Humber River Hospital
Research Operations, Financial Impact & Signatures Document

This form is intended for the internal review and approval of research studies at Humber River Hospital (HRH) that utilize the hospital's resources, space, patients, staff, data or biospecimens.

It is the responsibility of the Principal Investigator and/or delegate to inform all stakeholders impacted by the research project prior to research ethics submission. Where applicable, all issues must be resolved prior to finalization of budget negotiations with sponsors.

ELECTRONIC SUBMISSIONS ONLY

Protocol Title:		
Sponsor: (if applicable)		
Protocol Number: (if applicable)		
Principal Investigator (PI):	**Name:**	**Institution:**
Site Investigator at HRH: (if different from above)	**Name:**	**Department:**
Co-Investigator(s):	**Name(s):** **1.** **2.** **3.**	**Institution, Department:** **1.** **2.** **3.**

A. GENERAL INFORMATION

Brief Description of Study:

Will this study be:

☐ **Retrospective ➢ Estimated sample size at HRH: _____**

☐ **Prospective**

↳ ➢ **Estimated number of participants to be enrolled at HRH: _____**

➢ **Estimated number of participants to be enrolled per month at HRH: _____**

Site*: ☐ **Wilson** ☐ **Church RCC** ☐ **Church - Dialysis** ☐ **Finch RCC**

**where research will take place*

Will any research activity take place outside of HRH, e.g. in physician's private practice?

☐ **Yes ➢ Please specify:**

☐ **No**

Will there be Homecare involvement?

☐ **Yes ➢ Please specify:**

☐ **No**

B. FUNDING

Please note that 30% overhead applies to all funds awarded. Additionally, there are additional fees for the REB submission and future submissions. Any questions, please contact the Research Office.

Is the study funded?	☐ **Yes** ☐ **No**
Funding source:	
Total funds awarded:	

C. PHARMACY

Is HRH Pharmacy involved?

☐ **Yes ➢** ***Complete Pharmacy Accountability Document***

☐ **No ➢ Please complete the table below:**

Why is HRH Pharmacy not involved?	
Medications to be administered (list all required by the study):	- -
Who will be administering the medications?	
Who will be responsible for receiving, storing, destruction of drug supply, inventory logs, drug accountability records and returning the medications?	

Where and how will the medications be stored?	

D. HRH LABORATORY

Blood drawn by HRH Ambulatory Clinic Staff	☐ **Yes** ☐ **No**
Blood drawn by HRH Clinic Staff	☐ **Yes** ☐ **No**
Blood drawn by Research Coordinator	☐ **Yes** ☐ **No**
Specimen(s) sent to Central Lab	☐ **Yes** ☐ **No**

Blood work to be prepared, packaged and sent out by:

HRH Labs Involved

☐ **Yes** ➢ **Identify each lab test required as per study plan:**

☐ **No**

E. HRH MEDICAL IMAGING (MI)

Medical Imaging	☐ **Yes** ☐ **No**	**Impact:**
Neurodiagnostics	☐ **Yes** ☐ **No**	**Impact:**
RN required for any MI Procedure?	☐ **Yes** ☐ **No**	**Explain:**
Nuclear Medicine	☐ **Yes** ☐ **No**	**Impact:**

F. HRH PATHOLOGY

Will there be any use of human tissue?	☐ **Yes** ☐ **No**	**List all testing required for each specimen:**
Special handling required?	☐ **Yes** ☐ **No**	**Explain:**

