Human Research Ethics Application

Application Management Information
Application ID: 169106
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**This is the earliest application from which this application was copied.*
Parent Application ID:
**This is the immediate predecessor from which this application was copied.*
Version Number: HREA V1.3 (2017)
Application submitted to: Nepean Blue Mountains Local Health District, Nepean Blue Mountains Local Health District Human Research Ethics Committee

The applicant has requested that this ethics application be considered under the Low risk review pathway.

Section 1 – Core Information

Pre-application conditions

Before completing this application, acknowledge that:

1) The HREA has been designed for ethics review of human research, as defined in the National Statement.
2) Adequate resources must be available to conduct this research project.
3) All relevant institutional polices pertaining to the conduct of this research project should be considered and adhered to.
4) Research activities must not commence until ethics approval (and site authorisation, if appropriate) has been provided.
5) The HREA requires the attachment of a Project Description/Protocol.

◉ Acknowledge and Continue

PROJECT OVERVIEW

Q1.1. What is the project title (as presented in the Project Description/Protocol)?

Reducing hospital length of stay and readmission rates in surgical inpatients with diabetes mellitus through improved glycaemic control using an automated glucose system.

Q1.2. Provide a summary of the research project in non-technical language.

Our aim is to reduce average length of stay (ALOS, 28 day readmission rates and complications of surgical site infection for patients with diabetes mellitus and decrease costs to the health system whilst maintaining or improving patient outcomes.

The AMSL Connectivity glucose and ketone meter will replace the current AMSL StatStrip glucose and ketone meters in 2 inpatient Nepean Hospital surgical wards: E3I and E3H. Participants will be patients with diabetes in these wards.

METHODS
This prospective intervention study consists of 3 phases:
• Phase 1 (non-intervention): ensuring efficient and complete capture of all glucometer data and uploading of data to remote location of diabetes service using the new connectivity glucometers with usual management of diabetes mellitus.
• Phase 2 (intervention): review of all glucometer data by diabetes team and intervention for patients with glucometer readings which lie outside the range of 4-10mmol/l. The intervention will be assessment and

management by diabetes service to optimize glycaemic control.
• Phase 3: data collection and analysis

We expect to see a reduction in ALOS and RR for patients with diabetes and anticipate a substantial cost saving to the hospital.

Q1.3. Which category/ies of research best describes the project?

Clinical Research

Q1.4. In what environment/s will the research be conducted?

- ☐ Clinic(s)
- ☐ Community centre(s)
- ☐ Cultural/religious organisation(s)
- ☑ Hospital(s)
- ☐ Online
- ☐ Private residence(s)
- ☐ Professional organisation(s)
- ☐ Public place(s)
- ☐ Research institute(s)
- ☐ School system(s)
- ☐ University(ies)
- ☐ Workplace(s)
- ☐ Other

Q1.5. What organisation/entity has overall responsibility for this project?

Nepean Diabetes Service, Nepean Hospital. with oversight by NBMLHD Human Research Ethics Committee.

Q1.6. Describe how this research project is currently, or will be, funded.

There is no funding associated with this research. Research will be conducted during normal working hours of participating staff. AMSL connectivity glucometers have been loaned by AMSL, the company which manufactures them.

Q1.7. When do you anticipate starting the research project?

☑ As soon as ethics and any other relevant approvals have been provided.

Q1.8. What is the anticipated duration of the research project?

Years

PROJECT TEAM

Q1.9. Investigator/ Research team

Provide information on the investigator(s)/ researcher(s) conducting the research.

Investigator/ Researcher 1

Q1.9.1 Title

Mrs

Q1.9.2 First Name

Irene

Q1.9.3 Surname/family name

Kopp

Q1.9.4 Email Address

irene.kopp@health.nsw.gov.au

Q1.9.5 Is this person the contact person for this application?

(•) Yes ( ) No

Q1.9.5.1 Contact Email Address

irene.kopp@health.nsw.gov.au

Q1.9.5.2 Contact Phone number

0407217497

Q1.9.5.3 Contact Mailing address

Diabetes Service, Nepean Hospital
PO Box 63
Penrith NSW 2751

Q1.9.6 Is this person a student on this project?

