

15 April 2019

Dr Lucy Prentice  
National Women's Health  
Auckland District Health Board  
Women's Health, Level 9, Auckland City Hospital  
PO Box 92024  
Auckland 1142

Dear Dr Prentice,

Re:	<b>Ethics ref:</b>	<b>19/CEN/40</b>
	Study title:	The Fertility and IVF and Intrauterine Insemination trial in couples with unexplained infertility – The FIIX Study

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

#### Summary of resolved ethical issues

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

1. The Committee advised that the ACC statement in the PIS be reflected on, as the template suggests "If you were injured in this study, you would be eligible to apply for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery."

#### 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 Central Health and Disability Ethics Committee is required.

Standard conditions:

2. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.
3. 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](http://www.anzctr.org.au)) or <https://clinicaltrials.gov/>.

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.

After HDEC review

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

**Your next progress report is due by 15 April 2020.**

Participant access to ACC

The Central 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 Helen Walker  
Chairperson  
Central 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: CV L Prentice	1	26 February 2019
CVs for other Investigators: CV for C Curtis	1	26 February 2019
CVs for other Investigators: CV for C Farquhar, S Lensen, L Sadler	1	26 February 2019
Letter of support from NRFS	1	26 February 2019
Evidence of CI indemnity	1	26 February 2019
Protocol: Protocol	1	26 February 2019
Logo	1	26 February 2019
Covering Letter: Cover Letter	1	08 March 2019
CVs for other Investigators: Dr Edlin CV	1	08 March 2019
Evidence of scientific review: Peer review Dr Wilkinson	1	08 March 2019
Evidence of scientific review: Peer review Dr Wong	2	08 March 2019
Investigator's Brochure: Patient information poster	2	08 March 2019
Invitation to enter study letter	3	08 March 2019
PIS/CF: patient information sheet and consent form	2	08 March 2019
Survey/questionnaire: Treatment questionnaire	1	08 March 2019
Application		08 March 2019

## Appendix B Statement of compliance and list of members

### Statement of compliance

The Central 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 00008712) 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 Helen Walker	Lay (consumer/community perspectives)	01/07/2015	01/07/2018
Dr Peter Gallagher	Non-lay (health/disability service provision)	30/07/2015	30/07/2018
Mrs Sandy Gill	Lay (consumer/community perspectives)	30/07/2015	30/07/2018
Dr Patries Herst	Non-lay (intervention studies)	27/10/2015	27/10/2018
Dr Dean Quinn	Non-lay (intervention studies)	27/10/2015	27/10/2018
Dr Cordelia Thomas	Lay (the law)	20/05/2017	20/05/2020

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>