

22 May 2020

Associate Professor Katie Groom
Liggins Institute, The University of Auckland
Building 503, Level 2, 85 Park Road
Private Bag 92019
Auckland 1142

Dear Associate Professor Groom

Re: Ethics ref:	20/NTB/81
Study title:	COVID-19 in Pregnancy New Zealand Registry

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

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Opt-out consent: Please add a panel on the Data Collection Form for the health professional supplying information to the Registry, to put their name, designation and an acknowledgement that they have provided the woman with The COVID-19 Infection in Pregnancy in New Zealand Registry Information Sheet May 2020 V1.
2. Registry Information Sheet:
 - i. Please add a phone contact for someone senior in the research team so potential participants have the opportunity to discuss their inclusion or request their exclusion. For some women, sending an email may be difficult or may seem an impersonal way of 'having a conversation'.
 - ii. Please amend the PIS to include all the information you are collecting. Currently the PIS does not inform women you are collecting past obstetric history and information about them and their babe from the birth until 6 weeks postpartum.

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 B Health and Disability Ethics Committee is required.

Standard conditions:

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

4. 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.
5. Please provide the phone number (DD or mobile) for Maori health /cultural contact Dr Kasey Tawhara, Maori researcher.

Non-standard conditions:

6. Please update the participant information sheets and consent forms, taking into account the issues raised by the Committee.

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 21 May 2021.

Participant access to ACC

The Northern B 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,



Mrs Kate O'Connor
Chairperson
Northern B Health and Disability Ethics Committee

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

Appendix A
Documents submitted

<i>Document</i>	<i>Version</i>	<i>Date</i>
CV for CI: Katie Groom CV	1	01 April 2020
CVs for other Investigators: Laura Mackay CV	1	03 April 2020
CVs for other Investigators: Chris McKinlay CV	1	03 April 2020
CVs for other Investigators: Rebecca Hay CV	1	09 April 2020
Signed University of Auckland HOD approval form	1	07 April 2020
CVs for other Investigators: Lynn Sadler CV	1	09 April 2020
Covering Letter: cover letter, response to HDEC queries	2	03 May 2020
PIS/CF: Participant information sheet	v2	15 April 2020
Protocol: Study protocol, tracked changes.	v3	29 April 2020
Evidence of scientific review: Minutes of study investigator and advisory group meeting providing evidence of scientific review which informed study design and protocol	v1	06 April 2020
Letter from chair of Perinatal and Maternal Mortality Review Committee (PMMRC), proposal and protocol reviewed by PMMRC members and supported	v1	14 April 2020
Application		15 April 2020
PIS/CF: Version 3, information sheet. Clean.	3	29 April 2020
PIS/CF: Information sheet, version 3. Tracked changes.	3	29 April 2020
Data collection points/CRF	1	29 April 2020
Data governance charter	1	29 April 2020
Reference document AMOSS	1	02 July 2011
Reference document AMOSS 2017	1	15 May 2017
Response to Request for Further Information		

Appendix B Statement of compliance and list of members

Statement of compliance

The Northern B 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 00008715) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

<i>Name</i>	<i>Category</i>	<i>Appointed</i>	<i>Term Expires</i>
Mrs Kate O'Connor-Chair	Lay (ethical/moral reasoning)	14/12/2015	14/12/2018
Dr Nora Lynch	Non-lay (health/disability service provision)	24/07/2015	24/07/2022
Miss Tangihaere Macfarlane	Lay (consumer/community perspectives)	20/05/2017	20/05/2020
Mrs Helen Walker	Lay (ethical/moral reasoning)	01/07/2015	01/07/2018
Dr Ptries Herst	Non-lay (intervention studies)	27/10/2015	27/10/2018
Dr Sarah Gunningham	Non-lay (intervention studies), Non-lay (observational studies)	05/07/2019	05/07/2022
Ms Catherine Garvey	Lay (consumer/community perspectives)	19/03/2019	19/03/2022
Dr Kate Parker	Non-lay (intervention studies)	11/02/2020	11/02/2023

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>