



## ETHICS COMMITTEE CERTIFICATE OF APPROVAL

*This is to certify that*

**Project Number:** 107983 (Local Reference: Project 259/24)

**Project Title:** Microbial fermentative capacity of individuals with ulcerative colitis with an ileoanal pouch compared to a healthy or UC with intact colons: an in vitro study

**Coordinating Principal Investigator:** Dr Chu Kion Yao

*was considered under the National Mutual Acceptance (NMA) scheme by the Ethics Committee on **30-May-2024**, meets the requirements of the National Statement on Ethical Conduct in Human Research (2007) and was **APPROVED** on **7-Jun-2024**.*

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It is the Coordinating Principal Investigator's responsibility to ensure that all researchers associated with this project are aware of the conditions of approval and which documents have been approved.

***The Coordinating Principal Investigator is required to notify the Secretary of the Ethics Committee, via amendment or progress report, of***

- Any significant change to the project and the reason for that change, including an indication of ethical implications (if any);
- Serious adverse effects on participants and the action taken to address those effects;
- Any other unforeseen events or unexpected developments that merit notification;
- The inability of the Coordinating Principal Investigator to continue in that role, or any other change in research personnel involved in the project;
- Any expiry of the insurance coverage provided with respect to sponsored clinical trials and proof of re-insurance;
- A delay of more than 12 months in the commencement of the project; and,
- Termination or closure of the project.

***Additionally, the Coordinating Principal Investigator is required to submit***

- A Progress Report on the anniversary of approval and on completion of the project.

The Ethics Committee may conduct an audit at any time.

**All research subject to the Alfred Hospital Ethics Committee review must be conducted in accordance with the National Statement on Ethical Conduct in Human Research (2007).**

**The Alfred Hospital Ethics Committee is a properly constituted Human Research Ethics Committee in accordance with the National Statement on Ethical Conduct in Human Research (2007).**

### **SPECIAL CONDITIONS**

None

## APPROVED DOCUMENTS

Documents reviewed and approved at the meeting were:

Document	Version	Date
Protocol	3	20-May-2024
Participant Information Sheet & Consent Form – UC or pouch	3	16-May-2024
Participant Information Sheet & Consent Form – Healthy controls	4	22-May-2024
Social Media Post – UC patients	2	20-May-2024
Social Media Post – Pouch patients	2	20-May-2024
Social Media Post – Healthy controls	2	20-May-2024
Foods to avoid during participation in study	1	1-May-2024
Participant instructions for stool collection	2	16-May-2024
Partial Mayo score	1	1-May-2024
The Pouchitis Disease Activity Index (PDAI)	1	1-May-2024
Patient characteristics	1	8-May-2024
24 hour food diary	2	16-May-2024

Additional documents considered:

Document	Version	Date
Study Budget	2	20-May-2024
Researcher CVs	-	-
Researcher GCPs	-	-
Letters of support x 4	-	-

## APPROVED SITES

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

- Monash University (Coordinating Principal Investigator: Dr Chu Kion Yao)
- Alfred Health (Site Principal Investigator: Dr Chu Kion Yao)

*The Alfred Hospital Ethics Committee has approved the study but does not take responsibility for research governance processes at the participating sites. It is the responsibility of each participating site to create and implement research governance practices to adequately authorise, monitor and oversee the conduct of the study at their site.*

### 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.

The HREC wishes you and your colleagues every success in your research.

**SIGNED:**

**Chair, Ethics Committee (or delegate)**

***Please quote project number and title in all correspondence***