

ANNUAL/FINAL REPORT

Annual report to the Research Ethics Board for the continuing ethical review of research involving humans / Final report to conclude REB oversight

**A. ADMINISTRATIVE INFORMATION**

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| --- |
| This report is (*select one*): [ ]  An annual report [ ]  A final report |
| REB file number:  |  |
| Study title:  |   |
| Lead researcher (named on REB submission) | Name |  |
| Email |  | Phone |  |
| Current status of lead researcher (at Dalhousie University):[ ]  Employee/Academic Appointment [ ]  Former student[ ]  Current student [ ]  Other (please explain): |
| Supervisor *(if lead researcher is/was a student/resident/postdoc)*  | Name |  |
| Email |  |

|  |  |  |
| --- | --- | --- |
| Contact person for this report (if not lead researcher) | Name |  |
| Email |  | Phone |  |

**B. RECRUITMENT & DATA COLLECTION STATUS**

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| Instructions: Complete **ALL** sections relevant to this studyStudy involves/involved recruiting participants: [ ]  Yes [ ]  No*If yes, complete section B1.* Study involves/involved secondary use of data: [ ]  Yes [ ]  No *If yes, complete section B2.*Study involves/involved use of human biological materials: [ ]  Yes [ ]  No*If yes, complete section B2.* |

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| **B1. Recruitment of participants** | [ ]  Not Applicable |
| B1.1 How many participants did the researcher intend to recruit?*(provide number approved in the most recent REB application/amendment)* |  |
| B1.2 How many participants have been recruited?*(if applicable, identify by participant group/method e.g. interviews: 10, focus groups: 25)*a) In total, since the beginning of the study: b) Since the last annual report: |
| B1.3 Recruitment for this study is:[ ]  complete; or [ ]  on-going |
| B1.4 Data collection from participants for this study is: [ ]  complete; or [ ]  on-going |
| B1.5 Communication with participants related to this study is: [ ]  complete; or [ ]  on-going |

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| **B2. Use of secondary data and/or biological materials** | [ ]  Not Applicable |
| B2.1 How many individual records/biological materials did the researcher intend to access?*(provide number approved in the most recent REB application/amendment)* |  |
| B2.2 How many individual participant records/biological materials have been accessed? a) In total, since the beginning of the study:b) Since the last annual report: |

**C. PROJECT HISTORY**

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| *Since your last annual report (or since initial submission if this is your first annual report):*  |
| C1. Have there been any variations to the original research project that have NOT been approved with an amendment request? This includes changes to the research methods, recruitment material, consent documents, study instruments or research team.[ ]  Yes [ ]  NoIf yes, please explain:  |
| C2. Have you experienced any challenges or delays recruiting or retaining participants or accessing records or biological materials?[ ]  Yes [ ]  NoIf yes, please explain: |
| C3. Have you experienced any problems in carrying out this project?[ ]  Yes [ ]  NoIf yes, please explain: |
| C4. Have any participants experienced any harm as a result of their participation in this study? [ ]  Yes [ ]  No If yes, please explain: |
| C5. Has any study participant expressed complaints, or experienced any difficulties in relation to their participation in the study? [ ]  Yes [ ]  No If yes, please explain: |
| C6. Since the original approval, have there been any new reports in the literature that would suggest a change in the nature or likelihood of risks or benefits resulting from participation in this study? [ ]  Yes [ ]  NoIf yes, please explain: |

**D. APPLYING FOR STUDY CLOSURE**

*Complete this section only if this is a FINAL report as indicated in section A*

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| --- |
| D1. For studies involving recruitment of participants, a closure may be submitted when: [ ]  all research-related interventions or interactions with participants have been completed[ ]  N/A (this study did not involve recruitment of participants) |
| D2. For studies involving secondary use of data and/or human biological materials, a closure may be submitted when: [ ]  all data acquisition is complete, there will be no further access to participant records or collection of biological materials[ ]  N/A (this study did not involve secondary use of data and/or human biological materials) |
| D3. Closure Request[ ]  I am applying for study closure |

**E. ATTESTATION (both boxes *must* be checked for the report to be accepted by the REB)**

[ ]  I agree that the information provided in this report accurately portrays the status of this project and describes to the Research Ethics Board any new developments related to the study since initial approval or the latest report.

[ ]  I attest this project was, or will continue to be, completed in accordance with the approved REB application (or most recent approved amendment) and in compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2).

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**SUBMISSION INSTRUCTIONS**

1. Submit this completed form to Research Ethics, Dalhousie University, by email at ethics@dal.ca at least 21 days prior to the expiry date of your current Research Ethics Board approval.

2. Enter subject line: REB# (8-digit number), last name, annual (or final) report.

3. Student researchers (including postdoctoral fellows and medical residents) must copy their supervisor(s) in the cc. line of the annual/final report email.

**RESPONSE FROM THE REB**

Your report will be reviewed, and any follow-up inquiries will be directed to you. You must respond to inquiries as part of the continuing review process.

Annual reports will be reviewed and may be approved for up to an additional 12 months; you will receive an annual renewal letter of approval from the Board that will include your new expiry date.

Final reports will be reviewed and study closure acknowledged in writing.

**CONTACT RESEARCH ETHICS**

* Phone: 902-494-3423
* Email: ethics@dal.ca