Appendix A: Victoria University of Wellington Ethics Approval

TE WHARE WĀNANGA O TE ŪPOKO O TE IKA A MĀUI
VICTORIA
UNIVERSITY OF WELLINGTON

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MEMORANDUM

TO	Esther Calje
COPY TO	
FROM	Convener, Human Ethics Committee
DATE	25 June 2014
PAGES	1
SUBJECT	**Ethics Approval: 21113** A retrospective study of New Zealand Lead Maternity Carer midwives' diagnosis and treatment of maternal anaemia, iron deficiency and iron deficiency anaemia in one New Zealand area

Thank you for your application for ethical approval, which has now been considered by the Standing Committee of the Human Ethics Committee.

Your application has been approved from the above date and this approval continues until 31 July 2015. If your data collection is not completed by this date you should apply to the Human Ethics Committee for an extension to this approval.

Best wishes with the research.

Human Ethics Committee

Appendix B: District Health Board Ethics Approval

District Health Board
Te Poari Hauora o Waitaha

Research Office Project ID
14091

Request For Locality Authorisation Form Within District Health Board

Researcher complete sections 1-5 and project

Attach all required documentation

Contact Person/s: Esther Calje

Email: [redacted]

Principal Investigator: Esther Calje

Signature: [redacted]

Clinical Trial Information

Clinical Trial Protocol Number:

Short Title: A study of NZ LMCs management of anaemia and IDA

Long Title: A retrospective descriptive study of New Zealand Lead Maternity Carer midwives' management of maternal anaemia, iron deficiency and iron deficiency anaemia.

CDHB Research Office Process

Date Received by RO: 21. 10. 2014

Received by:

Progress of Request will be visible on the intranet under the project ID number (under development)

1 Check form and documents completeness

2 Finance

3 GM

4 Approval

District Health Board
Te Poari Hauora o Waitaha

Research Office Project ID
14091

1

Short Project Title *

Project Principal Investigator: A study of NZ LMCs management of anaemia and IDA

Primary/Host Institution: Victoria University of Wellington

Local Principal Investigator: Esther Calje

Organisation (Employer):

** Please provide project details on page 3*

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This project has ethics approval from:

- [ ] HDEC
- [ ] OU Health Committee
- [Vi] Other, please specify

This project does not require ethics, please specify who has advised this.

3

Documents required ***(Please send the following documents along with the completed Locality Form before submitting to Research Office)***

HARD COPY PLEASE

- [x] Local Maori Consultation: [✓] TKW [ ] UOC [ ] Other, please specify
- [x] **Approval Letter** from **Ethics** or Letter Stating not required (i.e., out of scope) Victoria University Ethics Letter dated 25 June 2014
- [x] Documentation of **Funding** to cover ALL costs beyond 'care as normal'
  - a. Source of funding NZ College of Midwives Post Grad Education grant email confirmation dated 30.06.2014
  - b. ~~Copy of Contract/Sub-contracts~~ No cost for CDHB
- [N/A] Proof of **Indemnity** (only if local PI not DHB or UOC staff)

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:DHB Resources Used: [ ] **Within standard of care** [x] **Outside standard of care**

DHB participants (recruitment process and number?)

Women whose midwives are participating in the study, who birthed from September 2013 -

DHB staff (names, occupation)

Esther Calje

. DHB facilities (all locations ie, PMH, Burwood, etc) ***:DHB alone is not enough detail***

Women's Hospital

:DHB Records

Access to pregnancy related blood test result to supplement results collected from primary care notes

District Health Board
Te Poari Hauora o Waitaha

Research Office Project ID
14091

Project Details *(continuation of step 1)*

Full Project Name

A retrospective study of New Zealand Lead Maternity Carer midwives management of maternal anaemia, iron deficiency and iron deficiency anaemia.

