**Draft: CBU Secondary Use of Data Ethics Application**

Secondary use of data/biological materials (e.g. survey data, student records, health records, or biological material surplus to diagnostic exams or surgical procedures) refers to both:

* Retrospectively\* accessing data/samples that has already been collected for a different purpose to answer a research question that is different from the original question, and,
* Re-analyzing an existing research data set with a different research question

\*In order for a study to be considered retrospective, the end date of data collection must be before the date of submission to the UREB.  Therefore, your study will not involve collecting any information prospectively.

**\*\*Both types of secondary use of data require research ethics review.**

If the study exclusively uses data that are publicly available or made accessible through legislation or regulation, it is exempt from REB review (TCPS [Article 2.2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter2-chapitre2/)).

# SECTION 1. ADMINISTRATIVE INFORMATION

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| --- | --- |
| Indicate the type of project being submitted. | [ ] New [ ] Resubmission [ ] Major Amendment  New: Project has not been submitted to the REB previously.  Resubmitting: Project was previously submitted to the REB but not approved.  Major Amendment:The project is connected to an existing REB protocol that has been approved. |
| Project Title |  |
| Existing Protocol Number  (for Resubmissions or Major Amendments) |  |

## 1.1 Research Team Information

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| --- | --- |
| Principal Investigator’s Name |  |
| Department |  |
| Email |  |
| Phone |  |
| Project Start Date |  |
| Project End Date |  |
| Co-Investigators names, affiliations and contact information | Name, Affiliation, Contact Information |

## 1.2 Student Submissions

* Please note student applications will **not be processed** unless the student’s supervisor has reviewed and approved the application.
* Students **must** have supervisors sign the [Supervisor Signature for Student Ethics Application](https://www.cbu.ca/wp-content/uploads/2019/08/Supervisor-Signature-for-Student-Ethics-Application_October-2018.docx)page and attach this completed form when submitting this application.
* Students are required to have completed the TCPS2 Tutorial before submitting their application to the REB. Visit [http://tcps2core.ca/welcome](http://tcps2core.ca/welcome%20)
* **Save the Completion Certificate and attach it to your application when submitting your form.**
* **If your supervisor is not primarily associated with Cape Breton University, please list their primary institutional affiliation.**

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| --- | --- |
| Program |  |
| This project is for: | [ ] Course [ ] Thesis [ ] Other |
| Name of Supervisor |  |
| Supervisor’s Affiliation  (Department, University) |  |
| Supervisor’s Email |  |
| Supervisor’s Phone |  |

**Overview of Study**

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| Research Abstract/Summary – In **layperson’s terms**, please provide a summary of your research study**.**  **Max 200 words**  Click or tap here to enter text. | |
| Who currently has custody of the records/database/materials to be used ? | Click or tap here to enter text. |
| Have you submitted your proposed research and request for secondary data to the custodian(s)? | Yes  No  If no, please provide the anticipated request date  Click or tap to enter a date. |
| Briefly describe the original purpose for collecting this data. If this data was part of a research study, please describe the study’s purpose and attach the consent form used to collect the original data. | Click or tap here to enter text. |
| What is the purpose and rationale of your proposed research? Be sure to explain how the proposed research differs from the original research. Also indicate whether the purpose of the proposed research deviates from what the participants originally gave consent to in the informed consent letter, and if so how. | Click or tap here to enter text. |
| Describe the population or sample included in the original data (or biological material) collection | Click or tap here to enter text. |
| For the current analysis, describe and justify the sample or sub-sample being used (inclusion/exclusion criteria). Explain the process of identifying, selecting and obtaining records (or materials). | Click or tap here to enter text. |
| Describe the data you will be using and how. (e.g., reviewing videotapes/ transcripts or analyzing a data set) | Click or tap here to enter text. |
| Describe the population or sample included in the original data (or biological material) collection | Click or tap here to enter text. |
| Describe how the data (or materials) were initially gathered, when, and by whom. | Click or tap here to enter text. |
| If information was collected for research, how were participants recruited? | Click or tap here to enter text. |
| Will the data you collect involve linking data sets (i.e., using data collected from multiple sources)? | Yes  No  If yes, explain how participants’ identities could be established or not through data linkage.  Click or tap here to enter text. |

**Consent**

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| Consent shall be maintained throughout the research project. Researchers have an **ongoing** duty to provide participants with all information relevant to their ongoing consent to participate in the research. Consent encompasses a process that begins with the initial contact (e.g., recruitment) and carries through to the end of participants’ involvement in the project or use of their data. Throughout the process, researchers have an enduring duty to provide participants and REBs with all information relevant to participants’ ongoing consent to participate in the research as well as an ethical and legal obligation to bring to participants’ attention any changes to the research project that may affect them. These changes may have ethical implications, or may be germane to their decision to continue research participation, or may be relevant to the particular circumstances of individual participants. In particular, researchers shall disclose changes to the risks or potential benefits of the research. This gives participants the opportunity to reconsider the basis for their consent in light of the new information. In the case of children who begin participation in a project on the basis of consent from an authorized third party, the researcher must seek their autonomous consent if they reach the age of majority during the research, in order for their participation to continue. (TCPS2, Ch. 3, Article 3.3) | |
| How was informed consent originally obtained? | Signed Consent  Online Consent  Oral Consent  Implied (action-relative) Consent  Assent  Parent/Guardian Consent  Other – Specify - Click or tap here to enter text. |
| What were the original parameters of data usage for which participants gave consent? | Click or tap here to enter text. |
| To what extent does the original consent address the purposes of the current study?  \*Attach original consent form if available. | Click or tap here to enter text. |
| Does this study use records or biological materials collected for non-research purposes | Yes  No  *If no, please proceed to Section I below.* |
| Does this research use health information? | Yes  No  If yes, this research may be subject to Nova Scotia’s [*Personal Health Information Act*](http://novascotia.ca/dhw/phia/). In accordance with this Act, please explain why the research cannot reasonably be accomplished without access to personal health information.  Click or tap here to enter text. |

# RISKS

## 4.1 Statement on Risk

Please review the statement on minimal risk from the [TCPS2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/):

“For the purposes of this Policy, ‘minimal risk’ research is defined as research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research.

