

## Ottawa Hospital Research Ethics Boards / Conseils d'éthique en recherches

Civic Box 411 725 Parkdale Avenue, Ottawa, Ontario K1Y 4E9 613-798-5555 ext. 14902 Fax : 613-761-4311  
http://www.ohri.ca/ohreb

Title of Project:	
Principal Investigator:	
Mailing Address (Room Number):	
Telephone Number:	- - Ext.:
Fax Number:	- -
E-mail Address:	
Anticipated Start Date:	Month: Year:
Co-ordinator:	
Telephone Number:	- - Ext.:
Fax Number:	- -
E-mail Address:	
Cost Centre for billing (if available):	

**Yes No**

☐ ☐ Does your research meet the appropriate standards of scientific validity, quality and public and professional ethics

### Major Review (New Submission)

☐ I have included the **original of each document plus:**

**Included N/A**

- |                          |                          |   |
|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | 18 copies of the fully completed and signed Common Research Ethics Board (COREB) Application Form (signed by the appropriate Department/Division Heads and all Investigators). Ensure to include all applicable Appendices, including the original signature. |
| <input type="checkbox"/> | <input type="checkbox"/> | 18 copies of the Interview Procedure (if the interview process used secures identifiable personal information from the subject)   |
| <input type="checkbox"/> | <input type="checkbox"/> | 18 copies of the Patient Information Sheet and Consent Form (PISCF) on original letterhead  |
| <input type="checkbox"/> | <input type="checkbox"/> | 5 copies of the full research protocol, <i>case report forms and/or questionnaires</i>  |
| <input type="checkbox"/> | <input type="checkbox"/> | 2 copies of the Investigator's Brochure (if applicable)   |

### Major Review (Re-submission)

☐ I have included the **original of each document plus:**

**Included N/A**

- |                          |                          |   |
|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | 18 copies of the letter of recommendation, the detailed response addressing each item point-by-point, and any supporting documentation, to the concerns and questions identified by the HREB during the initial review. |
| <input type="checkbox"/> | <input type="checkbox"/> | 18 copies of the revised application (specific page ONLY), if relevant to the response  |
|                          |                          | 18 copies of the summary of changes or highlighted revisions to the protocol, if applicable. 18 good copies of the protocol if applicable.  |
| <input type="checkbox"/> | <input type="checkbox"/> | 18 highlighted copies of the revised PISCF, as well as 18 good copies of the PISCF on original letterhead   |

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### Expedited Review

☐ I have included **the original of each document plus:**

#### Included N/A

- |                          |                          |  |
|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | 2 copies of the fully completed and signed COREB Application Form (signed by the appropriate Department/Division Heads and all Investigators) Ensure to include all applicable Appendices. |
| <input type="checkbox"/> | <input type="checkbox"/> | 2 copies of the Interview Procedure (if the interview process used secures identifiable personal information from the subject)   |
| <input type="checkbox"/> | <input type="checkbox"/> | 2 copies of the PISCF on original letterhead   |
| <input type="checkbox"/> | <input type="checkbox"/> | 2 copies of the full research protocol, <i>case report forms and/or questionnaire</i>  |
| <input type="checkbox"/> | <input type="checkbox"/> | 2 copies of the Investigator's Brochure  |

### Chart Review

☐ I have included:

#### Included N/A

- |                          |                          |   |
|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | 1 original copy of the fully completed and signed Chart Review Application Form (signed by the appropriate Department/Division Heads and all Investigators) Ensure to include all applicable Appendices. This form can be found at the following website: <a href="http://www.ohri.ca/OHREB/Hi_research.htm">http://www.ohri.ca/OHREB/Hi_research.htm</a> |
| <input type="checkbox"/> | <input type="checkbox"/> | 1 copy of the full research protocol (can be a one-page document), which should include any case report forms.  |

### Fifth Annual Renewal

☐ I have included **the original of each document plus:**

#### Included N/A

- |                          |                          |  |
|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | 18 copies of the completed 'Annual Renewal Form' including a summary of the project to date which should include: any interim results; any changes in co-investigators and/or personnel; and any changes in patient risks and benefits since the first approval. 18 highlighted copies of the revised PISCF, as well as 18 good copies on original letterhead. |
|--------------------------|--------------------------|--|

### Appendices

Only appendices which are applicable to the protocol being submitted for review should be submitted.

#### Included N/A

#### APPENDICES

- |                          |                          |   |
|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | A - Request for Clinical Services for a Research Protocol (Mandatory for all protocols). Approved & signed by UOHI V-P Clinical Services  |
| <input type="checkbox"/> | <input type="checkbox"/> | B – Request for Diagnostic Services for a Research Protocol. Approved & signed by the appropriate Medical Director  |
| <input type="checkbox"/> | <input type="checkbox"/> | C – Request for Pharmacy Services for a Research Protocol. Approved & signed by the UOHI Study Pharmacist   |
| <input type="checkbox"/> | <input type="checkbox"/> | D – Request for Pathology & Laboratory Services for a Research Protocol. Approved & signed by the Director of Administration –Laboratory Medicine, Ottawa Hospital - Civic Campus |

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- |                          |                          |  |
|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | E – Request for Health Record Services for a Research Protocol. Approved & signed by the Health Data and Information Services in Health Records, Ottawa Hospital - Civic Campus.   |
| <input type="checkbox"/> | <input type="checkbox"/> | F – Request for Isotope & X-Ray Safety Committee Approval. Approved & signed by the Chair of Isotope & X-Ray Committee of the Ottawa Hospital, Civic Campus and written confirmation from the Committee is attached                |
| <input type="checkbox"/> | <input type="checkbox"/> | H – Disclosure of Financial Interests (Mandatory for all industrially sponsored projects). Signed by the Investigator  |
| <input type="checkbox"/> | <input type="checkbox"/> | I – TOH Emergency Department Impact Form for New Research Projects (if a protocol involves the use of TOH Emergency Department). Completed & signed by the Investigator & submitted it to the Ottawa Hospital Emergency Department |
| <input type="checkbox"/> | <input type="checkbox"/> | P – PET Tracers Positron Emitting Radiopharmaceuticals Committee Review. Approved and signed by the PERC Committee Chairman.   |

### **OTHER DOCUMENTATION REQUIREMENTS** The following documents should be included:

- | Yes                      | No                       |  |
|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | <b>Is Advertising for Research Subjects Required?</b><br>(Advertising should be done in English & French including questionnaires, posters, radio ads, newspapers ads, etc.) |
| <input type="checkbox"/> | <input type="checkbox"/> | <b>Is the Health Canada 'No Objections Letter' provided or forthcoming? If 'No', then:</b>   |
| <input type="checkbox"/> | <input type="checkbox"/> | <b>Is the approval from PERC provided or forthcoming?</b>  |
| <input type="checkbox"/> | <input type="checkbox"/> | <b>Is Research Budget included?</b>  |
| <input type="checkbox"/> | <input type="checkbox"/> | <b>Is Ethics Review Fee Included? (Full contact information for invoicing purposes)</b>  |
| <input type="checkbox"/> | <input type="checkbox"/> | <b>Is any Payment(s) for Research Participation made?</b>  |

### **Patient Information Sheet & Consent Form**

➤ Please use the reference tools found on the following website:  
[http://www.ohri.ca/OHREB/HI\\_research.htm](http://www.ohri.ca/OHREB/HI_research.htm).