Early Nurse Initiated Fascia Iliaca Regional Nerve Blocks for Fractured Neck of Femur in Elderly Emergency Department Patients: an Implementation and Generalisability Study

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**STATEMENT OF COMPLIANCE**

This document is a protocol for a clinical research study. The study will be conducted in compliance with all stipulations of this protocol, the conditions of ethics committee approval, the NHMRC National Statement on Ethical Conduct in Human Research (2007) and the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95)

**PROTOCOL SYNOPSIS**

|  |  |
| --- | --- |
| Title | Early Nurse Initiated Fascia Iliaca Regional Nerve Blocks for Fractured Neck of Femur in Elderly Emergency Department Patients: an Implementation and Generalisability Study |
| Objectives | Primary: To study, inform and refine the process of implementing Nurse-Initiated Fascia Iliaca Blocks in order to facilitate State-wide roll out  Secondary: Small-scale follow-up to compare differences between NI-FIB recipients and non-recipients in terms of time to, and degree of, recovery |
| Study Design | Stepped wedge |
| Planned Sample Size | 900 |
| Selection Criteria | Primary Objective: All elderly patients with fractured neck of femur without medical contra-indications who consent to receive a regional nerve block.  Secondary Objective: All elderly neck of femur fracture patients who were living independently prior to their fracture, who consent to be part of the follow up study. |
| Study Procedures | Implementation study, small scale follow up of patient wellbeing |
| Statistical Procedures | Sample Size Calculation:  Analysis Plan: |
| Duration of the study | 24 Months |

# Study Management

* 1. **Principal Investigator**

|  |  |
| --- | --- |
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* 1. **Statistician**

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* 1. **Funding and resources**

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# INTRODUCTION AND BACKGROUND

* 1. **Background Information**

Approximately 17,000 predominantly older Australians sustain a fractured hip/neck of femur every year (ANZHFR 2014), a substantial proportion of whom also carry some degree of cognitive impairment.

Fractured neck of femur (#NOF) is a very painful condition. The NSW ACI *Minimum Standards for the management of hip fracture in the older person* (2014) state that “Pain should be presumed to be severe and ongoing following hip fracture. Effective pain management is a primary goal….” (p9)

Although pain is the commonest presenting feature to EDs (Cordell et al. 2002), there is evidence that pain is inadequately treated in EDs (Rupp &Delaney 2004), particularly so in elderly patients and the cognitively impaired.

Conventional analgesia is potentially problematic because opiate analgesia is associated with increased levels of delirium in elderly patients. Varied approaches are taken towards the management of pain in patients with hip fractures, including parenteral opiates and/or NSAIDS, and nerve blockades. A 2011 systematic review of 83 studies relating to these and other techniques ([Abou-Setta et al. 2011](#_ENREF_1)) concluded that nerve blockades in general are more effective than standard care, reducing the need for systemic analgesia and lowering the risk of delirium.

There are a variety of regional nerve block techniques available. including femoral nerve block (FNB), “ 3 in 1” blocks and fascia iliaca compartment blocks (FIB). These techniques are proven safe and are extremely effective in reducing pain in this condition irrespective of the particular technique employed.

A retrospective study of pre-operative analgesia consumption compared opiate analgesia dosages in patients who had received FIB with that in patients who received no nerve block (Chereshneva et al. 2011). A large and significant decrease in the amount of opiate analgesia required by the FIB recipients was reported; 80% of FIB recipients required no opiate analgesics.

