



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 HRH Research Ethics review. 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:
Lead Investigator at HRH: (if different from above)	Name:	Department:
Co-Investigator(s) at HRH:	Name(s):	Department(s):

A. GENERAL INFORMATION

Brief Description of Study:

Will this study be:
 Retrospective
 Prospective
 ↳ Estimated number of participants to be enrolled at HRH : _____
 ↳ Estimated number of participants to be enrolled per month at HRH: _____

Setting:
 Outpatient
 Inpatient

Site: HRH Wilson Church RCC Church - Dialysis Finch RCC

Will any research activity take place outside of HRH, e.g. in physician's private practice?
 No
 Yes ↳ Please specify:

Will there be Homecare involvement?
 No
 Yes ↳ Please provide details:

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?	<input type="checkbox"/> Yes <input type="checkbox"/> 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 Lab	<input type="checkbox"/> Yes <input type="checkbox"/> No
Blood drawn by HRH Clinic Staff	<input type="checkbox"/> Yes <input type="checkbox"/> No
Blood drawn by Research Coordinator	<input type="checkbox"/> Yes <input type="checkbox"/> No
Blood work sent out to Central Lab	<input type="checkbox"/> Yes <input type="checkbox"/> No
Blood work to be prepared, packaged and sent out by:	
HRH Labs Involved	
<input type="checkbox"/> No	
<input type="checkbox"/> Yes ➤ Identify each lab test required as per study plan:	

E. HRH DIAGNOSTIC IMAGING

Diagnostic Imaging	<input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No	Impact:
Neurodiagnostics	<input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No	Impact:
RN required for any DI Procedure?	<input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No	Explain:
Nuclear Medicine	<input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No	Impact:

F. HRH PATHOLOGY

Will there be any use of human tissue?	<input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No	List all testing required for each specimen:
Special handling Required?	<input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No	Explain:

G. CLINICAL AREAS

Surgical Day Care	<input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No	Pre-op impact: Post-op impact:
Post Anesthesia Care Unit (PACU)	<input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No	Impact:
Inpatient Units	<input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No	Identify Unit & Involvement:
Nephrology	<input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No	Impact:
Rehab Services	<input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No	Impact:
Emergency Dept	<input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No	Impact:
Cardio/Respiratory	<input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No	Impact:
Mental Health	<input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No	Impact:
Endoscopy	<input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No	Impact:
Outpatient Clinics	<input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No	Identify Clinic & Involvement:
In-service training required?	<input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No	Identify unit(s) to be trained:
Other (specify):	<input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No	Impact:

H. HEALTH INFORMATION SYSTEMS

Review of HRH Charts by External Research Staff	<input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No	Impact:
Data request fulfillment by HRH staff	<input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No	Impact:

Chart pull for Monitoring Visits	<input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No	Impact:
Charts from Storage	<input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No	Impact:
Delivery from Storage Company	<input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No	Impact:
Photocopying	<input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No	Impact:

I. FOCUS ON TECHNOLOGY		
HRH Command Centre	<input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No	Impact:
A New Medical Device	<input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No	Impact:
A New Analytic Tool	<input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No	Impact:
Other (specify):	<input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No	Impact:

J. RESEARCH STAFFING

Study Coordinator	<input type="checkbox"/> Study will require the support of a Coordinator from HRH Research Office <input type="checkbox"/> Study will use a coordinator from outside HRH <i>Please note that it is a mandatory requirement to register unpaid team members that are on site at HRH to ensure liability coverage, privacy and confidentiality training, etc.</i> <input type="checkbox"/> Study PI will hire own Research Coordinator at HRH <input type="checkbox"/> Other (specify):	Please provide details regarding staffing needs:
Where will the Coordinator conduct the Study?	<input type="checkbox"/> Onsite at HRH ➤ Please include office room number, if possible: <input type="checkbox"/> Offsite ➤ please specify:	
Other staff required?	<input type="checkbox"/> Statistician <input type="checkbox"/> Transcriptionist <input type="checkbox"/> Other (specify):	
Will the Study require any translation of materials?	<input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, please indicate language(s) required: - - -	
Will the Study involve contracts or agreements?	<input type="checkbox"/> Material Transfer Agreement (MTA) <input type="checkbox"/> Data Transfer/Data Sharing Agreement (DTA/DSA) <input type="checkbox"/> Funding Agreement <input type="checkbox"/> Other (specify):	

K. SIGNATURE* PAGES FOR IMPACTED AREAS

Please ensure that the appropriate Director(s) and Physician Chief(s) have been notified about this project and have received relevant documentation about the study. Please document your discussions and have them available if requested. **Email confirmation may be used in place of original signatures (except in the case of the PI, whose signature is required).*

Department	Director Signature* (person 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:	Physician Director Name:
	Signature:	Signature:
	Date:	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