre for Applied Research. |
| **Part A: Does this Research require Ethical Approval?** |
| **From the TCPS2:** **Article 2.1 The following requires ethics review and approval by an REB before the research commences:****(a) research involving living human participants;****(b) research involving human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individuals.** |
| **Does this project involve interaction or participation with living human participants?** |
| **Yes** | **No** | **Comments (if applicable)** |
|  |  |  |
| **Does this research involve human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells; including materials derived from living and deceased individuals.** |
| **Yes** | **No** | **Comments (if applicable)** |
|  |  |  |
| If you answered “No” to BOTH of the questions above, the research does not require Ethics Approval. You do not need to complete any other sections of this form. Please sign the application (see back page) and submit to the Centre for Applied Research.If you answer “Yes” to either of the questions above, please proceed to the Part B: “Is this research exempt from Ethics Approval.”Please contact the Centre for Applied Research if you have any further questions or concerns. |

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| **Section 2: Scope** |
| If your research involves humans of biological material, you must submit for Ethics Approval. However, there are some forms of research involving humans which may still be exempt from Ethical Approval. The questions in this section help the Ethics Review Board determine whether or not your research may be exempt.  |
| **Part B: Is this research exempt from Ethics Approval?** |
| **Article 2.2****Does the research rely exclusively on publicly available information that is legally accessible to the public and protected by law?** |
| **Yes** | **No** | **Comments (if applicable)** |
|  |  |  |
| **Does the research rely exclusively on publicly available information and where there is no reasonable expectation of privacy?** |
| **Yes** | **No** | **Comments (if applicable)** |
|  |  |  |
| **Does the research focus exclusively on public policy issues, writing of history, literary, and/or artistic criticism?** |
| **Yes** | **No** | **Comments (if applicable)** |
|  |  |  |
| **Article 2.3****Does the research involve observation of people in public places that does not involve any intervention staged by the researcher, or direct interaction with the individuals or groups?** |
| **Yes** | **No** | **Comments (if applicable)** |
|  |  |  |
| **Does the research involve observation of people in public places where individuals or groups targeted for observation have no reasonable expectation of privacy?** |
| **Yes** | **No** | **Comments (if applicable)** |
|  |  |  |
| **Does this research secure identifiable personal information about participants?** |
| **Yes** | **No** | **Comments (if applicable)** |
|  |  |  |
| **Does the research involve observation of people in public places where dissemination of research results will not allow identification of specific individuals?** |
| **Yes** | **No** | **Comments (if applicable)** |
|  |  |  |
| **Article 2.4****Will secondary use of anonymous information or anonymous human biological materials involve data linkage or recording or dissemination of results that generated identifiable information?** |
| **Yes** | **No** | **Comments (if applicable)** |
|  |  |  |
| **Article 2.5****Is the data collected in this research to be used exclusively for assessment, management or improvement purposes such as quality assurance and quality improvement studies, program evaluation activities, performance reviews, and/or testing within normal educational requirements?** |
| **Yes** | **No** | **Comments (if applicable)** |
|  |  |  |
| **Article 2.6****Does the research involve creative practice activities in and of themselves and having no identified application?** |
| **Yes** | **No** | **Comments (if applicable)** |
|  |  |  |
| If you checked ANY of the shaded boxes above, then the research requires Ethical Approval. Please proceed to the next section of this form.If you checked ALL of the unshaded boxes above, then the research is EXEMPT from further Ethical Review. Please sign and submit Section 1 and Section 2 of this form.Please contact the Centre for Applied Research if you have any further questions or concerns. |

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| **Section 3: Project Description** |
| The information in this section is used by the Reviewers to understand your research project and to guide their assessment of the ethical implications of the research. The Reviewers appreciate the balance between brevity and clarity. The information provided should be of sufficient detail to justify the answers you provide in the following sections. Please provide a ***summary*** of the relevant aspects of your research and not full quotes or sections from a research proposal.  |
| **From the TCPS 2:****Article 2.7 As part of research ethics review, the REB shall review the ethical implications of the methods and design of the research.** **The primary test to be used by REBs in evaluating a research project should be ethical acceptability and, where appropriate, relevant disciplinary scholarly standards.** |
| **Study Summary**Provide a short summary of the research in lay person language suitable for non-content specialist Reviewers. The summary should NOT be cut and paste from a Research Proposal. (Max. 150 words) |
|  |
| **Research Goal****Goal and/or Objective of the research**  |
|  |
| **Research Personnel****Name(s) of researcher(s) actually conducting the study and/or gathering data** |
|  |
| **Qualifications or background relevant to the research methodology being used (e.g. training, course work, degrees, experience)** |
|  |
| **If you do not yet know the names of the research personnel, please provide a description of the types of researchers you will engage and what backgrounds you will require.** |
|  |
| **Research Design****Provide a brief description of research approach and methodology.****(Max. 250 words)** |
|  |
| **List the primary site where research be conducted**. |
|  |
| **Identify other sites or locations where the research may be conducted.** |
|  |

