**RESEARCH APPLICATION PACKAGE A**

**Qualitative/Quantitative Studies involving Human Participants**

**Instructions for Completion and Submission:**

Application package A is to be used for **new** studies involving human participants. Please refer to packages B and C for epidemiological studies or retrospective data analysis, and emergency approvals, respectively. Submit the completed application, along with all required supporting documents (listed below) to the Trillium Health Partners REB. Complete applications received by the 1st weekday of the month will be reviewed at the Research Ethics Board meeting held on the 3rd Thursday of that month. 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](mailto: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:

**ELECTRONICALLY COMPLETED** application form and:

* 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

Itemized Study Budget

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

Advertisements or other recruitment tools (if applicable)

Any other documents that will be given to subjects

Your completed application package should be submitted via email to the Trillium Health Partners Research Ethics Board [THPREB@thp.ca](mailto:THPREB@thp.ca)

**APPLICATION A – Qualitative/Quantitative Studies involving Human Participants**

## 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 Address  Line 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):

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

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

d. Trillium Health Partners Contact (if Investigator and Coordinator are external applicants):

1. **Sponsor:**

a. Sponsor Protocol # and Version Date:

1. **Scientific Peer Review/External Ethics completed?**

Yes  No  Pending  Date       Not Planned

Contact Name and Phone Number:

1. **Study Period:**

Expected Start Date

Anticipated Total Study Duration

1. **Total volume of patients/participants from Trillium Health Partners anticipated to be part of this study:**

Inpatients  Outpatients  Staff

## Section II: STUDY SUMMARY

NOTE: THIS IS NOT A SUBSTITUTE FOR THE FULL PROPOSAL.

1. **Abstract:** Must be a summary of study **suitable for lay audience**; maximum 100 words. Please note that this abstract may be used to generate reports, which may be disseminated to various stakeholders.
2. **Rationale and Hypothesis/Research Question:**

1. **Study Design: If any of the items are not applicable to your study, please indicate N/A.**
2. Design/Methodology

i. Is this a Clinical Trial (define)?

Yes  No

If YES, indicate phase:

Pilot  Phase I  Phase II  Phase III  Phase IV

Indicate Design (check all that apply):

Randomized  Double Blind  Single Blind  Open Label

Placebo Controlled  Active Comparator

ii. Study Classification (check all that apply):

Diagnostic

Imaging  Lab Study  Medical Device  Other:

Intervention/Treatment

Chemotherapy  Radiotherapy  Surgery

Medical Device

Multi-modal (explain):

Tissue

Lab Study  Imaging  Tissue Bank

Genetics

Qualitative (describe how data will be collected, eg. semi-structured

interviews):

Other (describe):

W

* + 1. What are the primary outcome measures? ):

Not Applicable

* + 1. Briefly explain how data will be analyzed.
    2. List any criteria for premature withdrawal of a subject from the study for safety concerns.         
         
        Not Applicable
    3. If a placebo is used in this study please explain how this is justified (e.g., no alternative standard treatment available). Include any provisions in place to reduce risks to subjects assigned to placebo (e.g., increased monitoring, rescue medication).

Not Applicable

* + 1. Will subjects be withdrawn from or denied usual therapy for any condition or be subject to other restrictions in order to participate in the study?

YES  NO

If YES, explain.

* + 1. If this study involves a new drug, are their provisions for it to be made available to the study population once the study is complete, should efficacy be established?

1. **Subjects/Controls**
   1. How will subjects be chosen (main inclusion/exclusion criteria)?

If applicable, how was the proposed control group selected? If applicable, how will subjects be assigned to the study arms?

i. What is the age range of eligible subjects?

ii. Does the study population have any requirements based on language, ability, capacity or other diverse needs, and if so, how will these be accommodated or addressed?

* 1. Total study enrollment:

Approximate number to be enrolled at each study site:

* 1. What is rationale for sample size? (refer to protocol page #)
  2. 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 Involving Human Subjects**

Not Applicable (e.g. qualitative studies).

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 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. 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. 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.

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|  |

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

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

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1. Is there a relationship between the subjects and:
2. **Person obtaining consent**  YES  NO
3. **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.

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|  |

1. Have any provisions been made for patients who do not speak English?  NO  YES Describe:
2. What procedures will be followed for subjects who wish to withdraw at any point during or after the study (provide protocol page reference)?
3. **Risk/Benefit Estimates**
4. Document the risks to subjects involved in this research. Do not include risks of non-research related procedures (eg. routine scans, blood work).

NO known other risks

1. For studies involving placebo, washout or withholding of treatment, indicate risks related to absence of treatment.

Not applicable  
  
Risks

1. Is enrollment in multiple studies likely to be an issue in this subject population?

YES  NO

If YES, please indicate how this will be addressed.

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 (Principal 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**

Have specific funds been provided in the budget for payments or gifts to subjects, e.g. travel, parking, time spent, etc.?

YES  NO

If YES, please describe 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[[1]](#footnote-1) 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.

1. **Publication/Dissemination of Results**
2. 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

1. Is this clinical trial fully registered with a registry that meets the International Committee of Medical Journal Editors (ICMJE) standards?  YES  NO

If yes, indicate the registry name and registration identifier number and provide a copy of the entire Protocol Record from the registry.

**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**
2. 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

1. Will you require access to patient films? No  Yes
2. Will you require access to films done five years ago? No  Yes
3. Will the films be taken outside Diagnostic Imaging? No  Yes
4. Will Diagnostic Imaging be requested to track test completion for your patients? No  Yes
5. Will a written report be required for a referring physician and the research investigator?

No  Yes

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

1. **LABORATORY UTILIZATION:**
2. Does the research project involve additional laboratory testing over and above the current routine for this type of disorder/drug/patient? Yes  No
3. If yes, indicate the type and the projected volume of the additional test(s).

1. **HEALTH RECORDS UTILIZATION**
2. Will you require access to patient files through the Health Records Department? Yes  No
3. Will you require access to nursing notes or medication administration records through the Health Records Department? Yes  No
4. If you require access to the same files more than once please include an estimate the total number of files.
5. Will you need help to identify your research population? Yes  No
6. Will you require statistics from Health Records for your project? Yes  No
7. **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**

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, indicate and 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

**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 and 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[[2]](#footnote-2)\*[[3]](#footnote-3):**

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

**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.

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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.

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Signature of Principal Investigator (PI) Date

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Signature of Co-Investigator(s) Date

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Signature of Co-Investigator(s) Date

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Signature of Co-Investigator(s) Date

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Signature of Co-Investigator(s) Date

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Signature of Co-Investigator(s) Date

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Signature of Co-Investigator(s) Date

1. 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?

   [↑](#footnote-ref-1)
2. \* For all Diagnostic Imaging services testing, the cost per service/test is as per OHIP guidelines. [↑](#footnote-ref-2)
3. 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-3)