All Named Investigators/Department

Investigator/Sub Investigators	Department
Esther Calje	Women's
	Supervisor, Victoria Univerity of Wellington

Timeframe of recruitment with CDHB

Women (whose midwives are participating) who birthed September-December 2013. Data collection from July-October 2014

Timeframe of the project completion

31/7/2015

Brief Summary of project (click on the box below to enter text)

I am undertaking a Masters thesis research project. I am aiming to describe practice of LMC midwives in the diagnosis and treatment of maternal anaemia, iron deficiency and iron deficiency anaemia (IDA).. There is no intervention. The study is collecting data on women's laboratory results and midwives' practice in relation to the results. As well as beginning to address a shortfall in research in NZ on maternal anaemia and IDA, the overall purpose of the research is to ascertain if there may be a need for a guideline for NZ midwives in the diabnosis and treatment of maternal anaemia and IDA.

I am gathering retrospective data from LMC midwives primary care maternity notes, and seeking ethics approval to access laboratory results to supplement and complete data collected on eash women. I am primarily interested in complete blood count and serum ferritin results. I will gather data on women with Hb <110g/L and /or ferritin <20mcg/L. Data will be collected on a data collection tool (DCT spreadsheet), entered on to my password protected computer. Confidentiality for midwives is maintained throughout. Once the data entry is complete, the women's NHI will be removed and the dat anonymised. No person apart from myself, my supervisor ( ), and a statistician will view the DCT.

District Health Board
Te Poari Hauora o Waitaha

Research Office Project ID
14091

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Approval signatures from all areas where resources are accessed

	Department 1	Department 2	Department 3
Clinical Director	Clinical Director Obstetrics & Gynaecology Extn:		
Signature	✓ 28/10/14		
Service Manager			
Signature			
Other Approving Manager Name			
Title			
Signature			

RESEARCH OFFICE FACILITATES THE NEXT STEPS IN THE APPROVAL

For Financial sign-off

Funding covers resources used or fits within CD & SM Authority

N.A.

Name *Signature* *Date*

General Manager sign-off

This research will take place in your hospital, do you approve it? General Manager

Hospital 1	*Name:*	*Signature:*	*Date:* 28/10/14
Hospital 2	*Name:*	*Signature:*	*Date:*
Hospital 3	*Name:*	*Signature:*	*Date:*

Appendix C: Participant Information sheet

TE WHARE WĀNANGA O TE ŪPOKO O TE IKA A MĀUI
VICTORIA UNIVERSITY OF WELLINGTON

GRADUATE SCHOOL OF NURSING, MIDWIFERY & HEALTH

VICTORIA UNIVERSITY OF WELLINGTON, PO Box 7625, Newtown, Wellington 6242, New Zealand
Phone +64-4-463 5363 / 0800 108 005 Fax +64-4-463 5442 Email nmh@vuw.ac.nz
Website www.victoria.ac.nz/nmh

Midwives' Participant Information Sheet for "A retrospective study of New Zealand Lead Maternity Carer midwives' diagnosis and treatment of maternal anaemia, iron deficiency and iron deficiency anaemia".

Researcher: Esther Calje, School of Nursing, Midwifery and Health, Victoria University of Wellington.

I am a Masters student in the School of Nursing and Midwifery at Victoria University of Wellington. As part of this degree I am undertaking a research project leading to a thesis. The project I am undertaking is aiming to describe practice of New Zealand Lead Maternity Carer (LMC) midwives in the diagnosis and treatment of maternal anaemia, iron deficiency and iron deficiency anaemia (IDA). This research project has received approval from the Victoria University Human Ethics Committee.

There is no intervention in this research project. The study is collecting data on actual practice and does not attempt to influence midwives' clinical practice or judgement. As well as beginning to address a shortfall of research in NZ on maternal anaemia and IDA, the overall purpose of the research is to explore whether there may be a need for a guideline for NZ midwives in the diagnosis and treatment of maternal anaemia and IDA.

I am inviting LMC midwives to provide primary care maternity records on women in their care who birthed in the study period (September 2013-December 2013) who have had *any* blood tests results with a haemoglobin (Hb) level <110 g/L and/or a ferritin <20mcg/L, including booking and postpartum. Retrospective clinical data and demographic data from the women will be collected by the researcher on a data collection tool (DCT), primarily from the maternity records. Some laboratory results will be accessed from online hospital records. A short survey of LMC demographics will be completed by the midwives. The survey will be coded and matched to data sets, with no identifying information. Confidentiality for midwives will be maintained throughout the data collection period. Once data entry is completed for each woman, the NHI will be removed from the DCT and the data will be de-identified and become anonymous.

