

16 August 2021

Dr Nicholas West
G40_9.17, Griffith University,
Parklands Drive
Southport, QLD

Dear Dr West,

HREC Reference number: 21/07

Project title: Efficacy of Fucoidan for eosinophilic oesophagitis: a phase 2 pilot study

The Ramsay Health Care QLD HREC (RHC QLD HREC) has granted ethical approval to the above project. The sites for which ethical oversight will be provided by the RHC QLD HREC include:

Study Site	Site Principal Investigator
John Flynn Private Hospital	Dr Nicholas West

The RHC QLD HREC provides ethical approval for all RHC facilities in Queensland. Please note that site-specific approval must be granted before you commence your project at any RHC site.

Your project approval number is indicated above; please quote this number in all correspondence to the RHC QLD HREC.

Date of Approval: Monday, 16 August 2021 (out of session)

Date of Meeting: Monday, 02 August 2021 (initial review)

Period of Approval: 16 August 2021 to 16 August 2025

The documents approved as part of this submission include:

- Response to Ethics Committee, dated 10 August 2021
- HREA Application, created 27 May 2021
- Clinical Trial Protocol, V1, dated 19 July 2021
- Information and Consent Form, V1, dated 19 July 2021
- Consent to share contact information, V1, dated 19 July 2021
- Letter to Participate, V1, dated 19 July 2021
- Product Information Sheet, V1, dated 19 July 2021

Supporting Documents

- QoL Questionnaire
- Daily S&M Diary
- Diet Diary
- Faecal Collection Instruction
- GERD QoL
- Patient Flow Diagram
- RG2021.139 Ramsay Site Specific Assessment (for noting only)

CVs

- Amanda Cox CV, June 2021
- Amanda Cox GCP

- Peter Smith CV, June 2020
- Rebecca Ramsey CV, 2021
- Sarah Hanson CV
- Sarah Hanson GCP
- Nicholas West CV, January 2019
- Nicholas West GCP
- James Sinclair CV
- James Sinclair GCP

This HREC is constituted and operates in accordance with the National Statement on Ethical Conduct in Human Research (2007) updated 2018. The Committee's continuing approval is subject to the following conditions being met:

- The Coordinating Principal Investigator will immediately report anything that might warrant review of ethical approval of the project.
- The Coordinating Principal Investigator will notify the RHC QLD HREC of any event that requires a modification to the protocol or other project documents and submit any required amendments in accordance with the instructions provided by the HREC. These instructions can be found at <http://www.ramsayhealth.com.au/Research/Research-Ethics>
- The Coordinating Principal Investigator will submit any necessary reports related to the safety of research participants in accordance with RHC QLD HREC policy and procedures. These instructions can be found at <http://www.ramsayhealth.com.au/Research/Research-Ethics>
- That a report on the progress of the research will be made to the RHC QLD HREC on 26 February 2021 or on completion of the trial (if sooner) and then annually for the duration of the trial. This report is to indicate whether any ethical problems or complications have arisen, particularly side effects of drugs used or any other factor which may result in the investigation not producing any result as distinct from the anticipated result
- The Coordinating Principal Investigator will report to the RHC QLD HREC annually in the specified format and notify the HREC when the project is completed at all sites.
- The Coordinating Principal Investigator will notify the RHC QLD HREC if the project is discontinued at a participating site before the expected completion date, with reasons provided.
- Any extension to the initial approval period is to be requested in a writing to the RHC QLD HREC together with the inclusion of a progress report and any associated required documentation.
- The Coordinating Principal Investigator will notify the RHC QLD HREC of his or her inability to continue as Coordinating Principal Investigator including the name of and contact information for a replacement.
- The Coordinating Principal Investigator will notify the RHC QLD HREC if the project does not commence within six months of approval.

Your approval is initially for four years from date of approval; after this period, you may be asked to apply for an extension or re-apply. You are also required to notify the Committee promptly of any changes in your contact details.

A copy of this ethical approval letter should be presented when required as official confirmation of the approval of the RHC QLD HREC.

This letter constitutes ethical approval only. This project cannot proceed at any Ramsay Health Care Facility until separate research governance authorisation has been obtained from the CEO or Ramsay Health National Research Unit.

Should you have any queries about the RHC QLD HREC's consideration of your project please contact the Ethics Secretariat on 07 3394 7819 or RamsayHREC.QLD@ramsayhealth.com.au. The RHC QLD HREC Terms of Reference, Standard Operating Procedures, membership and

standard forms are available from <http://www.ramsayhealth.com.au/Research/Research-Ethics> or by contacting the Ethics Secretariat.

The RHC QLD HREC wishes you every success in your research.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Richard Lewandowski', written in a cursive style.

Associate Professor Richard Lewandowski
Chairperson
Ramsay Health Care QLD HREC