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Research Ethics Board

**Request for Exemption for Re-Use of Deidentified or Publicly Identified Human Somatic Cell Lines in Research**

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 a New Protocol Application form. **Note: A full application is not required if the researcher(s) are only seeking exemption from REB clearance for re-use of deidentified or publicly identified human somatic cell lines. If at any point data are identifiable outside of these terms, a New Protocol Application form is required for REB review.**

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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):**

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

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

|  |  |
| --- | --- |
| 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 (objectives) of the proposed research, including hypothesis(es) or research questions to be examined.

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1. Does the study include genetic research?

 [ ]  Yes [ ]  No

If Yes, please provide details:

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1. Please indicate the type of human tissue sample or biological materials being requested and list all cell lines here.

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1. Please indicate what location 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. If the specimen was obtained from an organization other than the University of Windsor, is there an agreement with the institution and/or supplier documenting permission for its use?

 [ ]  Yes [ ]  No

If yes, please attach a copy of that agreement.

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:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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. Is the donor identifiable by any member of the research team? [ ]  Yes [ ]  No

**Note: A ‘Yes’ response at any point throughout the project outside of the terms set out in this question means REB review is required. The only REB review exemptions permitted for re-use of identified human somatic cell lines are in cases where: a) the cell line is already available and identified in the public domain; b) it is impossible or impracticable to seek participant consent; c) the researcher will comply with known consent terms; and d) the research is unlikely to harm the participant.**

If Yes, please explain how the re-use of identified human somatic cell lines complies with the exemption specifications -or- if the re-use does not comply, please submit a New Protocol Application to the REB for review.

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If No,

1. Has the donor given consent for the tissue to be used in original research?

 [ ]  Yes [ ]  No [ ]  Unknown

1. Has the donor given consent for tissue to be used in subsequent research?

 [ ]  Yes [ ]  No [ ]  Unknown

If Yes to either a) or b) please specify the original consent parameters at the time of data collection and explain how the researcher will comply with the known consent terms.

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 If No or Unknown, to either a) or b) please explain:

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