( ) Yes (•) No

Q1.9.7 Institutional affiliation and position.

CNC for the Diabetes Service
Nepean Blue Mountains Local Health District

Q1.9.8 Staff ID Optional

26109934

Q1.9.9 ORCID Identifier Optional

Q1.9.10 What is the position of this person on the research project?

Chief Investigator/Researcher

Q1.9.11 Does this person have authorisation to sign the application on behalf of all members of the research team?

(•) Yes ( ) No

Q1.9.12 Describe the research activities this person will be responsible for.

Implementation of meters on the ward and training staff on use of meters
Collection of data
Data analysis
Review of patients with diabetes on the wards (part of normal role)
Education to patients with diabetes (part of normal role)
Education to nursing and medical staff (part of normal role)

Q1.9.13 Describe the person's expertise relevant to the research activity.

Irene is a Clinical Nurse Consultant at Nepean Diabetes Service, she has been a Credentialed Diabetes Educator at Service since 2004 and an Endorsed Nurse Practitioner since 2011. As a senior clinician she coordinates the diabetes inpatient service at Nepean Hospital and provide clinical leadership and support to nursing, medical and allied health staff to all the hospitals in our area health service. Irene provides comprehensive assessments and management of both inpatients and outpatients, develop and update policies for the Nepean Blue Mountains Local Health District (NBMLHD), coordinate and implement new procedures in relation to best practice Diabetes Management and, review current diabetes technology for the implementation of state-of-the-art equipment to hospitals within NBMLHD. She lectures at the University of Sydney and the University of Technology, Sydney (UTS) in both undergraduate and post graduate courses for medical and nursing students and was the course coordinator at UTS for the Master of Nursing, Nurse Practitioner and The Graduate Certificate in Diabetes Education and Management in 2012 and 2013.
1996 - Bachelor or Nursing, University of Western Sydney, Parramatta
2001 - Graduate Diploma of Clinical Practice, University of Western Sydney, Macarthur
2005 - Graduate Certificate in Diabetes Education and Management, UTS
2007 - Master of Nursing, Nurse Practitioner, UTS

Investigator/ Researcher 2

Q1.9.1 Title

Associate Professor

Q1.9.2 First Name

Emily

Q1.9.3 Surname/family name

Hibbert

Q1.9.4 Email Address

emily.hibbert@sydney.edu.au

Q1.9.5 Is this person the contact person for this application?
○ Yes ◉ No

Q1.9.6 Is this person a student on this project?
○ Yes ◉ No

Q1.9.7 Institutional affiliation and position.

Sydney Medical School, University of Sydney
Nepean Hospital, NBMLHD.

Q1.9.8 Staff ID Optional

40037739

Q1.9.9 ORCID Identifier Optional

0000-0002-1151-2816

Q1.9.10 What is the position of this person on the research project?

Associate /Assistant/Sub-/Co- Investigator/Researcher

Q1.9.11 Does this person have authorisation to sign the application on behalf of all members of the research team?

○ Yes ◉ No

Q1.9.12 Describe the research activities this person will be responsible for.

Supervision of the research team for project design, ethics application and project implementation, involvement in determining what interventions are required for individual patients as a clinical endocrinologist, data analysis and project write up.

Q1.9.13 Describe the person's expertise relevant to the research activity.

20 year history as clinical endocrinologist.
Similar period of time involved design and implementation of research projects in medical education and endocrinology.
Experience in supervision of medical students and junior doctors in research projects.

Investigator/ Researcher 3

Q1.9.1 Title

Dr

Q1.9.2 First Name

Jeff

Q1.9.3 Surname/family name

Ahn

Q1.9.4 Email Address

jeff.ahn@health.nsw.gov.au

Q1.9.5 Is this person the contact person for this application?

○ Yes ◉ No

Q1.9.6 Is this person a student on this project?

○ Yes ◉ No

Q1.9.7 Institutional affiliation and position.

