

16 March 2012

Dr Michael Schultz
Gastroenterology Unit
Southern District Health Board
201 Great King Street
Dunedin 9016

Dear Dr Schultz

Ethics ref: **LRS/12/EXP/009** (please quote in all correspondence)
Study title: The Prevalence of Hepatitis B and C viral infection in Dunedin

This study was given expedited ethical approval by the Chair of the Lower South Regional Ethics Committee on **15 March 2012**.

This approval is valid until **30 September 2012**, provided that Annual Progress Reports are submitted (see below).

Amendments and Protocol Deviations

All significant amendments to this proposal must receive prior approval from the Committee. Significant amendments include (but are not limited to) changes to:

- the researcher responsible for the conduct of the study at a study site
- the addition of an extra study site
- the design or duration of the study
- the method of recruitment
- information sheets and informed consent procedures.

Significant deviations from the approved protocol must be reported to the Committee as soon as possible.

Annual Progress Reports and Final Reports

The first Annual Progress Report for this study is due to the Committee by **15 March 2013**. The Annual Report Form that should be used is available at www.ethicscommittees.health.govt.nz. Please note that if you do not provide a progress report by this date, ethical approval may be withdrawn.

A Final Report is also required at the conclusion of the study. The Final Report Form is also available at www.ethicscommittees.health.govt.nz.

Statement of compliance

The committee is constituted in accordance with its Terms of Reference. It complies with the Operational Standard for Ethics Committees and the principles of international good clinical practice.

The committee is approved by the Health Research Council's Ethics Committee for the purposes of section 25(1)(c) of the Health Research Council Act 1990.

We wish you all the best with your study.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Awhina Rangiwai', with a horizontal line drawn underneath the name.

AWHINA RANGIWAI
ADMINISTRATOR
Lower South Ethics Committee

#00685

Health
and
Disability
Ethics
Committees

Northern Y Regional Ethics Committee
Ministry of Health
3rd Floor, BNZ Building
354 Victoria Street
PO Box 1031
Hamilton 3204
Phone (07) 858 7021
Fax (07) 858 7070
Email: northern_y_ethicscommittee@moh.govt.nz

24 December 2010

Dr Michael Schultz
Dept of Medical & Surgical Sciences
University of Otago Medical School
PO Box 913
Dunedin

Dear Dr Schultz-

Ethics ref: NTY/10/12/104 (please quote in all correspondence)
Study title: Survey of the prevalence of viral hepatitis in Dunedin
Investigators: Dr Michael Schultz, Dr Martin Schlup, Ms Margaret Fraser, Mr Heath Te Au

The Northern Y Regional Ethics Committee considered your study on 14 December 2010 and approved it subject to the following conditions.

Application Form:

- Please provide the name of the medical student involved in the study.
- *What does the researcher think of the reliability and dependability of the information/questionnaire? Will the results be skewed if people do not return the questionnaire?
- *Will the researcher be able to test if vaccination has been taken? HEP B - put in questionnaire.
- *A4.1. Clarify that 1400 people will be approached and 1000 people will be participants.
- C. As the study is considered a clinical trial, please provide a Form A.
- Please provide a copy of the questionnaire.

Information Sheet and Consent Form:

- A more inviting invitation letter should be used. - JAN's version?
- PIS. Page 2. Para 1. Please consider changing or removing the paragraph. - cohesive?
- Please provide some information in the PIS on why the person should participate. ✓
- ✓PIS. Page 1. 2nd sentence. Please remove 'in random fashion'.
- ✓CF. Clarify that only abnormal results will be informed to the GP.
- The PIS and CF should include a sentence stating that ethical approval has been given by the Northern Y Regional Ethics Committee. ✓

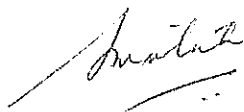
You may not proceed with your study until ethical approval has been given. In order to obtain ethical approval from the Committee, please forward evidence that the above conditions have been met, with one copy of amended documentation, including:

- amended pages of the National Application Form
- a full copy of the amended information sheet/consent form/questionnaire etc with updated version number and date.

Provided the conditions above have been met, final approval for your study will be given by the Chairperson of the Committee. You will receive a letter advising you that final approval has been given, and may then proceed with your study.

Please don't hesitate to contact me for further information.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Amrita', with a stylized flourish underneath.

Amrita Kuruvilla
Administrator
Northern Y Regional Ethics Committee
Email: amrita_kuruvilla@moh.govt.nz