



Providence Health Care - ICU, HAU, Critical Care Manager or Supervisor Declaration of Operational Approval

Research Study Title:

Principal Investigator:

Name:
Title:

Co-Investigator(s) - if the list is long, prioritize to those affiliated with the ICU:

Ethic Certificate No:

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PHC Manager/Medical Director/Database Steward:

I HEREBY CONFIRM that:

- All operational and clinical issues have been reviewed and resolved to my satisfaction
- I agree that the above mentioned study may proceed in the clinical area starting on _____ (date) pending receipt of the Certificate of Ethical Approval and PHC Institutional Certificate of Final Approval

The investigator is responsible for providing the Manager with copies of both certificates of approval.

If the time and/or resource commitment is greater than initially anticipated (as outlined in this document), we reserve the right to review our continued involvement in the need for the study budget to provide resources to the program/unit.

Signature _____

Date _____

PHC Manager's Name: _____

Title _____

Required for ALL applications

Signature _____

Date _____

PHC Medical Director's Name: _____

Title _____

Required IF research involves patients and/or patient data

Signature _____

Date _____

Database Steward's Name: _____

Title _____

Required IF research requires access to databases

Summary of Proposed Research

Principal Investigator:

Name:	
<input type="checkbox"/> Medical Staff	<input type="checkbox"/> Non-Medical Staff
<input type="checkbox"/> Other (Specify):	

Short Title:

Primary Contact for the Research:

Name:	Telephone:
Email:	

Areas in St. Paul’s Hospital where the study will be carried out:

Research Summary as per box 5.1.A of REB Application (Lay Summary, max 100 words)

Study Recruitment:

Target Population:	
<input type="checkbox"/> In-patients	<input type="checkbox"/> Chart Review
<input type="checkbox"/> Staff (specify):	
<input type="checkbox"/> Other (specify):	
Access to confidential and/or personal information:	
<input type="checkbox"/> Health Records	<input type="checkbox"/> ICU Database
<input type="checkbox"/> Code Blue Database	<input type="checkbox"/> Other (specify):
<input type="checkbox"/> PHCRI Confidentiality Agreement has been submitted	
Expected Start Date:	Expected End Date:
Expected number of participants at this site:	
Recruitment Strategies:	
• Who will make initial contact?	
• How will ICU be notified about eligible and enrolled patients?	
• Describe any involvement by ICU staff with recruitment?	