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| **Participants** |
| **From the TCPS 2:****Article 4.1** Taking into account the scope and objectives of their research, researchers should be inclusive in selecting participants. Researchers shall not exclude individuals from the opportunity to participate in research on the basis of attributes such as culture, language, religion, race, disability, sexual orientation, ethnicity, linguistic proficiency, gender or age, unless there is a valid reason for the exclusion.**Article 4.2** Women shall not be inappropriately excluded from research solely on the basis of gender or sex.**Article 4.3** Women shall not be inappropriately excluded from research solely on the basis of their reproductive capacity, or because they are pregnant or breastfeeding.**Article 4.4** Children shall not be inappropriately excluded from research solely on the basis of their age or developmental stage. The inclusion of children in research is subject to Article 4.6.**Article 4.5** Elderly people shall not be inappropriately excluded from research solely on thebasis of their age.**Article 4.6** Subject to applicable legal requirements, individuals who lack capacity to consent to participate in research shall not be inappropriately excluded from research.**Article 4.7** Individuals or groups whose circumstances may make them vulnerable in the context of research should not be inappropriately included or automatically excluded from participation in research on the basis of their circumstances. |
| **Who will be the participants in this research?** |
|  |
| **Describe the criteria for inclusion/selection of participants.** |
|  |
| **Describe the characteristics of participants who might be excluded from the research, the criteria for exclusion, and rationale for their exclusion.** |
|  |
| **If participants are excluded from participation in this research due to gender, age, lack of capacity, or vulnerability, please provide a rationale.** |
|  |
| **Describe the process for recruitment of participants****(max 250 words)** |
|  |
| **Who will contact potential participants and what methods will be used to contact them?** |
|  |
| **Please attach letters or correspondence of initial contact** **Will there be attached letters or correspondence of initial contact?** |
| **Yes** | **No** | **N/A** | **Comments** |
|  |  |  |  |
| **Does the research include Control or Normal Participants?** |
| **Yes** | **No** | **N/A** | **If yes, describe how prospective Control or Normal Participants will be identified, contacted, and recruited.** |
|  |  |  |  |
| **How much time will participants asked to dedicate to the research?** |
|  |
| **Data Collection**What types of data will be collected? |
|  |
| **Provide a brief summary of data collection and analysis procedures** **(max 350 words)** |
|  |
| **What data collection methods will be used? Check all that apply.** |
| **Item** | **Yes** | **No** | **Comment** |
| **Questionnaire / Survey** |  |  |  |
| **Interview**  |  |  |  |
| **Observation** |  |  |  |
| **Intervention** |  |  |  |
| **Test Instruments** |  |  |  |
| **Document Review** |  |  |  |
| **Audio Recording** |  |  |  |
| **Video Recording** |  |  |  |
| **Other (Please list or describe)** |  |  |  |
|  |  |  |  |
| **From the TCPS 2:****Article 5.1** Researchers shall safeguard information entrusted to them and not misuse or wrongfully disclose it. Institutions shall support their researchers in maintaining promises of confidentiality. |
| **How will participant anonymity or confidentiality be maintained? In anonymity or confidentiality is not required for this research, please explain.** |
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| **From the TCPS 2:****Article 5.2** Researchers shall describe measures for meeting confidentiality obligations and explain any reasonably foreseeable disclosure requirements: (a) in application materials they submit to the REB; and (b) during the consent process with prospective participants. |
| **Are there foreseeable situations in which the researchers may be ethically or legally required to disclose information obtained in the research context? If so, what strategies are in place during the consent process to ensure that participants are aware of the possibility of compelled disclosure?** |
| **Yes** | **No** | **N/A** | **Comments** |
|  |  |  |  |
| **From the TCPS 2:****Article 5.3** Researchers shall provide details to the REB regarding their proposed measures for safeguarding information, for the full life cycle of information: its collection, use, dissemination, retention and/or disposal.**Article 5.4** Institutions or organizations where research data are held have a responsibility to establish appropriate institutional security safeguards. |
| **How will data be stored?** |
|  |
| **Who will have access to data?** |
|  |
| **How and when will data be destroyed?** |
|  |
| **What provisions are there for providing feedback to participants? If feedback will not be provided, please give rationale.** |
|  |
| **From the TCPS 2:****Article 3.4** Researchers have an obligation to disclose to the participant any material incidental findings discovered in the course of research.“Incidental findings” is a term that describes unanticipated discoveries made in the course of research but that are outside the scope of the research. Material incidental findings are findings that have been interpreted as having significant welfare implications for the participant, whether health-related, psychological or social. If, in the course of research, material incidental findings are discovered, researchers have an obligation to inform the participant. |
| **What provisions are in place to disclose to participants any material incidental findings discovered in the course of the research?** |
| **None** | **N/A** | **Comments** |
|  |  |  |
| **From the TCPS 2:****Article 5.5** Researchers who have not obtained consent from participants for secondary use of identifiable information shall only use such information for these purposes if the REB is satisfied that:(a) identifiable information is essential to the research;(b) the use of identifiable information without the participants’ consent is unlikely to adversely affect the welfare of individuals to whom the information relates;(c) the researchers will take appropriate measures to protect the privacy of individuals, and to safeguard the identifiable information;(d) the researchers will comply with any known preferences previously expressed by individuals about any use of their information;(e) it is impossible or impracticable to seek consent from individuals to whom the information relates; and(f) the researchers have obtained any other necessary permission for secondary use of information for research purposes. |
