

Human Research Ethics Committee (HREC) Research and Innovation office

NH&MRC Code: EC00237

Notice of Approval

Date: 24 March 2023

26096 Project number:

Safety, tolerability, and impact of BioPB-01 dietary fibre with and Project title:

dietary and lifestyle modifications, on indicators of gut and without

homeostasis in healthy, overweight adults

Risk classification: More than low risk

Prof Harshan Gill Principal investigator:

Approval period: From: 24 March 2023

To: 30 September 2023

The above application has been approved by the RMIT University HREC as it meets the requirements of the National statement on ethical conduct in human research (NH&MRC, 2007).

Terms of approval:

metabolic

1. Responsibilities of principal investigator

It is the responsibility of the above chief investigator to ensure that all other investigators and staff on a project are aware of the terms of approval and to ensure that the project is conducted as approved by HREC. Approval is valid only whilst the chief investigator holds a position at RMIT University.

Approval must be sought from HREC to amend any aspect of a project. To apply for an amendment use the request for amendment form, which is available on the Research Ethics Platform. Amendments must not be implemented without first gaining approval from HREC.

3. Adverse events

You should notify the HREC immediately (within 24 hours) of any serious or unanticipated adverse effects of the research on participants, and unforeseen events that might affect the ethical acceptability of the project.

4. Annual reports

Continued approval of this project is dependent on the submission of an annual report. Annual reports must be submitted by the anniversary of approval (24 March 2023) of the project for each full year of the project.

5. Final report

A final report must be provided within six months of the end of the project. HREC must be notified if the project is discontinued before the expected date of completion.

6. Monitoring

Projects may be subject to an audit or any other form of monitoring by the HREC at any time.

7. Retention and storage of data

The investigator is responsible for the storage and retention of original data according to the requirements of the Australian code for the responsible conduct of research (section 2) and relevant RMIT policies.

8. Special conditions of approval

Nil.

In any future correspondence please quote the project number and project title above.

A/Prof Suzie Attiwill

Chairperson **RMIT HREC**

Ms Chintha Linkatillake, research student cc:



RMIT Classification: Trusted

Human Research Ethics Committee (HREC) Research and Innovation office NH&MRC Code: EC00237 Dr Peter Burke, HREC secretary.