Obtaining Institutional Approval for Research Projects

Institutional approval is required on **ALL** Humber River Hospital (HRH) research projects in order to assess how each research project impacts the operation(s) of various HRH departments on any procedure or research protocol which uses HRH resources above the normally required standard practice and care. These additional resources may include, but is not limited to, extra tests or procedures, preparation and dispensing of special medications used in drug trials, additional nursing work, training preparations or any other ancillary costs covered by the Institution. HRH will not normally absorb research costs associated with a research project. These extra costs must be clearly identified, and reviewed. Lead researchers (Investigators etc.) are advised to seek early consultation(s) with the appropriate departments to ensure that a proposal is prepared reflecting sound logistics and feasibility.

In order to obtain Institutional approval **PRIOR** to HRH-REB (Humber River Hospital Research Ethics Board) submission, researchers or their research personnel/delegate are required to complete the Research Application & Approval Form (RAAF). Further, within the RAAF application, indicate which department(s) your research project will be impacting, if applicable.

If you have any questions or uncertainties regarding this process of completing this application, please contact the Research Department at research@hrh.ca

Research Application & Approval Form

FOR OFFICE OF RESEARCH USE ONLY
☐ Approved
By:_____ Date:_____

1. INVESTIGATOR / RESEARCHER NAME

Title:	Last Name:	First Name:
Credentials (MD, PhD, etc):		

2. FULL STUDY TITLE

**** Please include a copy of the study information (e.g. protocol) and/or research proposal***

Protocol Number (if applicable):

3. STUDY DURATION

Expected start date:
Total study duration:

4. INVESTIGATOR / MAIN CONTACT INFORMATION

4A. Investigator / Main Contact Information and Signature

Department:			
Telephone:	Pager:	Fax:	
Street Address:		Room/Suite #:	
City:	Province:	Postal Code:	Email:
Signature		Date	

4B CONTACT PERSON FOR THIS APPLICATION IF NOT THE INVESTIGATOR / RESEARCHER (e.g. study coordinator, research administrative contact, research student, institutional liaison).

☐ Not Applicable

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Title:	Last Name:	First Name:	
Dept/Div:	Program:	Institution:	
Telephone:	Pager:	Fax:	
Street Address:			Room/Suite #:
City:	Province:	Postal Code:	Email:

Indicate to whom correspondence should be sent: ☐ Investigator/Researcher ☐ Study Coordinator/Contact Person

5 SITE OF RESEARCH ACTIVITY

PRIMARY	SECONDARY (if applicable)
☐ Wilson ☐ Finch ☐ Other (specify):	☐ Wilson ☐ Finch ☐ Other (specify):

6. FUNDING

***Please include a copy of any applicable study budget and/or funding information*

6A. Source of Funding/Funding Type

List of funder(s):
What category do(es) the funder(s) belong to?(mark all that apply)
☐ Industry (e.g. Pharmaceutical Company/ Test or Medical Device Companies / Biotech Company)
☐ Government Funding Agency (e.g. National Institute of Health, Canadian Institutes for Health Research)
☐ Government (e.g. Ministry of Health, Department of Defense)
☐ Charitable Foundation (e.g. Michael J Fox Foundation)
☐ Contract Research Organization
☐ Others (describe):

6B. Status of Funding

☐ Funding obtained	
☐ Funding applied for	Expected date of decision:
☐ No funding required	Explain:

6C. If funding is not awarded, do you plan to proceed with the study? ☐ Yes ☐ No ☐ n/a

7. WHAT DOES THIS STUDY INVOLVE?

Please specify the nature of the study (and sub studies), check **all** that apply.

☐ Chart Review (specify): ☐ Retrospective ☐ Prospective

☐ Clinical Trial (please also complete Question 11)
☐ Investigational Product or Device study

(Specify): ☐ Phase I ☐ Phase 2 ☐ Phase 3 ☐ Phase 4 ☐ unknown ☐ n/a

☐ Investigational drug(s)
☐ Investigational biologic(s)
☐ Investigational natural health product(s)
☐ Investigational medical device(s)
☐ Approved product for new indication (e.g. new patient population), dosage, or formulation

Name(s) of Investigational Product(s) or Device(s):

☐ Health-related Intervention(s) (e.g. surgical procedures, behavioral treatments, process-of-case changes, dietary interventions, etc.)
(Specify):

☐ Qualitative (please check all that apply)
☐ Focus Groups
☐ Interviews
☐ Observational (e.g. naturalistic, field etc.)
☐ Questionnaires/Surveys
☐ Other (specify):

☐ Human Tissue and Biological Specimens (e.g. cadavers, biological fluids, etc.)

☐ Banking ☐ Biomarker ☐ Genetic

☐ Other (e.g. pharmacokinetic/pharmacodynamic etc) (specify):

Indicate if the material is ☐ **INTEGRAL** to the main study or ☐ **OPTIONAL** to the main study.

☐ Sub-study; indicate the REB# of main/related study:
☐ Case Study
☐ Educational
☐ Epidemiological / Database
☐ Quality Assurance / Quality Improvement
☐ Other (specify):

Research Application & Approval Form

8. IMPACTED HRH DEPARTMENTS **Not Applicable** ☐

Department	Manager/Director Name	Signature	Date

APPLICANT/INVESTIGATOR SIGNATURE

_____ _____

Signature Date

_____

Print Name

Please submit the completed and signed-off form to research@hrh.ca

A representative from the Research Department will inform you by e-mail regarding the status of your application within 5 business days, from the time the application is received. You may be contacted further whether additional information or documentation is required to make a decision prior to the approval of the application. Approval timelines vary depending on the type of study and logistical characteristics impacting the institution.