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**University Research Ethics Board (UREB)**



**REB.FORM.017 | Human Biological Materials for Research Addendum**

The UREB uses the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS2) to guide ethical review. The three core principles of the TCPS2 - **Respect for Persons, Concern for Welfare, and Justice** – must be kept in mind to ensure a balance between the protection of participants and the value of human dignity, and the legitimate requirements of research. Applying the core principles will also maintain free, informed, and ongoing consent throughout the research process and lead to sharing the benefits of the research. These results will help to build and maintain the trust of participants and the public in the research process.

For more information:

* <http://www.msvu.ca/ethics>
* <http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/>

**Notes for Researchers:**

**Human biological materials** include tissues, organs, blood, plasma, serum, DNA, RNA, proteins, cells, stem cells, skin, hair, nail clippings, urine, saliva, and other body fluids. In addition, the following materials relating to human reproduction including embryos, fetuses, and fetal tissues. For more information, please refer to Chapter 2 of the TCPS 2.

**If you are collecting human biological materials, please complete this form in full and attach as an appendix to your standard ethics application (REB.FORM.001). If you are using biological material already collected, (by you or another researcher), you may normally use the Secondary Use of Data form (REB.FORM.005) ß Please contact** **ethics@msvu.ca** **for confirmation of the required forms.**

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| Section A – Ethics File Details |
| Title of Research Study | Click or tap here to enter text. |
| Proposed Study Start Date  | Click or tap to enter a date. |
| Anticipated Study End Date | Click or tap to enter a date. |
| Principal Investigatoror Nominated Principal Investigator - see REB.INFO.001 for definitions - as per REB.FORM.001 | Click or tap here to enter text. |

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| **Section B – Biological Samples Information** |
| 1. State what type of human biological sample(s) you will be obtaining and describe the amounts of samples to be collected.
 | Click or tap here to enter text. |
| 1. Select the purpose(s) for the collection of the samples.
 | [ ]  For the purpose of this study [ ]  For genetic testing (e.g., gene identification, gene mapping, genomic analysis, DNA, RNA and/or mtDNA screening) [ ]  To be stored, retained, or banked for any future testing |
| 1. Please indicate whether the samples collected as part of this study are
 | [ ]  Mandatory[ ]  Optional[ ]  Other, please specify belowClick or tap here to enter text. |
| 1. Please specify the components that will be mandatory and/or optional and describe how the samples will be used in this study
 | Click or tap here to enter text. |
| 1. If obtained from an organization other than MSVU, has that organization granted approval for it to be used in this research? (\*Please attach a copy of that approval)
 | [ ]  Yes[ ]  No |
| 1. Does the biological material pose any biosafety hazard?
 | [ ]  Yes[ ]  NoIf yes, please indicate the protentional hazard:Click or tap here to enter text.Do all members of the research team (who will be handing the material) have the appropriate biohazard safety training? Click or tap here to enter text. |
| 1. Explain how the samples will be obtained (attach any related SOP to this document)
 | Click or tap here to enter text. |
| 1. Are there any special handling requirements of the samples?
 | Click or tap here to enter text. |
| 1. How will the sample(s) be stored?
 | Click or tap here to enter text. |
| 1. Will the samples be transported - internally or externally?
 | [ ]  Yes[ ]  NoIf yes, please provide information on how this will occur:Click or tap here to enter text. |
| 1. Please indicate where the specimens will be sent (e.g., name & address, including country) and specify if a Material Transfer Agreement (MTA) or similar contract will be used to ensure the secure transfer and storage of specimens. If there is no transfer agreement in place, explain why no
 | Click or tap here to enter text. |
| 1. How long will you retain the samples?
 | Click or tap here to enter text. |
| 1. What will happen to the samples at the end of the study (returned, stored, destroyed) and how will process this end of study event?
 | Click or tap here to enter text. |

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| **Section C – Consent, Confidentiality & Security** |
| 1. Is the donor of biological materials identifiable by the MSVU researcher?
 | [ ]  Yes[ ]  NoIf yes, please ensure that the informed consent is clear for participants/donors and that it is attached in the application package. |
| 1. Has the donor given specific consent for the sample to be used in the original research?
 | [ ]  Yes[ ]  No |
| 1. Has the donor given specific consent for the sample to be used in future research by the research team?
 | [ ]  Yes[ ]  No |
| 1. Has the donor given specific consent for the sample to be deposited into a Biobank or similar repository, and used in future research by others?
 | [ ]  Yes[ ]  No |
| 1. What information will be used on the sample’s label?
 | Click or tap here to enter text. |
| 1. If material incidental findings are likely due to the genetic testing component of the study, include your plan for disclosing/not disclosing such findings to participants