| **Describe any potential secondary uses of data from this research.** |
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| **If secondary use of data is used without consent, explain how the use meets the requirements of Article 5.5.** |
| **N/A** | **Comments** |
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| **From the TCPS 2:**Article 5.7 Researchers who propose to engage in data linkage shall obtain REB approval prior to carrying out the data linkage, unless the research relies exclusively on publicly available information as discussed in Article 2.2. The application for approval shall describe the data that will be linked and the likelihood that identifiable information will be created through the data linkage. Where data linkage involves or is likely to produce identifiable information, researchers shall satisfy the REB that:(a) the data linkage is essential to the research; and(b) appropriate security measures will be implemented to safeguard information. |
| **Will this research involve data linking? If so, describe the data that will be linked, the likelihood that identifiable information will be created through the linkage and the security measures that will be implemented to safeguard information.** |
| **Yes** | **No** | **N/A** | **Comments** |
|  |  |  |  |
| **Other Ethical Reviews:****Please describe peer review and/or any other ethical reviews associated with this research.** |
|  |
| **Peer Review:****Have you received any information or are you aware of any rejection of this study by any research ethics board. If yes, please provide known details and attach any available relevant documentation, including actions taken to mitigate concerns raised by the previous review.** |
| **Yes** | **No** | **Comments** |
|  |  |  |
| **Has this research received independent scientific or methodological peer review (e.g. academic supervisor, funding competition, departmental review, etc.)? If yes, please provide names of the committees or individuals involved in the review.** |
| **Yes** | **No** | **Comments** |
|  |  |  |
| **If this research proposal has NOT received any independent scientific or methodological peer review, explain why no review has taken place.** |
| **Yes** | **No** | **N/A** | **Comments** |
|  |  |  |  |
| **List any external Ethics approvals obtained from other participating institutions involved in this research. Please attach a pdf copy of relevant approval certificates.** |
| **Yes** | **No** | **Comments** |
|  |  |  |
| **Will any portions this research be conducted in other jurisdictions or countries?** |
|  |

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| **Research Involving Aboriginal Peoples****Does this research focus on Aboriginal peoples, communities, or organizations?** |
| **Yes** | **No** | **Comments** |
|  |  |  |
| **If “No,” please skip the remainder of this section and continue to Section 4: Risks and Benefits.****If “Yes,” please complete the following questions.** |
| **If this research focuses on Aboriginal peoples, communities, or organizations, please indicate whether or not you have read the JIBC procedures on Research Involving Aboriginal Peoples.** |
| **Yes** | **No** | **Comments** |
|  |  |  |

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| **Describe measures taken to ensure that the research has engaged, or intends to engage, the community in approving, advising on, and/or managing the project.** |
|  |
| **Describe consultation with appropriate JIBC personnel and groups (e.g. Office of Indigenization, JIBC Aboriginal Education Advisory Council, etc.) or with other appropriate external individuals or groups** |
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| **Section 4: Risks and Benefits** |
| **Introduction (from TCPS 2):**The REB … assesses the ethical acceptability of the research through consideration of the foreseeable risks, the potential benefits, and the ethical implications of the research, both at the stage of the initial review and throughout the life of the project.**Potential Benefits**Research involving humans may produce benefits that positively affect the welfare of society as a whole though the advancement of knowledge for future generations, for participants themselves, or for other individuals However, much research offers little or no direct benefit to participants. In most research, the primary benefits produced are for society and for the advancement of knowledge. |
| **What are the potential benefits (if any) that may arise for individuals from this research?** |
|  |
| **What are the potential benefits (if any) that may arise for other individuals from this research?** |
|  |
| **What are the potential benefits (if any) that may arise for the advancement of knowledge from this research?** |
|  |
| **How will this research positively benefit (if at all) the welfare of society as a whole?** |
|  |
| **Potential Harm**Because research is a step into the unknown, its undertaking can involve harms to participants and to others. Harm is anything that has a negative effect on the welfare of participants, and the nature of the harm may be social, behavioural, psychological, physical or economic. |
| **What (if any) potentially negative effects are there on the social welfare of participants or others from this research?** |
| **None** | **N/A** | **Comments** |
|  |  |  |
| **What (if any) potentially negative effects are there on the behavioural welfare of participants or others from this research?** |
| **None** | **N/A** | **Comments** |
|  |  |  |
| **What (if any) potentially negative effects are there on the psychological welfare of participants or others from this research?** |
| **None** | **N/A** | **Comments** |
|  |  |  |
| **What (if any) potentially negative effects are there on the physical welfare of participants or others from this research?** |
