RMIT UNIVERSITY

Human Research Ethics Committee (HREC)
Research and Innovation office
NH&MRC Code: EC00237

Notice of Approval

Date:	**17 December 2018**
Project number:	**21784**
Project title:	***Microbial shift analysis: A new diagnostic tool for reporting changing gut microbial communities***
Risk classification:	**More than low risk**
Chief investigator:	**A/Prof Danilla Grando**
Approval period:	From: **17 December 2018** To: **17 December 2020**

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).

The following documents have been reviewed and approved:

Title	Version	Date
21784 Grando application	V3	17 December 2018
Microbial shift analysis study protocol	V4	17 December 2018
PICF	V3	17 December 2018
Recruitment		17 December 2018

The following documents have been noted:

Title	Date
Cover letter (V4)	17 December 2018

Terms of approval:

1. **Responsibilities of chief investigator/principal investigator**[1]
   It is the responsibility of the above chief investigator to ensure that all other investigators and staff on a project are aware of the clinical protocol and 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.
2. **Amendments**
   Approval must be sought from HREC to amend any aspect of a project. To apply for ethics approval of an amendment use the Request for Amendment Form, available on the RMIT Human Research Ethics website and submitted to the HREC secretary. 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. This notification can be made via email: humanethics@rmit.edu.au Following notification, an Adverse Event Report will need to completed and submitted.
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 (17/12/2018) of the project for each full year of the project. If the project is of less than 12 months duration then a final report only is required.
5. **Final report**

[1] The Chief Investigator, Co-ordinating Principal Investigator or Lead Investigator is the person with overall responsibility for the research project. For projects conducted at multiple sites, the Principal Investigator is the person with responsibility for managing the research project at each site.

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* (2018) and relevant RMIT policies, including those relating to Research Data Management and Information Management.
8. **Special conditions of approval**
   Nil.
9. **Other conditions of approval**
   I. The clinical trial must be conducted in a way that is consistent with National Statement and Good Clinical Practice Guidelines (GCPs). For information on GCPs in an Australian context please refer to *The Australian Clinical Trial Handbook: A simple, practical guide to the conduct of clinical trials to International standards of Good Clinical Practice (GCP) in the Australian context*
   II. The chief investigator is required to register and maintain registration of this clinical trial on the Australian and New Zealand Clinical Trial Registry (ANZCTR): http://www.anzctr.org.au/ Clinical trials must be prospectively registered, that is before the first participant is recruited.
   III. Where clinical trials use an unapproved therapeutic good they must be notified to the Therapeutic Goods Administration (TGA) via the Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) scheme. Such notifications must be made subsequent to HREC approval and prior to the use of the goods, and via the RMIT account administered by Research Governance. Recruitment may not commence until the CTN or CTX has been notified to the TGA.
   IV. A Clinical Trial Research Agreement (CTRA) is required for sponsored collaborative and/or multi-site clinical research. A copy of the final CTRA must be provided to the HREC when it is available.

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

Stephen Bird

Prof Stephen Bird
Chairperson
RMIT HREC

cc: Dr Peter Burke, HREC secretary
Dr Kyle Berean, Co-investigator