G. CLINICAL AREAS

Surgical Day Care	☐ **Yes** ☐ **No**	**Pre-op impact:** **Post-op impact:**
Post Anesthesia Care Unit (PACU)	☐ **Yes** ☐ **No**	**Impact:**
Inpatient Units	☐ **Yes** ☐ **No**	**Identify Unit & Involvement:**
Critical Care Unit	☐ **Yes** ☐ **No**	**Impact:**
Nephrology	☐ **Yes** ☐ **No**	**Impact:**
Rehab Services	☐ **Yes** ☐ **No**	**Impact:**
Emergency Dept	☐ **Yes** ☐ **No**	**Impact:**
Cardiology	☐ **Yes** ☐ **No**	**Impact:**
General Internal Medicine	☐ **Yes** ☐ **No**	**Impact:**
GI/Medicine	☐ **Yes** ☐ **No**	**Impact:**
Mental Health	☐ **Yes** ☐ **No**	**Impact:**
Endoscopy	☐ **Yes** ☐ **No**	**Impact:**
Paediatrics	☐ **Yes** ☐ **No**	**Impact:**
Oncology	☐ **Yes** ☐ **No**	**Impact:**
Respirology	☐ **Yes** ☐ **No**	**Impact:**
Outpatient Clinics	☐ **Yes** ☐ **No**	**Identify Clinic & Involvement:**

In-service training required?	☐ **Yes** ☐ **No**	**Identify unit(s) to be trained:**
Other (specify):	☐ **Yes** ☐ **No**	**Impact:**

H. HEALTH INFORMATION SYSTEMS

Review of HRH Charts by External Research Staff	☐ **Yes** ☐ **No**	**Impact:**
Data request fulfillment by HRH staff	☐ **Yes** ☐ **No**	**Impact:**
Charts from Storage	☐ **Yes** ☐ **No**	**Impact:**
Other (specify):	☐ **Yes** ☐ **No**	**Impact:**

I. FOCUS ON TECHNOLOGY

HRH Command Centre	☐ **Yes** ☐ **No**	**Impact:**
A New Medical Device	☐ **Yes** ☐ **No**	**Impact:**
A New Analytic Tool	☐ **Yes** ☐ **No**	**Impact:**
Other (specify):	☐ **Yes** ☐ **No**	**Impact:**

J. RESEARCH STAFFING

Study Coordinator (SC)	☐ **Study will require the support of a SC from HRH Research Office** ☐ **Study will use a SC from outside HRH** ***Please note that it is mandatory to register unpaid team members that are on site at HRH to ensure liability coverage, privacy and confidentiality training, etc.*** ☐ **Study PI will hire own SC at HRH** ☐ **Other (specify):**	**Please provide details & Name of SC:**

Where will the SC conduct the Study?	☐ **Onsite at HRH ➢ Please include office room number, if possible:** ☐ **Offsite ➢ Please specify:**
Other staff required?	☐ **Statistician** ☐ **Transcriptionist** ☐ **Other (specify):**
Will the Study require any translation of materials?	☐ **Yes ➢ Please specify language(s) required:** ☐ **No**

K. CONTRACTS / AGREEMENTS

Will the Study involve contracts or agreements?	☐ **Material Transfer Agreement (MTA)** ☐ **Data Transfer/Data Sharing Agreement (DTA/DSA)** ☐ **Funding Agreement** ☐ **Agreement Terms with Private Practice** ☐ **Other (specify):**

L. SIGNATURE PAGE

Please notify the appropriate Director(s) and Physician Chief(s) about this study. Please document your discussions and have them available if requested. Email confirmation may be used in place of signatures (except in the case of the PI, whose signature is required).

Department	**Director Signature*** (*Individual with budget responsibility)	**Physician Director/Chief Signature***
	Program Director Name: Signature: Date:	Physician Director Name: Signature: Date:
	Program Director Name: Signature: Date:	Physician Director Name: Signature: Date:
	Program Director Name: Signature: Date:	Physician Director Name: Signature: Date:
	Program Director Name: Signature: Date:	Physician Director Name: Signature: Date:
	Program Director Name: Signature: Date:	Physician Director Name: Signature: Date:

	Program Director Name: Signature: Date:	Physician Director Name: Signature: Date:

_____
Name of Principal Investigator

_____
Signature Date

Please submit the following package to the HRH Research Office at research@hrh.ca:

1. Research Impact Form (this form)
2. Study Protocol
3. Informed Consent Form (if applicable)
4. Study Budget
5. Study Agreement (if applicable)

For assistance, please contact:

Michele Petrovic
Research Manager
416-242-1000 x81263
mpetrovic@hrh.ca