

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:

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:

Short Title:

Primary Contact for the Research:

Name: Email: Telephone:

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:

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Target Population:
□ In-patients □ Chart Review □ Staff (specify):
Other (specify):
Access to confidential and/or personal information:
□ Health Records □ ICU Database □ Code Blue Database □ Other (specify):
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?



Process for Obtaining Consent:

Staff Impact: Are Nurses or other ICU staff:

1. participants in this study?
□ No □ Yes → estimated time:
describe tasks involved:
2. required to collect any additional data beyond routine care?
□ No □ Yes → estimated time:
describe tasks involved:
3. required to do any other tasks associated with this study beyond routine care?
\Box No \Box Yes \rightarrow estimated time:
➔ list tasks involved:

Impact on Resources:

4. Study funded? □ No □ Yes → list source:
5. Will the study result in additional cost to the program/unit?
□ No □ Yes (please describe)
Equipment:
Supplies:
Personnel:
Other:
6. Are those costs being completely covered by the Research Funding?
□ Yes □ No If no, please explain who will pay for the additional costs: