

13 August 2020

Enquiries to: HREC Coordinator
Phone: 07 5687 3879
HREC Ref: LNR/2020/QGC/67173
Project ID:
E-mail: GCHEthics@health.qld.gov.au

Dr Waled Mohsen
Gastroenterology and Hepatology
Gold Coast University Hospital

Dear Dr Mohsen

HREC Reference: LNR/2020/QGC/67173
Project title: Predictors Of Response To Therapy In Acute Severe Colitis

Thank you for submitting the above project for ethical and scientific review, which has been undertaken by a panel of the Gold Coast Hospital and Health Service Human Research Ethics Committee (HREC) (EC00160). On recommendation of the panel, approval for this project has been granted by the Chair, HREC Peer Review Expert Panel, Gold Coast Hospital and Health Service.

This decision will be ratified at the 30 September 2020 meeting of the Gold Coast Hospital and Health Service HREC.

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research 2007 (Updated 2018)*, *NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2018)* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. The GCHHS HREC has been certified by the NHMRC to review multi centre research.

This research project meets the requirements of the *National Statement on Ethical Conduct in Human Research (2007)-Updated May 2018*

HREC approval is valid for **3 years**. Expiry 13 August 2023

The documents reviewed and approved include:

Document	Version	Date
LNR Application		30 July 2020
Protocol	1	15 July 2020
CV – Dr Waled Mohsen		2020

Please note the following conditions of approval:

1. **This letter constitutes ethical approval only.** You must not commence this project at a public health service site until authorisation has been granted by the Institutional Chief Executive or delegate. A copy of this approval must be submitted to the HHS Research Governance Officer/(RGO) along with a completed Site-Specific Assessment (SSA) Form and applicable documents for authorisation from the CE to conduct this research within the HHS.

Once authorisation to conduct the research has been granted, please complete the Commencement Form (Attachment II) and return to the office of the Human Research Ethics Committee GCHEthics@health.qld.gov.au

2. In accordance with the requirements of the *National Statement*, sections 2.3.9 - 2.3.10, the HREC **waived** the requirement for consent for the collection, use and/or disclosure of personal information in medical research or personal health information for the research project listed.

Under s150 of the *Hospital and Health Boards Act 2011* you are permitted to access confidential information for the purposes of research without consent.

3. **Reporting to the HREC:** The following reports are required to be submitted to the HREC. Failure to fulfill these reporting requirements may result in withdrawal or suspension of HREC approval:
 - a. **Progress Reports:** The Coordinating/Principal Investigator will provide a progress report annually to the HREC and at completion of the project. Progress reports are due on the anniversary of the HREC approval date. Progress Reports are created as subforms of the ethics application form. The first annual report for this project is due by Month/Year.
 - b. **Safety Reporting:** In Queensland Health, all reporting to the Reviewing HREC aligns with the guidance of the NHMRC – *Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods* (NHMRC 2016). In this guidance, the responsibility of reporting to the Reviewing HREC is assigned to the sponsor of the research project. The sponsor may be an institution, investigator, collaborative group or commercial company.
 - c. **Other monitoring:** The HHS administration and/or the HREC may inquire into the conduct of any research or purported research, whether approved or not and regardless of the source of funding, being conducted on HHS premises or claiming any association with the HHS; or which the Committee has approved if conducted outside its HHS.
4. **Amendments to this project:**
 - Amendments for review by an HREC:**
 - a. Amendments to the research project which may affect the ongoing ethical acceptability of a project must be submitted to the HREC for review.
 - b. Amendments should be reflected in a cover letter from the Principal Investigator, providing a brief description and rationale for the changes, and their implications for the ongoing conduct of the study. All relevant updated documentation should also

be provided. Amendments should be submitted on a subform created from the ethics application.

c. **Amendments for review by an HREC Coordinator**

Amendments which do not affect either the ethical acceptability or site acceptability of the project (e.g. typographical errors) should be submitted using the relevant ERM subform. These should include a cover letter from the Principal Investigator providing a brief description of the changes and the rationale for the changes and accompanied by all relevant updated documents with tracked changes.

Amendments for review by an RGO:

- d. Amendments to the research project which affect only the ongoing site acceptability of the project are not required to be submitted to the HREC for review. These amendment requests should be submitted directly to the Research Governance Office/r (by-passing the HREC).

5. **Early termination or routine completion of the project:**

- a. The HREC must be notified if the project is discontinued at a site before the expected date of completion. Notification should be in the form of a cover letter from the Principal Investigator, providing a rationale for the early termination.
- b. For projects that are completed, the HREC must be notified by submission of a progress report, along with a copy of any research summaries or intended publications.

Should you have any queries about the panel's consideration of your project please contact the HREC Coordinator on ph. 07 5687 3879. The HREC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from http://www.health.qld.gov.au/ohmr/html/regu/regu_home.asp

We wish you every success in your research.

Yours sincerely



Vanessa Druett
Research Ethics and Governance
On behalf of
Dr Greta Ridley
Chair
Peer Review Expert Panel
Human Research Ethics Committee
Gold Coast Hospital and Health Service

Sites Approved

Site
Gold Coast HHS