Monash Health

Research Support Services
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15 November 2019

Dr Daniel Croagh
Monash Health
Department of Upper GI and HPB - General Surgery
246 Clayton Road
Clayton Vic 3168

Dear Researcher,

Study Title: A cohort study to evaluate the protocolised management of bile duct stones in emergency general surgery

ERM Reference Number: 58519
Monash Health Ref: RES-19-0000-778L

The Monash Health Human Research Ethics Committee Low Risk Panel has reviewed the above application. In addition, the Low Risk Panel is satisfied that the responses to our correspondence of 7 November 2019 have been sufficiently addressed.

The Low Risk Panel approved the above application on the basis of the information provided in the application form, protocol and supporting documentation.

This reviewing Low Risk Panel is a Sub-committee of the Human Research Ethics Committee which is accredited by the Consultative Council for Clinical Trial Research under the single ethical review system.

Approval

The Low Risk Human Research Ethics approval is from 15 November 2019.

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 (2018)*. The HREC has ethically approved this research according to the Memorandum of Understanding between the Consultative Council and the participating organisations conducting the research.

Approval is given for this research project to be conducted at the following sites and campuses:

- Monash Health

You must comply with the following conditions:

The Chief Principal Investigator is required to notify the Manager, Human Research Ethics Committees, Monash Health of:

1. Any change in protocol and the reason for that change together with an indication of ethical implications (if any)
2. Suspected Unexpected Serious Adverse Reactions (SUSARs) involving a Monash Health participant or a participant at site that Monash Health has provided HREC Review.

3. Serious Adverse Events (SAEs) that occur with a Monash Health participant or with a participant from a site that Monash Health has provided HREC review that are considered by the Investigator as being definitely related, probably related, possibly related and unknown.
4. Any unforeseen events that might affect continued ethical acceptability of the project.
5. Any expiry of the insurance coverage provided in respect of sponsored trials.
6. Discontinuation of the project before the expected date of completion, giving reasons.
7. Any change in personnel involved in the research project including any study member resigning from Monash Health &/or the study team.

At the conclusion of the project or every twelve months if the project continues, the Principal Investigator is required to complete and forward an annual progress report to the Committee.

Reminders to submit annual progress report forms will be forwarded to the researcher.

The Coordinating Principal Investigator is responsible for notifying Principal Investigators. The Coordinating Principal Investigator and Principal Investigators should forward a copy of this letter to their site's Research Governance Officer.

Approved documents

Documents reviewed and approved are as follows:

Document	*Version*	*Date*
Human Research Ethics Application Form	HREC/58519/MonH-2019-193739(v2)	13/11/2019
Study Protocol	1	15/10/2019
Victorian Specific Module		8/11/2019
Process Worksheet		

Site-Specific Assessment (SSA)

SSA authorisation is required at all sites participating in the study. SSA must be authorised at a site before the research project can commence.

The completed Site-Specific Assessment Form and a copy of this ethics approval letter must be submitted to the Research Governance Officer for authorisation by the Chief Executive or delegate. This applies to each site participating in the research.

If you should have any queries about your project please contact our team via email research@monashhealth.org or via telephone 9594 4611 and request to speak with a team member.

The Low Risk Panel wishes you and your colleagues every success in your research.

Yours sincerely

D. Dell

DEBORAH DELL
Manager, Human Research Ethics Committee
& Research Support Services

Cc: Ms Carole Matthews

Checklist: Post-ethics approval requirements that must be met before a research project can commence at a study site.

Please ensure that as a PI (including the CPI) the following are completed at each study site.

Requirements	**Yes/No/NA**
Ethics approval notification The PI must send a copy to the RGO at that study site.	Yes
HREC Review Only Indemnity The PI must forward a copy of the signed HREC Review Only Indemnity to the RGO at that study site.	N/A
SSA authorisation notification The PI must forward the SSA form and attached documents (e.g. CTRA) to the RGO so the authority approving the conduct of the trial, at that site, can complete and sign.	N/A
Other Commonwealth statutory requirements Ensure compliance with the following e.g. Office of the Gene Technology Regulator, NHMRC Licensing Committee, NHMRC Cellular Therapies Advisory Committee.	Yes