Endocrinology Advanced Trainee, Nepean Hospital

Q1.9.8 Staff ID Optional

60001813

Q1.9.9 ORCID Identifier Optional

Q1.9.10 What is the position of this person on the research project?

Associate /Assistant/Sub-/Co- Investigator/Researcher

Q1.9.11 Does this person have authorisation to sign the application on behalf of all members of the research team?

○ Yes ◉ No

Q1.9.12 Describe the research activities this person will be responsible for.

Data collection, patient review and intervention as required. Data analysis and project write up.

Q1.9.13 Describe the person's expertise relevant to the research activity.

Endocrinology advanced trainee with experience in management of diabetes.

Investigator/ Researcher 4

Q1.9.1 Title

Dr

Q1.9.2 First Name

Kathryn

Q1.9.3 Surname/family name

Williams

Q1.9.4 Email Address

kath.williams@sydney.edu.au

Q1.9.5 Is this person the contact person for this application?
○ Yes ◉ No

Q1.9.6 Is this person a student on this project?
○ Yes ◉ No

Q1.9.7 Institutional affiliation and position.

Staff Specialist Endocrinology NBMLHD
Senior Lecturer University of Sydney

Q1.9.8 Staff ID Optional

56152418

Q1.9.9 ORCID Identifier Optional

0000-0002-1922-3058

Q1.9.10 What is the position of this person on the research project?

Associate /Assistant/Sub-/Co- Investigator/Researcher

Q1.9.11 Does this person have authorisation to sign the application on behalf of all members of the research team?
○ Yes ◉ No

Q1.9.12 Describe the research activities this person will be responsible for.

Contribution to study protocol, conduct study methods and ensure methods align to protocol, assistance with analysis and publication of results.

Q1.9.13 Describe the person's expertise relevant to the research activity.

Kathryn is the Clinical Lead of the Family Obesity Services and a specialist in metabolic health. She is a staff specialist in endocrinology. She completed a PhD in diabetes and non-alcoholic fatty liver disease. She is an AI in several metabolic studies through the Boden Institute of Medical Research and through the University of Sydney.

Investigator/ Researcher 5

Q1.9.1 Title

Professor

Q1.9.2 First Name

Michael

Q1.9.3 Surname/family name

Cox

Q1.9.4 Email Address

m.cox@sydney.edu.au

Q1.9.5 Is this person the contact person for this application?
○ Yes ◉ No

Q1.9.6 Is this person a student on this project?
○ Yes ◉ No

Q1.9.7 Institutional affiliation and position.

Professor of Surgery Nepean Clinical Shcool
Sydney Medical School - Nepean, University of Sydney
Nepean and Blue Mountains Hospitals

Q1.9.8 Staff ID Optional

26116853

Q1.9.9 ORCID Identifier Optional

Q1.9.10 What is the position of this person on the research project?

Associate /Assistant/Sub-/Co- Investigator/Researcher

Q1.9.11 Does this person have authorisation to sign the application on behalf of all members of the research team?
○ Yes ◉ No

Q1.9.12 Describe the research activities this person will be responsible for.

Contribution to study protocol, promotion of study with surgical teams, advice on clinical practice improvement from surgical perspective, assistance with analysis and publication of results.

Q1.9.13 Describe the person's expertise relevant to the research activity.

Michael is a Professor of Surgery.
He has a clinical and research interest in improving glycaemic control in patients both with diagnosed diabetes and with stress hyperglycaemia. He is informed about the initiatives occurring under ACS (American College of Surgeons) NSQIP (National Surgical Quality Improvement Program) which has been used at Nepean Hospital for the last 3 years.

General Surgeon having competed his FRACS in General Surgery in 1990. From 1991 until 1993, he did additional post Fellowship training in Upper Gastrointestinal Surgery, which included training in ERCP, laparoscopic surgery as well as major complex hepatobiliary surgery. In 1994, he commenced his consultant Upper GI surgical practice as a staff specialist at Nepean Hospital. Since 1994 in addition to providing major complex Upper GI surgery, he has also been providing an ERCP service performing an average of 150 ERCP's per annum. He has an interest in emergency surgery, biliary surgery and quality in surgery having published over 80 papers on these and related topics.

