**REB TEMPLATE FOR ANNUAL RENEWAL AND STUDY PROGRESS FORM DEVELOPMENT**

**PLEASE DO NOT SUBMIT THIS FORM TO THE REB.**

**This form is intended for development purposes of annual renewal and study progress only.**

**If you would like to make changes for your study at the time of renewal, you must complete both a Study Amendment Form as well as the Annual Renewal and Study Progress form.**

All substantive changes proposed for a study are to be submitted to, and approved by the REB before being implemented, except when necessary to eliminate an immediate risk(s) to the participants [TCPS2 Article 6.16].

Minor deviations that have occurred during the course of the research that do not have ethical implications (e.g., minor wording changes in survey questions, adjustment of testing times) are to be reported annually at the time of renewal through submission of an Amendment.

**This form must be submitted at least a week before the date of expiry listed on the latest approval letter. If your study is complete, please fill out the "Study Closure Form" instead. If you have changes to be reviewed for this study, they will need to be recorded on an Amendment Form and submitted separate from the "Annual Renewal and Study Progress Form". The processes for a renewal or an amendment have been separated.**

\*ASTERISK INDICATES A MANDATORY QUESTION

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**TAB 1. Project Funding**

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| **#** | **Question** | | **Guidance Note** |
| 1.1\* | Have there been any changes to the funding for this protocol since the most recent ethics approval? | | If you answered "Yes", provide details of funding by submitting an Amendment Form as well. |
| Yes  No | | | |
| 1.2\* | Is this renewal being submitted in fewer than 10 work days before approval expires? | If responding “no”, please then advance to Tab 2, otherwise complete responses for questions 1.3, and 1.4 | |
| Yes  No | | | |
| 1.3 | If the Research Ethics Board approval has expired, or is within 10 work days of expiring, please state if any study related actions have taken place during the time over which there was no valid ethical approval. |  | |
| No study related actions have occurred during the lapsed study status  Study related actions have occurred during the lapsed study status, and the PI will be/has been in contact with the REB regarding the noncompliance to TCPS2 | | | |
| 1.4 | If the Research Ethics Board approval has expired, please provide a written explanation for the late renewal, and explain what strategies have now been put in place to prevent future lapses. |  | |
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**TAB 2. CONFLICT OF INTEREST**

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| **#** | **Question** | **Guidance Note** |
| 2.1\* | New Conflict of Interest - Have there been any changes in the conflict of interest status of the Principal Investigator, Co-investigator, or members of the research team that have not previously been reported to the Research Ethics Board? | While not exhaustive, below are examples that may give rise to a Conflict of Interest (COI).  The PI, Co-I, research team members and/or their partners/immediate family members (partners and children either living in the same household or not):  (a) occupy more than one role with respect to potential participants (e.g., acting as both a researcher and a health care provider, teacher, supervisor, manager, employer, student, etc.);  (b) has a financial interest in or expects to receive a financial interest (e.g., ownership of stock, stock options, salary, consulting fees, retainers, honoraria, bonuses, gifts, speaker’s fees, advisory board remuneration) in or from any entity (e.g., a company, partnership, or non-profit corporation) whose interests could be affected by the outcome of this research;  (c) provides services (e.g., non or fee-paying consulting, advisory, board membership, etc.) to any entity (e.g., a company partnership, or non-profit corporation) whose financial interests could be affected by the outcome of this research;  (d) has intellectual property rights or interests linked in any way to this study (e.g., patents, copyrights, royalties or other payments, etc.). |
| ☐ Yes  ☐ No | | |
| 2.2 | If you answered "Yes" to the question above, please briefly describe the nature of the conflict below, and submit an Amendment Form to address it fully for mitigation, and review by the REB. |  |
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**TAB 3. PARTICIPANTS**

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| **#** | **Question** | **Guidance Note** |
| 3.1\* | What stage of recruitment is your study? |  |
| ☐ Ongoing  ☐ Complete  ☐ Paused  ☐ Not Applicable | | |
| 3.2\* | Provide further details around the recruitment of participants for your study. | For example: Challenges encountered; number of persons who have provided consent; total number desired. |
|  | | |
| 3.3\* | How many participants have withdrawn consent in the study? |  |
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| 3.4 | If individuals have withdrawn consent, briefly describe the reason(s) for the withdrawal. |  |

**TAB 4. STUDY PROGRESS**

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| **#** | **Question** | **Guidance Note** |
| 4.1\* | Provide a brief summary of the progress of the study. | Include information around study implementation, whether the study is proceeding as planned, and any issues that might affect the study meeting its proposed timelines. Max 200 words. |
|  | | |
| 4.2\* | Since the most recent ethics approval, has there been any new information or changes in scientific knowledge that might affect the ethical basis of the research design? |  |
| ☐ Yes  ☐ No | | |
| 4.3 | If you answered "Yes" to the question above, please provide details. |  |
|  | | |
| 4.4\* | Unanticipated Problems - Have there been any unanticipated problems experienced during the course of the research? | An Unanticipated Problem is any incident, experience or outcome that meets all of the following criteria:  (a) Unexpected (in terms of nature, severity, or frequency);  (b) Related or possibly related to the participation in the research;  (c) Suggests that the research places the research participants, or others, at a greater risk of harm than was previously known or recognized. |
| ☐ Yes  ☐ Possibly  ☐ No | | |
| 4.5 | If you answered "Yes" or "Possibly", did you complete and submit an Unanticipated Problem Form? |  |
| ☐ Yes  ☐ No | | |
| 4.6 | If you have not submitted an Unanticipated Problem Form, please explain why. |  |
|  | | |
| 4.7 | If your research involves Indigenous peoples in Canada (First Nations, Inuit, Metis), how has community engagement and consultation been maintained during the course of the research? |  |
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**TAB 5. In-Person Research activities with increased risk of communicable diseases**

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| **#** | **Question** | **Guidance Note** |
| 5.1\* | Since the most recent ethics approval, has there been any new information or changes in the Public Health Officer's ongoing updates and recommendations that impact this study? |  |
| ☐ Yes  ☐ No | | |
| 5.2 | If you answered "Yes", please explain the mitigation for your study, and confirm whether an Amendment Form has been submitted to accommodate necessary changes to be made. |  |
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