

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

26 November 2020

Assoc. Prof. P Herst Radiation Therapy (Wgnt) Faculty of Medicine University of Otago, Wellington

Dear Assoc. Prof. Herst,

I am again writing to you concerning your proposal entitled "Mepitel Film vs StrataXRT in managing radiation-induced skin reactions in chest wall patients", Ethics Committee reference number H20/130.

Thank you for your email of 25th November 2020 with response attached 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.

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

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.farrondediaz@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.

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.

Yours sincerely,

Mr Gary Witte

Manager, Academic Committees and Services

Tel: 479 8256

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Say With

c.c. Ms K L Coleman Head Radiation Therapy (Wgnt)