# Providence Health Care – Emergency Department
# Manager or Supervisor Declaration of Operational Approval

**Research Study Title:**

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**Principal Investigator:**

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|---|
| **Name:** |
| **Title:** |

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

| | |
|---|---|
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**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:

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|---|
| **Name:** |
| ☐ Medical Staff ☐ Non-Medical Staff ☐ Other (Specify): |

## Short Title:

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|---|
| |

## Primary Contact for the Research:

| | |
|---|---|
| **Name:** | **Telephone:** |
| **Email:** | |

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

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

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## 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 ☐ Clinical System 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 the ED be notified about eligible and enrolled patients?** |
| • **Describe any involvement by ED staff with recruitment?** |

## Process for Obtaining Consent:

## Staff Impact: Are Nurses or other ED 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?**
☐ No ☐ Yes ➔ 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: