



HUMAN RESEARCH ETHICS COMMITTEE

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<https://www.seslhd.health.nsw.gov.au/services-clinics/directory/seslhd-research>
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09 November 2018

Dr Linda Zhang
Gastroenterology Department
Burt Nielsen Wing
St George Hospital
KOGARAH NSW 2217

Dear Dr Zhang,

HREC ref no: 18/199 (LNR/18/POWH/477)

Project title: Clinical utility of intra-procedural cricopharyngeal distensibility measurement in Zenker's diverticulum managed by endoscopic myotomy

Thank you for submitting the above Low/Negligible Risk (LNR) Application for review by the Human Research Ethics Committee (HREC). Based on the information you have provided and in accordance with the NHMRC guidelines [National Statement 2007 – Section 5 Institutional Responsibilities and “*When does quality assurance in health care require independent ethical review?*” (2003)], this project has been assessed as low risk and is therefore exempt from full HREC review.

The project was first considered by the LNR Committee on 23 October 2018.

I am pleased to advise that ethics approval has been granted for this project to be conducted at the following site(s):

- St George Hospital

The following documentation has been approved:

- HREA, submission code AU/1/BFB8313, dated 27 September 2018
- Project Description Version 1 dated 27 September 2018
- Data Collection Sheet Version 1 dated 27 September 2018
- Response dated 07 November 2018 to LNR Committee queries

Conditions of approval

1. This approval is valid for 5 years from the date of this letter.
2. Annual reports must be provided on the anniversary of approval.
3. A final report must be provided at the completion of the project.

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Community Health Services



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4. Proposed changes to the research protocol, conduct of the research, or length of approval will be provided to the Committee.
5. The Principal Investigator will immediately report matters which might warrant review of ethical approval, including unforeseen events which might affect the ethical acceptability of the project and any complaints made by study participants.

For NSW Public Health sites only: You are reminded that this letter constitutes ethics approval only. You must not commence this research project until you have submitted your Site Specific Assessment (SSA) to the Research Governance Officer of the appropriate institution and have received a letter of authorisation from them.

Should you have any queries, please contact the Research Support Office on (02) 9382 3587. The HREC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the Research Support Office website:

<https://www.seslhd.health.nsw.gov.au/services-clinics/directory/seslhd-research/for-researchers>

Please quote **HREC ref no: 18/199** in all correspondence.

We wish you every success in your research.

Yours sincerely



Andrew Bohlken

Executive Officer, Human Research Ethics Committee

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*.