

REQUEST FOR PROGRAM APPROVAL – PHARMACY

Project Title:	Click here to enter text.		
Principal Investigator (PI):	Click here to enter text.		
Main Project Contact: <i>If not the same as the PI</i>	Click here to enter text.		
Contact Phone #:	Click here to enter text.	Contact Email:	Click here to enter text.

Please refer to Appendix A for instructions and request requirements

REQUEST DETAILS

Number of Inpatients:	Click here to enter text.	Number of Outpatients:	Click here to enter text.
Is randomization required?	<input type="checkbox"/> Yes <input type="checkbox"/> No	If yes, who is responsible for randomization?	Click here to enter text.
Is the sponsor providing the drug?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Is the sponsor reimbursing for pharmaceutical supplies used?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Drug name(s) and Therapeutic Classification(s):		Click here to enter text.	
Dose Preparation , Administration, Guidelines, Cautions, etc.:		Click here to enter text.	
Significant Adverse Events:		Click here to enter a date.	
List the person(s) who will administer the study drug(s) (e.g., Clinical Research Coordinator, Unit Nurse, etc.):		Click here to enter a date.	
Resources required for this project over and above standard of care are as follows:		Click here to enter a date.	

Manager - Please read carefully.

When approached for Program Approval, ensure you are provided with sufficient information to evaluate the project's impact on your program.

APPROVAL

PROGRAM DECLARATION

Please note that the expected turn-around time for review and approval is two (2) weeks.

As evidenced by my signature below, my program is aware of the research project being proposed and acknowledges that this program is supportive of the research and able to accommodate and support the project as set out herein.

Pharmacy Manager/Director Signature:	
Date of Approval:	Click here to enter text.
Please Print Name:	Click here to enter text.

Please retain a copy of this document for your records and return the original to the Principal Investigator.

APPENDIX A

Why are Requests for Program Approval (RPA) necessary?

To track the impact research projects have on hospital operations and to ensure the necessary supports are in place to conduct a research project, every program affected by the project must approve to provide support. ***Impact is defined as any procedure or research protocol which uses hospital resources above those normally required for practice and care.***

The Pharmacy must review all research study protocols involving the administration of any drug (this includes both investigational and marketed drugs) regardless if the drug is the focus of the research study.

Pharmacy involvement is necessary for research studies that involve administration of a drug to in-patients within HSN and, and may be necessary for out-patients in HSN clinics.

When are Requests for Program Approval made?

Prior to commencing work on a research project, researchers are required to interact with appropriate site/department/unit/program leadership regarding the study requirements. An RPA is intended to facilitate communication about the feasibility of new research projects and cost recovery between the study team and affected hospital programs.

Instructions to Complete the Request for Program Approval:

1. Populate the Request for Program Approval with your project information
2. Attach the following to complete the Request:
 - a copy of the protocol for the research project
 - a copy of the Investigator's Brochure and/or Product Monograph (if applicable)
 - a copy of the Pharmacy Manual (if available)
3. Submit the documents to the Director of Pharmacy in order to obtain their approval.
4. Once signed, please forward a copy of the RPA to reb@hsnsudbury.ca and keep a copy for your records.

Note: If required, you may need to attend the Pharmacy & Therapeutics Committee meeting, present your project and address any concerns the committee may have.

Assistance

If you have any questions regarding the Request for Program Approval form, please contact the Research Services Office at 705-523-7300 ext. 2409 or by email at reb@hsnsudbury.ca