In this assessment of the acceptable threshold of minimal risk, REBs have special ethical obligations to individuals or groups whose situation or circumstances make them vulnerable in the context of a specific research project, and to those who live with relatively high levels of risk on a daily basis. Their inclusion in research should not exacerbate their vulnerability”

Risk can apply to both participants and non-participants.

|  |  |
| --- | --- |
| Based on the definition provided, I believe this project: | [ ] Meets the criteria for minimal risk research  [ ] May be or is above the threshold for minimal risk  *If a proposed research project is deemed above minimal risk, or if the reviewing member of the REB believes that a proposed project may be above minimal risk, the application must go to the full REB for review.* |

## 4.2 Description of Risk: Minimal Risk

All research has potential risks even projects that can be described as having minimal risk. Note that risks can apply to both participants and non-participants (researcher, community members). For more information around risk please view 2.2b in the TCPS2 “Concepts of Risks and Potential Benefits”

**Researchers must also briefly describe how the disruptions caused by COVID 19 have impacted this project and how those disruptions may impact risks.** [**Review to Article 6.19 of the TCPS 2 for more information**](https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter6-chapitre6.html#d)

**Please note “N/A” is not an acceptable answer for this section.**

|  |  |
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| Identify potential harms to participants that may occur during this research project.  **Researchers must also briefly describe how the disruptions caused by COVID 19 have impacted this project and how those disruptions may impact risks.** [**Review to Article 6.19 of the TCPS** 2 **for more information**](https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter6-chapitre6.html#d)**.**  *Suggested word count: 150* |  |
| Please describe any provisions you will put in place to minimize risk, to ensure security of data and confidentiality of information, and to handle any harm that participants may experience.  Identify some potential harms that may occur during the research project.  *Suggested word count: 100* |  |

## 4.3 Description of Risk: Above Minimal Risk

Fill out this section if you have indicated that the proposed project is above minimal risk. Note that risks can apply to both participants and non-participants (researcher, community members). For more information around risk please view 2.2b in the TCPS2 “Concepts of Risks and Potential Benefits”

|  |  |
| --- | --- |
| Explain how the research benefits of your project justify these risks, and how you plan to mitigate risks to participants in the study from which you are using secondary data. Identify potential harms to participants that may arise during the research project.  **Researchers must also briefly describe how the disruptions caused by COVID 19 have impacted this project and how those disruptions may impact risks.** [**Review to Article 6.19 of the TCPS** 2 **for more information**](https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter6-chapitre6.html#d)  *Suggested word count: 200* |  |
| If your research **involves more than minimal risk**, describe the measures to you propose for facilitating continuing review of this research, during the entire course of the project.  Identify some potential harms that may occur during the research project.  *Suggested word count: 200* |  |

**Privacy, Confidentiality and Anonymity**

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| --- | --- |
| Will participants be anonymous? (Anonymous means that no link can be established between he participant and the research and that no one, including the research(s) know who participated in the research study.) | Yes  No |
| Will the confidentiality of participants and their data be protected? (Confidentiality means that no link can be established between the collected data and the participant’s identity.) | Yes  No |
| Are there any limits to confidentiality? (select all that apply)  Limits due to the nature of the research activity (e.g., focus groups – the researcher cannot guarantee confidentiality)  Limits due to context – individual participants could be identified because of the nature or size of the sample or because of their relationship with the researcher  Limits due to selection – procedures for recruiting or selecting participants may compromise the confidentiality of participants (e.g., participants are referred to the study by someone outside the research team)  Duty to report (e.g., participant self-harm, harm to others, child or elder abuse)  Other – specify – Click or tap here to enter text.  Please describe how you will manage limits to confidentiality and ensure that this is also addressed in the informed consent.  Click or tap here to enter text. | |

**Dissemination and Future Use of Data**

|  |  |
| --- | --- |
| Is it your intention to reanalyze the data **for purposes other than described in this application**? | Yes  No |
| Have you informed your participants about future use of data collected? | Yes  No |
| Is it your intention to allow the study and data to be reanalyzed by colleagues, students, or other researchers outside of the original research purposes? If this is the case, explain how you will allow your participants the opportunity to choose to participate in a study where their data would be distributed to others (state how you will contact participants to obtain their re-consent) | Yes  No  If yes, please describe below.  Click or tap here to enter text. |
| If there are no plans to reanalyze the data for secondary purposes and, yet, you wish to keep the data indefinitely, please explain why. | Click or tap here to enter text. |
| Describe how you will disseminate the results to the participants | Click or tap here to enter text. |
| Describe how stakeholders, the public, the academic community will be informed of the results of the study. | Click or tap here to enter text. |

*Current draft uses language from MSVU Secondary Use of Data Ethics Application*