



Queensland
Government

Metro North
Hospital and Health Service

Royal Brisbane & Women's Hospital
Human Research Ethics Committee

Enquiries to: Ann-Maree Gordon
Coordinator
Telephone: 07 3646 5490
File Ref: HREC/2021/QRBW/70042
Email: RBWH-Ethics@health.qld.gov.au

Miss Emilie Croisier
Department of Nutrition and Dietetics
Royal Brisbane & Women's Hospital
Herston Qld 4029

Dear Miss Croisier,

Re: Ref N^o: HREC/2021/QRBW/70042: Dietary counselling to increase soluble fibre in patients with gynaecological cancers undergoing pelvic radiotherapy: a feasibility study

Thank you for submitting the above research project for single ethical review. This project was considered by the Royal Brisbane & Women's Hospital Human Research Ethics Committee (RBWH HREC) (**EC00172**) at its meeting held on 09 December 2021.

I am pleased to advise that this research project meets the requirements of the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007)* and that the RBWH Human Research Ethics Committee has granted ethical approval of this research project.

This letter constitutes ethical approval only. This project cannot proceed at any site until separate research governance authorisation has been obtained from the CEO or Delegate of the institution under whose auspices the research will be conducted at that site.

The approved documents include:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Data Collection Sheet	1.0	24 November 2020
Curriculum Vitae of Emilie Croisier		
ICH GCP Certificate		11 December 2019
Response to request for further information		27 January 2021
Participant Information Sheet	4.0	27 January 2021
Response to request for further information		02 February 2021
HREA	Feb ver 3	02 February 2021
Protocol	4.0	02 February 2021

<i>Document</i>	<i>Version</i>	<i>Date</i>
Appendix 2: Consent Form – Adult providing own consent	4.0	02 February 2021
Appendix 3: Form for Withdrawal of Participation	4.0	02 February 2021
Appendix 4: Example of Food Diary (1 out of 3 days completed)	4.0	02 February 2021
Appendix 5: Modified Inflammatory Bowel Disease Questionnaire to assess GI toxicity	4.0	02 February 2021
Appendix 6: Stool Diary using the Bristol Stool Chart to assess GI toxicity	4.0	02 February 2021
Appendix 7: Patient-reported outcomes version of the Common Terminology Criteria for Adverse Events to assess GI toxicity	4.0	02 February 2021
Appendix 8: Patient generated – subjective global assessment (PG-SGA) to assess nutrition status	4.0	02 February 2021
Appendix 9: European Organization for Research and Treatment of Cancer quality of life questionnaire (EORTC-QLQ) – Ovarian subset specimen	4.0	02 February 2021

Ongoing approval is for the duration of the project, conditional on:

1. In accordance with Section 5.5.6 (b) of the National Statement, the Principal Investigator will report to the HREC annually (**Due by 30 April each year**) in the specified format with a final report to be submitted on completion of the study.
<https://www.health.qld.gov.au/metronorth/research/ethics-governance/post-approval-reporting/default.asp>
2. The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project, in the specified format, including:
 - a. Unforeseen events that might affect continued ethical acceptability of the project.
 - b. Serious Adverse Events that materially impact on the continued ethical acceptability of the project.
3. Amendments to the research project are to be submitted to the HREC for review. Amendments should be reflected in a cover letter from the Principal Investigator, providing a description of the changes, the rationale for the changes, and their implications for the ongoing conduct of the study. Further advice on submitting amendments is available from:
<https://metronorth.health.qld.gov.au/research/ethics-and-governance/post-approval-reporting>

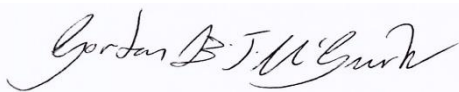
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4. The Principal Investigator will notify the HREC if the project is discontinued at the participating site(s) with reasons provided.
 5. If additional sites are engaged prior to the commencement of, or during the research project, the Principal Investigator is required to notify the HREC. Notification of the withdrawn sites should also be provided to the HREC in a timely fashion accompanying a close out report for that site.
- **Please advise the HREC of the date you commence the research project for the approved site(s) using the Notification of Commencement Form:**
<https://www.health.qld.gov.au/metronorth/research/ethics-governance/post-approval-reporting/default.asp>
 - The HREC's Terms of Reference, Standard Operating Procedures, membership and standard forms are available from:
<https://www.health.qld.gov.au/metronorth/research/ethics-governance/hrec-approval/membership/default.asp>.

The nominated participating site for this project is:

- Royal Brisbane & Women's Hospital

The Royal Brisbane & Women's Hospital Human Research Ethics Committee wishes you every success in your research.

Yours sincerely,



Dr Gordon McGurk
Chairperson RBWH Human Research Ethics Committee
Metro North Hospital and Health Service
03 February 2021

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007)*. The processes used by this HREC to review multi-centre research proposals have been certified by the National Health and Medical Research Council.