ST VINCENT'S HOSPITAL
MELBOURNE
A FACILITY OF ST VINCENT'S HEALTH AUSTRALIA

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28 February 2022

Dr Jess Howell
Department of Gastroenterology
St Vincent's Hospital Melbourne

Dear Dr Howell,

Project ID: 81922
St Vincent's local reference number: LRR 315/21

'Using automated APRI calculation in pathology to improve diagnosis of liver cirrhosis and linkage to care: The Cirrhosis Automated APRI Screening Evaluation (CAPRISE) Study'

Approval is given in accordance with the research conforming to the *National Health and Medical Research Council Act 1992* and the *National Statement on Ethical Conduct in Human Research 2007 (updated July 2018)*

This HREC is organised and operates in accordance with the National Health and Medical Research Council's (NHMRC) National Statement on Ethical Conduct in Research Involving Humans 2007 (updated *July 2018*), and in accordance with the Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95), the Health Privacy Principles described in the Health Records Act 2001 (Vic) and Section 95A of the Privacy Act 1988 (and subsequent Guidelines).

Approval Date: 28 February 2022

Ethical approval is given for this research project to be conducted at the following sites:

- St Vincent's Hospital Melbourne, VIC

This approval will be ratified by St Vincent's Hospital (Melbourne) HREC at the next meeting.

Approved documents
The following documents have been reviewed and approved:

Document	Version	Date
VSM	-	29 Nov 2021
CAPRISE Protocol	2.0	21 Dec 2021

Governance approval *is given for this research project to be conducted at St Vincent's Hospital Melbourne*

Approved Governance Documents

Document	Version	Date
HREA	-	-
Letter of Support – Acting Chief Medical Officer	-	29 Nov 2021
CV – Jess Howell	-	-
CV – Alexander Thompson	-	01 Jul 2020
CV – Ericka Flores	-	-
CV – Christina Trambas	-	-
GCP – Jess Howell	-	21 Dec 2021
GCP – Alexander Thompson	-	24 Feb 2021
GCP – Ericka Flores	-	09 Dec 2019
GCP – Christina Trambas	-	02 Dec 2021

Terms of approval:

1. It is the responsibility of the Principal Researcher to ensure that all investigators are aware of the terms of approval and to ensure the project is conducted as specified in the application.
2. The Principal Researcher is to notify the Research Governance Unit of all significant safety issues in accordance with the NHMRC Guidance: Safety monitoring and reporting in clinical trials involving therapeutic goods (including all updates).
3. Immediate notification of any unforeseen events that may affect the continuing ethical acceptability of the project;
4. Amendments to the approved project: Changes to any aspect of the project require the submission of a Request for Amendment to the Low Risk Research Sub-committee and must not begin without written approval. Substantial variations may require a new application.
5. Future correspondence: Please quote the reference number and project title above in any further correspondence.
6. **An Annual Progress Report (that covers all sites listed on approval) for the duration of the project. This report is due on the 01 May each year for the duration of the project. Continuation of ethics approval is contingent on submission of an annual report. Failure to comply with this requirement may result in suspension of the project by the HREC.**
7. Final report: A Final Report must be provided at the conclusion of the project.
8. Monitoring: Projects may be subject to an audit or any other form of monitoring by the Research Governance Unit at any time.

As the research project involves the collection, use and/or disclosure of identifiable health information without consent, the Victorian Health Records Act Statutory Guidelines for Research were applied by the Committee. The request for a waiver of the requirement for consent is approved, and will be ratified at the next full HREC meeting.

We wish you well with your project.

Yours sincerely,

Alexandra Braun
Research Governance Unit
St Vincent's Hospital (Melbourne)