

2 October 2012

Associate Professor Lindsay D Plank
University of Auckland
Dept of Surgery
Auckland Hospital
Private Bag 92024
Auckland

Dear Associate Professor Plank

Re:	Ethics ref:	NTX/12/06/056
	Study title:	Effect of preoperative immunonutrition on outcome in patients undergoing partial hepatectomy: a randomised pilot study

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 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 *any* locality in New Zealand, it must be registered in a WHO-approved clinical trials registry (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au).
3. 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

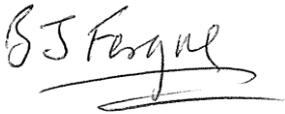
Please refer to the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on www.ethics.health.govt.nz) for HDEC requirements relating to amendments and other post-approval processes.

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>
Amended National Application Form		
Locality Assessment - Auckland District Health Board		17 July 2012
MRRC Support letter – ADHB		10 September 2012
Participant Information Sheet	version 2	30 August 2012
Consent Form	version 2	30 August 2012

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)	01/07/2012	01/07/2015
Ms Susan Buckland	Lay (consumer/community perspectives)	01/07/2012	01/07/2015
Ms Shamim Chagani	Non-lay (health/disability service provision)	01/07/2012	01/07/2014
Dr Marewa Glover	Non-lay (observational studies)	01/07/2012	01/07/2015
Mr Kerry Hiini	Lay (consumer/community perspectives)	01/07/2012	01/07/2014
Prof Wayne Miles	Non-lay (intervention studies), Non-lay (health/disability service provision)	01/07/2012	01/07/2013
Dr Etuate Saafi	Non-lay (intervention studies)	01/07/2012	01/07/2014
Ms Michele Stanton	Lay (the law)	01/07/2012	01/07/2014

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