It is expected that the data collection will take the researcher 3-4 months. All participants will be given a summary of their data as feedback, and they will go in to the draw for a pamper pack valued at $100. Any midwife wishing to discontinue participation can withdraw from the research project at any stage by contacting the researcher.

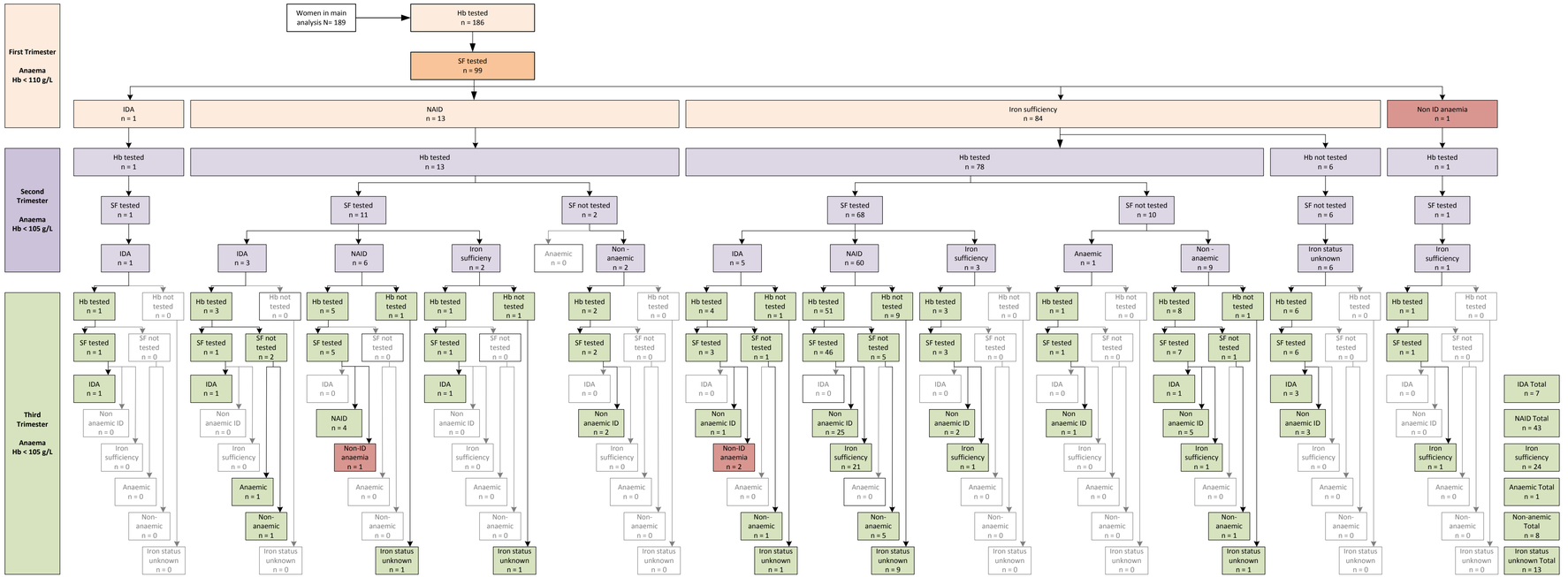
No person apart from myself and my supervisor will see the DCT. The thesis will be submitted for marking to the School of Nursing, Midwifery and Health and deposited in the University Library. It is intended that the research findings will be disseminated at academic or professional conferences, and one or two articles will be submitted for publication in scholarly journals. Data will be destroyed after five years.

Thank you for your interest in participating in this research project. If you have any further questions or would like to receive further information about the project, please contact me on phone or at or my supervisor (Skinner) at the School of Nursing, Midwifery and Health at Victoria University (ph or email). If there are any ethical concerns about the research, please contact .

