



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):

[Empty text box for Local Responsible Investigator]

2. Project title (max 400 characters):

[Empty text box for Project title]

3. Executive Summary

a. Research Question (max 350 characters):

[Empty text box for Research Question]

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

- Cambridge Memorial Hospital
Grand River Hospital
St. Mary's General Hospital
Community - specify:
Other - specify:

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

[Empty text box for staff involvement]

d. Interventions involved including diagnostic and labwork:

Are any interventions non-standard? Yes No If "yes" which (max 250 characters) ?

[Empty text box for interventions]

e. Expected number of patients: []

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

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

4. 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.)

5. 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.

Contact information for CMH, GRH, and SMGH.

Signature and Print name lines.

RESOURCES UTILIZATION TEMPLATE PAGE FOR THREB Associated Hospitals

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? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| 2. | Will you require Decision Support Services to identify your research population? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| 3. | Do you require patient specific data from Decision Support to support your project? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| 4. | Do you require summary cost data to support your project? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| 5. | If YES to any of 1 to 4 above, have you allowed for these services in the budget? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |

CHECK AREAS BELOW WHERE RESOURCES ARE REQUIRED (✓)

		<u>Type Name of Authorized Official OR Designate</u>	Signature:
1.	<input type="checkbox"/> Health Information/Records	<input style="width: 40px; height: 15px;" type="text"/> Name	_____ Signature
2.	<input type="checkbox"/> Laboratory Services	<input style="width: 40px; height: 15px;" type="text"/> Name	_____ Signature
3.	<input type="checkbox"/> Medication/Drugs <i>(Pharmacy)</i>	<input style="width: 40px; height: 15px;" type="text"/> Name	_____ Signature
4.	<input type="checkbox"/> Radiology/Diagnostic/Medical Imaging Resources	<input style="width: 40px; height: 15px;" type="text"/> Name	_____ Signature
5.	<input type="checkbox"/> Nuclear Medicine Resources	<input style="width: 40px; height: 15px;" type="text"/> Name	_____ Signature
6.	<input type="checkbox"/> Radiation Safety	<input style="width: 40px; height: 15px;" type="text"/>	_____

7. **Other** (please specify) _____ Name _____ Signature _____
 _____ 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
BUDGET TEMPLATE**

Study title:

Project #:

Estimated Itemized Cost Per Participant

	<u># Visits</u>	<u>x</u>	<u>Cost</u>	<u>=</u>	<u>Total</u>
History & Physical (or other remuneration to investigators)			<input type="text"/>	=	<input type="text"/>
Imaging:					
X-rays	<input type="text"/>	x	<input type="text"/>	=	<input type="text"/>
Ultrasound	<input type="text"/>	x	<input type="text"/>	=	<input type="text"/>
Bone Scans	<input type="text"/>	x	<input type="text"/>	=	<input type="text"/>
CT Scans	<input type="text"/>	x	<input type="text"/>	=	<input type="text"/>
MRI	<input type="text"/>	x	<input type="text"/>	=	<input type="text"/>
Other (specify)	<input type="text"/>	x	<input type="text"/>	=	<input type="text"/>
Lab Work:					
Haematology	<input type="text"/>	x	<input type="text"/>	=	<input type="text"/>
Chemistry	<input type="text"/>	x	<input type="text"/>	=	<input type="text"/>
Urinalysis	<input type="text"/>	x	<input type="text"/>	=	<input type="text"/>
Pathology	<input type="text"/>	x	<input type="text"/>	=	<input type="text"/>
Other (specify)	<input type="text"/>	x	<input type="text"/>	=	<input type="text"/>
ECG	<input type="text"/>	x	<input type="text"/>	=	<input type="text"/>
Pharmacy	<input type="text"/>	x	<input type="text"/>	=	<input type="text"/>
Reimbursements and other payments to Participants	<input type="text"/>	x	<input type="text"/>	=	<input type="text"/>
Total Cost Per Participant				=	<input type="text"/> (a)
Total Participant Costs:	_____	Participants x	(a)	=	<input type="text"/> (b)
<u>Personnel Costs</u>					
1. Nurse/Coordinator @ \$/hr x hrs/pt x n pts				=	<input type="text"/>
2. Nurse/Coordinator @ \$/hr x hrs/pt x n pts				=	<input type="text"/>
3. Nurse/Coordinator @ \$/hr x hrs/pt x n pts				=	<input type="text"/>
Total Personnel:				=	<input type="text"/> (c)
<u>Equipment Costs</u>					
Specify equipment				=	<input type="text"/>
Total Equipment:				=	<input type="text"/> (d)
<u>Administrative Costs</u>					
Administrative (Meetings, telephone, stationery, etc.)				=	<input type="text"/>
Total Administrative Costs:				=	<input type="text"/> (e)
<u>Industry-Sponsored Studies</u>					
Overhead for Industry-Sponsored Studies				=	<input type="text"/>
REB Admin Fee for Industry-Sponsored Studies (As of Sept 1, 2007: \$2000)				=	<input type="text"/>
Total Indirect Costs:				=	<input type="text"/> (f)
Total Cost for Complete Study:				=	<input type="text"/> (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.).