

**Humber River Hospital
Research Operations Financial Impact and Signature Page**



REB Number:

REB Office Use Only

Protocol Title:

Sponsor:

Protocol Number:

**Principal
Investigator:**

Does the study impact on hospital departments or services? Yes No

If yes, the Principal Investigator is responsible to ensure that all areas impacted by the study have been consulted.

The Principal Investigator or delegate is required to attend the Research Operations meeting to discuss the study and respond to questions or issues that the Manager(s), CPLs and Director(s) may have regarding the study. All issues must be resolved prior to the Sponsor budget negotiations being finalized.

It is the responsibility of the Principal Investigator and/or Research Coordinator to obtain signatures of all stakeholders (Director(s), Manager(s) and Sr. Team) impacted by the research project prior to forwarding the submission to the Humber River Hospital Research Ethics Board for presentation on the appropriate REB Agenda.

All Studies

Identify departments/units where this study will be conducted, the impact to each department /unit and provide details of inservicing for each department/unit (Medical Floors, Surgical Floors, SDC, PATT, PACU, Short Term Rehab, Social Work/DCC, Laboratory, Endoscopy, Neuordiagnostics, Diagnostic Imaging, Surgical Ambulatory Clinics (etc):

Standard of Care Treatment vs Study Treatment at Humber River Hospital:

N/A

Provide complete details in the chart below (each cell will expand by hitting the return key. Chart will expand by using the tab key):

	HRH STANDARD OF CARE TREATMENT	STUDY TREATMENT AS PER PROTOCOL
Length of Stay (Inpatient)	<input type="checkbox"/> N/A •	•
Length of stay longer than normal? (If yes indicate additional length of stay)	<input type="checkbox"/> N/A • <input type="checkbox"/> Yes <input type="checkbox"/> No	•
Length of Follow-Up	<input type="checkbox"/> N/A •	•
Frequency of Visits	<input type="checkbox"/> N/A •	•
Identify Drugs Administered (All)	<input type="checkbox"/> N/A •	•
Frequency of Drug Dispensing	<input type="checkbox"/> N/A •	•
Departments Impacted (List All)	<input type="checkbox"/> N/A •	•
Procedures Required (List All)	<input type="checkbox"/> N/A •	•
Procedures – Frequency	<input type="checkbox"/> N/A •	•

Brief Description of Study:

Site: HRH Church HRH Finch HRH Keele

Outpatient Study Yes No Inpatient Study Yes No
Estimated Total Number of Participants to be Enrolled at HRH :

Estimated Number of Participants to be Enrolled Per Week at HRH:

Community Care Access Centre Involvement? Yes No
If yes, provide details:

Pharmacy Role: HRH Pharmacy Involved Yes No
If yes, complete Pharmacy Accountability Document attached.

If No provide the following details:

- Why is HRH Pharmacy not involved

- Medications to be administered (list all required by the study):

- Who will be administering the medications?

- Who is 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?

Lab Testing required as per study plan: Identify each Lab test to be performed at HRH for cost recovery on the HRH Cost Recovery Worksheet

- Blood Drawn by HRH Lab N/A Yes No
- Blood Drawn by HRH Clinic Staff N/A Yes No
- Blood Drawn by Research Coordinator N/A Yes No
- Blood Work sent out to Central Lab N/A Yes No

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

Impact to Clinical Areas

Outline Involvement & Process Clearly

Cost Centre .12023

PATT	<input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No	Patient must be identified as <i>study participant</i> when booking PATT Visit: •
SDC	<input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No	Pre-op impact: • Post-op impact: •
PACU:	<input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No	Impact: •
Anaesthetist Notification Process:	<input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No	Pre-op Medication: • Post-op Medication: • Anaesthetist Study Notification: •
Inpatient Units	<input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Involvement: • •
Inpatient Inservicing	<input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No	Identify Units to be Inserviced: • •
Nephrology	<input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Involvement: • •
Outpatient Clinics	<input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No	Identify Clinic & Involvement: • •
Outpatient Clinic Inservicing A200/A300	<input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No	Identify Clinics to be Inserviced: • • Impact • •
A3 South –	<input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No	Impact:

