

From: no_reply@regis.health.nsw.gov.au
Subject: 2021/ETH00229: Application HREA - Approved
Date: 4 May 2021 at 2:10:03 pm AEST
To: Cameron.Parkin@health.nsw.gov.au
Reply-To: no_reply@regis.health.nsw.gov.au

Date of Decision Notification: **04 May 2021**

Dear Cameron Parkin,

Thank you for submitting the following Human Research Ethics Application (HREA) for HREC review;

2021/ETH00229: Ureteric Stent Removal – Should it be left in the patient’s hands?

Thank you for your correspondence, received 29 April 2021, responding to the Northern Sydney Local Health District HREC’s request for additional information/modification for the above project, which was first considered by the HREC at its meeting held on **12 April 2021**.

This application was assessed as a **greater than low risk project**.

I am pleased to advise that the Committee at a meeting of the Executive held on out of session on **04 May 2021** has granted ethical and scientific approval of the above **multi centre project**. The HREC were satisfied that this project meets the requirements of the National Statement.

This project has been approved to be conducted at the following sites:

- Royal North Shore Hospital, NSW
- Gosford Hospital, NSW
- Northern Beaches Hospital, NSW

The following documentation was reviewed and is included in this approval:

- Study Protocol, version 2, dated 19 April 2021
- Participant Information Sheet and Consent Form, version 2, dated 19 April 2021

[Application Documents](#) - The Human Research Ethics Application reviewed by the HREC was:
Version: 3, Date: 19 April 2021

This email constitutes ethical and scientific approval only.

This project cannot proceed at any site until separate research governance authorisation has been obtained from the Institution under whose auspices the research will be conducted at that site.

This HREC is constituted and operates in accordance with the 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. No HREC members with a conflict of interest were present for review of this project. Please note the following conditions of approval:

- HREC approval is valid for **5 years** from the date of approval and expires on **04 May 2026**. The Co-ordinating Investigator is required to notify the HREC 6 months prior to this date if the project is expected to extend beyond the original approval date at which time the HREC will advise of the requirements for ongoing approval of the study.

- The Co-ordinating Investigator will provide an annual progress report **at the anniversary date of the project** as well as a final study report at the completion of the project at all sites. This will be through the submission of a milestone report within the Research Ethics and Governance Information System (REGIS).
- The Co-ordinating Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including unforeseen events that might affect continued ethical acceptability of the project and any complaints made by study participants regarding the conduct of the study.
- Proposed changes to the research protocol including; the general conduct of the research, changes to CPI or site PI, and extension to HREC approval, or the addition of research sites must be provided to the HREC for review, in the specified format before changes can take effect. This will be through a notification of an amendment in REGIS.
- Investigators holding an academic appointment (including conjoint appointments) and students undertaking a project as part of a university course are advised to contact the relevant university HREC regarding any additional requirements for the project.

Please contact us if you would like to discuss any aspects of this process further, as per the contact details below. We look forward to managing this application with you throughout the project lifecycle.

Kind regards,

Hang Zhen (Amy) Wang

Research Ethics Officer | NSLHD Research Office

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