**ADMINISTRATIVE APPROVAL OF RESEARCH FORM**

**Part 1**

All proposed research must receive Administrative Approval prior to review by the Waterloo-Wellington Research Ethics Board (WWREB; formerly known as THREB). Please submit your completed form to the Research Administrative Representative at each hospital in which your research will be conducted. Your submission package must include this form, the WWREB submission checklist and all study documents.

**1. Local Principal Investigator:**

**2. Study Principal Investigator:** (if different from local)

**3. Study Title:**

**4. Study Sponsor/Funder:**

**5. Brief Research Summary:**

|  |
| --- |
| Click here to enter text. |

 6. **Research Setting:** (Where will the study take place? Check all that apply)

[ ] Cambridge Memorial Hospital [ ] Grand River Hospital

 [ ] St. Mary’s General Hospital [ ] Grand River Regional Cancer Centre

 [ ] Community – specify: Click here to enter text. [ ] Grand River Hospital - Freeport

 [ ] Other – specify: Click here to enter text.

 7. **Education/Training Requirements**:

Please ensure that all research team members have completed the appropriate requirements for conducting research. Each hospital has its own process for verifying training completion, please consult the administrative representative at the hospital(s) where you wish to conduct research for their process.

**All hospital-affiliated study team members are required to complete training as directed by the affiliated institution:**

1. Good Clinical Practices (to be renewed bi-annually)
2. Division 5 (For Health Canada regulated studies)
3. TCPS 2

8. **Interventions involved including diagnostic and lab work**:

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

|  |
| --- |
| Click here to enter text. |

 9. **Expected number of participants at each Waterloo-Wellington research site**: Click here to enter text.

10. **Privacy Implications**:

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

11. **Clinical Impact/Resource Utilization**

* If your participants 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 access to **Health Records/Information**? [ ] 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 (✓)**

|  |  |  |
| --- | --- | --- |
| **Area** | **Authorized Official** | **Signature** |
| [ ] **Health Information/Records**  | Click here to enter text. |  |
| [ ] **Decision Support** | Click here to enter text. |  |
| [ ] **Laboratory Services** | Click here to enter text. |  |
| [ ] **Medication/Drugs**(*Pharmacy)* | Click here to enter text. |  |
| [ ] **Radiology/Diagnostic/Medical Imaging Resources** | Click here to enter text. |  |
| [ ] **Nuclear Medicine** | Click here to enter text. |  |
| [ ] **Radiation Safety** | Click here to enter text. |  |
| [ ] **Other** (*please specify)*Click here to enter text. | Click here to enter text. |  |

**5. Contract**

**If any money, data, or material (biological or otherwise) is being transferred outside of or between institutions/parties, a contract/agreement will be required.**

[ ] **The Contracts office has been or will be contacted (if already contacted, please attach a copy to this application)**

[ ] **This study does not involve transfer of money, data or material (biological or otherwise)**

**NOTE**: If a contract is required, research activities cannot begin until the contract has been signed by the institution and WWREB approval has been given.

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Name of Local Principal Investigator Signature Date

**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 WWREB review of this project.

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 (Signature)

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

 (Print name) (Date)

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

For CMH: Stephanie Pearsall 519-621-2333 x2416

For GRH: Carla Girolametto 519-749-4300 x2307

For SMGH: Nicole Johnson 519-749-6403

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

|  |  |  |
| --- | --- | --- |
| **Hospital Area** **(E.g. Inpatient/Outpatient Location)** | **Authorized Official****(Manager/Director)** | **Signature** |
| Click here to enter text. | Click here to enter text. |  |
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**BUDGET TEMPLATE**

**Study title:** Click here to enter text.

**Local Investigator:** Click here to enter text.

**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**

**Hospital Overhead** for Industry-Sponsored Studies =

**REB Review Fee** for Industry-supported 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.).*