| **None** | **N/A** | **Comments** |
|  |  |  |
| **What (if any) potentially negative effects are there on the economic welfare of participants or others from this research?** |
| **None** | **N/A** | **Comments** |
|  |  |  |
| **What (if any) potential is there for:** * **Injury to reputation and privacy**
* **Potential breach of any relevant law**
 |
| **None** | **N/A** | **Comments** |
|  |  |  |

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| **Potential Risks****Risk is a function of the magnitude or seriousness of the harm, and the probability that it will occur, whether to participants or to third parties. A proper ethical analysis of research should consider both the foreseeable risk and the available methods of eliminating or mitigating the risk.** |
| **What is the magnitude or seriousness of potential harms identified in the section above (e.g. minimal to substantial; temporary, longer lasting, permanent, etc.)?** |
| **None** | **N/A** | **Comments** |
|  |  |  |
| **What is the probability of occurrence for potential harms identified in the section above (based on the researchers’ past experience)?** |
| **None** | **N/A** | **Comments** |
|  |  |  |
| **What cultural aspects, values, or beliefs of the specific population (if any) should be taken into account when assessing the potential risks of this research?** |
| **None** | **N/A** | **Comments** |
|  |  |  |
| **What potential risks are there to researchers conducting this research?** |
| **None** | **N/A** | **Comments** |
|  |  |  |
| **Are student researchers involved in this research, and if so, what procedures are in place to ensure that they are not subject to pressure from supervisors to conduct research in unsafe situations?** |
| **None** | **N/A** | **Comments** |
|  |  |  |
|  |
| **None** | **N/A** | **Comments** |
|  |  |  |
| **Mitigating Risks****A proper ethical analysis of research should consider both the foreseeable risk and the available methods of eliminating or mitigating the risk.** |
| **What strategies will be in place to mitigate or eliminate potential risks and harms?** |
| **None** | **N/A** | **Comments** |
|  |  |  |
| **Expertise for Review****The REB should make its assessment in light of the context of the research – that is, elements of the research that may produce benefits or harms, or otherwise have an impact on the ethics of research. Regardless of the level of review, the review should include the necessary expertise. Ad hoc advisors may be recruited for review of specific proposals if necessary.** |
| **What special expertise or contextual knowledge is required (if any) by the REB to adequately assess the potential benefits and risks of this research?** |
| **None** | **N/A** | **Comments** |
|  |  |  |
| **Conflict of Interest** |
| **From TCPS 2:****Researchers and research students hold trust relationships, either directly or indirectly, with participants, research sponsors, institutions, their professional bodies and society. These trust relationships can be put at risk by conflicts of interest that may compromise independence, objectivity or ethical duties of loyalty. Although the potential for such conflicts has always existed,****pressures on researchers (e.g., to delay or withhold dissemination of research outcomes or to use inappropriate recruitment strategies) heighten concerns that conflicts of interest may affect ethical behaviour.****Researchers’ conflicts of interest may arise from interpersonal relationships (e.g., family or community relationships), financial partnerships, other economic interests (e.g., spin-off companies in which researchers have stakes or private contract research outside of the academic realm), academic interests or any other incentives that may compromise integrity or respect for the core principles of this Policy. Conflicts may arise from an individual’s involvement in dual and multiple roles within or outside an institution. While it may not be possible to eliminate all conflicts of interest, researchers are expected to identify, minimize or otherwise manage their individual conflicts in a manner that is satisfactory to the REB.** |
| **From TCPS 2:****Article 7.4 Researchers shall disclose in research proposals they submit to the REB any real, potential or perceived individual conflicts of interest, as well as any institutional conflicts of interest of which they are aware that may have an impact on their research. Upon discussion with the researcher, the REB shall determine the appropriate steps to manage the conflict of interest.** |
| **Are any of the researchers aware of any real, potential, or perceived conflicts of interest that may have an impact on the research? If so, please explain and provide suggested strategies to mitigate or eliminate the conflict.** |
| **Yes** | **No** | **N/A** | **Comments** |
|  |  |  |  |
| **Will any of the investigators and/or their partners/immediate family members receive personal benefits in connection with this study over and above the direct cost of conducting the study (e.g. being paid by the funder for consulting) (reminder: finders fees for each participant enrolled is not allowed). If so, please explain and provide suggested strategies to mitigate or eliminate the conflict.** |
| **Yes** | **No** | **N/A** | **Comments** |
|  |  |  |  |
| **Will any of the investigators and/or their partners/immediate family members have a non-financial relationship with research sponsors or funders such as unpaid consultant, advisor, board member or other non-financial interest? If so, please explain and provide suggested strategies to mitigate or eliminate the conflict.** |
| **Yes** | **No** | **N/A** | **Comments** |
|  |  |  |  |
|  |
| **Yes** | **No** | **N/A** | **Comments** |
|  |  |  |  |
| **Will any of the investigators and/or their partners/immediate family members have direct financial involvement with the research sponsors or funders via ownership of stock, stock options, or or membership on a board? If so, please explain and provide suggested strategies to mitigate or eliminate the conflict.** |
| **Yes** | **No** | **N/A** | **Comments** |
|  |  |  |  |
| **Will any of the investigators and/or their partners/immediate family members hold patent rights or IP rights linked in any way to this study or its sponsor (source of funds)? If so, please explain and provide suggested strategies to mitigate or eliminate the conflict.** |
