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**SECONDARY USE OF DATA AND BIOLOGICAL SAMPLES**

Office of Research – Research Ethics Unit – GM 900 – 514-848-2424 ext.  2425 – oor.ethics@concordia.ca – [www.concordia.ca/offices/oor.html](http://www.concordia.ca/offices/oor.html)

All researchers (faculty and students), as well as anyone who is part of the research team, who will be working directly or indirectly with human participants and/or data derived from human participants, will be required to complete the TCPS [CORE](https://tcps2core.ca/welcome) Certification. Once completed, please forward your certificate to oor.ethics@concordia.ca.

**IMPORTANT INFORMATION FOR ALL RESEARCHERS**

This form is to be used for projects involving the proposed secondary use of human derived data or biological samples.

Please note that if your research relies exclusively on the use of anonymous information or biological samples the REB review is not required unless the data or samples might be re-identified. Data or biological samples are considered anonymous if they never had identifiers associated with them and the risk of identification of individuals is low or very low. Note that anonymous differs from anonymized.

Definitions:

* 1. **Identifiable data:** Datathat has either direct identifiers (e.g. name, email address), or indirect identifiers (e.g. DOB, IP address, postal code, rare diagnosis) linked to it.
	2. **Coded data:** Direct identifiers will be removed and replaced with a code on the information provided. Only specific individuals on the research team will have access to the code, meaning that they can re-identify the participant if necessary. The real identity of the participant will not be revealed in disseminated results.
	3. **Anonymized data**: The data or biological sample had identifiers associated with it at the time of collection, but these identifiers were entirely removed from the data set before the data were made available to the Concordia research team. The research team will not be able to link the information provided to the participant’s real identity.
	4. **Anonymous data:** The information provided never had identifiers associated with it, and the risk of identification of individuals is low, or very low.

Only research that relies exclusively on the use of **anonymous** data is exempt from REB review.

Note: Use of **identifiable** secondary data **without consent** requires that **ALL** the following conditions are met:

* It is essential to the research that data or samples be identifiable;
* The use of identifiable information without the participants’ consent is unlikely to adversely affect the welfare of individuals to whom the information relates;
* You will take appropriate measures to protect the privacy of individuals and to safeguard the identifiable information;
* You will comply with any known preferences previously expressed by individuals about the use of their information or samples;
* it is impossible or impracticable to seek consent from individuals to whom the information relates; and
* You have obtained any other necessary permission for secondary use of information for research purposes;

The questions asked are drawn from the Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans, 2nd Edition ([TCPS2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/))

1. **BASIC INFORMATION**

**STUDY TITLE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Principal Investigator’s Status:**

[ ]  Concordia faculty

[ ]  Concordia staff

[ ]  Visiting scholar

[ ]  Affiliate researcher

[ ]  Postdoctoral fellow

[ ]  PhD Student

[ ]  Master’s student

[ ]  Undergraduate student (Honours thesis and Science College only)

[ ]  Other (please specify):

1. **STUDY TEAM AND CONTACT INFORMATION**

*Please be reminded that submissions containing attachments will only be accepted from an official Concordia email address*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Role** | **Name** | **Department** | **Phone #** | **Concordia Email Address** |
| Principal Investigator |  |  |  |  |
| Faculty Supervisor (For student research only) |  |  |  |  |

**Additional Team Members**

**Please provide the names of all team members who will be handling human derived research data or biological samples, as well as those authorized to correspond with the OOR on behalf of the PI.**

**For all external co-PIs and collaborators, please note that you must contact your respective REB to determine local requirements. Copies of alternate ethics certification will be required for full approval to be obtained at Concordia University.**

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| --- | --- | --- | --- | --- |
| **Role** | **Name** | **Department**  | **Phone #** | **e-mail address** |
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**Committee Members (For research conducted by PhD/Master students):**

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| --- | --- |
| **Committee Member** | **Department** |
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**Multi-Jurisdictional Research**

Does the research involve researchers affiliated with an institution other than Concordia? If so, please complete the following table, including the Concordia researcher’s role and description of the activities to be conducted at Concordia. If researchers have multiple institutional affiliations, please include a line for each institution.

