Health and Disability Ethics Committees
Ministry of Health
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11 September 2019

Dr Helen Winrow
Department of Obstetrics and Gynaecology
Auckland City Hospital
Grafton, Auckland 1023

Dear Dr Winrow

Re:	**Ethics ref:**	**19/NTA/117**
	Study title:	Prevention of Surgical Site Infection following Caesarean Section: Implementation of a peri-operative bundle at National Women's, Auckland City Hospital, New Zealand.

I am pleased to advise that this application has been *approved* by the Northern A Health and Disability Ethics Committee. This decision was made through the HDEC-Full Review pathway.

Summary of Study

1. The study will evaluate the value of using a bundled approach to peri-operative care for women undergoing Caesarean delivery in reducing post-partum infective complications. It is hypothesised that the bundle will lead to a reduction in the rates of post-partum infection. This study is a cohort study including two cohorts, one retrospective and one prospective. It is also a Quality Improvement study, as described by the SQUIRE criteria.
2. A bundle compliance checklist will be completed for each eligible patient undergoing caesarean delivery during the post-implementation period. The bundle consists of five interventions. The same techniques for follow-up will be employed for the post-implementation patients.

Summary of resolved ethical issues

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

3. The Committee noted that the study meets the HDEC definition of Quality Improvement, which is an audit or related activity. The NEAC Guidelines for Observational Studies provide that, for audits and related activities, it may be ethical to use health information without additional or specific consent and allow the secondary use of identifiable health information without consent where it is used for the purposes of quality assurance or outcome analysis. The Guidelines also note that it may be ethically justifiable, in the case of audits and related activities, to use record linkages without specific or additional consent when those activities are part of high-quality health care delivery (paras *6.47, 8.12 and 11.5*).
4. The Committee noted that, although methodological, the Researcher might not need to contact the Lead Maternity Carer, as they could retrieve the same information from Pharmaceutical Databases about antibiotic dispensing.

Summary of outstanding ethical issues

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

5. The Committee requested that data collected in the study be given a de-identified study code, rather than retaining NHI numbers.
6. The Committee noted that the peer review refers to compliance being defined as implementation of 6 out of 10 of the bundle components, but the protocol only outlines 5 indicators. Please clarify.
7. In answering question P.4.2 of the application form, the Researchers stated that they had consulted with a Māori midwifery manager who stated that return of data to Māori participants was required due to Māori data sovereignty. The Committee noted the importance of Māori data sovereignty, however suggested that as the data was de-identified this did not appear to be feasible. The Researchers may consider this further, for example summary data dissemination strategy.

Conditions of HDEC approval

HDEC approval for this study is subject to the following conditions being met prior to the commencement of the study in New Zealand. It is your responsibility, and that of the study's sponsor, to ensure that these conditions are met. No further review by the Northern A Health and Disability Ethics Committee is required.

Standard conditions:

8. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.

9. Before the study commences at *any* locality in New Zealand, it must be registered in a clinical trials registry. This should be a WHO-approved registry (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au) or https://clinicaltrials.gov/.

10. Before the study commences at *each given* locality in New Zealand, it must be authorised by that locality in Online Forms. Locality authorisation confirms that the locality is suitable for the safe and effective conduct of the study, and that local research governance issues have been addressed.

Non-standard conditions:

- please amend the protocol, stating that data collected will be de-identified with a study code
- please address the inconsistency identified at (6) between the peer review and the protocol.

Non-standard conditions must be completed before commencing your study, however, they do not need to be submitted to or reviewed by HDEC.

If you would like an acknowledgement of completion of your non-standard conditions you may submit a post approval form amendment through Online Forms. Please clearly identify in the amendment form that the changes relate to non-standard conditions and ensure that supporting documents (if requested) are tracked/highlighted with changes.

For information on non-standard conditions please see section 128 and 129 of the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on www.ethics.health.govt.nz)

After HDEC review

Please refer to the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on www.ethics.health.govt.nz) for HDEC requirements relating to amendments and other post-approval processes.

Your next progress report is due by 10 September 2020.

Participant access to ACC

The Northern A Health and Disability Ethics Committee is satisfied that your study is not a clinical trial that is to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled. Participants injured as a result of treatment received as part of your study may therefore be eligible for publicly-funded compensation through the Accident Compensation Corporation (ACC).

Please don't hesitate to contact the HDEC secretariat for further information. We wish you all the best for your study.

Yours sincerely,

A/Prof Manuka Henare
Chairperson
Northern A Health and Disability Ethics Committee

Encl: appendix A: documents submitted
appendix B: statement of compliance and list of members

Appendix A
Documents submitted

Document	*Version*	*Date*
CV for CI	1	15 June 2019
Evidence of scientific review	1	15 June 2019
Grant Award letter from RANZCOG Mercia Barnes trust	1	15 June 2019
Protocol: Study protocol	2	06 August 2019
Covering Letter: Covering letter	1	06 August 2019
Application		06 August 2019

Appendix B
Statement of compliance and list of members

Statement of compliance

The Northern A Health and Disability Ethics Committee:

- is constituted in accordance with its Terms of Reference
- operates in accordance with the *Standard Operating Procedures for Health and Disability Ethics Committees*, and with the principles of international good clinical practice (GCP)
- is approved by the Health Research Council of New Zealand's Ethics Committee for the purposes of section 25(1)(c) of the Health Research Council Act 1990
- is registered (number 00008714) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

Name	*Category*	*Appointed*	*Term Expires*	*Present on 20/08/2019?*	*Declaration of interest?*
A/Prof Manuka Henare	Lay (consumer/community perspectives)	19/03/2019	19/03/2022	Yes	No
Dr Karen Bartholomew	Non-lay (intervention studies)	18/07/2016	18/07/2022	Yes	No
Dr Christine Crooks	Non-lay (intervention studies)	11/11/2015	11/11/2018	Yes	No
Ms Catherine Garvey	Lay (the law)	19/03/2019	19/03/2022	Yes	No
Dr Kate Parker	Non-lay (observational studies)	11/11/2015	11/11/2018	Yes	No
Ms Rochelle Style	Lay (ethical/moral reasoning)	14/06/2017	14/06/2020	Yes	No

Unless members resign, vacate or are removed from their office, every member of HDEC shall continue in office until their successor comes into office (HDEC Terms of Reference)

http://www.ethics.health.govt.nz