  

# TRI-HOSPITAL RESEARCH ETHICS BOARD (THREB)

## Application – Part 3

### ADMINISTRATIVE/INSTITUTIONAL APPROVAL OF RESEARCH PROJECT

(Projects must receive separate approval from each institution involved.)

 **Project #** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 (will be assigned by THREB)

**1. Local Responsible Investigator** (max 100 characters)**:**

|  |
| --- |
|       |

**2. Principal Investigator** if different from local investigator(max 100 characters)**:**

|  |
| --- |
|       |

**3. Project title** (max 400 characters)**:**

|  |
| --- |
|       |

**4. Executive Summary**

 a. Research Question (max 350 characters):

|  |
| --- |
|            |

 b. Setting (Where will the study take place?):

**[ ]** Cambridge Memorial Hospital

 [ ] Grand River Hospital

 [ ] Grand River Regional Cancer Centre

 [ ] St. Mary’s General Hospital

 [ ] Community – specify

 [ ] Other – specify:

 c. Identify any staff involvement (max 250 characters):

|  |
| --- |
|       |

 d. Interventions involved including diagnostic and labwork:

 Are any interventions non-standard? [ ] Yes [ ] No If “yes” which (max 250 characters) ?

|  |
| --- |
|       |

 e. Expected number of participants:

 f. Will access to personal health information (e.g. charts) be required? [ ] Yes [ ] No

 g. Resource Utilization Form (attached) is submitted: [ ] Yes [ ] No

**5. Contract**

Is there a contract involved? [ ] Yes [ ] No

 If “yes,” has the contract been submitted to the institution? [ ]  Yes [ ]  No

**NOTE**: If there is a contract, authorization to begin a study will require a completed contract approved by the institution.)

**6. ADMINISTRATIVE APPROVAL**

I have reviewed the attached protocol and confirm that resource and contract issues at this institution have been or are being satisfactorily addressed and I give administrative approval for the THREB review of this project.

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

 (Signature)

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

 (Print name) (Date)

 Institution\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# CMH_K_3

For CMH: Sandra Hett 519-621-2333 x2416

For GRH: Tina Mah 519-749-4300 x4243

For SMGH: Diane Wilkinson 519-749-6403

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**RESOURCES UTILIZATION TEMPLATE PAGE FOR**

### THREB Associated Hospitals

**NOTE: This Resource Utilization Template is only a reference model and will be adapted in different ways by each of the three hospitals. Contact the person responsible for administrative approval to clarify the approval process in a particular hospital.**

**THREB itself requires only the signed Administrative Approval page and the budget.**

**Requirements:**

* It is the responsibility of the applicant to ensure that all areas from which resources will be required have been consulted and have indicated agreement by signing this form.
* Approval of the project is conditional upon satisfactory completion of this section.
* A separate resources form must be filled in for each institution in which the research will be conducted.
* If a required area has not been consulted and approval received, the application may be returned for completion.

**Institutional Services, Staff or Equipment:**

* If your participant will be admitted to hospital and/or will require any hospital services, as a requirement of this study, which are over and above standard treatment, you **must** obtain appropriate signatures.
* If the study involves more than one unit or service in the hospital, signatures **must** be obtained from all areas involved.
* In all cases, budgets should cover institutional costs and overhead if required, unless otherwise agreed upon by the appropriate Administrator.

**Health Records/Health Information/Decision Support Services:**

1. Will you require **Health Records/Information** to pull charts for you? [ ]  YES [ ]  NO

2. Will you require **Decision Support** Services to identify your research population? [ ]  YES [ ]  NO

3. Do you require patient specific data from **Decision Support** to support your project? [ ]  YES [ ]  NO

4. Do you require summary cost data to support your project? [ ]  YES [ ]  NO

5. If **YES** to any of 1 to 4 above, have you allowed for these services in the budget? [ ]  YES [ ]  NO

**CHECK AREAS BELOW WHERE RESOURCES ARE REQUIRED (✓)**

 **Type Name of Authorized Signature:**

 **Official OR Designate**

**1.** **[ ]  Health Information/Records**       \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name Signature

**2.** **[ ]  Laboratory Services** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Name Signature

**3.** **[ ]  Medication/Drugs**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(*Pharmacy)* Name Signature

**4.** **[ ]  Radiology/Diagnostic/Medical**

 **Imaging Resources**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Name Signature

**5.** **[ ]  Nuclear Medicine**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 **Resources** Name Signature

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**6.** **[ ]**  **Radiation Safety**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Name Signature

**7.** **[ ]  Other** (*please specify)*

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

 Name Signature

**Approvals are required from individuals responsible for nursing and clinical care of each patient area to be utilized**

**8.** **[ ]  Inpatient Area(s):**

*(Specify area(s) and provide signature(s) as applicable)*

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

 Area 1 Name Signature

 Nurse Manager/Clinical Director

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

 Area 2 Name Signature

 Nurse Manager/Clinical Director

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

 Area 3 Name Signature

 Nurse Manager/Clinical Director

**9.** **[ ]  Outpatient Area(s):**

 *(Specify area(s) and provide signature(s) as applicable)*

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

 Area 1 Name Signature

 Nurse Manager/Clinical Director

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

 Area 2 Name Signature

 Title\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

 Area 3 Name Signature

 Title\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

 **Local Responsible Investigator Date**

**RESEARCH ETHICS BOARD**

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**BUDGET TEMPLATE**

**Study title:****Project #:**

**Estimated Itemized Cost Per Participant**

 # Visits x Cost = Total

**History & Physical** (or other       =

 remuneration to investigators)

**Imaging:** X-rays       x       =

 Ultrasound       x       =

 Bone Scans       x       =

 CT Scans       x       =

 MRI       x       =

 Other (specify)       x       =

**Lab Work:**

 Haematology       x       =

 Chemistry       x       =

 Urinalysis       x       =

 Pathology       x       =

Other (specify)       x       =

**ECG**       x       =

**Pharmacy**       x       =

**Reimbursements and**

**other payments to Participants**       x       =

 **Total Cost Per Participant** =       (a)

 **Total Participant Costs:** \_\_\_\_\_ **Participants x** (a) =       (b)

**Personnel Costs**

1. Nurse/Coordinator @ $/hr x hrs/pt x n pts =

2. Nurse/Coordinator @ $/hr x hrs/pt x n pts =

3. Nurse/Coordinator @ $/hr x hrs/pt x n pts =

 **Total Personnel:** =       (c)

**Equipment Costs**

Specify equipment =

 **Total Equipment:** =       (d)

**Administrative Costs**

Administrative (Meetings, telephone, stationery, etc.) =

 **Total Administrative Costs:** =       (e)

**Industry-Sponsored Studies**

**Overhead** for Industry-Sponsored Studies =

**REB Admin Fee** for Industry-Sponsored Studies ($3000) =

 Total Indirect Costs: =       (f)

 Total Cost for Complete Study: =       (b+c+d+e+f)

*N.B. If your budget is reported as cost/patient enrolled, be sure to provide a detailed justification of what is included in the cost/patient (i.e. how many hours of nursing time, etc.).*

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