



**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: <i>(REB Use Only)</i>
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**Full Study Title:**

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PRINCIPAL INVESTIGATOR:			
Telephone:		Fax:	
Pager:		Email:	
Program:	<input type="checkbox"/> OB/GYN	<input type="checkbox"/> Medical:	<input type="checkbox"/> Behavioural
	<input type="checkbox"/> Primary Care	<input type="checkbox"/> Surgical:	<input type="checkbox"/> Other:
	<input type="checkbox"/> Maternal Child	<input type="checkbox"/> Mental Health	
Institution & Mailing Address:			

HHS (HEALTH AND HUMAN SERVICES) SUPPORTED YES <input type="checkbox"/> NO <input type="checkbox"/>	FDA (FOOD AND DRUG ADMINISTRATION) REPORTING YES <input type="checkbox"/> NO <input type="checkbox"/>
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<b>REB Date of Receipt</b>	<b>REB Database Entry Date</b>

CO-INVESTIGATORS:			
Name	Address	Check (✓)	
		<input type="checkbox"/>	HRH <input type="checkbox"/> Non-HRH
		<input type="checkbox"/>	HRH <input type="checkbox"/> Non-HRH
		<input type="checkbox"/>	HRH <input type="checkbox"/> Non-HRH
HRH CONTACT NAME:			
Department:		Room Number:	
Site:	<input type="checkbox"/> Church <input type="checkbox"/> Finch <input type="checkbox"/> Wilson	Telephone:	

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

DATA ABTRACTOR:			
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.

\_\_\_\_\_ Date

Abstractors Signature

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	<input type="checkbox"/>
	To Access Data for Administrative Purposes	<input type="checkbox"/>
	Other (Explain)	<input type="checkbox"/>

*\* 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**

<input type="checkbox"/> Breast	<input type="checkbox"/> Hematologic, benign
<input type="checkbox"/> Endocrine (thyroid and pituitary)	<input type="checkbox"/> Hematologic, malignant
<input type="checkbox"/> Gastrointestinal	<input type="checkbox"/> Lymphoma
<input type="checkbox"/> Genitourinary (bladder and prostate)	<input type="checkbox"/> Nervous System (brain and spinal cord)
<input type="checkbox"/> Gynecology	<input type="checkbox"/> Pulmonary (lung)
<input type="checkbox"/> Colorectal	<input type="checkbox"/> Skin and Sarcoma
<input type="checkbox"/> Head and Neck	

**Non-Oncology**

<input type="checkbox"/> Medical	<input type="checkbox"/> Cardiology	<input type="checkbox"/> Infectious Diseases
	<input type="checkbox"/> Neurology	<input type="checkbox"/> Renal
		<input type="checkbox"/> Other: Specify _____
<input type="checkbox"/> Surgical	<input type="checkbox"/> Ophthalmology	<input type="checkbox"/> Orthopedic
	<input type="checkbox"/> Urology	<input type="checkbox"/> Other: Specify _____

Study Sites & Locations:

<input type="checkbox"/> Single Site (HRH Only)	<input type="checkbox"/> Multi-Site (HRH Only)
<input type="checkbox"/> Multi-Centre with Single HRH Site	<input type="checkbox"/> Multi-Centre with multi HRH Sites
<input type="checkbox"/> HRH Church Site	<input type="checkbox"/> HRH Finch Site
	<input type="checkbox"/> HRH Wilson Site

Will/has another REB review this study?

Yes  NO

If yes, please attach the REB Approval Letters

Attached

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

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?			<input type="checkbox"/> Yes <input type="checkbox"/> No
If No, when will it be forwarded for REB review?			

Confidentiality

Will there be linkage to personally identifiable information?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If Yes, please justify:	

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

<i>Protection of Data (All data must have participant identifiers removed).</i>	
Will the data be linked to other data?	<input type="checkbox"/> Yes <input type="checkbox"/> 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?	<input type="checkbox"/> Yes <input type="checkbox"/> 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?	
<input type="checkbox"/> Computerized Files	<input type="checkbox"/> Audio Recordings
<input type="checkbox"/> Hard Copy	<input type="checkbox"/> Video Tape
<input type="checkbox"/> Other: <i>Specify</i>	

Who will conduct data collection?	
<input type="checkbox"/>	Investigators/ delegates <input type="checkbox"/> Sponsor
<input type="checkbox"/>	Outside Agency: Specify Name, etc.
<input type="checkbox"/>	CRO: Specify Name, etc.
<input type="checkbox"/>	Other:
Has a list of potential participants been developed <input type="checkbox"/> Yes <input type="checkbox"/> No	
How were these Participants identified (under what authority - explain):	
<u>How were these participants identified</u>	
Will the participant data be transferred external to Humber River Hospital? <input type="checkbox"/> Yes <input type="checkbox"/> No	
If Yes, indicate What country(ies) - other than the U.S.A.:	
Will participant data be held in a U.S. database? <input type="checkbox"/> Yes <input type="checkbox"/> No	
Will the data be de-identified? <input type="checkbox"/> Yes <input type="checkbox"/> No	
If <b>Yes</b> , 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 <input type="checkbox"/> NO <input type="checkbox"/> N/A <input type="checkbox"/> 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	<i>Manager &amp; Director Signature</i>	<i>Name of Manager/Director (Please print or type name)</i>
	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, Respiriology, Neurodiagnostics, Oncology Services, Women’s & Children’s Health Program; Professional Practice; Infection Control; Pharmac	Chief Nursing Officer: _____	

Departments	<i>Manager &amp; Director Signature</i>	<i>Name of Manager/Director (Please print or type name)</i>
Services; Laboratory Service	Date: _____	

Will the data be published?  Yes  No

Is there an independent steering committee regarding publication?

<input type="checkbox"/>	YES	<input type="checkbox"/>	No
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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)
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**DO NOT FAX OR EMAIL**

**SEND TYPED SIGNED ORIGINAL TO:**

**HUMBER RIVER HOSPITAL  
1235 WILSON AVENUE, ROOM 3B2002  
TORONTO, ONTARIO M3M 0B2**

**Phone: 416-242-1000 x81263**