Other factors preferencing FIB over other techniques are that FIB is easier to learn and can be performed by trained health care providers including nurses and paramedics who do not have formal anaesthetics backgrounds ([Obideyi et al. 2008](#_ENREF_7), [Randall et al. 2008](#_ENREF_9), [Dochez et al. 2014](#_ENREF_3), [McRae et al. 2015](#_ENREF_5), [Pinson 2015](#_ENREF_8)); that in experienced hands, FIB takes about half the time or less to perform as other techniques, therefore reducing time to analgesia ([Reavley et al. 2014](#_ENREF_11)). In addition, Nurse-initiated FIB (NI-FIB) can be performed at Triage (early in the patient journey), whereas medically-initiated FNB tends to occur (sometimes several hours) later

Although a 2014 NSW Statewide facility audit states that nerve blocks are offered to patients ‘frequently’ for pre-operative pain management in 21 out of 37 hospitals which perform hip replacement surgery (ANZHFR 2014a, p11), this may be an over-estimate. ([Holdgate et al. 2010](#_ENREF_4)) conducted a retrospective medical chart audit across Australian Emergency Departments and found that only 7% of hip fracture patients received a nerve block in the Emergency Department, morphine was administered to nearly 60% of patients, and the median time to analgesia of any form was 75 minutes. In addition, pain was in general found to be “poorly documented:” fewer than 50% of patients had documented pain scores.

It is clear that providing timely and effective pain relief is a desirable outcome for patients and staff, and NI-FIB has great potential in this regard. Current ACI (NSW) policy supports this approach (NSW ACI 2016). However, this means the introduction of a new practice to Australian EDs.

* 1. **Research Question**

This project has a strong emphasis on knowledge translation. We know that early, effective pain management can be achieved by ***E***arly, ***N***urse ***I***nitiated ***F***ascia ***I***liaca ***B***lock (ENI FIB). We are seeking to answer the question: ‘what needs to happen in order to get Nurse-initiated FIB to become standard practice in a NSW ED?’

The secondary research question is: how many elderly #NOF patients recover to their pre-fracture levels of movement and does the provision of ENI FIB have any association with recovery rates/degree of recovery?

* 1. **Rationale for Current Study**

It is clear from section 2.1 above that providing timely and effective pain relief is a desirable outcome for patients and staff, and ENI-FIB has great potential in this regard. Current ACI (NSW) policy supports this approach. However, this means the introduction of a new practice to Australian EDs. This NSW Health-funded study seeks to answer the question: ‘what needs to happen in order to get Nurse-initiated FIB to become standard practice in a NSW ED?’

# STUDY OBJECTIVES

* 1. **Primary Objective**

The primary objective of this study is the generation of data to support/disprove the following hypotheses:

1. The process of early, nurse initiated, standardised FIB (ENI FIB) for suspected fractured NOF can be successfully, safely, sustainably and economically introduced into a busy, tertiary level metropolitan emergency department.
2. ENI FIB can be generalised to a busy, regional emergency department with no deterioration of efficacy, safety, sustainability or economic performance.
   1. **Secondary Objectives**

The secondary objectives of this study are to support/disprove the following hypotheses:

1. ENI FIB provides equi-analgesia but more rapid pain relief compared to standard, medically instituted FNB
2. The use of ENI FIB will reduce opiate drug requirements in some patients and lead to a corresponding decrease in opiate related delirium.
3. ENI FIB can provide adequate and safe analgesia to patients with mild to moderate cognitive impairment as judged by a triage applied Six Item Scanner (SIS) tool.

# STUDY DESIGN

* 1. **Type of Study**

This study uses a prospective, stepped wedge design, which will allow comparability (both vertically and horizontally) of pre and post-intervention data. The pre-intervention data collection phase provides a control.

* 1. **Study Design**

***Overview:*** This study design will allow comparability (both vertically and horizontally) of pre and post-intervention data. The pre-intervention data collection phase provides a control.

The study will be conducted over two sites: Royal North Shore Hospital Emergency Department, a tertiary level metropolitan ED; and Gosford Hospital ED, which is regionally situated. The patient population for the study will be all patients >65 years of age presenting to either ED with a suspected #NOF. The provider population will be senior nursing staff trained to perform FIBs. The study duration will be 24 months.

We will first implement a practice change at RNSH: from the existing model where patients with #NOF are administered a medically initiated nerve block usually relatively late in their ED stay, if at all, to a new model where senior nursing staff are trained to perform early FIB at or within 30 minutes of triage.

