**RESEARCH APPLICATION PACKAGE C**

**Emergency Approval of Research Studies**

**Instructions for Completion and Submission:**

This package applies to research or investigations that are required, as part of a particular patient’s care, but require ethics approval before being allowed to proceed. Such categories might include: Access to research medications for rare or life threatening conditions in which there is no adequate alternative available. Please refer to packages A and B for quantitative/qualitative studies involving human participants, or epidemiological studies or retrospective data analysis, respectively.

Submit the completed application, along with all required supporting documents (listed below) to the Trillium Health Partners REB. Complete applications will be reviewed by two members of the Research Ethics Board. Following approval of this emergency application, a complete Application A must be submitted for any further Trillium patients to be enrolled.

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

**Notification of Privacy Breaches:**

If during the course of the study, the Sponsor(s), Principal Investigator, Co-investigator(s) or study co-ordinator(s) become aware that the privacy of study subjects has been breached, please contact the Chair of the Research Ethics Board. The Chair will address the incident in keeping with Trillium Health Partners’ *Incident Reporting and Management* protocol.

**Application Submission Checklist:**

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

[ ]  Completed typed application form – Attach:

* Appendix A – Resource Impact Estimate Form
* Appendix B if there is **no** contract – Sponsor Certification
* Appendix C if there **is** a contract – Investigator Certification

[ ]  The full study protocol

[ ]  Sponsoring company investigator brochure (where relevant)

[ ]  Health Canada CTA number and no-objection letter (if applicable and available)

[ ]  All questionnaire(s)/study instruments(s) to be used in this study

[ ]  Sample Consent Form(s)/Assent Form(s)

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

**APPLICATION C - Emergency Approval of Research Studies**

## Section I: GENERAL INFORMATION

1. **Full Study Title:**
2. **Participating 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.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Principle Investigator (PI) Date

b. Co-Investigators (please list):

c. Clinical Trials Nurse/Study Coordinator (if applicable):

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

d. Trillium Health Partners Contact:

1. **Sponsor:**

a. Sponsor Protocol # and Version Date:

1. **Expected start date:** **Expected completion date:**
2. **Scientific Peer Review/External Ethics completed?**

Yes [ ]  No [ ]  Pending [ ]  Date \_\_\_\_\_\_\_\_\_\_\_\_ Not Planned [ ]

Contact Name and Phone Number:

1. **Patient involved:** Inpatient [ ]  Outpatient [ ]

## Section II: STUDY SUMMARY

1. **Abstract:** Summarize the goals and expected benefits for the patient on this study; including why this study is necessary for this patient. Maximum 100 words. Please note that this abstract may be used to generate reports, which may be disseminated to various stakeholders.

**Section III: ETHICAL ISSUES**

1. **Recruitment and Consent**

# Note: An information and consent form on institutional letterhead must be included with the application. Please refer to the *Guidelines for Research Project Consent Documents* for more detailed instructions.

1. Describe the consent process. (E.g., Will consent be written and who will obtain consent.)*If the patient requires special consent considerations (e.g. child, incompetent adult, unable to communicate) you may refer to item d. of this section.*

|  |
| --- |
|       |

1. How much time will be given to subjects to review the information before being asked to give consent?

|  |
| --- |
|       |

1. Is there a relationship between the subjects and:

 **Person obtaining consent** [ ]  YES [ ]  NO

 **Investigator**  [ ]  YES [ ]  NO

 If YES, explain the nature of the relationship (e.g, physician, employer) and what steps will be taken to minimize a potential perception of coercion.

|  |
| --- |
|       |

1. Have any provisions been made if this patient does not speak English?

[ ]  NO [ ]  YES Describe:

1. What procedures will be followed if the patient wishes to withdraw at any point

during or after the study (provide protocol page reference)?

1. **Risk/Benefit Estimates**
2. Document the risks to the patient involved in this research.

[ ]  NO known other risks

Risks

1. Does participation in this study affect alternatives for future care?

[ ]  YES [ ]  NO

If YES, please explain.

1. Might potentially hazardous duties be required of research personnel beyond the risks encountered in their normal work routine?

