Form # 12-965

Research Review Application
Health Research Ethics Authority Approved Projects

In keeping with the commitment to review and to approve research projects in a timely and efficient manner, Western Health has a two step research approval process.

All projects to be conducted within Western Health are required to have review and full approval of the Health Research Ethics Authority (HREA). Applications should be completed and forwarded to:

Ethics Office
Health Research Ethics Authority
Suite 200, 2nd floor, 92 Bonaventure Avenue
St. John's, NL. A1B 2X5
t: 709-777-6974
f: 709-777-8776
e: info@hrea.ca
web: www.hrea.ca

Once full approval has been granted by the HREA, application for research to be conducted within Western Health must be made to the Western Health Research Review Committee. The primary mandate of this committee is to review resource utilization, impact on the organization and access to confidential information for any project to be conducted within Western Health. In addition, a database of all research within Western Health will be maintained. Review requires submission of the attached "Research Review Application", which requires a brief explanation of the project, associated costs and sources of funding.

All projects are reviewed and approved by a Western Health Research Review Committee before receiving final full approval.

It is the responsibility of the Principal Investigator of a research project to ensure that the research project is approved by the HREA and the Western Health Research Review Committee prior to undertaking any research project.

Completed and signed applications are to be sent to:

Mariel Parcon
Regional Manager Research and Evaluation
Western Health
Information and Quality
P.O. Box 2005
Corner Brook, NL A2H 6J7
Telephone: 709-634-4306 Facsimile: 709-634-4591
marielparcon@westernhealth.nl.ca
Web Site: www.westernhealth.nl.ca

*** An electronic version is preferred**.

To complete this application form you will need:

1. A copy of your HREA Application
2. A copy of your HREA Approval Letter
3. A copy of the budget for your research project
4. A copy of the research protocol
5. If applicable, the completed Western Health Impact Statement, Pharmacy Impact Statement, or Pharmacy Registration Form. Forms are attached.

- **HREA Reference Number:**
- **Project Title:**
- **Principal Investigator:**
- **Anticipated Start Date:** **Anticipated End Date:**
- **Budget:**

Description of Research Project

- **Research Objectives:**

- **Description of Methodology:**

- **How do you wish to partner with Western Health for this research project? Please be specific with respect to resources ie. a room, office, equipment, human resources, medication administration, health records, etc.**

- **How will the Western Health Research Review Committee be informed of the results of this research project?**

Pharmacy

- Does this research project involve the use of medication (including placebos) ***other than those normally used for patients?*** **YES** ☐ **NO** ☐

- Will medications (active or placebos) be dispensed by the Hospital Pharmacy? **YES** ☐ **NO** ☐
- **Please provide additional pertinent information, if required:**

If yes to the both of these questions, please complete the Pharmacy Impact Statement (attached) and include with this application. If yes to only the first question, please complete the Pharmacy Registration Form (attached) and include with this application.

Tests and Procedures

- Does this research project involve local laboratory tests, x-rays, or other imaging techniques ***other than required for normal patient care?*** **YES** ☐ **NO** ☐

- Will samples be sent to Western Health laboratories for testing? **YES** ☐ **NO** ☐

- Does this project request use of archived biological samples? **YES** ☐ **NO** ☐

- **Please provide additional pertinent information, if required:**

If yes to either of these questions, please complete the Impact Statement (attached) and include with this application.

Health Records

- Does this research project require access to Health Records? **YES** ☐ **NO** ☐

If yes…

- From what years?

- From which settings (e.g. Hospital, Community Health, Long Term Care)?

- How many records?

- What information will be collected?

- Paper records, electronic records or both?

Please provide a detailed description of your requirements for access to Western Health Records:

If yes to the first question, please complete the Impact Statement (attached) and include with this application.

Other Supports

- Does this research project require assistance of nurses or hospital staff other than the research personnel? **YES** ☐ **NO** ☐

- Does this research project necessitate admission of subjects to the hospital? **YES** ☐ **NO** ☐
    - **If yes, please describe:**

- **Please provide additional pertinent information, if required:**

If yes to either of these questions, please complete the Impact Statement (attached) and include with this application.

Consent

Your signature on this form gives approval to list your research project in our database monitoring research involving Western Health.

Signature of Principal Investigator **Date**

Please submit this form electronically or fax to:

Ms. Mariel Parcon, Regional Manager Research and Evaluation
Information and Quality
Western Health
P.O. Box 2005
Corner Brook, NL A2H 6J7
Phone: (709) 634-4306
Fax: (709) 634-4591

marielparcon@westernhealth.nl.ca

Western Health

IMPACT STATEMENT

THE PROGRAMS/SERVICES/DEPARTMENTS OF _____ WILL PROVIDE SERVICES IN SUPPORT OF THE FOLLOWING PROJECT, AND RECOVERIES FOR THE RESEARCH ACTIVITY WILL BE CHARGED TO THE FOLLOWING:

INVESTIGATOR:	
PROTOCOL NO.:	
SHORT TITLE:	
ANTICIPATED START:	
ANTICIPATED END:	

Resources required for this project over and above routine clinical care are as follows: (add second page if additional space required)

TEST/PROCEDURE/MISCELLANEOUS	COST ($)	# OF TESTS/ PATIENTS	TOTAL ($)
Total Cost Per Patient:			
Projected # Patients:	Total:		

I believe that providing this service will not compromise regular service. Impact statements will be revisited if regular service becomes impacted throughout the study.

_____ _____

Principal Investigator or Designate Date Regional Director or Designate Date

Western Health

PHARMACY IMPACT STATEMENT

THE DEPARTMENT OF **PHARMACY** WILL PROVIDE SERVICES IN SUPPORT OF THE FOLLOWING PROJECT, AND RECOVERIES FOR THE RESEARCH ACTIVITY WILL BE CHARGED TO THE FOLLOWING:

INVESTIGATOR:	
PROTOCOL NO.:	
SHORT TITLE:	
# PATIENTS EXPECTED:	
DURATION OF DRUG ADMINISTRATION:	
ANTICPATED START:	
ANTICIPATED END:	

Resources required for this project over and above routine clinical care are as follows: (add second page if additional space required)

TESTING TYPE	COST ($)	# OF TESTS/ PATIENTS	TOTAL ($)
SET UP COSTS			
DISPENSING COSTS			
STUDY MAINTENANCE			
MISCELLANEOUS COSTS			
Total Cost Per Patient:			
Projected # Patients:	Total:		

I believe that providing this service will not compromise regular service. Impact statements will be revisited if regular service becomes impacted throughout the study.

_____ _____

Principal Investigator or Designate Date Regional Director of Pharmacy Date

PHARMACY REGISTRATION FORM

The Pharmacy Department must be informed of all research studies that involve the use of medication, but do not require Pharmacy involvement in either their storage or administration. Please fill out the Pharmacy Registration Form and return to the Regional Manager Research and Evaluation, Quality Management and Research Branch, Western Health, Western Memorial Health Clinic. This information will be forwarded to the Regional Director of Pharmacy.

PRINCIPAL INVESTIGATOR	
CONTACT INFORMATION	
DRUG	
SHORT STUDY NAME	
STUDY TITLE	
BRIEF STUDY DESCRIPTION	