| **Yes** | **No** | **N/A** | **Comments** |
|  |  |  |  |

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| **Section 5: Consent**  |
| **From TCPS 2:** **The Principle of Respect for Persons implies that individuals who participate in research should do so voluntarily, understanding the purpose of the research, its risks and potential benefits, as fully as reasonably possible. This principle also implies that those who lack the capacity to decide for themselves should nevertheless have the opportunity to participate in research that may be of benefit to themselves and others. Certain types of research require alternate processes for seeking consent. Researchers are responsible for ensuring that all applicable legal and regulatory requirements with respect to consent are met.** |
| **From TCPS 2:****Article 3.1 (a) Consent shall be given voluntarily.****(b) Consent can be withdrawn at any time.****(c) If a participant withdraws consent, the participant can also request the withdrawal of their data or human biological materials.** |
| **Will participants be able to give truly informed consent? In “No,” please explain.**  |
| **Yes** | **No** | **Comments** |
|  |  |  |
| **What factors might influence the ability of participants to provide truly informed consent (e.g. underage, language, capacity to understand.)** |
| **None** | **N/A** | **Comments** |
|  |  |  |
| **What strategies will be in place to mitigate or eliminate factors that might influence the ability of participants to provide truly informed consent?** |
| **None** | **N/A** | **Comments** |
|  |  |  |
| **Will participants be able to withdraw from the research at any time?** |
| **Yes** | **No** | **N/A** | **Comments** |
|  |  |  |  |
| **Will participants who withdraw consent be able to withdraw their data or human biological materials from the study?** |
| **Yes** | **No** | **N/A** | **Comments** |
|  |  |  |  |
| **If their data is unable to be withdrawn (e.g. participation in a focus group session), how will participants be notified of this fact?** |
| **Yes** | **No** | **N/A** | **Comments** |
|  |  |  |  |
| **Undue Influence**The voluntariness of consent is important because it respects human dignity and means that individuals have chosen to participate in research according to their own values, preferences and wishes. The approach to recruitment is an important element in assuring voluntariness. In particular, how, when and where participants are approached, and who recruits them are important elements in assuring voluntariness… REBs must be cognizant of situations where undue influence, coercion or the offer of incentives may undermine the voluntariness of a participant’s consent to participate in research.Undue influence and manipulation may arise when prospective participants are recruited by individuals in a position of authority. The influence of power relationships on the voluntariness of consent should be judged from the perspective of prospective participants, since the individuals being recruited may feel constrained to follow the wishes of those who have some form of control over them. This control may be physical, psychological, financial or professional, for example, and may involve offering some form of inducement or threatening some form of deprivation. In such situations, the control exerted in a power relationship may place undue pressure on the prospective participants. At the extreme, there can be no voluntariness if consent is secured by the order of authorities. |
| **From TCPS 2:****Article 4.7 Individuals or groups whose circumstances may make them vulnerable in the context of research should not be inappropriately included or automatically excluded from participation in research on the basis of their circumstances.** |
| **Are there cultural, social or economic circumstances of prospective participants, groups, or communities that might impact the voluntariness of their participation in the research?** |
| **Yes** | **No** | **N/A** | **Comments** |
|  |  |  |  |
| **Are there power relationships between the researcher and potential participants (e.g., employers and employees, teachers and students, commanding officers and members of the military or correctional officers and prisoners, etc.)?** |
| **Yes** | **No** | **N/A** | **Comments** |
|  |  |  |  |
| **Are researchers in a position to exert physical, psychological, financial, and/or professional control of participants?** |
| **Yes** | **No** | **N/A** | **Comments** |
|  |  |  |  |
| **Are researchers and participants in a position of trust or dependency? (e.g., between patients and physicians, or faculty and students?)** |
| **Yes** | **No** | **N/A** | **Comments** |
|  |  |  |  |
| **What measures will be in place to mitigate or eliminate potential for undue influence on the participants’ ability to give voluntary consent?** |
| **None** | **N/A** | **Comments** |
|  |  |  |
| **Incentives** |
| **Where incentives are offered to participants, they should not be so large or attractive as to encourage reckless disregard of risks. This is a particular consideration in the case of healthy volunteers for the early phases of clinical trials. The offer of incentives in some contexts may be perceived by prospective participants as a way for them to gain favour or improve their situation. This may amount to undue inducement and thus negate the voluntariness of participants’ consent. This Policy neither recommends nor discourages the use of incentives. The onus is on the researcher to justify to the REB the use of a particular model and the level of incentives. In considering the possibility of undue influence in research involving financial or other incentives, researchers and REBs should be sensitive to issues such as the economic circumstances of those in the pool of prospective participants, the age and capacity of participants, the customs and practices of the community, and the magnitude and probability of harms. Guardians and authorized third parties should not receive incentives for arranging the involvement in research of the individual they represent. However, they may accept reasonable incentives or compensation on behalf of that individual, as long as these are suitable to the circumstances.** |
