

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>

**Ethics reference:** 2022 AM 8410

18 February 2022

Tēnā koe

**APPROVAL OF AMENDMENT**

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 amendment was **approved** by the Central Health and Disability Ethics Committee (the Committee). This decision was made through the post-approval pathway.

**Further information and assistance**

Please contact the HDECs Secretariat at [hdecs@health.govt.nz](mailto:hdecs@health.govt.nz) or visit our website at [www.ethics.health.govt.nz](http://www.ethics.health.govt.nz) for more information, as well as our [General FAQ](#) and [Ethics RM FAQ](#).

Nāku noa, nā



Mrs Helen Walker

Chair

Central Health and Disability Ethics Committee

Encl: Appendix A: documents submitted

**Appendix A: Documents submitted**

<b>Document Type</b>	<b>File Name</b>	<b>Date</b>	<b>Version</b>
PAF	FIIX Participant Information Sheet_7month	15/02/2022	2
PAF	FIIX Participant Information Sheet_7monthtracked	15/02/2022	2
PAF	PROTOCOL FIIX v3.0_feb2022	15/02/2022	2
PAF	PROTOCOL FIIX v3.0_feb2022tracked	15/02/2022	2

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

29 July 2019

Dr Lucy (LR) 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/AM01</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 amendment has been approved by the Central Health and Disability Ethics Committee. This decision was made through the HDEC Expedited Review pathway.

Non-standard conditions:

1. Please ensure there are systems in place to ascertain the validity of the person "signing" the online consent.

Non-standard conditions must be completed before commencing any changes as a result of this amendment, 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](http://www.ethics.health.govt.nz))

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

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Helen Walker', written in a cursive style.

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 and approved**

Document	Version	Date
PIS/CF	2	10 July 2019
Logo	2	10 July 2019
Protocol	2	10 July 2019
Post Approval Form	AM01	10 July 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
Ms Helen Davidson	Lay (ethical/moral reasoning)	06/12/2018	06/12/2021
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 Ptries 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>

12 May 2020

Dr Lucy (LR) 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/AM02</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 annual progress report has been approved, following review by the Chairperson of the Central Health and Disability Ethics Committee on 12 May 2020. Existing approval remains valid.

Your **next progress report** is due by **14 April 2021**.

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 A**  
**Documents submitted and approved**

Document	Version	Date
Protocol	v1.8	02 March 2020
Post Approval Form	AM02	10 March 2020
Participant study information video	1	05 May 2020
Participant study information brochure	1	05 May 2020
Covering letter: Letter outlining what is included in response to amendment application. Also includes website link.	1	05 May 2020
Survey/questionnaire: Thank you letter and information outlining what to expect for the duration of the study (up to 18-months post-randomisation)	1	05 May 2020
Survey/questionnaire: Questionnaire to be sent through REDCap to participants who are not pregnant up until 18-months post-randomisation	1	05 May 2020
Response to Request for Further Information		

21 October 2020

Dr Lucy (LR) 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/AM03</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 amendment has been approved by the Central Health and Disability Ethics Committee. This decision was made through the HDEC Expedited Review pathway.

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 and approved**

Document	Version	Date
Post Approval Form	AM03	07 October 2020

## 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)	22/05/2018	22/05/2023
Ms Helen Davidson	Lay (ethical/moral reasoning)	06/12/2018	06/12/2021
Dr Peter Gallagher	Non-lay (health/disability service provision)	22/05/2020	22/05/2023
Mrs Sandy Gill	Lay (consumer/community perspectives)	22/05/2020	22/05/2023
Dr Patries Herst	Non-lay (intervention studies)	22/05/2020	22/05/2023
Ms Julie Jones	Non-lay (intervention studies)	22/05/2020	22/05/2022
Dr Cordelia Thomas	Lay (the law)	20/05/2017	20/05/2020
Dr Jill Wilkinson	Non-lay (observational studies)	22/05/2020	22/05/2023

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>

14 June 2021

Dr Lucy (LR) 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/AM05</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 annual progress report has been approved, following review by the Chairperson of the Central Health and Disability Ethics Committee on 4 June 2021. Existing approval remains valid.

Your next progress report is due by **14 April 2022**.

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 A**  
**Documents submitted and approved**

Document	Version	Date
Post Approval Form	AM05	30 May 2021

15 February 2021

Dr Lucy (LR) 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/AM04</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 amendment has been approved by the Central Health and Disability Ethics Committee. This decision was made through the HDEC Expedited Review pathway.

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 and approved**

Document	Version	Date
Survey/questionnaire	1.0	26 January 2021
Post Approval Form	AM04	26 January 2021
PIS/CF: Amended PIS	2	09 February 2021
Response to Request for Further Information		

## 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)	22/05/2018	22/05/2023
Ms Helen Davidson	Lay (ethical/moral reasoning)	06/12/2018	06/12/2021
Dr Peter Gallagher	Non-lay (health/disability service provision)	22/05/2020	22/05/2023
Mrs Sandy Gill	Lay (consumer/community perspectives)	22/05/2020	22/05/2023
Dr Ptries Herst	Non-lay (intervention studies)	22/05/2020	22/05/2023
Ms Julie Jones	Non-lay (intervention studies)	22/05/2020	22/05/2022
Dr Cordelia Thomas	Lay (the law)	20/05/2017	20/05/2020
Dr Jill Wilkinson	Non-lay (observational studies)	22/05/2020	22/05/2023

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>

**Ethics reference:** 2022 PR 8410

22 September 2022

Dr Lucy (LR) Prentice

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

Tēnā koe Dr Prentice

**APPROVAL OF PROGRESS REPORT**

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 annual progress report has been **approved** following review by the Chair of the Central Health and Disability Ethics Committee on 21 September 2022. Existing approval remains valid.

Your next progress report is due by 15 April 2023.

**Further information and assistance**

Please contact the HDECs Secretariat at [hdecs@health.govt.nz](mailto:hdecs@health.govt.nz) or visit our website at [www.ethics.health.govt.nz](http://www.ethics.health.govt.nz) for more information, as well as our [General FAQ](#) and [Ethics RM manual](#).

Nāku noa, nā



Mrs Helen Walker

Chair

Central Health and Disability Ethics Committee

Encl: Appendix A: documents submitted

Appendix A: Documents submitted

Review Document Type	Review Document File Name	Review Document Version Date
----------------------	---------------------------	------------------------------

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