The initial success of the practice change at RNSH will be assessed prior to moving towards implementation at the second site. Using a ‘train the trainer’ model, trained operators from the RNSH site will travel to Gosford ED to undertake initial training of Gosford ED nurses. This on-site training will mirror the training provided at RNSH and will include testing of essential pre-reading (sent out prior to the site visit), didactic teaching of the relevant anatomy, pharmacology and the procedure itself, orientation to the target site’s ultrasound machine, identification of relevant inguinal region anatomy on a human volunteer, FIB technique demonstration on an animal model and finally a post- test/analysis. Credentialling of the new operator group will rely on sign off of three successful /safe FIBs on patients by Gosford ED senior medical staff who are already credentialed to perform this block. Ongoing site visits by nursing champions from the primary site will occur to analyse uptake, provide practical advice and feedback.

The study design, and data collection points are summarised in Figure 1. Study design and timeline and Figure 2. Data collection points.

***Sample size****:* In order to detect an increase in the procedure rate from a current baseline (25% of eligible patients) to a conservative target (50% of eligible patients) with 80% power and alpha 0.05/ beta 0.2, estimated minimum sample size across the preparation/audit and intervention phases is 58 patients per group ie total sample size 116. This sample size is attainable as RNSH and Gosford EDs currently see in excess of 500 patients per annum, of whom approximately 70% would be eligible for ENI FIB.

***Governance*:** The project will be overseen by a Steering Committee which will meet monthly in 2016 then bi-monthly in 2017 and monthly or as required in 2018. This Committee will comprise the Project team, key partners and patient representatives.

A compact Project Monitoring Group (the Chief Investigator, Nurse Champion, NUM, Director of ED) will be constituted during the implementation phase which will conduct monthly meetings: more frequently if indicated by adverse events, staff feedback, unforeseen issues.

***Safety:*** Patients receiving ENI FIB will be observed for procedural and drug toxicity within the ED and the orthopaedic ward as per standard practice. All potential safety issues will be fed back to the PI (or designated officer in the case of absence of PI) as soon as practicable depending on the severity of any issue. The Project Monitoring Group will review safety issues as a regular part of their monthly meeting or will meet at short notice if required.

**Data collection**

***Auditing***: The audit will capture data on the pre-implementation rate of RNBs in patients with suspected #NOF, details of pharmacological analgesia administered (drug route of administration, individual and total dosages), pain scale data, time to initial and adequate analgesia. The data extractor will include all of the target population falling into the mild to moderate cognitive impairment group utilising the Six Item Screener (Callahan et al 2002). Data extraction will be performed at both sites by a single, trained operator using a standardised data extraction tool. A random sample of the audit will be reviewed periodically by the PI to ensure data quality.

***Qualitative data***: tools will be developed to assess the acceptability of the new process with staff (nursing and medical), ED administrative staff (DEM, NUM, CNC) and patients. Staff at RNSH will be surveyed during the early part of the implementation phase to ascertain the acceptability of the newly introduced ENI FIB process and again near the end of the implementation phase. Staff at Gosford will be similarly surveyed.

***Patient data:*** Data will be collated from ED records relating to number of patients who did/did not receive ENI FIB; time from arrival at ED to ENI FIB; pain scores at arrival to ED, immediately prior to ENI FIB, one hour post ENI FIB and on discharge from ED; Total opiate drug load in patients who did/ did not receive ENI FIB; number of defined adverse events related to ENI FIB.

**Implementation Phase**

All patients >65 years presenting with suspected # NOF will be triaged and given early parenteral analgesia as per established protocols. Triage will perform a Six Item Scanner screen for cognitive impairment and apply a pain scale relevant to the degree of cognitive impairment ie 10cm VAS in patients with SIS five or six, PAINAD score in patients with SIS < or = 4.

