



Queensland
Government

The Prince Charles Hospital
Human Research Ethics Committee

Metro North
Hospital and Health Service

Enquiries to: Research Ethics & Governance Unit
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Email: ResearchTPCH@health.qld.gov.au
File Ref: ERM: 84516 Approval

07 April 2022

Prof Andreas Obermair
Department of Gynaecological Oncology
UQ Centre for Clinical Research
Building 71/918
Royal Brisbane & Women's Hospital
Herston Qld 4029

Dear Prof Obermair,

Re: HREC/2022/QPCH/84516: Feasibility of Groin Ultrasound to Predict Groin Lymph Node Involvement in Patients with Histologically Proven Vulvar Cancer

Thank you for submitting the above research project for single ethical review. This project was considered by The Prince Charles Hospital Human Research Ethics Committee (TPCH HREC) (**EC00168**) at its meeting held on 24 March 2022.

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 TPCH Human Research Ethics Committee has granted final ethical approval of this research project.

Note: If additional sites are engaged prior to the commencement of, or during the research project, the Coordinating Principal Investigator is required to notify the HREC. Notification of withdrawn sites should also be provided to the HREC in a timely fashion.

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>
Master Form for Withdrawal of Participation	1.0	23 February 2022
Curriculum Vitae of Prof Andreas Obermair		

<i>Document</i>	<i>Version</i>	<i>Date</i>
Curriculum Vitae of A/Prof Carlos Salomon		
Curriculum Vitae of Eva Louise Baxter		
Curriculum Vitae of Prof Neville Frederick Hacker		
Curriculum Vitae of Shohreh Rezai		
Response to request for further information		05 April 2022
HREA	Apr ver 2	06 April 2022
Pre-ANVU Research Protocol	1.1	31 March 2022
Master Participant Information Sheet & Consent Form	1.1	07 April 2022

This information will be tabled for noting at the HREC meeting to be held on 28 April 2022.

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 and a final report is to be submitted on completion of the study.
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:
www.health.qld.gov.au/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.
- **Please advise the HREC of the date you commence the research project for the approved site(s) using the Notification of Commencement Form:**
www.health.qld.gov.au/metronorth/research/ethics-governance/post-approval-

[reporting/default.asp](#)

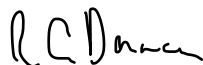
- The HREC's Terms of Reference, Standard Operating Procedures, membership and standard forms are available from:
https://www.health.qld.gov.au/hiiro/html/regu/regu_home

The nominated participating sites for this project are:

No.	Site
1.	Royal Brisbane & Women's Hospital
2.	Mater Misericordiae Limited

The Prince Charles Hospital Human Research Ethics Committee wishes you every success in your research.

Yours sincerely,



Dr Russell Denman
Chair
The Prince Charles Hospital Human Research Ethics Committee
[Metro North Hospital and Health Service](#)

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)*, NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007) and the CPMP/ICH Note for Guidance on Good Clinical Practice.