*If applicable, please provide a copy of any additional submissions and ethics certification from the collaborating institutions.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Researcher’sName** | **Institutional Affiliation** | **Role in the research (e.g. principal investigator, co-investigator, collaborator)** | **Research activities that will be conducted at this specific institution** |
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1. **PROJECT AND FUNDING SOURCES**

Please list all sources of funds that will be used for this research. Provide the exact title of the funding source, if different from the title of this research and indicate the Principal Investigator of the award if not yourself.

Please note that fellowships or scholarships are not considered research funding for the purposes of this section

|  |  |
| --- | --- |
|  | **Award Period** |
| **Funding Source** | **Grant Holder** | **Project Title\*** | **Start Date** | **End Date** |
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Notes:

\* Please provide the project title as it appears on the Notice of Award or equivalent documentation.

† If you have applied for funding and the decision is still pending, please enter “applied”.

1. **OTHER CERTIFICATION REQUIREMENTS**

*Please include copies of all applicable certification with this application*

1. Have you completed your TCPS CORE Certification?

*Note that this is a requirement for all research involving human data or biological samples*

[ ]  No [ ]  Yes

1. Will the research take place at the PERFORM Centre?

[ ]  No [ ]  Yes

1. Does the research involve any of the following? Check all that apply:

 [ ]  Controlled goods or technology

 [ ]  Hazardous materials or explosives

 [ ]  Biohazardous materials

 [ ]  Human biological specimens

 [ ]  Radioisotopes, lasers, x-ray equipment or magnetic fields

 [ ]  Protected acts (requiring professional certification)

 [ ]  A medical intervention, healthcare intervention or invasive procedures

*Please submit any certification or authorization documents that may be relevant to ethics review for research involving human participants.*

**Do not delete, re-order, or omit any section or any of the questions under each section heading. Answer every part of each section. Forms with incomplete sections will be returned.**

1. **LAY SUMMARY**

Please provide a brief description of the research in everyday language. The summary should make sense to a person with no discipline-specific training, and it should not use overly technical terms. Please describe the project and its objectives, including any research questions to be investigated. Please also include the anticipated value or benefits to society of the research. Finally, how will results be disseminated (e.g. thesis, presentations, internet, film, publications)?

Please do not copy / paste the thesis proposal or grant application.

1. **DESCRIPTION OF THE ORIGINAL DATA OR SAMPLE COLLECTION**
2. Will you be reanalyzing a data set you collected, for purposes other than described in the original application/consent form?

[ ]  No

[ ]  Yes

Please describe:

1. Will you be reanalyzing a data set collected by someone else?

[ ]  No

[ ]  Yes

If yes, please describe who is providing the data. Provide copies of the original protocol clearance letter, contract/data sharing agreement, or permission letter/email. Attach initial consent form if available. If this information is not available, please explain. If you are obtaining data or samples from a databank or biobank, please provide the name and indicate whether it is a public or private bank.

1. What kinds of data, biological samples, or images (e.g., medical files, blood samples, school records, etc.) will be used?
2. Describe the characteristics of the participants from whom the information was originally collected.
3. What was the participants’ understanding of the primary use of the data? Is this understanding consistent with the proposed use? If not, please explain.
4. **IDENTIFIABILITY OF SECONDARY INFORMATION**
5. Was an identifier associated with the data at the time of collection?

[ ]  No

[ ]  Yes

**If you answered ‘no’, please note that REB review is NOT required for secondary use of anonymous data but is required for data which can be linked (coded data) or anonymized data. See definitions at the top of this form**

1. Under the appropriate category, please describe the specific characteristics of the data you will be receiving from the originating research team/source. Multiple categories may apply.
	1. [ ]  **Identifiable data:**
	2. [ ]  **Coded data:**
	3. [ ]  **Anonymized data:**

**If you checked only B or C above: Skip to section 10**

1. **CONSENT (Complete only if you checked A in question 7b)**

Did the participant from whom the data was originally collected express preferences about secondary use of their data?

