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Research Ethics Board

**Request for Use of Human Tissues, Samples and/or Human Biological Materials in Research (Not for De-identified or Publicly Identified Human Somatic Cell Lines)**

Researchers planning to collect, analyze, or bank human biological materials including tissues, organs, blood, plasma, skin, serum, DNA, RNA, proteins, cells, hair, nail clippings, urine, saliva, and other body fluids, whether taken prospectively or retrospectively with regard to REB clearance, must complete this form or a Main Application form, whichever is most applicable to your project. **Note: If you are seeking exemption for the use of de-identified or publicly identifiable human somatic cell lines, please complete the “Request for Exemption for Re-Use of Deidentified or Publicly Identified Human Somatic Cell Lines in Research” form.**

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| **SECTION A – GENERAL INFORMATION** |

**Principal Investigator:**

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| Title:  | Name:  |
| Department (or organization if not affiliated with U of Windsor):  |
| Mailing address:       |
| Phone:        | Email:       |

**Co-Investigator(s):**

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| Title:  | Name:  |
| Department (or organization if not affiliated with U of Windsor):  |
| Mailing address:       |
| Phone:        | Email:       |

**Faculty Supervisor(s)/Sponsor(s):**

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| Title:        | Name:       |
| Department (or organization if not affiliated with U of Windsor):       |
| Mailing address:       |
| Phone:        | Email:       |

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| Title of the Research Project:  |

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| Anticipated Start Date: | Anticipated End Date:  |

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| **SECTION B – PROPOSED RESEARCH** |

1. In lay language (100-250 words) briefly describe the purpose and rationale (objectives) of the proposed research, including hypothesis(es) or research questions to be examined.

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1. Is this part of a larger cleared Standard Operating Procedure (SOP)? [ ] No [ ] Yes

If Yes, please provide the corresponding REB Application Number xx-xxx.

1. Is this project similar to another previously cleared REB application? [ ] No [ ] Yes

If Yes, please provide the REB Application Number xx-xxx and provide a brief description of similarities and differences.

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1. Are any of the following agreements in place? Please attach relevant documents and agreements as appendices. **Please note that agreements requiring signature(s) and/or authorization must be completed first and then submitted to the REB with this application.**

[ ]  Research Grant/Finance Grant Acct #: Click or tap here to enter text.
[ ]  Data Sharing Use Agreement (Please append)
[ ]  Material Transfer Agreement (MTA) (Please append)
[ ]  Other, please specify: Click or tap here to enter text.

1. Does the study include genetic sequencing or genetic modifications?

 [ ]  Yes [ ]  No

If Yes, please provide details:

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1. Does the research have potential for commercial use or profit? If Yes, participant ownership needs to be clarified or a disclaimer included in the consent form.

[ ]  Yes [ ]  No

1. Please indicate the type of human tissue sample or biological materials being requested.

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1. Check the source from where the biological materials or tissues are obtained. If an MTA is relevant, please attach and/or any other relevant agreements or contracts.

[ ]  Archived Fixed Tissue

[ ]  Frozen Tumor Bank.

[ ]  Autopsy

[ ]  Fresh Tissue obtained from a Surgical Specimen

[ ]  Fresh Tissue obtained from Excess Bodily Fluid (e.g.: urine, saliva etc.)

[ ]  Fresh Tissue obtained from Excess Blood Sample (e.g.: blood, plasma, or serum)

[ ]  Human DNA/RNA/proteins

[ ]  Material related to Human Reproduction (e.g.: embryos, including pluripotent or totipotent stem cell, fetuses, fetal tissue, cord blood)

[ ]  Other (e.g.: skin, hair, nail etc.) Please Specify: Click or tap here to enter text.

1. Please indicate from whom the biologic materials will be from (e.g., hospital names, commercial supplier(s) and/or site names and geographical location if outside of Canada, etc.).

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1. Research involving human pluripotent or human totipotent stem cells that have been derived from an embryonic source, and/or that will be grafted or transferred in any other form into humans or non-human animals requires review and approval by CIHR’s Stem Cell Oversight Committee (SCOC) and an REB.
2. Is this project using any stem cells as described herein? [ ]  Yes [ ]  No
3. If Yes, please append the SCOC approval. [ ]  Approval Appended

1. Does this specimen pose any potential biosafety hazards?

 [ ]  Yes [ ]  No

If Yes, please indicate potential hazards here:

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1. Will approval be sought from the Research Safety Committee?

