

## HUMAN RESEARCH ETHICS APPROVAL

The University of Sydney confirms that this project meets the requirements of the National Statement on Ethical Conduct in Human Research.

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<b>Project identifier:</b>	2023/HE000803
<b>Project title:</b>	Active Women over 50: an effectiveness-implementation randomised controlled trial
<b>Version:</b>	1.02
<b>Chief Investigator:</b>	Professor Anne Tiedemann
<b>Authorised project team:</b>	Miss Courtney West Ms Geraldine Wallbank Dr Juliana Souza de Oliveira Mrs Sandra O'Rourke
<b>Date of approval:</b>	Friday, 12 July, 2024
<b>Project end date:</b>	20 Dec 2027

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### Project summary

Despite the clear physical and mental health benefits of physical activity, as few as 13% of Australian women aged 45-64 years meet both the physical activity (150 minutes of moderate to vigorous activity per week) and strength (muscle strength twice per week) guidelines. Middle-aged and older adults are a priority for targeted physical activity programs, since physical capacity starts to decline at around age 50. This project aims to test the effectiveness of the Active Women over 50 program (intervention) on physical activity, over 6 months compared with a no intervention wait-list (control), among women aged 50 years and over.

### Summary of changes

We propose to amend the procedure for recruitment. We propose to include advertising for trial participants through online registries for research volunteers that enable volunteers to register their interest in taking part in ageing related research by a self-registration service. Registries will be provided ethics-approved study documentation such as the ethics approval letter, trial protocol, participant information sheet, advertising flyers that contain the URL and a QR link to the Active Women over 50 study recruitment website. Registries will be requested to advertise the trial according to their privacy policy and will include but are not limited to 'StepUp for Research'.

### Documents approved

Document type	File name	Document version	Application version
Other	Cover letter 9Jul2024.docx	1	1.02
Project description / Protocol	2023_HE000803_v1_01 - AWo50 Protocol_Version 2.1_09.07.24_clean.docx	2	1.02

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### Conditions of Approval

- Research must be conducted according to the approved proposal.



- An annual progress report must be submitted on or before the anniversary of approval and a final report on completion of the project.
- You must report as soon as practicable anything that might warrant review of ethical approval of the project including:
  - Serious or unexpected adverse events (which should be reported within 72 hours).
  - Unforeseen events that might affect continued ethical acceptability of the project.
- Any changes to the proposal must be approved prior to their implementation (except where an amendment is undertaken to eliminate *immediate* risk to participants).
- Researchers working on this project must be sufficiently qualified by education, training, and experience for their role, or adequately supervised. Changes to the project team must be reported and approved.
- Researchers must disclose any actual, potential or perceived conflicts of interest, including any financial or other interest or affiliation, as relevant to this project.
- Research data and primary materials must be retained and stored in accordance with relevant legislation and University guidelines.
- Ethics approval is dependent upon ongoing compliance of the research with the *National Statement on Ethical Conduct in Human Research*, the *Australian Code for the Responsible Conduct of Research*, applicable legal requirements, and with University policies, procedures, and governance requirements.
- If your research project is a clinical trial and is being sponsored by the University or is to be conducted on a University of Sydney site, you must comply with additional University governance requirements prior to commencing your Clinical Trial.
- The University may conduct audits on approved projects.
- The Chief Investigator has ultimate responsibility for the conduct of the research and is responsible for ensuring all others involved will conduct the research in accordance with the above.

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### **Ethics Committee Representative**

Chair

On behalf of the University of Sydney

**The University of Sydney HRECs are constituted and operate in accordance with the National Statement on Ethical Conduct in Human Research and the Australian Code for the Responsible Conduct of Research (NHMRC). All personnel named on the project should be acquainted with these documents.**

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