The Protocol aims to provide ENI FIB to all eligible patients within the first hour of ED presentation and ideally within the first thirty minutes. Pain scales will be recorded upon arrival at ED (Triage), immediately prior to ENI FIB, one hour post ENI FIB and upon discharge from ED. All patients (FIB recipients or otherwise) will be offered additional pain relief as required and as per standard practice.

Ineligible patients: Exclusion criteria for administration of ENI FIB will be:

1. Refusal of regional nerve block for any reason
2. Body habitus of type deemed likely to make FIB difficult or dangerous eg extreme obesity, deranged injection site anatomy
3. Patient behavior deemed likely to make FIB difficult or dangerous eg agitation, severe cognitive impairment, inability/unwillingness to remain still
4. Localised groin infection
5. Coagulopathy of any cause

**Data Analysis**

Data analysis will proceed as indicated in Figure 2. Data collection points.

***Project aims/ primary outcomes***. Calculate number and proportion of patients who received a successful ENI FIB (PD 1-4) within target time, incidence of adverse events

1. Determine the safety of ENI FIB at each site: compare between sites
2. Compare horizontally at each site: Does the effectiveness of the intervention drop off or is it sustained or increased?
3. Compare vertically between sites: Does the intervention have the same or different effectiveness at the different sites?
4. Evaluate AI 1&2: data to inform a) - c) above as required

***Secondary hypotheses***

1. Compare time to FIB (PD1-4) with time to medically initiated nerve block using data from audit (secondary hypothesis 1)
2. Determine differences, if any, in opiate drug requirements and incidence of delirium between FIB recipients, FIB non-recipients (PD 1-4) and medically initiated nerve block using data from audit (secondary hypothesis 2)
3. Determine (PD 1-4) the level of cognitive impairment at which FIB is not feasible or practicable (secondary hypothesis 3)

***Qualitative analysis***. Determine key stakeholder concerns: embed in learning and teaching materials as indicated

***Costing:*** Calculate:

1. cost for host institutions to maintain momentum (ie ongoing training and credentialling)
2. total costs to implement at other sites using RNSH-centred trainer
   1. **Number of Participants**

900 / (500 for follow-up)

* 1. **Study sites**

This study will be conducted over two sites: Royal North Shore Hospital Emergency Department, a tertiary level metropolitan ED; and Gosford Hospital ED, which is regionally situated. The patient population for the study will be all patients >60 years of age presenting to either ED with a suspected #NOF. Both sites are expected to involve approximately 450 participants.

The change in practice will first be implemented at RNSH. Data from RNSH will inform and refine the roll-out of the new practice at Gosford.

* 1. **Expected Duration of Study**

This study will run for 24 months beginning in September 2016. Recruitment will occur throughout the study.

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Month**  **number** | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** | **11** | **12** | **13** | | **14** | **15** | **16** | **17** | **18** | **19** | **20** | **21** | **22** | **23** | **24** |
| Activity | **Pre-Implementation period RNSH** | | | | | | **Implementation - RNSH**  Data collection  Data  collection  PD 2, AI 1  PD 1, EI 1 | | | | | | | | | | | | | | | **Reporting period**  Assess Sustainability,  Generalisability,  Finalise Toolkits, Project Reporting etc | | | |
| Training, develop protocols, develop & test survey tools to assess attitudes/barriers etc. Departmental orientation to upcoming practice change | | | | | |
| **Pre-Implementation period - Gosford Hospital** | | | | | | | | | | | | | **Implementation**  **Gosford Hospital**  Data  Data  collection  PD 4, AI 2  collection  PD 3, EI 2 | | | | | | | | | |  | |
|  | | | | | | Training, Departmental orientation to upcoming practice change | | | | | | |

