

08 May 2019

Sarah Romero
Gastroenterology Advanced Trainee
Monash Health

Dear Researcher,

Quality Assurance Title: Outcomes in hepatic hydrothorax

Monash Health Ref: RES-19-0000-343Q

Thank you for your application. It is our understanding that this project is a quality & service improvement exercise involving collection, use and disclosure of data in a de-identified format to be conducted at Monash Health. Such data is to be accessed by a Monash Health employee only. As such, we advise that it does not raise any ethical concerns and does not fall within the category of a 'research' project within the National Statement on Ethical Conduct In Human Research (NHMRC, 2007). This project does not require submission to the Monash Health Human Research Ethics Committee. In addition, this Quality & Service Improvement activity can be described as an activity to monitor, improve and evaluate the quality of health services provided by Monash Health.

For our record-keeping purposes, we will deem this activity will be in progress for 12 months from this date, unless we hear from you to the contrary. It will then be classified as completed.

Please note this letter only pertains to the Quality & Service Improvement activity being conducted at Monash Health. If it is intended the Quality & Service Improvement activity will be conducted at another institution appropriate review and authorisation will be required prior to commencement at another institution.

Should you have any queries please contact me on 03 9594 4090.

Yours sincerely



JULIE GEPHART
HREC Coordinator
Research Support Services

cc: Quality & Safety Unit
cc: Mr Ross Major, HIS

Austin Hospital

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APPROVAL OF AUDIT ACTIVITY

Dr. Preet Singh,
Gastroenterology, Austin Health

10 March 2020

Project Number: Audit/20/Austin/27

Austin Health Reference Number: Audit 20/27

Project Title: Natural history and outcomes of patients with liver cirrhosis complicated by hepatic hydrothorax.

Dear Dr. Preet Singh,

Thank you for your application. The project has been reviewed by Austin Health Office for Research against the principles of the National Statement on Ethical Conduct in Research (2007, updated 2018) and **we believe that this project does not require submission to the Austin Health Human Research Ethics Committee.** It is our understanding that this application is a clinical audit project involving the collection, use and disclosure of the data in a de-identified format to be conducted at Austin Health. Such data is to be accessed by an Austin Health employee only.

Approval for the study to be conducted as an audit is now granted.

Please note this letter only pertains to the project being conducted at Austin Health. If it is intended for the project to be conducted at another site/institution, the appropriate review and authorisation will be required prior to the commencement at respective site/institution.

Conditions of Audit Approval:

You are required to submit to the Office for Research:

- An Annual Progress Report (that covers all sites listed on approval) for the duration of the project. This report is due on the anniversary of Audit approval. Continuation of Audit approval is contingent on submission of an annual report, due within one month of the approval anniversary. Failure to comply with this requirement may result in suspension of the project by the Office for Research.
- A comprehensive Final Report upon completion of the project.

Audit Approval V6 dated 17 April 2019

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Audit approval for this project applies at the following sites:

| Site |
|---------------|
| Austin Health |

Document/s Approved:

| Document | Version | Date |
|---|---------|------------------|
| Austin Health Audit Activity Application Form | 1 | 25 February 2020 |
| Data Collection Tool | 2 | 10 March 2020 |

Yours sincerely,

Priyanka Sathe

HREC Manager – Drug Trials

Office for Research, Austin Health

Level 8 HSB

E-mail: ethics@austin.org.au

Web: <http://www.austin.org.au/researchethics>