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Office of Research Ethics

**Request for Use of Human Tissues, Samples and/or Human Biological Materials in Research**

**General Information**

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| --- | --- | --- | --- | --- | --- |
|  | Name | Rank (EX: faculty, student etc.) | Dept./Address or Affiliation if other than U of Windsor | Phone Number | E-Mail Address |
| Principal Investigator |  |  |  |  |  |
| Co-Investigator(s) |  |  |  |  |  |
| Faculty Supervisor(s) |  |  |  |  |  |

Title of the Research Project:

Anticipated Start Date:

Anticipated End Date:

**Proposed Research**

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

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

[ ] Research Grant Agreement: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ [ ] Data Transfer Agreement: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ [ ] Material Transfer Agreement: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ [ ] Other, please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_1. Does the study include genetic research?

 If Yes, please provide details: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_1. Does the research have potential for commercial use or profit?

If Yes, the subject’s ownership needs to be disclaimed in the consent form.  | [ ] YES [ ] NO[ ] YES [ ] NO |
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1. 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 coming.

[ ] Archived Fixed Tissue

[ ] Frozen Tumor Bank.

[ ] Autopsy

[ ] Fresh Tissue obtained from a Surgical Specimen

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

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

[ ] Human DNA/RNA/proteins

[ ] Material related to Human Reproduction (EX: embryos, fetuses, fetal tissue, cord blood)

[ ] Other (EX: skin, hair, nail etc.) Please Specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Please attach the MTA if relevant.
2. Please indicate the location that the biological materials will be obtained. (EX: hospital names or geographical location if outside of Canada)

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| 1. If the specimen was obtained from an organization other than the University of Windsor, has that organization granted approval for it to be used for this research? If Yes, please attach a copy of that approval.
2. Dose this specimen pose any potential biosafety hazards?

If Yes, please indicate potential hazards here: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_1. Has approval been sought from Research Safety Committee?

If Yes, please indicate the date on which this approval was granted and the certificate number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 1. Could there be any leftover tissue or biological material upon completion of the research.

 If Yes, please provide the plan for the left over tissue or destruction. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Consent and Confidentiality for Samples Already Collected (Retrospective)**1. Is the donor identifiable by the University of Windsor researcher(s)?

If Yes, please include a copy of the consent given for the tissue/biological material to be used in subsequent research.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 tissue/biological material to be used in subsequent research?

**Consent and Confidentiality for Samples to be Collected (Prospective)** 1. How many participants will be recruited? \_\_\_\_\_\_
2. Please indicate who will make 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.
3. Check the method of participant recruitment.

[ ] Advertising (all materials require approval before use)[ ] Database, please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ] Referrals[ ] Subject contact (EX: patients, students)[ ] Registration on a Public Registry (EX: [www.clinicaltrial.gov](http://www.clinicaltrial.gov)) [ ] Other, please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ] Not applicable 1. Please describe the consent process and who will obtain consent. Please include the consent form or consent script as an appendix.
2. Will personal health information be collected directly from clinical charts and linked to the individual?

 If Yes, specify the data to be collected: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_1. Are there any conflicts of interest, either real or perceived, that could arise from the research?

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. **Potential Harms or Benefits to Participants/Donor(s)**1. Is the donor of the sample still identifiable or is the tissue de-identified with a unique study code identifier?
2. Could the study results lead to a discovery of a genetic condition?

If Yes, is there:[ ] Potential benefit[ ] Potential risk[ ] No apparent benefit for the subject?[ ] Non-paternity1. Could the study results lead to a discovery of an unsuspected condition?

If Yes, is there:[ ] Potential benefit[ ] Potential risk[ ] No apparent benefit 1. If so, please describe how materials findings will be handled including information to the participants.
 | [ ] YES [ ] NO[ ] YES [ ] NO[ ] YES [ ] NO[ ] YES [ ] NO[ ] YES [ ] NO[ ] YES [ ] NO[ ] YES [ ] NO[ ] YES [ ] NO [ ] YES [ ] NO[ ] YES [ ] NO[ ] Identifiable[ ] De-identified [ ] YES [ ] NO[ ] YES [ ] NO |

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