[ ]  YES [ ]  NO

If YES, please describe.

**15. Protection of Personal Health Information (Principle Investigator)**

1. Accountability
2. Please describe how you ensure that all of your staff and agents are appropriately informed of their duties regarding protection of the study subject’s personal health information.

1. Please describe how you protect personal health information that is disclosed to a third party (other than the sponsor).

[ ]  Not applicable

1. Collection and use of the study subject’s personal health information

The sponsor’s informed consent form describes what personal health information is being collected, and how it will be used by the sponsor. The form also provides the study subject with the ability to opt out of secondary uses and still participate in the study.

1. Please indicate if you will be using the personal health information for reasons other than conducting the study on behalf of the sponsor (secondary uses).

 [ ]  YES [ ]  NO

1. If yes, please describe the secondary uses, any reasonably foreseeable harms and benefits that could arise from the use of the information, and how you intend to address the harms. Note that consent is required for secondary uses (refer to section D).

1. Access to and Disclosure of the study subject’s personal health information

Please list the name, affiliation, roles and qualifications of everyone working on the research and accessing the study subject’s personal health information.

Please state justification for disclosing the participant’s study record to these persons.

Please indicate if you will be disclosing the study subject’s personal health information to anyone other than those listed above, and why.

[ ]  Not applicable

1. Consent to collection, use and disclosure of the study subject’s personal health information

The informed consent form is the mechanism by which the sponsor obtains permission to collect, use or disclose a study subject’s personal health information.

* + - 1. You collect a study subject’s personal health information on behalf of the sponsor. If you are going to use or disclose the information for reasons other than the study (secondary uses), you must provide the study subject with the ability to accept or refuse the secondary uses and still participate in the study. Please describe how permission was/will be obtained.

 [ ]  Not applicable

* + - 1. Explain how you will address withdrawal of the study subject’s consent to secondary uses.

 [ ]  Not applicable

1. Retention, accuracy, safeguards to protect confidentiality and security, and disposal of the study subject’s personal health information
	1. Will you be storing the study subject’s personal health information?

 [ ]  YES [ ]  NO

* 1. How long will you be storing the study subject’s personal health information?

* 1. You must contact the hospital if a study subject’s personal health information is lost, stolen or accessed in an unauthorized manner. You must not contact the study subject directly.
1. Indicate how the study subject’s personal health information will be stored:

[ ]  Electronic (computerized files)

[ ]  Physical (hard copy, audio recordings, video tape, other – please

 specify)

1. Regarding electronic storage, please describe how you safeguard the confidentiality and security of the information (e.g. type of identifiers, methods to anonymize the data, access controls, whether the database resides on a computer that also has internet service, and in such an instance whether you have installed software to prevent hacking and cookies such as spyware)

1. Regarding physical storage, please describe how you safeguard the confidentiality and security of the information.
|

1. Will a study subject’s personal health information be transferred electronically?

[ ]  YES [ ]  NO

If yes, by what medium, and how do you safeguard the confidentiality and security of the information that is being transferred (e.g. CD’s or floppy discs protected by passwords, encryption)?

* 1. How will you dispose of the study subject’s personal health information at the end of the study?

* 1. In the event of unanticipated harms or benefits identified through the sponsor’s ‘use’ of the study subject’s personal health information for future studies, will you be involved in ‘track-back’?

 [ ]  YES [ ]  NO

* 1. If yes, in the context of storage and disposal, how will you address ‘track-back’?

1. **Payments to Subjects**

Please describe any payments planned to be provided to the patient (e.g. travel, parking, time for the study) and include amount if applicable.

1. **Monitoring**
2. Is there a steering committee?

[ ]  YES [ ]  NO [ ]  Not applicable

1. Is there a plan for monitoring of the study (eg. sponsor-initiated site visits)?

[ ]  YES [ ]  NO [ ]  Not applicable

If YES, please describe.

1. Is an interim analysis planned?

[ ]  YES [ ]  NO

If YES, please describe briefly.

