

01 February 2018

A/Prof. Greg O'Grady
Department of Surgery
University of Auckland
Private Bag 92019
Auckland Mail Centre
Auckland 1142

Dear Associate Professor. O'Grady

Re: Ethics ref:	17/NTA/241
Study title:	Re-infusion of ileostomy and fistula output within a stoma appliance

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.

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:

1. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.
2. Before the study commences at a *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) for HDEC requirements relating to amendments and other post-approval processes.

Your **next progress report** is due by **31 January 2019**.

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 handwritten signature in black ink, appearing to read 'B J Fergus', with a horizontal line underneath.

Dr Brian Fergus
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

<i>Document</i>	<i>Version</i>	<i>Date</i>
CVs for other Investigators: CV for Professor Bissett	1	08 August 2017
CVs for other Investigators: CV for Celia Keane	1	08 August 2017
Declined letter for previous application in respect of the same (or substantially similar) study: Central HDEC Letter	1	07 November 2017
PIS/CF: PIS for feasibility study	2	07 November 2017
PIS/CF	2	07 November 2017
PIS/CF: PIS for pilot RCT	2	07 November 2017
PIS/CF: Consent form for pilot RCT	2	07 November 2017
Evidence of scientific review: Peer review	1	02 October 2017
Survey/questionnaire: Questionnaire for feasibility and pilot RCT	2	07 November 2017
Survey/questionnaire: Patient diary for feasibility study	2	07 November 2017
Survey/questionnaire: For the pilot RCT and feasibility studies the diary will be a booklet with questions repeating each day throughout the study period.	2	07 November 2017
Protocol: Study protocol	4	07 November 2017
CV for CI: CV for A/Prof O'Grady	1	02 June 2017
Head of School / Head of Department Approval	1	04 October 2017
Covering Letter	1	07 November 2017
Application		
PIS/CF: PIS for feasibility study	3	22 November 2017
PIS/CF: Consent form for feasibility study	3	22 November 2017
PIS/CF: Consent form for pilot RCT	3	22 November 2017
PIS/CF: PIS for the pilot RCT	3	22 November 2017
Covering Letter: Covering letter - response to provisional approval letter dated 5.12.17	1	12 December 2017
Response to Request for Further Information		

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

<i>Name</i>	<i>Category</i>	<i>Appointed</i>	<i>Term Expires</i>
Dr Brian Fergus	Lay (consumer/community perspectives)	11/11/2015	11/11/2018
Dr Karen Bartholomew	Non-lay (intervention studies)	13/05/2016	13/05/2019
Dr Christine Crooks	Non-lay (intervention studies)	11/11/2015	11/11/2018
Dr Catherine Jackson	Non-lay (health/disability service provision)	11/11/2016	11/11/2019
Ms Toni Millar	Lay (consumer/community perspectives)	11/11/2016	11/11/2019
Dr Kate Parker	Non-lay (observational studies)	11/11/2015	11/11/2018
Ms Rochelle Style	Lay (ethical/moral reasoning)	14/06/2017	14/06/2020

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>