

Metro North Hospital and Health Service

Royal Brisbane & Women's Hospital Human Research Ethics Committee

Enquiries to: Mamta Tanwar

Assistant Coordinator

Telephone: 07 3646 6132

File Ref: HREC/2020/QRBW/66388
Email: RBWH-Ethics@health.qld.gov.au

Dr Theresa Brown Nutrition & Dietetics Level 2, James Mayne Building Royal Brisbane & Women's Hospital Herston QLD 4029

Dear Dr Brown,

Re: Ref Nº: HREC/2020/QRBW/66388: A feasibility study to investigate taste changes and their association with genes and dietary behaviour in patients with head and neck cancer

Thank you for submitting the above research project for single ethical review. This project was received by the Royal Brisbane & Women's Hospital Human Research Ethics Committee (RBWH HREC) (**EC00172**) on 26 November 2020 and was reviewed by a sub-Committee of the HREC. The research project meets the requirements of the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research* (2007).

I am pleased to advise that the sub-Committee has approved of this low risk research project. This approval will be noted by the RBWH Human Research Ethics Committee at its meeting to be held on 08 February 2021.

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

- 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

- 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.

<u>This letter constitutes ethical approval only</u>. 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:

Document	Version	Date
Cover letter		20 November 2020
HREA Form	Nov ver 2	26 November 2020
Protocol	3	30 October 2020
Participant Information Sheet & Consent Form	2	20 November 2020
Participant Instruction & Assessment Booklet	1	20 November 2020
Data Collection Tool - REDCap		19 November 2020
Common Terminology Criteria for Adverse Events (CTCAE)	5.0	27 November 2017
Curriculum Vitae of Dr Liang-Dar Hwang		
Curriculum Vitae of Prof Penelope Webb		

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

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15.12.2020

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.