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 <u>prior to forwarding the submission</u> to the Humber River Hospital Research Ethics Board for presentation on the appropriate REB Agenda.

<u>All Studies</u>

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)	☐ N/A	•	•
Length of stay longer than normal? (If yes indicate additional length of stay	☐ N/A ☐ Yes ☐ No	•	•
Length of Follow-Up	☐ N/A	• •	• •
Frequency of Visits	☐ N/A	•	•
Identify Drugs Administered (All)	☐ N/A	• •	• •
Frequency of Drug Dispensing	☐ N/A	• •	• •
Departments Impacted (List All)	☐ N/A	• • • •	• • • •
Procedures Required (List All)	☐ N/A	• • • • •	• • • • •
Procedures – Frequency	☐ 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	☐ **N/A** ☐ **Yes** ☐ **No**	**Patient must be identified as *study participant* when booking PATT Visit:** •	
SDC	☐ **N/A** ☐ **Yes** ☐ **No**	**Pre-op impact:** • **Post-op impact:** •	
PACU:	☐ **N/A** ☐ **Yes** ☐ **No**	**Impact:** •	
Anaesthethist Notification Process:	☐ **N/A** ☐ **Yes** ☐ **No**	**Pre-op Medication:** • **Post-op Medication:** • **Anaesthetist Study Notification:** •	
Inpatient Units	☐ **N/A** ☐ **Yes** ☐ **No**	**Unit Involvement:** • •	
Inpatient Inservicing	☐ **N/A** ☐ **Yes** ☐ **No**	**Identify Units to be Inserviced:** • •	
Nephrology	☐ **N/A** ☐ **Yes** ☐ **No**	**Unit Involvement:** • •	
Outpatient Clinics	☐ **N/A** ☐ **Yes** ☐ **No**	**Identify Clinic & Involvement:** • •	
Outpatient Clinic Inservicing	☐ **N/A** ☐ **Yes** ☐ **No**	**Identify Clinics to be Inserviced:** • •	
A200/A300	☐ **N/A** ☐ **Yes** ☐ **No**	**Impact** • •	
A3 South –	☐ **N/A** ☐ **Yes** ☐ **No**	**Impact:**	

Impact to Clinical Areas		Outline Involvement & Process Clearly	Cost Centre .12023
Rehab:		•	
ER:	☐ N/A ☐ Yes ☐ No	**Impact:** •	
Cardio/ Respiratory	☐ N/A ☐ Yes ☐ No	**Impact:** • •	
Endoscopy	☐ N/A ☐ Yes ☐ No	**Impact:** •	
Neurodiagnosti	☐ N/A ☐ Yes ☐ No	**Impact:** •	
Other (Specify) • •	☐ N/A ☐ Yes ☐ No	**Impact:** • •	
Diagnostic Imaging (enter recovery procedures on Cost Recovery Spreadsheet	☐ N/A ☐ Yes ☐ No	**Impact:** • •	
RN required for Any DI Procedure?	☐ N/A ☐ Yes ☐ No	**Impact:** •	
Nuclear Medicine	☐ N/A ☐ Yes ☐ No	**Impact:** •	

Special Assessments		(Identify Unit responsible and Involvement /Process:
Vital Signs and Assessments: • •	☐ N/A ☐ Yes ☐ No	• •
Special Monitoring • • •	☐ N/A ☐ Yes ☐ No	• •

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	**$4.00 per Chart Pull**	**$8.00 per Double Chart Pull**
Charts from Storage	**$4.00 per Chart Pull**	
Delivery from Storage Company	**$25.00 per trip**	
Photocopy Charge	**$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 __________	______ ______ **Jake Harmina** ______
	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 ________	Scott Jarrett
VP Emergency, Primary Care, Medical B – Acute Care, Mental Health Program, Surgical Program, Clinical Utilization, Diagnostic Imaging	Vice President ______________________________ Date ________	Scott Jarrett
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__________	Margaret Czaus
VP of Medical and Academic Affairs	Vice President ________________________ Date__________	Dr. Ray Martin

____ ______
Signature of Principal Investigator Date

____
Typed Name of Principal Investigator