NSW GOVERNMENT
Health
South Eastern Sydney
Local Health District

HUMAN RESEARCH ETHICS COMMITTEE
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16 August 2018

Dr Michael Szczesniak
Department of Gastroenterology and Hepatology
St George Hospital
KOGARAH NSW 2217

Dear Dr Szczesniak

HREC ref no: 18/145 (HREC/18/POWH/294)
Project title: Effect of adjuvant Pentoxifylline and Vitamin E on compliance of pharyngoesophageal junction after endoscopic dilatation.

Thank you for submitting the above application for ethical and scientific review and for your correspondence dated **16 August 2018** to the Executive Officer responding to questions which arose at the Executive Committee meeting on **08 August 2018.**

Authority to grant final approval was delegated to the Executive Officer. I am pleased to advise that that the proposal meets the requirements of the National Statement on Ethical Conduct of Human Research and ethics approval has been given for the following:

- HREA submission AU/1/F7C639 dated 31/05/2018
- Protocol version 3 dated 13 Aug 2018
- Participant Information Sheet & Consent Form version 3.0 dated 13 Aug 2018
- Visit 1 Screening Guide

The following document is acknowledged

- Pentoxifylline Product Information, trental-ccdsv7-piv6-25sep15

Ethics approval is valid for the following site(s):

- St George Hospital

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.
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.

It is the responsibility of the sponsor or the principal (or co-ordinating) investigator of the project to register this study on a publicly available online registry (eg Australian New Zealand Clinical Trials Registry www.anzctr.org.au).

For Public Health Sites: 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 the General Manager or Chief Executive of that institution.

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: http://www.seslhd.health.nsw.gov.au/POWH/researchsupport/default.asp.

Please quote **18/145** 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*.