Figure 1. Study design and timeline

|  |  |  |
| --- | --- | --- |
| **Data collection** | **Data collected** | **Purpose** |
| **PD 1, PD 2, PD 3 & PD4** | Number of patients who received ENI FIB/ received no nerve blockade  Time from arrival in ED to regional nerve blockade with ENI FIB  Pain scores at arrival in ED, immediately prior to ENI FIB, one hour post ENI FIB and on discharge from ED  Total opiate drug load in patients who/ did not received ENI FIB  Number of defined adverse events related to ENI FIB  Opiate induced delirium in all #NOF patients  Cognitive status of all #NOF patients | Determine Primary outcome (number and proportion of patients provided with successful FIB)  Determine Secondary outcomes  Information about sustainability (compare PD 1 & PD 2)  Information about generalisability (compare PD1, PD2 & PD3) |
| **EI 1 & EI 2** | ***E***arly ***I***mplementation survey: attitudes towards procedure, confidence/fear, acceptability, barriers, enabling factors | Assessing generalisability (are different concerns found at different sites?) allows feedback, adjustments |
| **AI 1 & AI 2** | ***A***fter***I***mplementation survey: attitudes, confidence/fear, acceptability, barriers, enabling factors, satisfaction | Embedding sustainability (training and other requirements to maintain momentum) |

Figure 2. Data collection points

* 1. **Primary and Secondary Outcome Measures**

***Primary outcomes***. Calculate number and proportion of patients who received a successful ENI FIB (PD 1-4) within target time, incidence of adverse events

1. Determine the safety of ENI FIB at each site: compare between sites
2. Compare horizontally at each site: Does the effectiveness of the intervention drop off or is it sustained or increased?
3. Compare vertically between sites: Does the intervention have the same or different effectiveness at the different sites?
4. Evaluate AI 1&2: data to inform a) - c) above as required
5. *Qualitative analysis*: Determine key stakeholder concerns, inform and refine teaching/ implementation approach as indicated
6. Generate ENI FIB implementation tool kit for future use in State wide roll out

***Secondary hypotheses***

1. Compare time to FIB (PD1-4) with time to medically initiated nerve block using data from audit (secondary hypothesis 1)
2. Determine differences, if any, in opiate drug requirements and incidence of delirium between FIB recipients, FIB non-recipients (PD 1-4) and medically initiated nerve block using data from audit (secondary hypothesis 2)
3. Determine (PD 1-4) the level of cognitive impairment at which FIB is not feasible or practicable (secondary hypothesis 3)

***Qualitative analysis***. Determine key stakeholder concerns: embed in learning and teaching materials as indicated

1. **PARTICIPANT ENROLLMENT** 
   1. **Recruitment**

All patients over the age of 65 years with a suspected fractured neck of femur and who do not have medical contra-indications for a nerve block will be offered a Nurse-initiated Fascia Iliaca Block within one hour of their presentation to ED. Anonymous data collection regarding uptake of ENI-FIB, pain scores, other analgesic dosages and adverse events will be collected for all #NOF patients.

With respect to the Secondary objective: all patients over the age of 65 years with a suspected #NOF who were living independently prior to their fracture, and who are relatively cognitively intact (as estimated by a SIS score of 4 or above) will be invited to participate in the follow-up arm of the study, regardless of whether they had a ENI-FIB. A Research Assistant (RA) will identify potential participants on the electronic records system and gain the consent of the treating doctor to approach the patient, while they remain in the ED, after they have received adequate pain relief. The RA will introduce him/herself, explain the follow-up study to the patient, offer written information, and invite the patient to become a participant by giving informed consent.

* 1. **Eligibility Criteria**
     1. **Inclusion Criteria**

Primary Objective: All patients presenting to the ED with a #NOF or suspected #NOF who are older than 65 years.

Secondary Objective: All patients presenting to the ED with a #NOF or suspected #NOF who are older than 65 years, were living independently prior to their fracture, and have a SIS score of five or six and who consent to a short follow up interview after their discharge home.