| **What incentives are offered for participation in this research?** |
| **Yes** | **No** | **N/A** | **Comments** |
|  |  |  |  |
| **What factors (if any), such as economic circumstances, age and capacity of potential participants, or customs and practices of the community might affect participants’ ability to give voluntary consent?** |
| **Yes** | **No** | **N/A** | **Comments** |
|  |  |  |  |
| **What incentives (if any) are offered to guardians or authorized third parties?** |
| **Yes** | **No** | **N/A** | **Comments** |
|  |  |  |  |
| **What measures will be taken to ensure that incentives do not create undue influence or impact the voluntariness of consent?** |
| **Yes** | **No** | **N/A** | **Comments** |
|  |  |  |  |
| **Situations in which Consent is NOT Required****Consent Not Required****NOTE: This section is only completed if consent will NOT be obtained from participants.**  |
| **From TCPS 2:****Article 3.7 The REB may approve research without requiring that the researcher obtain the participant’s consent in accordance with Articles 3.1 to 3.5 where the REB is satisfied, and documents, that all of the following apply:****(a) the research involves no more than minimal risk to the participants;****(b) the lack of the participant’s consent is unlikely to adversely affect the welfare of the participant;****(c) it is impossible or impracticable to carry out the research and to answer the research question properly, given the research design, if the prior consent of the participant is required;****(d) whenever possible and appropriate, after participation, or at a later time during the study, participants will be debriefed and provided with additional pertinent information in accordance with Articles 3.2 and 3.4, at which point they will have the opportunity to refuse consent in accordance with Article 3.1; and****(e) the research does not involve a therapeutic intervention, or other clinical or diagnostic interventions.** |
| **Determining whether or not Consent must be obtained****Does the research meet the requirements for Minimum Risk?** |
| **Yes** | **No** | **N/A** | **Comments** |
|  |  |  |  |
| **Is the lack of participants’ consent likely to adversely affect the welfare of the participant?** |
| **Yes** | **No** | **N/A** | **Comments** |
|  |  |  |  |
| **Is it impossible or impracticable to carry out the research and to answer the research question properly, given the research design, if the prior consent of the participants is required?** |
| **Yes** | **No** | **N/A** | **Comments** |
|  |  |  |  |
| **Will the research involve a therapeutic intervention, or other clinical or diagnostic intervention?** |
| **Yes** | **No** | **N/A** | **Comments** |
|  |  |  |  |
| **If any of the shaded boxes are checked, then consent MUST be obtained prior to participation in the research.** |
| **If consent is not given, what strategies are in place to debrief participants at a later time and provide them with additional pertinent information, and – if they chose – withdraw their consent and contributions to the research?** |
|  |
| **Deception or Partial Disclosure** |
| **From TCPS 2:****Some types of research can be carried out only if the participants do not know the true purpose of the research in advance. For example, some social science research that critically probes the inner workings of publicly accountable institutions might never be conducted without the limited use of partial disclosure. In some research that uses partial disclosure or deception, participants may not know that they are part of a research project until it is over, or they may be asked to perform a task and told about only one of several elements the researchers are observing. Research employing deception can involve a number of techniques, such as giving participants false information about themselves, events, social conditions and/or the purpose of the research. For such techniques to fall within the exception to the general requirement of full disclosure for consent, the research must meet the requirements of Article 3.7.****Article 3.7 The REB may approve research without requiring that the researcher obtain the participant’s consent in accordance with Articles 3.1 to 3.5 where the REB is satisfied, and documents, that all of the following apply:** 1. **the research involves no more than minimal risk to the participants;**
2. **the lack of the participant’s consent is unlikely to adversely affect the welfare of the participant;**
3. **it is impossible or impracticable to carry out the research and to answer the research question properly, given the research design, if the prior consent of the participant is required;**
4. **whenever possible and appropriate, after participation, or at a later time during the study, participants will be debriefed and provided with additional pertinent information in accordance with Articles 3.2 and 3.4, at which point they will have the opportunity to refuse consent in accordance with Article 3.1; and**
5. **the research does not involve a therapeutic intervention, or other clinical or diagnostic interventions.**
 |
| **Does this research involve deception or partial disclosure? If Yes, describe the form of deception or partial disclosure to be used and provide a rationale in terms of the criteria listed in Article 3.7 a), b), c), and e).** |
| **Yes** | **No** | **N/A** | **Comments** |
|  |  |  |  |
| **If this research involves deception or partial disclosure, describe strategies to ensure that adequate debriefing will be provided in accordance with Article 3.7 d).** |
|  |
| **Medical Emergencies****To be completed ONLY if research involves situations involving medical emergencies.** |
| **From TCPS 2:****Article 3.8 Subject to all applicable legal and regulatory requirements, research involving medical emergencies shall be conducted only if it addresses the emergency needs of the individuals involved, and then only in accordance with criteria established in advance of such research by the REB.** |
| **Will the research involve situations involving medical emergencies and in which consent may not be obtained prior to treatment of the participant?** **If Yes, what strategies are place to identify situations in which consent may not be obtained prior to treatment, and describe how consent will be sought and obtained when the participant regains capacity or when an authorized third party is found to provide consent.** |