1. Is there a data safety monitoring board (DSMB).

[ ]  YES [ ]  NO

If YES, is it independent of the sponsor?

[ ]  YES [ ]  NO

1. **Continuing Review**

Indicate the suggested level of continuing review required for this study (check all that apply):

[ ]  Annual renewal

[ ]  More frequent renewal; indicate interval in months

[ ]  Other (eg. audit, observation of consent process, interview with participants)

 Please specify:

1. **Conflict of Interest**

Are you aware of any actual or apparent Conflict of Interest\* for any Investigators or Co-investigators involved in this research study or any member of their immediate family?

[ ]  YES [ ]  NO

If YES, please append a letter detailing these activities to Trillium Health Partners REB. Please disclose any conflicts of interest (actual, apparent, perceived, or potential) relating to this project.

\*Examples of activities that may be a conflict of interest include:

* Functioning as an advisor, employee, officer, director, or consultant for the study sponsor?
* Having direct or indirect financial interest in the drug, device, or technology employed (including patents or stocks) in this research study?
* Receiving an honorarium or other personal benefits from the sponsor (apart from fees for service)?
* Receiving payment for each subject enrolled or a recruitment bonus, e.g. for meeting enrolment targets?
1. **Publication/Dissemination of Results**

How will the results be communicated to participants and other stakeholders (eg. advocacy groups, scientific community)?

Check all that apply:

[ ]  Individual debriefing at end [ ]  Publication (eg. journal article,

 of test session presentation)

[ ]  Group debriefing [ ]  No plan

[ ]  Letter of Appreciation at [ ]  Other (please specify):

 end of study

**Section IV: RESOURCE IMPACT AND CONTRACTS**

# FUNDING

**[ ]  No Funding Required (explain)**

**[ ]  Funding Required**

Source:

[ ]  Obtained [ ] Applied for (expected date of decision):

*Do the funds presently available or applied for cover all requirements to conduct the project?*

*[ ]  YES [ ]  NO*

If NO, please explain how the shortfall will be made up:

**IMPACT ON TRILLIUM HEALTH PARTNERS:**

*Trillium Health Partners is not a funded academic research centre. We must ensure that participation in research projects does not decrease funding available for our primary focus of provision of patient care. The investigator is expected to work with the hospital to develop a plan to address additional costs that can be attributed to the study. Costs are reviewed annually and the funding plan may be adjusted annually.*

**Please Note: It is the Investigators responsibility to ensure that there is a mechanism in place to capture and cover these costs on a continuous basis.**

Identify the services that will be impacted by this research project. Provide the name of the nursing unit if the patient will be admitted. A completed & signed Study Cost Estimate Form for each impacted area must be attached at the time of application.

[ ]  Diagnostic Imaging [ ]  Administrative, e.g. contract review

[ ]  Laboratory [ ]  Nutrition and Food Services

[ ]  Health Records [ ]  Emergency Department

[ ]  Pharmacy [ ]  Other

[ ]  Nursing unit(s)

1. **DIAGNOSTIC UTILIZATION**

a. Please identify the type and frequency of Radiologic tests that will be required:

 CT: No [ ]  Yes [ ]  Frequency

 MRI: No [ ]  Yes [ ]  Frequency

 US: No [ ]  Yes [ ]  Frequency

 Nuclear Medicine: No [ ]  Yes [ ]  Frequency

 General Radiography: No [ ]  Yes [ ]  Frequency

b. Will you require access to patient films? No [ ]  Yes [ ]

c. Will you require access to films done five years ago? No [ ]  Yes [ ]

d. Will the films be taken outside Diagnostic Imaging? No [ ]  Yes [ ]

e. Will Diagnostic Imaging be requested to track test completion for your

 patients? No [ ]  Yes [ ]

f. Will a written report be required for a referring physician and the

 research investigator? No [ ]  Yes [ ]

g. Will you require direct consultation with the Radiologist? No [ ]  Yes [ ]

1. **LABORATORY UTILIZATION:**

a. Does the research project involve additional laboratory testing over and above the current routine for this type of disorder/drug/patient? Yes [ ]  No [ ]

b. If yes, indicate the type and the projected volume of the additional

 test(s).