DISCLOSURE OF INTERESTS

Q1.10. Do any members of the research team (including persons not listed in this application), have any financial or non-financial interests related to this research?

○ Yes ◉ No

RESTRICTIONS

Q1.11. Are there any restrictions or limits on publication of data or dissemination of research outcomes of this project?

○ Yes ◉ No

EVALUATIONS

Q1.12. Has the scientific or academic merit of the research project been evaluated?

○ Yes ◉ No

Q1.13. Has this research project had prior ethics review?

○ Yes ◉ No

Q1.14. Will any further or additional specialised review of this application be sought?

○ Yes ◉ No

LOCATION

Q1.15. Will this research project be conducted at multiple sites?

○ Yes ◉ No

Q1.16. Will separate institutional approvals or authorisations be required prior to commencing research at each site?

○ Yes ◉ No

Section 2 - Research Details and Participants

METHODS

Q1.17. From the list below, select all the research methods that will be used in the research project.

- [x] Action research
- [ ] Biospecimen analysis research
- [ ] Data linkage research
- [ ] Ethnographic research
- [ ] Epidemiological research
- [ ] Interventional/ Clinical Trial research
- [ ] Observational research

☐ Survey/Interview/Focus Group research

☐ Textual analysis research

☐ None of the above

PARTICIPANTS

Q1.18. Indicate with whom or with what the research will be conducted.

○ Human beings (via active participation), including their associated biospecimens and/or data

○ Human biospecimens only

◉ Data associated with human beings only (i.e. as the primary object of research)

Q1.18.1 Does your research involve the prospective collection of data?

◉ Yes ○ No

Q1.19. Will your research involve participation of any of the following?

☐ Women who are pregnant and the human fetus

☐ Children and young people

☐ People highly dependent on medical care who may be unable to give consent

☐ People with a cognitive impairment, intellectual disability or mental illness

☐ People in dependent or unequal relationships

☐ People who may be involved in illegal activities

☐ People in other countries

☐ Aboriginal and Torres Strait Islander peoples

Method Specific Questions

ACTION RESEARCH

M1.1. What is the challenge, need, phenomenon or question that the research will explore?

Having diabetes as a hospital inpatient is associated with increased length of stay, increased readmission rates and poorer patient outcomes. In particular, surgical inpatients with diabetes have longer lengths of stay than surgical inpatients without diabetes and higher 28 day readmission rates. This creates bed block in surgical wards and is costly to the health system.

The research question is:
Can rapid identification of surgical inpatients with poor glycaemic control and specific intervention to optimise glycaemic control reduce length of stay and readmission rates?

M1.2. What process/es will be used to refine the objectives and design of the research, and how frequently will this be repeated during the project?

The research will use a PDSA clinical practice improvement style of research. The research team will collect baseline data during standard current inpatient diabetes management for 2 months. Following this, the team will

use the remotely uploaded glucometer data from the 2 participating surgical wards to identify patients with glucose levels outside optimal inpatient hospital range of 4-10mmol/l. Those patients will receive assessment by a diabetes educator and if needed by the on call endocrinologist in order to optimise glucose control. The impact of these interventions will be assessed and modified based on the results in terms of glucose control. There is a plan to introduce 2 other specific interventions during the project, which include education of nurses on management of hypoglycaemia and the introduction of a basal-bolus booster insulin evidence based protocol for management of hyperglycaemia. The interventions will be modified based on their impact and there may be new interventions based on learnings from the project and data analysis. The research team will meet every 1-2 weeks to review interventions and their impact and determine whether modification of interventions or new interventions are required.

M1.3. What outputs do you anticipate will be generated by the research?