| **Yes** | **No** | **N/A** | **Comments** |
|  |  |  |  |

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| **Lack of Capacity****To be completed ONLY if research involves situations involving medical emergencies.** |
| **From TCPS 2:****Article 3.9 For research involving individuals who lack the capacity, either permanently or temporarily, to decide for themselves whether to participate, the REB shall ensure that, as a minimum, the following conditions are met: (a) the researcher involves participants who lack the capacity to consent on their own behalf to the greatest extent possible in the decision-making process; (b) the researcher seeks and maintains consent from authorized third parties in accordance with the best interests of the persons concerned; (c) the authorized third party is not the researcher or any other member of the research team; (d) the researcher demonstrates that the research is being carried out for the participant’s direct benefit, or for the benefit of other persons in the same category. If the research does not have the potential for direct benefit to the participant but only for the benefit of the other persons in the same category, the researcher shall demonstrate that the research will expose the participant to only a minimal risk and minimal burden, and demonstrate how the participant’s welfare will be protected throughout the participation in research; and (e) when authorization for participation was granted by an authorized third party, and a participant acquires or regains capacity during the course of the research, the researcher shall promptly seek the participant’s consent as a condition of continuing participation.** |
| **From TCPS 2:****Article 3.10 Where an authorized third party has consented on behalf of an individual who lacks legal capacity, but that person has some ability to understand the significance of the research, the researcher shall ascertain the wishes of that individual with respect to participation. Prospective participants’ dissent will preclude their participation.** |
| **Are potential participants who lack the legal capacity to make decisions, such as children whose capacity for judgment and self-direction is maturing, those whose capacity is diminishing or fluctuating, or those whose capacity remains only partially developed, such as those living with permanent cognitive impairment?** |
| **Yes** | **No** | **N/A** | **Comments** |
|  |  |  |  |
| **Will the research involves participants who have signed research directives indicating their preferences for future participation in research?** |
| **Yes** | **No** | **N/A** | **Comments** |
|  |  |  |  |
| **If answered “no” to either of the questions above, what strategies are in place to ensure that participants are given the opportunity to consent on their own behalf to the greatest extent possible in the decision-making process, that consent is obtained from authorized third parties who are not part of the research team, and that the researcher demonstrates that the research is being carried out for the benefit of the patient or other persons in the same category.** |
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| **Section 6: Consent Letters Checklist** |
| **From TCPS 2:** **Article 3.2 Researchers shall provide to prospective participants, or authorized third parties, full disclosure of all information necessary for making an informed decision to participate in a research project.** **At the commencement of any process of consent, researchers shall provide prospective participants with the information set out in the following list, as appropriate to the particular research project. Not all the listed elements are required for all research. However, additional information may be required in particular types of research or under particular circumstances. If a researcher does not include some of the listed disclosure requirements, they should explain to the REB why these requirements do not apply to that particular project.****Article 3.12 Evidence of consent shall be contained either in a signed consent form or in documentation by the researcher of another appropriate means of consent.** |
| **Are the following components included in the consent letter? If not, please provide rationale.** |
| **Item** | **Yes** | **No** | **Comment** |
| (a) information that the individual is being invited to participate in a research project; |  |  |  |
| (b) a statement of the research purpose in plain language, the identity of the researcher, the identity of the funder or sponsor, the expected duration and nature of participation, a description of research procedures, and an explanation of the responsibilities of the participant; |  |  |  |
| (c) a plain language description of all reasonably foreseeable risks and potential benefits, both to the participants and in general, that may arise from research participation; |  |  |  |
| (d) an assurance that prospective participants:• are under no obligation to participate; are free to withdraw at any time without prejudice to pre-existing entitlements;• will be given, in a timely manner throughout the course of the research project, information that is relevant to their decision to continue or withdraw from participation; and• will be given information on the participant’s right to request the withdrawal of data or human biological materials, including any limitations on the feasibility of that withdrawal; |  |  |  |
| (e) information concerning the possibility of commercialization of research findings, and the presence of any real, potential or perceived conflicts of interest on the part of the researchers, their institutions or the research sponsors; |  |  |  |
| (f) the measures to be undertaken for dissemination of research results and whether participants will be identified directly or indirectly; |  |  |  |
| (g) the identity and contact information of a qualified designated representative who can explain scientific or scholarly aspects of the research to participants; |  |  |  |
| (h) the identity and contact information of the appropriate individual(s) outside the research team whom participants may contact regarding possible ethical issues in the research; |  |  |  |
