

**Amended**

Enquiries to: Metro South  
Human Research Ethics Committee  
Phone: 07 3443 8049  
Fax: 07 3443 8003  
HREC Ref: HREC/18/QPAH/238  
E-mail: [MSH-Ethics@health.qld.gov.au](mailto:MSH-Ethics@health.qld.gov.au)

Dr Simon Wood  
Department of Urology  
Princess Alexandra Hospital

Dear Dr Wood,

**HREC Reference number: HREC/18/QPAH/238**  
**Protocol title: The Urological Society of Australia and New Zealand (USANZ) Clinical Quality Registry**

Thank you for submitting the above research protocol to the Metro South Health Human Research Ethics Committee for ethical and scientific review. This protocol was considered by the Low Risk Review Panel and will be ratified at the next Metro South HREC meeting.

*You are reminded that this letter constitutes ethical approval only. You must not commence this research protocol at a site until separate authorisation from the Hospital Health Service Chief Executive (CE) or Delegate of that site has been obtained.*

*A copy of this approval must be submitted to the Research Governance Office(r)/Delegate of the relevant institution with a completed Site Specific Assessment (SSA) Form for authorisation from the CE or Delegate to conduct this research at as in Appendix table.*

*If this study currently receives grant funding, please remember to forward a copy of this approval letter to the relevant Grants Office of the Administering Institution(s) for the grant.*

I am pleased to advise that the Low Risk Review Panel of the HREC has granted approval of this research protocol. The documents reviewed and approved include:

Document	Version	Date
Low or Negligible Risk Application AU/10/0D55319		03/04/2018
Master Nephrectomy Registry PIS and OPT OUT Form	3.0	11/05/2018
Metro South Nephrectomy Registry PIS and OPT OUT Form	2.0 (as rec'd)	11/05/2018
Research Protocol	3.0	19/02/2018
Nephrectomy Registry Data Collection Tool & Dataset		03/04/2018
Ethics Submission Letter	1.2	03/04/2018
MSF31 Checklist Form		03/04/2018
Research study checklist for Coordinating Principal Investigators		n.d
CV for Investigator		n.d
Email Correspondence in response to LRRP questions		23/05/2018

This HREC approval is valid from 28/05/2018 until 28/05/2021

Please note the following conditions of approval:

1. The Principal Investigator will immediately report anything which might warrant review of ethical approval of the protocol in the specified format, including unforeseen events that might affect continued ethical acceptability of the protocol.
2. Amendments to the research protocol which may affect the ongoing ethical acceptability of a protocol must be submitted to the HREC for review. Major amendments should be reflected in revised study documentation and a cover letter from the principal investigator, providing a brief description of the changes, the rationale for the changes, and their implications for the ongoing conduct of the study. Hard



copies of the revised documents and the cover letter, with *tracked changes*, must also be submitted to the HREC office as per standard HREC SOP.

3. Amendments to the research protocol which only affect the ongoing site acceptability of the protocol are not required to be submitted to the HREC for review. These amendment requests should be submitted directly to the Research Governance Office/r.
4. Proposed amendments to the research protocol which may affect both the ethical acceptability and site suitability of the protocol must be submitted firstly to the HREC for review and, once HREC approval has been granted, then submitted to the Research Governance Office/r.
5. Amendments which do not affect either the ethical acceptability or site acceptability of the protocol (e.g. typographical errors) should be submitted electronically (track changes) and in hard copy (final clean copy) to the HREC Coordinator. These should include a cover letter from the Principal Investigator or Study Co-ordinator providing a brief description of the changes and the rationale for the changes, and accompanied by all relevant updated documents with tracked changes.
6. The HREC will be notified, giving reasons, if the protocol is discontinued at a site before the expected date of completion.
7. The Coordinating Principal Investigator will provide an annual report to the HREC and at completion of the study in the specified format.
8. If you require an extension for your study, please submit a request for an extension in writing outlining the reasons. Note: One of the criteria for granting an extension is the compliance with the approval's conditions including submission of progress reports.
9. Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes ([WHO / ICMJE 2008 definition](#)) should be registered, including early phase and late phase clinical trials (phases I-III) in patients or healthy volunteers ([WHO Recommendation / ICMJE policy](#)). If in doubt, registration is recommended. All studies must be registered prior to the study's inception, i.e. prospectively. <http://www.anzctr.org.au/>

Should you have any queries about the HREC's consideration of your protocol please contact Ethics Secretariat on 07 3443 8049.

Please note that the Metro South 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*. Attached is the HREC Composition with specialty and affiliation with the Hospital (Attachment I).

The Metro South HREC wishes you every success in your research.

Yours sincerely,



Nicolla Lewin  
**Chair - Low Risk Review Panel**  
**Metro South Hospital and Health Service**  
**Human Research Ethics Committee (EC00167)**  
**Centres for Health Research**  
**Princess Alexandra Hospital**

\_\_28\_\_/\_05\_\_/\_2018\_\_

**C.c.** Miss Jayde Archer, Urological Society of Australia and New Zealand

## Appendix:

### List of Sites Approved

No.	Site
1.	Princess Alexandra Hospital
2.	Mater Hospital Brisbane
3.	Mater Private Hospital Townsville
4.	Townsville Hospital
5.	Royal Brisbane and Women's Hospital
6.	Wesley Hospital
7.	St Andrews Hospital
8.	Repatriation General Hospital
9.	Flinders Medical Centre
10.	Royal Adelaide Hospital
11.	Noarlunga Health Service
12.	Armidale Private Hospital
13.	Port Macquarie Public Hospital
14.	Newcastle Private Hospital
15.	John Hunter Hospital (Newcastle)
16.	Westmead Private Hospital
17.	Hurstville Private Hospital
18.	Lingard Private Hospital
19.	Lake Macquarie Private Hospital
20.	Belmont Hospital
21.	Epworth Hospital
22.	Cabrini Hospital
23.	Monash Medical Centre
24.	Peninsula Health
25.	Peter MacCallum Cancer Centre
26.	Masada Hospital East
27.	Bairnsdale Hospital
28.	Alfred Hospital
29.	St John of God Hospital Subiaco
30.	St John of god Hospital Murdoch
31.	Hollywood Private Hospital
32.	Osborne Park Hospital