*‘Incidental findings’ is a term that describes unanticipated discoveries made in the course of research that are outside the scope of the research. Participants should be given the option to find out about any unanticipated genetic testing discoveries.* | Click or tap here to enter text. |
| 1. If biological samples will be stored, retained, or banked for any future use, specify, and describe.

Include relevant security information about how the samples will be stored (e.g., anonymized): | Click or tap here to enter text. |
| 1. If biological samples will be stored, retained, or banked for any future use, specify, and describe. \*Include relevant security information about how the samples will be stored (e.g., anonymized). Include location/address if not MSVU
 | Click or tap here to enter text. |
| 1. Who will have access to the banked samples?
 | Click or tap here to enter text. |
| 1. Describe what will happen to the specimens (e.g., destroyed, returned) at the end of the banking period or if a participant withdraws their consent:
 | Click or tap here to enter text. |
| 1. Indicate to what extent the study participant can withdraw banked specimens, and any limitations to the withdrawal
 | Click or tap here to enter text. |

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| Section D – Signature and Agreement |
| **Researcher Responsibilities:*** No research activity with human participants (recruitment or data collection) may take place prior to the PI receiving notification from the UREB that the study has been cleared by the UREB
* The researcher must ensure appropriate training for all members of the research team
* Researchers must notify the UREB when the study is complete or if the researcher wishes to place the study on hold. This is accomplished by filing REB.FORM.004 – Final Report
* All adverse events must be reported promptly to the UREB as per MSVU UREB Policies and Procedures
* All privacy breaches and/or unanticipated research events must be reported promptly to the UREB as per MSVU UREB Policies and Procedures
* All modification requests for cleared protocols must be reviewed and cleared by the UREB prior to their implementation as per MSVU UREB Policies and Procedures
* Researchers must request a renewal extension using REB.FORM.003 30 days prior to expiry
* Research studies receive research ethics clearance for an initial one-year period, at which time the researcher must close or renew the study. Renewals may, upon receipt of the appropriate application, be renewed for up to an additional 4 years, at which time, if the research is still on-going, the PI must re-apply with a new application. This re-review shall be delegated normally to the Chair or Vice-Chair
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| My/Our signature(s) below, and submission of this application, confirms that I/we will ensure that all procedures conducted as part of the project will be conducted in accordance with the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans (TCPS) found online at <http://www.pre.ethics.gc.ca/eng/index/> as well as all relevant MSVU University Research Ethics Board policies and procedures and agree to comply with the policies and procedures outlined therein. |
| Signature of Principal Investigator or Nominated Principal Investigator | Name: Click or tap here to enter text. | Date: Click or tap to enter a date. |

**Submission Process:**

1. Researchers are asked to submit this addendum electronically to ethics@msvu.ca with their standard application
2. Please note that recruitment and data collection may not begin until a certificate of Research Ethics Clearance has been issued.
3. Researchers may **only** use letters and/or numbers for file names and refrain from using any special characters (e.g., #; &; etc.).
4. All documents must be clearly labeled and reflect how they are referenced in the application.
5. Note - a **maximum of 2 attachments** are permitted for submission– the application (1) and the combined appendices (2)
6. Application packages shall only be accepted in the form of Word documents (\*.doc or \*.docx) or Portable Document Format (\*.pdf)

For details on specific submission criteria, please see [**Guidance Documents**](https://www.msvu.ca/research-at-the-mount/research-ethics/policies-procedures-guidelines/):

* REB.INFO.401 – Faculty & Staff
* REB.INFO.402 – Graduate Students
* REB.INFO.403 – Undergraduate Students

***Acknowledgement****:* The University Research Ethics Board wishes to acknowledge that we have utilized documents from Research Ethics Boards at Brock University, Queens University, and the University of British Columbia in the creation of this form and in some cases, have embedded several aspects of their ethics applications into this current UREB iteration.