



Academic Services
Manager, Academic Committees and Services, Mr Gary Witte

23 May 2022

Professor R Gearry
Department of Medicine (ChCh)
University of Otago, Christchurch
University of Otago Medical School

Dear Professor Gearry,

I am writing to let you know that, at its recent meeting, the Ethics Committee considered your proposal entitled “**Bread Related Effects on Microbial Distribution (BREAD) Study**”.

As a result of that consideration, the current status of your proposal is:- **Approved**

For your future reference, the Ethics Committee’s reference code for this project is:- **H22/061**.

The comments and views expressed by the Ethics Committee concerning your proposal are as follows:-

While approving the application, the Committee would be grateful if you would respond to the following:

Research Consultation with Māori (Question 14.3)

Please provide evidence of consultation, once this becomes available.

Please provide the Committee with copies of the updated documents, if changes have been necessary.

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.

Conditions of approval: Upon approval, it is expected that all members of the research team are made aware of what the standard conditions of ethical approval covers. This includes the date ethical approval expires, as well as the process regarding applying for amendments to the research.

Approval period: 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.

Final report: A Final Report is required by the Committee upon completion of the study. The Final Report template can be found on the Human Ethics Web Page

<https://www.otago.ac.nz/council/committees/committees/HumanEthicsCommittees.html>

Adverse or unforeseen events: 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>

Privacy breach: A privacy breach occurs when there is unauthorised or accidental access to someone's personal information or disclosure, alteration, loss or destruction of personal information. Any breach of privacy needs to be reported to the University of Otago Privacy Officer immediately. This can be done via an online form <https://www.otago.ac.nz/administration/privacy-information/#breach>, or emailed to the registrar@otago.ac.nz or policycompliance@otago.ac.nz. In the case where a report has been submitted, please also inform the Academic Committees and Services Office.

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

Amendments: 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.farronediaz@otago.ac.nz

Locality authorisation: Studies requiring locality authorisation, i.e. permission from the organisations at which the study is taking place or from which participants are being accessed, must be confirmed before the study commences.

Yours sincerely,

A handwritten signature in black ink, appearing to read "Gary Witte". The signature is written in a cursive style with a large initial "G" and "W".

Mr Gary Witte

Manager, Academic Committees and Services

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c.c. Professor R Geary Head Department of Medicine (ChCh)