



Approval Date: 09 June 2016

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CALHN reference number: R20160616

please quote this number in all future correspondence

Central Adelaide Local Health Network
Royal Adelaide Hospital Human Research Ethics Committee
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Dr Stephanie Wong
Gastroenterology and Hepatology
ROYAL ADELAIDE HOSPITAL

Dear Dr Wong

Project title: The use of Aspartate Transaminase to Platelet Ratio to predict the need for FibroScan in the identification of advanced liver fibrosis.

RE: Audit APPROVAL

Thank you for submitting the above project for ethical review. This project was considered under the expedited approval process of the Royal Adelaide Hospital Human Research Ethics Committee and deemed to be an audit according to the requirements of the National Statement on Ethical Conduct in Human Research. I also note that you have identified an appropriate strategy for review by the Medical Administration of the Institution of any publications arising from the activity prior to their submission.

The documents reviewed and approved include:

- **SA Health LNR Application Form (AU/15/07B629)**
- **Protocol, Version 1 dated 8 June 2016**
- **Email response**

GENERAL TERMS AND CONDITIONS OF APPROVAL OF QA:

- Adequate record-keeping and data security is important. The duration of record retention for all clinical research data is 15 years.
- Confidentiality is important. The data collected should as much as possible protect the identity of individuals. Where this is not possible, a separate file of subject identifiers should be maintained such that clinical information is kept separately from subject identifiers.
- You must notify the Research Ethics Committee of any changes which might warrant review of the approval.
- Approval is ongoing. Annual or final reports are **not** required.
- The REC must be advised within 30 days of completion so that the file can be closed.

Should you have any queries about the HREC's consideration of your project, please contact Ms Heather O'Dea on 08 8222 4139, or Health.CALHNResearchEthics@sa.gov.au.

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at a SA Health site until governance authorisation at that site has been obtained. Please contact the CALHN Research Office Health.CALHNResearchLNR@sa.gov.au

This Committee is constituted in accordance with the NHMRC *National Statement on the Ethical Conduct of Human Research (2007)* and incorporating all updates.

The HREC wishes you every success in your research.

Yours sincerely,

**A/Prof A Thornton
CHAIRMAN
RESEARCH ETHICS COMMITTEE**