**EXTERNAL RESEARCH ADVERTISEMENT/RECRUITMENT APPLICATION PACKAGE D**

**(Research Study Recruitment Posters, Information Letters and Advertisements)**

**Instructions for Completion and Submission:**

Application package D is to be used for **external** (research being conducted at a non-Trillium Health Partners site by an external researcher)research studies involving human participants wishing to receive authorization to recruit participants through Trillium Health Partners’ staff and/or patient population. All advertisement and recruitment documents must receive local REB approval from Trillium Health Partners’ REB prior to posting or distribution at Trillium Health Partners. The completed application, along with all required supporting documents (listed below) must be submitted to the Trillium Health Partners REB. The submission of incomplete packages may result in delays in REB review. THIS DOCUMENT MUST BE COMPLETED ELECTRONICALLY.

Please contact the REB Coordinator at THPREB@thp.ca with questions regarding the Application Submission Form or the submission process.

**Application Submission Checklist:**

One copy of each of the following Forms/Attachments is required:

[ ]  **ELECTRONICALLY COMPLETED**

* Application Form – External Research Advertisement/Recruitment
* Appendix A – Resource Impact Estimate Form (if applicable)

[ ]  Study Protocol

[ ]  REB Approval Letter from Investigator’s Site

**Advertisements or Other Recruitment Tools to be used at Trillium Health Partners**:

[ ]  Study Flyer

[ ]  Study Poster

[ ]  Study Brochure

[ ]  Study Information Letter

[ ]  Advertisements or other recruitment tools (if applicable)

Your completed application package should be submitted via email to the Trillium Health Partners Research Ethics Board THPREB@thp.ca

**APPLICATION D – External Research Advertisement/Recruitment**

## Section I: GENERAL INFORMATION

1. **Full Study Title:**
2. **Targeted Health System/SBU and/or Service/Department:**

[ ]  Cardiac [ ]  Surgery [ ]  Professional Practice

[ ]  Emergency [ ]  Diagnostics/ [ ]  Student

 Laboratory/Pharmacy

[ ]  Mental Health [ ]  Elder Health [ ]  Other:

[ ]  Women’s & Children’s [ ]  People Support [ ]  Oncology (Use OCREB

 Application)

[ ]  Neuro/MSK [ ]  Decision Support

[ ]  Medicine [ ]  Operational Support

1. **Applicant:**

a. Principal Investigator

|  |  |  |
| --- | --- | --- |
| Title:       | First Name:       | Surname:       |
| Street AddressLine 1      |
| Line 2      |
| City      | Province/State      | Postal/Zip Code      | Country      |
| Telephone      | Pager      | Email      | Fax Number      |

PI Agreement – I certify that the methods I will use to conduct this study are in compliance with the Tri-Council Policy Statement, ICH Good Clinical Practices: Consolidated Guidelines, Division 5, Canadian Food and Drug Regulations (if applicable), the Personal Health Information Protection Act, and all other applicable laws and regulations. This application contains the current and complete protocol, including any sub-studies.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:

Signature of Principal Investigator (PI)

b. Co-Investigators (please list):

1. **External Research Ethics Board review completed?**

Yes [ ]  No [ ]  Pending [ ]  Date

Contact Name and Phone Number:

**Section II: STUDY SUMMARY**

1. **Abstract:** Please provide a summary of study suitable for lay audience (approx. 100-150 words).

1. **Target participant population:**

Inpatients [ ]  Outpatients [ ]  Staff [ ]

1. **Subjects**
	1. Will this research involve any of the following?

 [ ]  women of child-bearing potential [ ]  pregnant women

 [ ]  infants/children [ ]  students

 [ ]  staff [ ]  subjects without capacity to consent

 [ ]  prisoners [ ]  patients with impaired cognition

 [ ]  emergency patients [ ]  fetal tissue or placenta

 [ ]  genetic research [ ]  tissue samples

1. **Study Interventions or Procedures**

1. **Changes/additions to usual standard of care.**

Indicate what procedures are to be carried out in the study that are NOT considered part of the diagnostic, therapeutic “routine” or standard care of the subject, or how standard care is altered.

**[ ]  Not Applicable**

1. **Usual standard of care.**

Document what is the usual standard of care at this institution for this population, as it relates to the study procedures discussed above.

**[ ]  Not Applicable**

1. **Subject Time Commitments.**

Indicate time commitment (length, number, and frequency of test sessions) or duration of visits.

**Section III: ETHICAL ISSUES**

1. **Recruitment Process**
2. How will potential subjects be identified and/or referred?

[ ]  Healthcare Professional

[ ]  Permanent Health Record/Clinical Chart

[ ]  Other Existing Database (specify):

[ ]  Advertisements, including web based recruitment tools

[ ]  Other (specify):

1. Please describe the recruitment process. Explain who will make initial contact with subjects or authorized third party and how (e.g., in person, phone, letter, e-mail/web site). Please attach a copy of the script or any written materials if applicable. If assistance is required from local staff in the recruitment process, please identify who will be involved and describe how they will be informed of their role.

|  |
| --- |
|       |

1. Have any provisions been made for patients who do not speak English? [ ]  NO [ ]  YES Describe:

1. **HEALTH SYSTEM(S) REVIEW**

The following individual(s) who have been identified as the key Trillium Health Partners system(s) clinical and administrative contacts for this study have reviewed the above study and have determined that there that there is sufficient scientific and ethical merit to the study to recommend approval of recruitment at Trillium Health Partners.

Name:       Signature ­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:

Name:       Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:

**Appendix A: RESOURCE IMPACT ESTIMATE FORM**

**This form is to be completed by the Principal Investigator with input from each Health System or department where costs may be incurred specifically due to recruitment for the research project.**

Calculate on a per patient basis.

**1. Health System/Department name:**

**2. Short title of research project/Principal Investigator Contact information:**

**3. Description of additional costs[[1]](#footnote-1)\*[[2]](#footnote-2):**

|  |  |
| --- | --- |
| **Description** | **#/patient (over/above standard of care)** |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

1. **Provide billing address:**

**6. Additional comments or concerns about the study.**

**7. Director/Manager Signature:****Date:**

**8. Health Systems Chief/Department Head Signature:****Date:**

* 1. **Principal Investigator or Designate Signature (this signature acknowledges the impact as outlined above and a commitment for provision of reimbursement to the specified HS/Dept):**

 **Signature:** **Date:**

1. \* For all Diagnostic Imaging services testing, the cost per service/test is as per OHIP guidelines. [↑](#footnote-ref-1)
2. For all Health Records service usage and Laboratory Services testing, the costs per service used are as per Trillium Health Partners’ established rates. [↑](#footnote-ref-2)