* + 1. **Exclusion Criteria**

Exclusion criteria for administration of ENI FIB:

1. Patient under the age of 65 years
2. Patient refusal of regional nerve block
3. Body habitus of type deemed likely to make FIB difficult or dangerous eg extreme obesity, deranged injection site anatomy
4. Patient behavior deemed likely to make FIB difficult or dangerous eg agitation, severe cognitive impairment, inability/unwillingness to remain still
5. Localised groin infection
6. Coagulopathy of any cause

# Informed Consent Process

With respect to the primary objective, consent is sought for the FIB as it would be for any other standard medical intervention, as NI-FIB is standard practice in this ED. We are not seeking consent for data collection as this is an implementation study and data collection will be anonymous harvesting of data that is collected as part of standard care (eg pain scores, analgesia dosages, length of stay on hospital, consent/refusal of block, adverse events etc). Subsections a) to f) of section 2.3.1 of the National Statement apply and the method for the primary objective satisfies these: ie there is no/low risk (a), the benefits from the research justify any risks of harm associated with not seeking consent (b), it is impracticable to obtain consent (c), there is no known or likely reason for thinking that participants would not have consented if they had been asked (d), there is sufficient protection of their privacy (e) and there is an adequate plan to protect the confidentiality of data (f).

With respect to the secondary objective, after having identified potential participants and gained the permission of the treating doctor, the RA will approach the patient, introduce him/her self, and briefly explain the study to the patient. If the patient shows interest in the study, the RA will explain the study in more detail and give the patient an information sheet. The RA will encourage potential participants to ask any questions they may have, and will ensure that it is understood that participation is voluntary, any information given will be treated in confidence, and that consent can be withdrawn at any point without affecting their treatment or their relationship with their treating team. The patient will then be asked to sign a consent form.

* 1. **Participant Withdrawal**
     1. **Reasons for withdrawal**

It will be made clear to patients at the recruitment phase that they are able to withdraw at any time without penalty and without affecting their treatment. Patient withdrawals will not compromise the study (unless it were a very large scale withdrawal) due to the large numbers we anticipate enrolling.

Early termination of this study is extremely unlikely: the study is a fully funded implementation study of a non-controversial and medically-accepted procedure. In the unlikely event that the study was terminated early, participants would still be treated with NI-FIB, but the study team would cease collecting and analysing data.

# STUDY VISITS AND PROCEDURES SCHEDULE

These procedures will be ‘rolling’ as patients present to the ED over the course of the study (24 months).

Data extraction: The electronics records system (‘FirstNet’) will be interrogated for all patients older than 65 years who present to the ED and are triaged under the following headings: ‘fractured neck of femur”, “suspected fractured neck of femur”, “fractured NOF”, “suspected fractured NOF”, “hip pain”, “thigh pain”, “leg pain”, “leg shortening”, ‘leg internally rotated” and “unable to weight bear” Relevant patient information (pre-operative pain scores, analgesic use) will be extracted.

Secondary objectives: enrolled patients will be interviewed about their pre-fracture Activities of Daily living whilst awaiting ward transfer from ED. These patients will be contacted three months later by telephone and will be asked the same questions about their Activities of Daily Living.

# ADVERSE EVENT REPORTING

Dr Mark Gillett is the nominated contact person for any and all issues relating to safety on this project. A compact Project Monitoring Group (the Chief Investigator, Nurse Champion, NUM, Director of ED) will be constituted during the implementation phase which will conduct monthly meetings: more frequently if indicated by adverse events, staff feedback, unforeseen issues.

Patients receiving ENI FIB will be observed for procedural and drug toxicity within the ED and the orthopaedic ward as per standard practice. All potential safety issues will be fed back to the CI Dr Mark Gillett (or designated officer in the case of absence of CI) as soon as practicable depending on the severity of any issue. The Project Monitoring Group will review safety issues as a regular part of their monthly meeting or will meet at short notice if required.