1. **HEALTH RECORDS UTILIZATION**

a. Will you require access to patient files through the Health Records Department?

 Yes [ ]  No [ ]

b. Will you require access to nursing notes or medication administration records through the Health Records Department? Yes [ ]  No [ ]

c. If you require access to the same files more than once please include an estimate the

 total number of files.

d. Will you need help to identify your research population? Yes [ ]  No [ ]

e. Will you require statistics from Health Records for your project? Yes [ ]  No [ ]

1. **PHARMACY UTILIZATION**

a. Indicate what additional expenses or cost-avoidance for medication/drugs might occur as a result of the patient being involved in the study as compared with the normal protocol of care.

b. Does the research project involve any additional workload, e.g. processing of unusual orders, inclusion on MAR, over and above the current routine for this type of disorder/drug/patient?

1. **NURSING UNITS**

a. Does the research project involve any additional workload to nursing care, over and above the current routine for this type of disorder/drug/patient, e.g. staff education, decision process for clinical interventions?

1. **OTHER**

Please describe the workload implications for all other services checked off in the top section of this question:

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

The following individuals 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 are sufficient methods in place to protect the personal health information associated with the study subject and have determined that there is sufficient scientific and ethical merit to the study to recommend approval:

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

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

**ENSURE THAT A RESOURCE IMPACT ESTIMATE FORM (Appendix A) IS ATTACHED FOR EACH IMPACTED DEPARTMENT.**

1. **CONTRACT**

**Is there a contract involved for this study?**

[ ]  YES [ ]  NO

**If YES, attach the contract.**

* **Attach Appendix C**
* **Name of sponsor(s)/agencies on contract:**

If **NO** contract involved:

* Do not complete the remainder of this section
* Attach Appendix B and C

 **If YES:**

* + 1. **Name of sponsor(s)/agencies on contract:**

* + 1. **Liability Insurance:**

Is there liability insurance?

[ ]  YES [ ]  NO

* + 1. If the subject suffers an injury as a result of participation in the study, who will cover reasonable out-of pocket expenses to ensure that immediate medical care is provided?

[ ]  Sponsor [ ]  Institution

[ ]  Other (Please specify):

**C. Publication Agreements:**

i. Is there an agreement between the investigator and the sponsor regarding use, publication or disposal of the data?

[ ]  YES [ ]  NO

If YES, does the funding agency or sponsoring company place any restrictions on publication of findings or reporting of interim results?

### [ ]  YES [ ]  NO

If YES, explain any restrictions.

ii. Does the contract permit the disclosure of research results, including SAEs, to stakeholders (subject and/or guardian, sponsor, REB, REBs of other sites, and regulatory agencies) if required to protect the health of subjects?

[ ]  YES [ ]  NO

**D. Does the funding agency or sponsoring company place any restrictions on publication of findings or reporting of interim results?**

**[ ]  YES [ ]  NO**

 If YES, indicate and explain any restrictions.

**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 the research project. Only additional costs should be calculated i.e., costs that are not part of the regular component of care provided by your department for patients of a similar diagnosis.**

Calculate on a per patient basis.

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

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

**3. Definition of the typical use of service your department provides for patients with the same diagnosis outside the research project.**

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

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

**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:**

**Appendix B: SPONSOR CERTIFICATION (to be signed if there is *no* Contract)**

I certify that:

1. No study records that contain personal health information will be disclosed to any organizations/countries that do not subscribe to ICH GCP.
2. The methods I/we 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.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Sponsor Date

**Appendix C: INVESTIGATOR CERTIFICATION**

I acknowledge that I am a Health Information Custodian as defined in the Personal Health Information Protection Act.

I certify that:

1. No study records that contain personal health information will be disclosed to any organizations/countries that do not subscribe to ICH GCP.
2. The methods I/we 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.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Principle Investigator (PI) Date

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Co-Investigator(s) 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 all Laboratory Services testing, the costs per service used are as per Trillium Health Partners established rates. [↑](#footnote-ref-2)