| (i) an indication of what information will be collected about participants and for what purposes; an indication of who will have access to information collected about the identity of participants, a description of how confidentiality will be protected (see Article 5.2), a description of the anticipated uses of data; and information indicating who may have a duty to disclose information collected, and to whom such disclosures could be made; |  |  |  |
| (j) information about any payments, including incentives for participants, reimbursement for participation-related expenses and compensation for injury; |  |  |  |
| (k) a statement to the effect that, by consenting, participants have not waived any rights to legal recourse in the event of research-related harm; and |  |  |  |
| (l) in clinical trials, information on stopping rules and when researchers mayremove participants from trial. |  |  |  |

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| **Section 7: Expedited Review**The Ethics Review Board may consider applications for Expedited Review as per the criteria below. Please complete this section if you are seeking Expedited Review of your research. |
| **From TCPS 2:** **Article 6.11 Researchers shall submit their research proposals, including proposals for pilot studies, for REB review and approval of its ethical acceptability prior to the start of recruitment of participants, access to data, or collection of human biological materials. REB review is not required for the initial exploratory phase, which may involve contact with individuals or communities intended to establish research partnerships or to inform the design of a research proposal.** |
| **Data Collection****Has the research begun recruitment of participants or data collection?** |
| **Yes** | **No** | **Comments** |
|  |  |  |
| **If “yes,” then this research is not eligible for Expedited Review.** |
| **Annual Renewal****Complete these questions only if this is an annual renewal of approved research.** |
| **Will the remaining research include new interventions to current participants?** |
| **Yes** | **No** | **Comments** |
|  |  |  |
| **Will the remaining research include recruitment of new participants?** |
| **Yes** | **No** | **Comments** |
|  |  |  |
| **Are all remaining research activities are limited to data analysis?** |
| **Yes** | **No** | **Comments** |
|  |  |  |
| **If you answered any of these questions as “No,” then this research is not eligible for Expedited Review.** |
| **Changes to Approved Research****Complete these questions only if the application for renewal includes changes to the approved research procedures.** |
| **From TCPS 2:****Article 6.16 Researchers shall submit to their REBs in a timely manner requests for substantive changes to their originally approved research. REBs shall decide on the ethical acceptability of those changes to the research in accordance with a proportionate approach to research ethics review.** |
| **Do the changes to the approved research meet the requirements for minimum risk (please see criteria below)?** |
| **Yes** | **No** | **Comments** |
|  |  |  |
| **If you answered “No,” then this research is not eligible for Expedited Review.** |

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| **Criteria for Minimum Risk****Complete this section to apply for Minimum Risk status for the research. Note that many of the questions are similar to questions in the full application.**  |
| **General assessment of risk****Is the probability and magnitude of possible harms implied by participation in the research greater than those encountered by participants in those aspects of their everyday life that relate to the research?** |
| **Yes** | **No** | **Comments** |
|  |  |  |
| **Vulnerability****Some individuals or groups have situations or circumstances which make them vulnerable in the context of a research project. Does this research involve any of the following factors that may impact on vulnerability of participants?** |
| **Item** | **Yes** | **No** | **Comment** |
| **Children (18 years or younger)** |  |  |  |
| **Vulnerable cultural, social, and/or economic circumstances** |  |  |  |
| **Participants who lack the capacity to consent for themselves**  |  |  |  |
| **Medical emergencies** |  |  |  |
| **Health or wellness status** |  |  |  |
| **Institutionalized**  |  |  |  |
| **Setting and/or recruitment (e.g. power relationships between researchers and participants)** |  |  |  |
| **Gender and gender identify** |  |  |  |
| **Dependency** |  |  |  |
| **Are there foreseeable situations in which the researchers may be ethically or legally required to disclose information obtained in the research context?** |
| **Yes** | **No** | **Comments** |
|  |  |  |
| **Does this research involve deception or partial disclosure?** |
| **Yes** | **No** | **Comments** |
|  |  |  |
| **Will all participants be able to provide truly informed consent?** |
| **Yes** | **No** | **Comments** |
|  |  |  |
| **Methodology****Will the research involve any of the following methodologies or procedures:** |
| **Item** | **Yes** | **No** | **Comment** |
| **Clinical research involving preventative or therapeutic measures** |  |  |  |
| **Clinical research involving invasive procedures** |  |  |  |
| **Human health related behavior** |  |  |  |
| **Potential Harm****Will the research potentially involve situations or circumstances which may result in harm to either participants or researchers, including:** |
| **Item** | **Yes** | **No** | **Comment** |
| **Physical harm** |  |  |  |
| **Psychological harm** |  |  |  |
| **Injury to reputation and privacy** |  |  |  |
| **A breach of any relevant law** |  |  |  |

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| **If you answered “yes” to any of the questions above, the research does not qualify as Minimal Risk.** |

**Submission of Request for Ethical Review**

|  |  |
| --- | --- |
| **Project Title** |  |
| **Applicant/PI** |  |
| **Signature** |  |
|  |  |
| **Date Submitted** |  |
|  |
| **Are you requesting Expedited Review?** |
| **Yes** | **No** | **Comments** |
|  |  |  |
| **Does the research meet the requirements for Expedited Review in Section 7?** |
| **Yes** | **No** | **Comments** |
|  |  |  |
| **Additional Comments to Reviewers** |
|  |
|  |  |