# THE UNIVERSITY OF SYDNEY

# Research Integrity & Ethics Administration HUMAN RESEARCH ETHICS COMMITTEE

Tuesday, 3 May 2022

Dr Wayne Cotton

School of Education and Social Work Research Operations; Faculty of Arts and Social Sciences Email: wayne.cotton@sydney.edu.au

Dear Wayne,

The University of Sydney Human Research Ethics Committee (HREC) has considered your application.

After consideration of your response to the comments raised your project has been approved.

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.

Protocol Number: 2021/935

A technology-based physical education course to increase university students physical activity levels: A Randomised

controlled trial (RCT)

**Sites Approved:** 

Authorised Persons: Cotton Wayne; Peralta Louisa; Sultoni Kuston;

Approval Period: 03/05/2022 to 03/05/2026

First Annual Report Due: 03/05/2023

### **Documents Approved:**

Date Uploaded	Version Number	Document Name
17/03/2022	Version 3	Final 3. Phase 6 RCT PIS Lecturers V3
17/03/2022	Version 3	Final 6. Phase 6 RCT PIS Students V3
15/02/2022	Version 2	final 9. Phase 6 IPAQ
15/02/2022	Version 2	final 2. Phase 6 RCT PCF Lecturer
15/02/2022	Version 2	Final 7. Phase 6 Instrument Physical Activity Knowledge Qu
15/02/2022	Version 2	final 5. Phase 6 RCT PCF Students
15/02/2022	Version 2	final 4. Phase 6 Email of invitation to students
15/02/2022	Version 2	final 1. Phase 6 Email of invitation to Lecturers
15/02/2022	Version 2	Final 11. Phase 6 Semi-Structured students FGD guideline
15/02/2022	Version 2	Final 8. Phase 6 BREQ-2 (motivation questionare)
15/02/2022	Version 2	final RCT Protocol
15/02/2022	Version 2	final 10. Phase 6 Fidelity Check
25/10/2021	Version 1	Safety Protocol
25/10/2021	Version 1	AC. Re_ Expression of Interest conducting research at UPI
19/11/2021	Version 1	Protocol Signature Page

#### Special Condition/s of Approval

It is a condition of approval to ensure that research data is stored on a University supported platform.

# **Special Conditions of Approval for Clinical Trials**

• This letter constitutes ethical approval only. This project cannot proceed at any site until the necessary research governance authorisation is obtained. If your study is sponsored by the University or is to be conducted on a University of Sydney site you may need to comply with



additional University governance requirements prior to commencing. Please contact the Clinical Trials Governance Office at <a href="mailto:clinical-trials.research@sydney.edu.au">clinical-trials.research@sydney.edu.au</a>

 Clinical Trials must be registered on a clinical trials registry that complies with the International Committee of Medical Journal Editors (ICMJE). For trials conducted in Australia or New Zealand registration should be on the Australian New Zealand Clinical Trial Registry before recruitment of the first subject (<a href="http://www.anzctr.org.au/">http://www.anzctr.org.au/</a>).

## **Condition/s of Approval**

- · Research must be conducted according to the approved proposal.
- An annual progress report must be submitted to the Ethics Office on or before the anniversary of approval and 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).
- Personnel working on this project must be sufficiently qualified by education, training and experience for their role, or adequately supervised. Changes to personnel must be reported and approved.
- Personnel must disclose any actual or potential conflicts of interest, including any financial or other interest or affiliation, as relevant to this project.
- Data and primary materials must be retained and stored in accordance with the 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.
- The Ethics Office 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.

Please contact the Ethics Office should you require further information or clarification.

Sincerely,

Associate Professor Helen Mitchell Chair

**Human Research Ethics Committee (HREC 1)** 

The University of Sydney HRECs are constituted and operate in accordance with the National Health and Medical Research Council's (NHMRC) <u>National Statement on Ethical Conduct in Human Research (2018)</u> and the NHMRC's <u>Australian Code for the Responsible Conduct of Research (2018)</u>.