 [ ] Yes [ ]  No

If Yes, please indicate the intended submission date: Click or tap here to enter text.

If No, or conditional approval has been given, please explain:

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1. Could there be any leftover tissue or biological material upon completion of the research?

 [ ]  Yes [ ]  No

If Yes, please describe the plan for the leftover tissue (e.g., cryopreservation and onsite retention, if so, describe the options for its future use) or its destruction:

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| **SECTION C – CONSENT AND CONFIDENTIALITY FOR SAMPLES ALREADY COLLECTED (RETROSPECTIVE)** |

1. Was direct consent obtained from the donor? If Yes, please include a copy of the consent given for the tissue/biological material to be used in research.

 [ ]  Yes [ ]  No

If No,

1. Has the donor given consent for the tissue/biological material to be used in original research?
2. Has the donor given consent for the tissue/biological material to be used in subsequent research?

Please provide any additional comments on the consent process and/or consent obtained from the donor here if relevant.

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| **SECTION D – CONSENT AND CONFIDENTIALITY FOR SAMPLES TO BE COLLECTED (PROSPECTIVE)** |

1. How many participants will be recruited? Click or tap here to enter text.
2. Please indicate who will make the initial contact with potential participants or authorized third party, whether they are already known to the participants or authorized third party, and how this contact will be made.

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1. Check the method of participant recruitment.

[ ]  Advertising (all materials require REB clearance, please append them)

[ ]  Database, please specify: Click or tap here to enter text.

[ ]  Referrals

[ ]  Subject Contact (e.g.: patients, students)

[ ]  Registration on a Public Registry (e.g.: [www.clinicaltrials.gov](http://www.clinicaltrials.gov))

[ ]  Other, please specify: Click or tap here to enter text.

[ ]  Not Applicable

1. Please describe the consent process and who will obtain consent. Please include the consent form or consent script as an appendix.

[ ]  Appendix Attached

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1. Will personal health information be collected directly from clinical charts and linked to the individual?

[ ]  Yes [ ]  No

If Yes, please indicate what information will be collected from clinical charts.

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1. Are there any conflicts of interest, either real or perceived, that could arise from the research?

[ ]  Yes [ ]  No

If Yes, append a letter to the Chair of the REB detailing these activities and how they will be managed if conflicts of interest apply to any of the investigators involved in the research study, or any member of their immediate family. Please disclose all contracts and any conflicts of interest (actual, apparent, perceived, or potential) relating to this project. Conflicts of interest may also arise with regard to the disclosure of personal health information.

[ ]  Letter Appended

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| **SECTION E – ENGAGEMENT AND CONSENT WITHIN A RECOGNIZED COMMUNITY OR POPULATION** |

1. If the research is taking place within a recognized community such as First Nations, Inuit or Metis communities or another Indigenous population, please explain how the researcher has engaged with the community and obtained consent for the collection and/or use of biological materials. If consent will not be sought, please provide a justification, and describe any alternative forms of consultation that may take place.

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| **SECTION F – POTENTIAL HARMS OR BENEFITS TO PARTICIPANTS/DONOR(S)** |

1. Is the donor of the sample still identifiable or is the tissue/biological de-identified with a unique study code identifier?

[ ]  Identifiable

[ ]  De-identified

1. Could the study results lead to a discovery of a genetic condition? [ ]  Yes [ ]  No

If Yes, is there:

[ ]  Potential benefit for individuals or community(ies)

[ ]  Potential risk for individuals or community(ies)

[ ]  No apparent benefit for the participant(s)

[ ]  Could information identify any genetic lineage not previously known?

Please provide any other relevant details if necessary:

1. Could the study results lead to a discovery of an unsuspected condition? [ ]  Yes [ ]  No

If Yes, is there:

[ ]  Potential benefit

[ ]  Potential risk

[ ]  No apparent benefit

1. Please describe how [material incidental findings](https://ethics.gc.ca/eng/documents/incidental_findings_en.pdf#:~:text=This%20guidance%20on%20how%20to%20address%20material%20incidental,for%20Research%20Involving%20Humans%20%E2%80%93%20TCPS%202%20%282018%29.) will be handled including information to the participants.

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The University of Windsor Research Ethics Board reminds researchers that if they derive genomic data from the human tissues, the data still belongs to the human participants. We encourage you to keep this in mind during your protocol application.