**Impact to
Clinical Areas**

Outline Involvement & Process Clearly

**Cost Centre
.12023**

Rehab: •
ER: N/A Yes No Impact: _____
•
Cardio/ N/A Yes No Impact: _____
Respiratory •
•
Endoscopy N/A Yes No Impact: _____
•
Neurodiagnostics N/A Yes No Impact: _____
•
Other (Specify): N/A Yes No Impact: _____
•
•
Diagnostic N/A Yes No Impact: _____
Imaging •
(enter •
recovery •
procedures on
Cost Recovery
Spreadsheet
RN required
for Any DI
Procedure? N/A Yes No Impact: _____
•
Nuclear N/A Yes No Impact: _____
Medicine •

Special Assessments

(Identify Unit responsible and Involvement /Process:

Vital Signs N/A Yes No
and Assessments: •
•
•
Special N/A Yes No
Monitoring •
•
•

Special Assessments

(Identify Unit responsible and Involvement /Process:

**Special
Treatments**

N/A Yes No

-
-

-
-

**Special Equipment or Equipment Maintenance
required (List all)**

**Identify who will be responsible for calibration
or maintenance of equipment**

N/A Yes No

-
-

-
-

IS Involvement:

List each IS requirement

Impact or Process required

N/A Yes No

-
-

-
-

Space requirements for Research Coordinator or Sponsor Monitoring Visits

**Space
required
(list all
areas
required)**

**Describe requirements including number of hours required per
day**

N/A Yes No

-
-

-
-

Health Information Services:

**Chart pull for Monitoring Visits
Charts from Storage
Delivery from Storage Company
Photocopy Charge**

**\$4.00 per Chart Pull \$8.00 per Double Chart Pull
\$4.00 per Chart Pull
\$25.00 per trip
\$0.25 per copy
\$25.00 per hour if HRH staff required to copy records**

Do not sign off on Research Financial Impact without reviewing the Departmental Impact of this Study
Please ensure that your cost-centre has been included in the above chart for procedure cost recovery

Departments (List all impacted Units)	Manager(s) & Director(s) Signatures	PRINT or TYPE Name of Manager(s) & Director(s)
	Manager: _____ Date _____ Clinical Practice Leader _____ Date _____ Program Director: _____ Date _____ Chief of Department _____ Date _____	_____ _____ _____ _____
Health Information Services	Manager: _____ Date _____ Clinical Practice Leader _____ Date _____ Program Director: _____ Date _____ Chief of Department _____ Date _____	_____ _____ _____ _____
	Manager: _____ Date _____ Clinical Practice Leader _____ Date _____ Program Director: _____ Date _____ Chief of Department _____ Date _____	_____ _____ _____ _____
	Manager: _____ Date _____ Clinical Practice Leader _____ Date _____ Program Director: _____ Date _____	_____ _____ _____

Departments (List all impacted Units)	Manager(s) & Director(s) Signatures	PRINT or TYPE Name of Manager(s) & Director(s)
	Chief of Department _____ Date _____	_____
	Manager: _____ Date _____ Clinical Practice Leader _____ Date _____ Program Director: _____ Date _____ Chief of Department _____ Date _____	_____ _____ _____ _____
	Manager: _____ Date _____ Clinical Practice Leader _____ Date _____ Program Director: _____ Date _____ Chief of Department _____ Date _____	_____ _____ _____ _____
	Manager: _____ Date _____ Clinical Practice Leader _____ Date _____ Program Director: _____ Date _____ Chief of Department _____ Date _____	_____ _____ _____ _____

Programs	Signatures - Administration	Print or Type Name
VP Nephrology & Support Services	Vice President _____ Date _____	_____
VP Emergency, Primary Care, Medical B – Acute Care, Mental Health Program, Surgical Program, Clinical Utilization, Diagnostic Imaging	Vice President _____ Date _____	_____
Medical Program A – Critical Care, Cardiology, Respirology, Neurodiagnostics, Oncology Services; Women’s & Children’s Health Program; Professional Practice; Infection Control; Pharmacy Services; Laboratory Services	Chief Nursing Officer _____ Date _____	_____
VP of Medical and Academic Affairs	Vice President _____ Date _____	_____

Signature of Principal Investigator

Date

Typed Name of Principal Investigator