HUMBER RIVER HOSPITAL	**Research Ethics Board (REB)** **APPLICATION FOR RETROSPECTIVE CHART REVIEW/HEALTH RECORDS** ***Typed Original Signed Hardcopies ONLY***

DO NOT STAMP OR AMEND THE REB SUBMISSION FORM

DO NOT SEND BY FAX OR EMAIL

Submission Date:	HRH REB Number: *(REB Use Only)*

Full Study Title:

PRINCIPAL INVESTIGATOR:			
Telephone:		Fax:	
Pager:		Email:	
Program: ☐ OB/GYN ☐ Medical: ☐ Behavioural ☐ Primary Care ☐ Surgical: ☐ Other: ☐ Maternal Child ☐ Mental Health			
Institution & Mailing Address:			

HHS (HEALTH AND HUMAN SERVICES) SUPPORTED YES ☐ NO ☐	FDA (FOOD AND DRUG ADMINISTRATION) REPORTING YES ☐ NO ☐

REB Date of Receipt	REB Database Entry Date

CO-INVESTIGATORS:					
Name	Address	Check (✔)			
		☐	HRH	☐	Non–HRH
		☐	HRH	☐	Non–HRH
		☐	HRH	☐	Non–HRH

HRH CONTACT NAME:			
Department:		Room Number:	
Site:	☐ Church ☐ Finch ☐ Keele	Telephone:	

STUDY COORDINATOR:			
Telephone:		Fax:	
Pager:		Email:	
Mailing Address:			

DATA ABSTRACTOR:			
Telephone:		Fax:	
Pager:		Email:	
Mailing Address:			

Confidentiality Agreement:

I, the undersigned, agree to adhere to the HRH Confidentiality Agreements policy No. ADM.210.1 and understand that a breach of this policy will be just cause for termination of my employment and /or affiliation with this hospital. I agree that all health information, which I may have access to, is to be dealt with in keeping with the policies and procedures of the Humber River Hospital with respect to confidentiality. If identifying information is collected, the information will be kept secure and identifiers removed at the completion of collection. I also accept full responsibility for protection of information that has been collected by a delegate of my behalf.

_____ _____

Abstractors Signature Date

Tri-Council Policy Statement (TCPS) Tutorial is to be completed by all Investigators and Research Staff (http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel)	
Anyone wishing to complete a retrospective review of health records is required to provide a certificate of completion for the protection of human participant prior to submitting the REB Application	
Have all personnel completed the TCPS tutorial?	☐ YES ☐ NO
Certificate(s) attached	☐ YES
All personnel are required to attach the following:	
A signed and dated copy of their CV	ATTACHED ☐
A copy of their license (if applicable)	Attached ☐ ☐ N/A

Please Indicate to whom correspondence should be sent	☐ Principal Investigator ☐ Study Coordinator

Is the Purpose of the Proposed study one of the following?	To Access Retrospective Data for Research Purposes	☐
	To Access Data for Administrative Purposes	☐
	Other (Explain) _____	☐
** If none of the selections have been checked then a Full Board Application is required for REB approval consideration*		

Please Indicate to whether the study is:	☐ Non–Oncology ☐ Oncology

GENERAL INFORMATION

Is this a Student Project? YES ☐ NO ☐
Is this a Quality Assurance Study? YES ☐ NO ☐

Sponsor Protocol Number: N/A ☐ _____
Protocol Version Date: N/A ☐ _____

Is this a sequel to previous approved research? YES ☐ NO ☐

If Yes:
Indicate REB Number(s): _____

Describe the differences from the previous approved protocol(s): _____

Primary Objectives of the Study:

List specific data to be abstracted (attach data abstraction forms):

Briefly describe the study in lay terms:

List 5 Keywords that Describe this Project:

1) _____ 3) _____

2) _____ 4) _____

5) _____

Disease Site: (Check all that apply) N/A ☐

Oncology

☐ Breast	☐ Hematologic, benign
☐ Endocrine (thyroid and pituitary)	☐ Hematologic, malignant
☐ Gastrointestinal	☐ Lymphoma
☐ Genitourinary (bladder and prostate)	☐ Nervous System (brain and spinal cord)
☐ Gynecology	☐ Pulmonary (lung)
☐ Colorectal	☐ Skin and Sarcoma
☐ Head and Neck	

Non–Oncology

☐ Medical	☐ Cardiology	☐ Infectious Diseases
	☐ Neurology	☐ Renal
		☐ Other: Specify _____
☐ Surgical	☐ Ophthalmology	☐ Orthopedic
	☐ Urology	☐ Other: Specify

Study Sites & Locations:

☐ Single Site (HRH Only)	☐ Multi–Site (HRH Only)
☐ Multi–Centre with Single HRH Site	☐ Multi–Centre with multi HRH Sites