The outputs will be:
- glucose data showing levels of glucose control in surgical inpatients and excursions outside the recommended inpatient glucose range
- glucose data showing whether the interventions improve glucose control or not
- data showing length of stay (LOS) of inpatients with diabetes during standard management in (Phase 1) and comparing this with length of stay during the intervention phase (Phase 2)
- data showing 28 day readmission rates of inpatients with diabetes during standard management in (Phase 1) and comparing this with 28 day readmission rates during the intervention phase (Phase 2)
-surgical complication rates during phase 1 and phase 2.
-comparison of LOS and 28 day readmission rates during the intervention phase compared with historical data for patients wiht diabetes and without diabetes during the same time period in the year prior.
These data outputs will be analysed and presented at conferences and submitted for publication in medical journals.
The data will inform the value of upscaling this project to more wards and hospitals.

BIOSPECIMEN ANALYSIS RESEARCH

DATA LINKAGE RESEARCH

ETHNOGRAPHIC RESEARCH

EPIDEMIOLOGICAL RESEARCH

INTERVENTIONAL/CLINICAL TRIALS RESEARCH

OBSERVATIONAL RESEARCH

SURVEY/INTERVIEW/FOCUS GROUP RESEARCH

TEXTUAL ANALYSIS RESEARCH

Participant Specific Questions

Pregnant women and human fetus

Children and young people

People highly dependent on medical care who may be unable to give consent

People with a cognitive impairment, an intellectual disability, or a mental illness

People in dependent or unequal relationships

People who may be involved in illegal activities

People in other countries

Aboriginal and Torres Strait Islander Peoples

Recruitment - General

Recruitment - Action Research

Recruitment - Observational Research

Consent

Q2.2.1. Indicate the relevant section/s of your Project Description/Protocol that address/es consent.

We will not be seeking specific consent from patients in the study. The reason for this is that the protocol does not involve any change in diabetes management from that considered optimal practice. The difference in the project approach from the standard approach at Nepean Hospital to diabetes management in surgical inpatients is that patients whose glucose control is outside the optimal in hospital ranges will be identified by the diabetes service through remote glucose automatic uploads and actively assessed by diabetes service team members without the need for a formal consultation by the admitting team. This is likely to identify a larger proportion of patients with diabetes sooner than they would other be identified otherwise. It is envisioned that the utilisation of the automatic glucose meter as well as training to healthcare professional staff in this study will lead to favourable outcomes for patients with diabetes in hospital.

Q2.2.2. Will you be obtaining consent from some or all participants to participate in the research?

- ○ Yes for all participants
- ○ Yes for some participants
- ◉ Not for any participants

Q2.2.3. Are family members, authorised representatives or any others involved in the participants' decision to participate in the research?

○ Yes ◉ No

Q2.2.4. Will there be an opportunity to confirm or re-negotiate consent during the research project?

○ Yes ◉ No

Refer to the relevant section/s of your Project Description/Protocol that detail the process for confirming or re-negotiating consent at Q1 (Consent - General)

Q2.2.6. Describe any ethical considerations related to the approach to consent that you will be seeking and your strategies for addressing and managing these issues.

Consent will be assumed by consent being given to usual care provided by the hospital eg. measurement of glucose levels.

Q2.2.7. Are you proposing to use an opt-out approach with respect to some or all of the participants?

○ Yes ◉ No

Q2.2.8. Are you requesting a waiver of the requirement for consent with respect to some or all participants?

○ Yes ◉ No

Consent - Ethnographic Research

Consent - Children and young people

Consent - People highly dependent on medical care

Consent - People with a cognitive impairment

Consent - Involvement in illegal activities

Risk - General

Q2.3.1. Describe the risks and burdens associated with your research, referencing any relevant sections of your Project Description/Protocol as appropriate.

There are no increased risks or burdens associated with this research. Nursing staff will be checking patient's blood glucose levels as per routine ward protocols, but using a glucometer that will upload that glucose data for review remotely at the diabetes service. The project has potential to provide improved care of diabetes for inpatients in the participating surgical wards.

Q2.3.2. Describe how these risks will be mitigated and managed.

Nil risks

Risk - People in dependent or unequal relationships

Benefit

Q2.4.1. Describe the benefits associated with your research, referencing any relevant sections of your Project Description/Protocol as appropriate.