Esther Calje (RM, PGCert)

Appendix D: LMC midwives antenatal decision tree: Serum ferritin tested in the first trimester

Appendix D: Lead Maternity Carer Midwives antenatal decision tree: Serum Ferritin tested in the first trimester

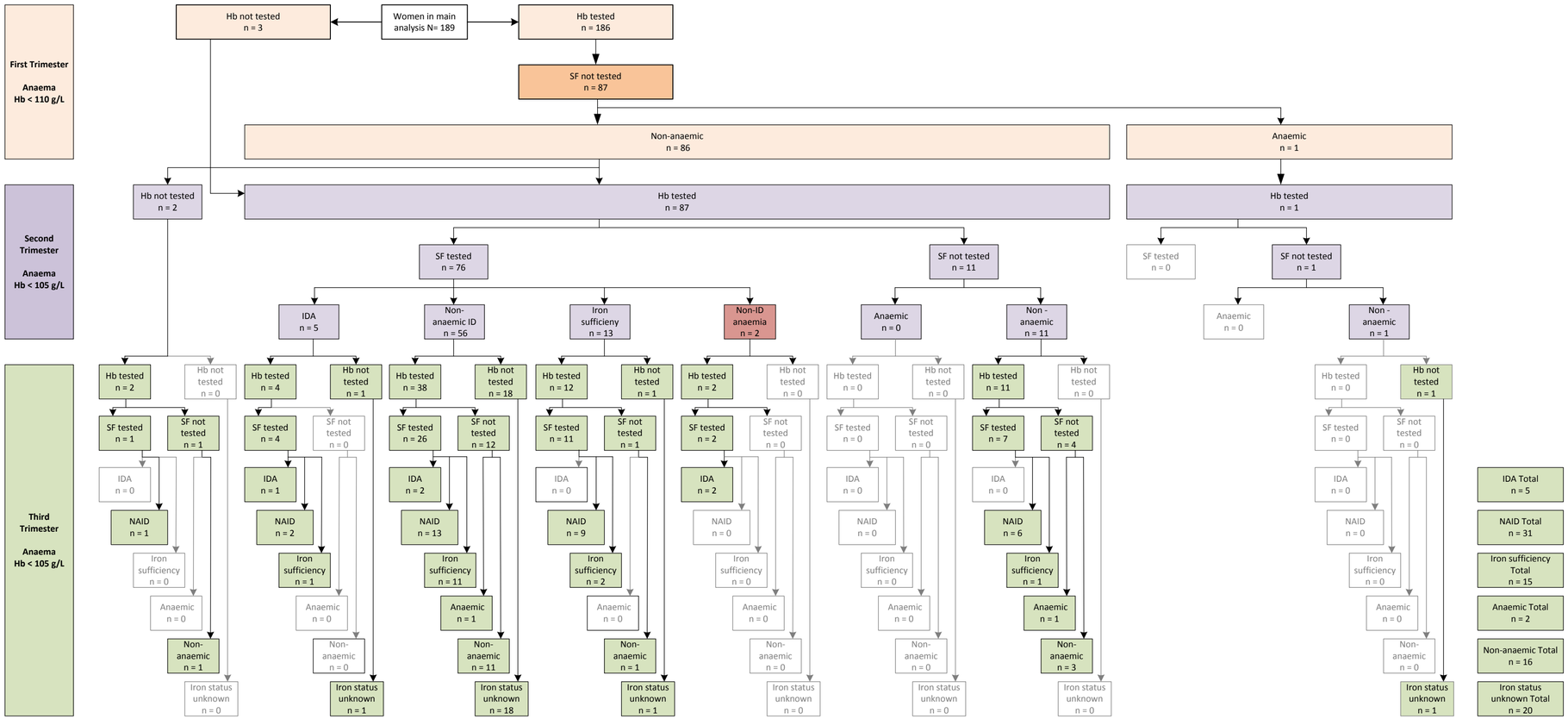


Key:

Hb: Haemoglobin
IDA: Iron Deficiency Anaemia , anaemia with iron deficiency or absent iron stores
Iron sufficiency: Non-anaemic, non-iron deficient (confirmed and unconfirmed)
NAID: Non-Anaemic Iron Deficiency, (SF < 20 µg/L or SF < 50 µg/l with CRP > 5)
Non-anaemic: SF not tested, iron stores unknown
Non-ID anaemia: anaemic and SF ≥ 20 µg/L (possible anaemia of inflammation)
SF: Serum Ferritin
= non-iron deficient anaemia: possible anaemia of inflammation, or false high or false normal as serum ferritin not adjusted for inflammation

Appendix E: LMC midwives antenatal decision tree: Serum ferritin not tested in the first trimester

Appendix E: Lead Maternity Carer Midwives antenatal decision tree where Serum Ferritin not tested in the first trimester



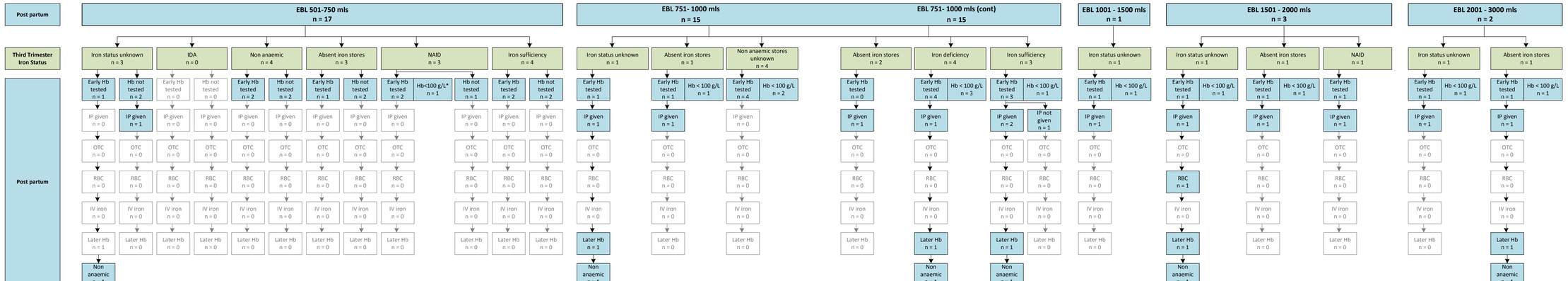
Key:

Hb: Haemoglobin
IDA: Iron Deficiency Anaemia , anaemia with iron deficiency or absent iron stores
Iron sufficiency: Non-anaemic, non-iron deficient (confirmed and unconfirmed)
NAID: Non-Anaemic Iron Deficiency, (SF < 20 µg/L or SF < 50 µg/l with CRP > 5)
Non-anaemic: SF not tested, iron stores unknown
Non-ID anaemia: anaemic and SF ≥ 20 µg/L (possible anaemia of inflammation)
SF: Serum Ferritin

= non-iron deficient anaemia: possible anaemia of inflammation, or false high or false normal as serum ferritin not adjusted for inflammation

Appendix F: LMC midwives postpartum decision tree

Appendix F: Lead Maternity Carer Midwives postpartum decision tree where estimated blood loss (EBL) > 500 mls



Key:

Absent iron stores: non anaemic and SF < 12 µg/L
Early Hb tested: within 72 hours postpartum
EBL: Estimated blood loss
Hb: Haemoglobin
IDA: Iron Deficiency Anaemia , anaemia with iron deficiency or absent iron stores
IP: Iron prescription
Iron sufficiency: Non-anaemic, non-iron deficient (confirmed and unconfirmed)
IV Iron: Intravenous iron
Later Hb: Hb tested ≥ 10 days postpartum prior to discharge
NAID: Non-Anaemic Iron Deficiency, (SF 12-19 µg/L or SF < 50 µg/l with CRP > 5)
Non-anaemic: SF not tested, iron stores unknown
Non-ID anaemia: anaemic and SF ≥ 20 µg/L (possible anaemia of inflammation)
OTC: Over the counter
RBC: Red blood cell transfusion
SF: Serum Ferritin
* Early postpartum Hb < 100 g/L clinically significant (Breymann et al. 2010)