

ALFRED HOSPITAL ETHICS COMMITTEE CERTIFICATE OF APPROVAL

This is to certify that

Project Number: 114169 (Local Reference: Project 766/24)

Project Title: Lifelong Exercise training and vAscular function in Females – The LEAF Study

Principal Investigator: Associate Professor Erin Howden

*was considered by the Alfred Hospital Ethics Committee on **18-DECEMBER-2024** meets the requirements of the National Statement on Ethical Conduct in Human Research 2023 and was **APPROVED** on **28-JANUARY-2024**.*

It is the 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 Principal Investigator is required to notify the Alfred Hospital Ethics Committee, via amendment or progress report, of

- Any change to the project and the reason for that change, including an indication of ethical implications (if any);
- Any reportable safety issues according to the NHMRC's Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods (2016) or Alfred HREC requirements;
- Any reportable serious breaches according to the NHMRC's Reporting of serious breaches of Good Clinical Practice (GCP) or the protocol for trials involving therapeutic goods (2018);
- Any other unforeseen events or unexpected developments that merit notification;
- The inability of the Principal Investigator to continue in that role, or any other change in research personnel involved in the project;
- A delay of more than 12 months in the commencement of the project; and
- Termination or closure of the project.

The conditions of Ethics Approval of this project are:

- All research projects approved by the Alfred Hospital Ethics Committee are subject to, and must be carried out in compliance with, the most recent applicable COVID-19 government and relevant institution's restrictions.
- Continuous insurance coverage must be maintained by the Sponsor, irrespective of the Sponsor type, throughout the project until the Final Report has been submitted to the Ethics Committee for acknowledgement and the project is ready to be archived. Therefore, if an insurance policy expires it is expected that it will be renewed under the same terms and submitted to the Ethics Committee.
- Submission each year of a Progress Report on the anniversary of Ethics Approval and on completion of the project.
- The HREC notes that it is the responsibility of the researchers to ensure that they and any other people or entities involved in the conduct of the study comply with all applicable laws regarding the conduct of the study, including
 - privacy legislation, both Commonwealth and state/territory

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 2023.

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 2023.

APPROVED DOCUMENTS

Documents reviewed and approved:

Document	Version	Date
Protocol:	2	27Nov2024
Participant Information Sheet & Consent Form	4	22Dec2024
Data Collection Sheet	1	18Nov2024
Appendix 4 – DASI	2	27Nov2024
Appendix 5 - Menstrual Cycle History Questionnaire	2	27Nov2024
MoCA Cognitive Assessment	8.2	18May2024
MRI Patient Screening Questions	-	Apr2015
Appendix 7 – Physical Activity Diary	1	18Nov2024
Telephone Script	2	27Nov2024
Social Media Advertising	-	-

ACKNOWLEDGED DOCUMENTS

Documents reviewed and acknowledged:

Document	Version	Date
Data & Materials Management Plan	1.0	18Nov2024
User Guide - ActiGraph wGT3X-BT + ActiLife	Revision 5	02/18/2020
Medical Physics Report: Alfred Health	-	06Jan2025

HIGHEST RADIATION RISK CATEGORY

The Medical Physics/RSO Report with the highest radiation risk category reviewed by the Ethics Committee assessed the Risk Category (as defined in the ARPANSA *Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes*, Radiation Protection Series (RPS) 8 (2005)) as:

- **Category I (minimal risk)**

APPROVED SITE

Approval is given for this research project to be conducted at the following site:

- Baker Heart & Diabetes Institute (Site PI: A/Prof Erin Howden)

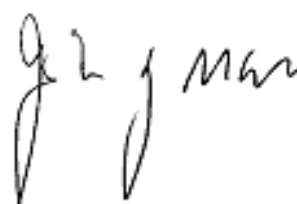
The Alfred Hospital Ethics Committee has approved the study but does not take responsibility for research governance processes at the participating sites. It is the responsibility of each participating site to create and implement research governance practices to adequately authorise, monitor and oversee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

Site-Specific Assessment (SSA) Authorisation

This Ethics Approval Certificate constitutes ethical approval only. This project cannot commence at any site, including Alfred Health, until separate site authorisation (research governance authorisation) has been obtained.

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

SIGNED:



Professor John McNeil
Chair, Ethics Committee

Please quote project number and title in all correspondence.