To determine if optimal glycaemic management for patients with Diabetes Mellitus can reduce Average Length of Stay and Readmission Rates using a proactive technology-assisted approach.

Our aim is to reduce ALOS for patients with DM and decrease costs to the health system whilst maintaining or improving patient outcomes. We plan to achieve this through early identification of glycaemic excursions then to proactively follow-up all patients with diabetes on these wards.

Q2.4.2. Explain how the benefits of this research justify any risks or burdens associated with the research.

There are no risks or burdens associated with this research.

Q2.4.3. How will you manage participants' expectations of the perceived benefit of participating in the research?

There is unlikely to be misconception as the diabetes care provided to optimize glycaemic control will be standard care including:

- Patient education
- Staff education
- Dietitian review
- Review of patient by Endocrinology team doctors

However, there will be better identification of patients who require optimisation of glucose control via uploading of glucose data remotely to the diabetes service.

Section 3 - Data and Privacy

Data and Privacy - Data Characteristics

Q3.1. Indicate the type of information/data you will be collecting for this project.

- [ ] Personal information
- [ ] Sensitive information
- [x] Health information
- [ ] Not personal information

Q3.2. Indicate the type of information/data you will be using in this project.

- [ ] Personal information
- [ ] Sensitive information
- [x] Health information
- [ ] Not personal information

Q3.3. Indicate the degree of identifiability of information/data you will be collecting for this project.

- [ ] Individually identifiable information
- [x] Re-identifiable (coded) information
- [ ] Non-identifiable information

Q3.4. Indicate the degree of identifiability of information/data you will be using in this project.

- [ ] Individually identifiable information
- [x] Re-identifiable (coded) information
- [ ] Non-identifiable information

Q3.5. Describe any ethical considerations relating to the collection and/or use of the information/data in this project.

All data will be treated confidentially, collected and stored on the password protected PCs in the Diabetes service (Level 3 West Block, Nepean Hospital). All hardcopy files that are obtained from print outs will be stored in locked cabinets at the Diabetes service (Level 3 West Block, Nepean Hospital). All data will be accessible only to the lead researcher and diabetes team. All softcopy data will be permanently deleted off computer hard drives and all hardcopy data will be destroyed after 15 years of storage as per the NHMRC guidelines.Data will be coded for analysis.

Q3.6. Identify the source/s of the information/data that you will be collecting and/or using in this project.

- [ ] Individual participants
- [ ] Relatives or associates of participants
- [x] Medical/health/mental health record
- [ ] Electoral roll
- [ ] Held by a law enforcement agency or judicial body
- [ ] Publicly held database (Commonwealth)
- [ ] Publicly held database (State or local)
- [ ] Privately held database

Q3.7. Describe any ethical considerations relating to the source of information/data as indicated in the response to the previous question.

N/A

Q3.8. Was the information/data that you are using previously collected for a purpose other than research?

(•) Yes ( ) No

Q3.8.1 Provide a rationale for your use of information/data for a purpose other than that for which it was originally collected.

We are collecting information that has already been collected for patient care eg. by medical records and via the ABN portal for NSW health. We are not collecting anything over and above what is normally collected for the patient. We are just assessing patient's BGL's in a different way.

Data and Privacy - Activities with Data

Q3.9. Do you plan to disclose any personal information/data in this project to a third party?

( ) Yes (•) No

Q3.10. How will you protect the privacy of participants and non-participants in any notes and/or publications arising from your research.

No personal or individual data will be disclosed in any publication resulting from the research. Coded data will be analysed, to look at the impact of glucose control on the outcomes of interest.

Q3.11. Are there any restrictions on your ability to assure the confidentiality of participants?

( ) Yes (•) No

Q3.12. Do you plan to share any individual research results obtained during this research to the participants?

( ) Yes (•) No

Q3.13. Describe how you will handle any secondary or incidental findings that arise from the analysis of personal information/data.

There are no data to be collected for which this might be relevant.

Q3.14. Describe how the information/data will be stored, accessed, archived and/or destroyed.

