

Academic Services Manager, Academic Committees, Mr Gary Witte

2 June 2016

Professor F Frizelle
Department of Surgery (ChCh)
Christchurch Hospital
University of Otago, Christchurch

Dear Professor Frizelle,

I am again writing to you concerning your proposal entitled "The 10Ten study: Quality of Life after Surgery for Recurrent Rectal Cancer", Ethics Committee reference number H16/061.

Thank you to Liane Dixon, co-investigator on the above project, for her response of 1st June 2016 addressing the issues raised by the Committee.

On the basis of this response, I am pleased to confirm that the proposal now has full ethical approval to proceed.

The standard conditions of approval for all human research projects reviewed and approved by the Committee are the following:

Conduct the research project strictly in accordance with the research proposal submitted and granted ethics approval, including any amendments required to be made to the proposal by the Human Research Ethics Committee.

Inform the Human Research Ethics Committee immediately of anything which may warrant review of ethics approval of the research project, including: serious or unexpected adverse effects on participants; unforeseen events that might affect continued ethical acceptability of the project; and a written report about these matters must be submitted to the Academic Committees Office by no later than the next working day after recognition of an adverse occurrence/event. Please note that in cases of adverse events an incident report should also be made to the Health and Safety Office:

http://www.otago.ac.nz/healthandsafety/index.html

Advise the Committee in writing as soon as practicable if the research project is discontinued.

Make no change to the project as approved in its entirety by the Committee, including any wording in any document approved as part of the project, without prior written approval of the Committee for any change. If you are applying for an amendment to your approved research, please email your request to the Academic Committees Office:

gary.witte@otago.ac.nz

jo.farrondediaz@otago.ac.nz

Approval is for up to three years from the date of this letter. If this project has not been completed within three years from the date of this letter, re-approval or an extension of approval must be requested. If the nature, consent, location, procedures or personnel of your approved application change, please advise me in writing.

The Human Ethics Committee (Health) asks for a Final Report to be provided upon completion of the study. The Final Report template can be found on the Human Ethics Web Page http://www.otago.ac.nz/council/committees/committees/thumanEthicsCommittees.html

Yours sincerely,

Mr Gary Witte

Manager, Academic Committees

Tel: 479 8256

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Say With

c.c. Professor F A Frizelle Head Department of Surgery (ChCh)