

14 April 2021

Dr Aparna Morgan
Department of Gastroenterology
Monash Health

Dear Researcher,

Quality Project Title: Survival outcomes and current practices for acute severe variceal bleeding requiring balloon tamponade

ERM Reference No. 70254

HREC Reference Number: HREC/70254/MonH-2021-256196(v1)

Our Local HREC Reference No. RES-21-0000-218Q – 70254

I am pleased to advise that the above clinical audit/quality assurance project has been reviewed by the Monash Health research office (Research Support Services). The office confirms that this proposal is exempt from HREC review and therefore has been reviewed and approved via an alternate pathway.

The proposal is consistent with the NHMRC Ethical Considerations in Quality Assurance and Evaluation Activities (2014) guideline. The project is authorised to commence on the provision that the Head of Department has provided you with approval to undertake the activity.

Approval Date: 14 April 2021

****Please note the project is approved up to two years. Progress (or final) reports are not required for negligible risk research, clinical audits or quality activity projects.***

Approved Documents:

The following documents have been reviewed and approved:

Document	Version	Date
Quality Assurance Application For	HREC/70254/MonH- 2021-256196(v1)	24/03/2021

Conditions of Organisational Approval:

- The project must adhere to the NHMRC Ethical Considerations in Quality Assurance and Evaluation Activities (2014) guideline
- Notify the reviewing research office of your inability to continue as Coordinating Principal Investigator.
- Notify the reviewing research office of any matters which may impact the conduct of the project.
- The reviewing research office, authorising institution and/or their delegate/s may conduct an audit of the project at any time.
- This study will last no longer than two years past the above approval date; at this time a new application will be required.
- Projects submitted via this pathway cannot be amended once approved; amendments must be submitted as a new application.

Yours sincerely,



DEBORAH DELL

Manager, Human Research Ethics Committee
Research Support Services

Cc: Dr Charlotte Keung, Gastroenterology, Monash Health; Ross Major-HIS