All data will be treated confidentially, collected and stored on the password protected PCs in the Diabetes service (Level 3 West Block, Nepean Hospital). All hardcopy files that are obtained from print outs will be stored in locked cabinets at the Diabetes service (Level 3 West Block, Nepean Hospital). All data will be accessible only to the lead researcher and diabetic team (listed on page 1). All softcopy data will be permanently deleted off computer hard drives and all hardcopy data will be destroyed after 15 years of storage as per the NHMRC guidelines.

Q3.15. Describe any ethical considerations relating to the storage of, access to or destruction of information/data in this project.

All data will be treated confidentially, collected and stored on the password protected PCs in the Diabetes service (Level 3 West Block, Nepean Hospital). All hardcopy files that are obtained from print outs will be stored in locked cabinets at the Diabetic service (Level 3 West Block, Nepean Hospital). All data will be accessible only to the lead researcher and diabetic team (listed on page 1). All softcopy data will be permanently deleted off computer hard drives and all hardcopy data will be destroyed after 15 years of storage as per the NHMRC guidelines.

Q3.16. Will the outcomes of this project be disseminated to the participants?

○ Yes ◉ No

Q3.16.2.1 Justify why the outcomes of this project will not be disseminated to the participants.

The results may be disseminated to participants via the media. However, it is not practical to contact all patients admitted with diabetes to inform them of the study outcomes, when we are not requiring informed specific consent from them and do not therefore have access to their contract details.

Q3.17. Describe any foreseeable future activities for which information/data collected and/or used in this project may be made available.

The data collected may be used for further research into this area by our team. Data will only be made available to staff at the diabetes service. There is no external funding for this research.

Q3.18. Describe any ethical considerations relating to the planned or possible future use of information/data in this project.

Non identifiable data could not be of value as for use in future research, as long as coded individuals' data could be examined rather than pooled. Its would depend on the nature of the research as to whether the research required the data to be reidentified, in which case a separate ethics proposal would likely be required.

Section 4 – Attachments and Declarations

ATTACHMENTS

The following documents have been attached to this HREA.

Document Type	Attachment File Name	Attachment Description
Investigator CV	Irene CV 2015.docx	Irene Kopp's CV
Other	JeffAhnCVJan2018.pdf	Jeff Ahn's CV
Other	Master Participant Sheet.xlsx	Master Participant Sheet
Other	LOS, RR & Comp Data Sheet.xlsx	LOS,RR & Comp Data Sheet
Other	Data Collection Sheet.xlsx	Data Collection Sheet
Other	Submission Checklist.pdf	Submission Checklist
Other	Ethics Submission Fee.pdf	Ethics Submission Fee Form
Protocol	Inpatient Glucose Control, final .doc	Scientific Protocol

DECLARATIONS

1. DECLARATIONS

I/we certify that:

- All information in this application and supporting documentation is correct and as complete as possible;
- I have read and addressed in this application the requirements of the National Statement and any other relevant guidelines;
- I have familiarised myself with, considered and addressed in this application any relevant legislation, regulations, research guidelines and organisational policies;
- All relevant financial and non-financial interests of the project team have been disclosed; and
- In the capacity of a supervisor, as applicable, I have reviewed this application and I will provide appropriate supervision to the student(s) in accordance with the arrangements specified in this application and those associated with the student's educational program.

Chief Investigator/Researcher, Co-ordinating Principal Investigator/Researcher, Lead Investigator

Chief Investigator/Researcher
Mrs Irene Kopp

..... Signature

16/02/18 Date

Principal Investigator

Associate /Assistant/Sub-/Co- Investigator

Associate /Assistant/Sub-/Co-Investigator/Researcher
Associate Professor Emily Hibbert

..... Signature

...../...../..... Date

Associate /Assistant/Sub-/Co-Investigator/Researcher
Dr Jeff Ahn

..... Signature

...../...../..... Date

Associate /Assistant/Sub-/Co-Investigator/Researcher
Dr Kathryn Williams

..... Signature

...../...../..... Date

Associate /Assistant/Sub-/Co-Investigator/Researcher
Professor Michael Cox

..... Signature

...../...../..... Date

Investigator and Other