☐ HRH Church Site ☐ HRH Finch Site ☐ HRH Keele Site

Will/has another REB review this study? ☐ Yes ☐ NO

If yes, please attach the REB Approval Letters Attached ☐

Anticipated Project dates:	Start Date Completion Date Planned Study Duration
Date Range of Data Required:	Start Date End Date
Proposed number of HRH participant/charts for review	Church Site Finch Site
Proposed number of charts for review for entire study (All institutions if available)	

Funding : ☐ Grant ☐ Industry ☐ N/A

(All grants and contracts are to be submitted to the Office of Research Administration for review and Signature)

SPONSOR/ AGENCY NAME:			
CONTACT NAME:			
Telephone:		Fax:	
Email:		Website:	
Mailing Address:			
Additional Invoicing Information:			
Itemized, detailed Sponsor Budget/ Grant attached? ☐ Yes ☐ No			
If No, when will it be forwarded for REB review?			

Confidentiality

Will there be linkage to personally identifiable information?	☐ Yes ☐ No
If Yes, please justify:	

Indicate the participant identifiers that will be used on data collection forms ***or*** in the electronic case report form:		
☐ HRH Medical Record Number	☐ Gender	☐ Address
☐ Health Card Number	☐ Participant Initials	☐ Age
☐ Date of Birth	☐ Family Member contact information	☐ Telephone Number
☐ Email Address	☐ Date of initial treatment	☐ Race/ethnicity
☐ Surgical Pathology Number	☐ Investigator Name & Address	☐ HRH Site #
☐ Other: Specify		

Protection of Data (All data must have participant identifiers removed).	
Will the data be linked to other data?	☐ Yes ☐ No If yes, please provide details (i.e. why is it being linked; how will linkage occur; identify the data set):
Will the data be de-identified?	☐ Yes ☐ No If no, please indicate steps taken to ensure security of any data with personal identifiers:
Indicate where will the data be stored?	

How will data be stored?

☐	Computerized Files	☐	Audio Recordings
☐	Hard Copy	☐	Video Tape
☐	Other: *Specify*		

Who will conduct data collection?			
☐	Investigators/ delegates	☐	Sponsor
☐	Outside Agency: Specify Name, etc.		
☐	CRO: Specify Name, etc.		
☐	Other:		

Has a list of potential participants been developed	☐ Yes ☐ No
How were these Participants identified (under what authority - explain):	
How were these participants identified	

Will the participant data be transferred external to Humber River Hospital?	☐ Yes ☐ No

If Yes, indicate What country(ies) – other that the U.S.A.:

Will participant data be held in a U.S. database?	☐ Yes ☐ No
Will the data be de-identified?	☐ Yes ☐ No

If **Yes**, indicate the data to be stored in the database and how it will be de-identified:

-
-

Indicate how data will be sent and describe security at receptor site/attach encryption protocol)

What will happen to the data at the end of the study (e.g. anonymized, destroyed)?

Will the data be entered into a database for future use? YES ☐ NO ☐ N/A ☐

If YES, provide details:

Who will have access to data in the future?

How will confidentiality be maintained during long-term storage of study records?

How long will the data be retained?

Health Records Impact

Health Records:	
Chart pull for Monitoring Visits	$4.00 per Chart Pull (Single Pull) $8.00 per Double Pull
Charts from Storage	$4.00 per Chart Pull
Delivery from Storage Company	$25.00 per trip
Photocopy/data Charge	$0.25 per copy $25.00 per hour if HRH staff required to copy records $25.00 per hour if HRH staff required to prepare data

Departments	*Manager & Director Signature*	*Name of Manager/Director* (Please print or type name)
	Manager: _____ Date: _____ Program Director: Date:	
	Manager: _____ Date: _____ Program Director: Date:	
Director Health Records	Date: _____ Director: Date:	
VP of Medical And Academic Affairs	Date: _____ Vice President: Date:	
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 / Critical Care, Cardiology, Respirology, Neurodiagnostics, Oncology Services Women's & Children's Health Program; Professional Practice; Infection Control; Pharmac Services; Laboratory Servic	Chief Nursing Officer: _____ Date: _____	

Will the data be published? ☐ Yes	☐ No

Is there an independent steering committee regarding publication?			
☐	YES	☐	No
Will the Institution be identified in the publication/ final report? ☐ YES ☐ NO			

Signature of HRH Principal Investigator/Researcher attesting that:

a) all co-investigator(s)/researcher(s) have reviewed the protocol contents and are in agreement with the protocol as submitted;
b) The study will not start until the contract/ agreement (if applicable) has been approved by the appropriate hospital official.
c) All supporting documentation has been attached for the Research Ethics Board to review

Print Investigator's Name	Investigators' Signature	Date *(dd-mmm-yyyy)*

DO NOT FAX OR EMAIL.
SEND SIGNED ORIGINAL TO THE OFFICE OF RESEARCH ETHICS,
HUMBER RIVER HOSPITAL, 200 CHURCH STREET, ROOM CB-21,
WESTON, ONTARIO M9N 1N8
Phone: 416-243-4562