It is not anticipated that the brief follow-up interviews would cause distress to participants. However, the Research Assistant will be experienced in conducting telephone interviews and will be alert to potential distress, and will advise the participants that if they are experiencing distress, the interview can be terminated. The Research Assistant conducting the interview will have materials at hand in order to refer a distressed participant to relevant services if required.

# STATISTICAL METHODS

* 1. **Sample Size Estimation**

In order to detect an increase in the procedure rate from a current baseline (25% of eligible patients) to a conservative target (50% of eligible patients) with 80% power and alpha 0.05/ beta 0.2, estimated minimum sample size across the preparation/audit and intervention phases is 58 patients per group ie total sample size 116.

* 1. **Statistical Analysis Plan**

Percentage outcome measures of uptake of RNB with initiation of ENI FIB and percentage of patients returning to pre-fracture functional level will be analysed by Chi Square Analysis. Comparison of VAS Pain Scale data between operator groups will be by Two Sample T-testing.

As there is estimated to be little (if any) missing data, no compensatory techniques will be applied.

* 1. **Interim Analyses** (not applicable)

# DATA MANAGEMENT

* 1. **Data Collection**

Data collection will be conducted by the Project Officer and Research Assistant via extraction from the ED’s electronic records system (‘FirstNet’) and, in the case of the Secondary Objective, directly from the patient participants. The staff survey forms will be distributed via customary places for surveys in the staff lunch room and the completed surveys will be collected from a nominated drop box in the same location.

* 1. **Data Storage**

The project database will be held within Excel spread sheets. All electronic data will be held on a password-protected computer which is located in a secure, staff access-only office area. Weekly backups will take place onto an external hard drive which will be stored in a locked cabinet in the Chief Investigator’s office. No person other than the project Investigators and the Project Officer and Research Assistant will have access to the data.

The Project Officer or one of the Investigators will be responsible for assigning a unique code to participants enrolled in the follow-up study: subsequent data analysis will proceed using coded data. The Master key linking participants’ personal details with the assigned code will be stored in a locked cabinet in the Chief Investigator’s office. No person other than the Project Investigators and/or the Project Officer will have access to the Master key.

* 1. **Data confidentiality**

Participants’ privacy will be protected at all times. Data analysis will proceed with coded data only, and after data analysis, all data held in the project database will be permanently de-identified prior to storage and archiving. Staff participant data will be collected anonymously: therefore incurring no confidentiality concerns. With respect to publication, patient confidentiality is protected because only de-identified data will be published.

* 1. **Study Record Retention**

Project data and all other records will be retained securely, under the circumstances detailed above, for 5 years after the completion of the study, after which point it will be destroyed via Hospital procedures for the destruction of secure data.

# ADMINISTRATIVE ASPECTS

* 1. **Independent HREC approval**

This study has been approved by the Northern Sydney Local Health District HREC, reference number: HREC/16/HAWKE/203

* 1. **Amendments to the protocol**

Any amendments will be submitted to the HREC for review prior to implementation as per HREC guidelines.

* 1. **Participant reimbursement**

There will be no patient reimbursements or other payments of any kind.

* 1. **Financial disclosure and conflicts of interest**

No person will receive any financial benefit from either being a study participant or a member of the research team and there are nil conflicts of interest.

# USE OF DATA AND PUBLICATIONS POLICY

Data generated during this study will be published in a variety of formats. These include:

* ENI FIB Implementation Toolkit produced in conjunction with the (NSW) Agency for Clinical Innovation
* NSW Health final policy on ENI FIB
* 3 peer reviewed scientific articles. Dr Mark Gillett will lead authorship on one paper, Ms Lesley Fitzpatrick will lead a paper with nursing perspective, and Dr John Vassiliadis will lead authorship of the third paper
* Two conference papers; one presented by Dr Mark Gillett, one by Ms Lesley Fitzpatrick

All Investigators, the Project Officer and potentially the Research Assistant will be acknowledged on all publications subject to fulfilling guidelines on authorship as contained in the Vancouver Protocol. Patient confidentiality will be upheld at all times.

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