[ ]  Yes, **skip to question 9**

[ ]  No

**If yes, provide a copy of the original consent form where these preferences where expressed. If the original consent form is not available, please explain:**

Verify that the following is true for your project and provide comments on how it applies:

* 1. Access to non-anonymous information is essential to the researcher

[ ]  No

[ ]  Yes

Describe:

* 1. The use of non-anonymous information without the participant’s consent is unlikely to adversely affect the welfare of individuals to whom the information relates.

[ ]  No

[ ]  Yes

Please describe. Could the secondary use of these data lead to any potential harm (e.g. physical, psychological, social, legal)? If yes, describe the nature of the potential harms and the measures you will take to minimize these harms.

* 1. The researchers will comply with any known preferences previously expressed by individuals about any use of their information.

[ ]  No

[ ]  Yes

Describe:

* 1. The researchers will take appropriate measures to protect the privacy of individuals, and to safeguard the identifiable information.

[ ]  No

[ ]  Yes

Describe if and how the identity of the individuals will be safeguarded:

* 1. It is impossible or impracticable to seek consent from individuals to whom the information relates.

[ ]  No

[ ]  Yes

Describe:

* 1. The researchers have obtained necessary permission for the secondary use of information for research purposes.

[ ]  No

[ ]  Yes

Describe:

**NOTE: All the above (sections 8a – 8f) must be ‘yes’ for the REB to consider approving the research without requiring consent from the individuals to whom the information relates.**

[ ]  I attest that all six criteria for consent waiver have been met

1. **DATA ACCESS**
	1. Will published data identify any study participants? [ ]  No [ ]  Yes

If yes, please explain.

* 1. Describe the measures that will be used to securely protect the secondary data/biological materials. This includes any physical measures (e.g. locked filing cabinet), and/or technical measures taken to prevent unauthorized access (e.g. encryption). Include details on short and long-term storage (format, duration, and location), who will have access, and final destination (including archiving, or destruction).
1. **ATTACHMENTS**

Documents to be submitted with this application, confirming the approval and modalities of secondary use of human derived data and/or biological samples. For each document provided, please indicate the relevant section where the approval for secondary use and its modalities are addressed:

[ ]  Sample of original consent document (see section\_\_\_) or [ ]  N/A

[ ]  Agreement/permission/REB clearance (see section\_\_\_) or [ ]  N/A

[ ]  Other, specify:

1. **DECLARATION AND SIGNATURE**

**Study Title:**

**Please complete the following:**

[ ]  I agree that this ethics application accurately describes the research project that I plan to conduct.

[ ]  I agree that no data or biological material will be received or accessed for this protocol before ethics clearance is obtained.

[ ]  No changes will be made to the research project as described in this protocol without receiving ethics clearance from the Research Ethics Board. I will submit a detailed amendment request if I wish to make modifications to this research.

[ ]  The Research Ethics Board will be notified immediately of any alleged or real ethical breaches or concerns, adverse events, or participant complaints that arise during after the course of this research project.

[ ]  An Annual Report must be submitted to the Office of Research, in the month prior to the expiration of the current certificate, in order to renew the ethics approval for an additional year.

I agree that all activities conducted in relation to the research described in this form are in compliance with all applicable laws, regulations, and guidelines, including:

* + The [*Tri Council Policy Statement: Ethical Conduct for Research Involving Humans*](https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2018.html)
	+ The policies and guidelines of the funding/award agency
	+ The [*Official Policies of Concordia University*](http://www.concordia.ca/about/policies/theme.html), including the *Policy for the Ethical Review of Research Involving Human Participants, VPRGS-3*.

### Principal Investigator Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

### Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**FACULTY SUPERVISOR STATEMENT (REQUIRED FOR STUDENT PRINCIPAL INVESTIGATORS):**

[ ]  I have read and approved this project.

[ ]  I affirm that it has received the appropriate academic approval, and that the student investigator is aware of the applicable policies and procedures governing the ethical conduct of human participant research at Concordia University. I agree to provide all necessary supervision to the student.

### Faculty Supervisor Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

### Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_