Research Integrity & Ethics Administration
HUMAN RESEARCH ETHICS COMMITTEE

Monday, 17 December 2018

Mr Paul Newman
DVC Research & Innovation; DVC Research
Email: paul.newman@sydney.edu.au

Dear Paul,

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.

Protocol Number:	**2018/882**
Protocol Title:	**The Health4Life Initiative: Evaluation of an eHealth school-based program targeting multiple chronic disease risk factors among young Australians**
Sites Approved:	80 school sites across 3 Australian States, NSW, (Sydney, Newcastle, regional NSW), QLD (Brisbane and Gold Coast), WA (Perth).
Authorised Persons:	**Newman Paul; Allsop Steve J; Bauer Judy; Champion Katrina E.; Chapman Cath; Gardner Lauren; Hides Leanne; Kay-Lambkin Frances; Lubans David; McBride Nyanda; Mills Katherine; Newton Nicola C.; Parmenter Belinda; Slade Tim; Spring Bonnie; Sunderland Matthew; Teesson Maree; Thornton Louise;**
Approval Period:	**17 December 2018** to **17 December 2022**
First Annual Report Due:	**17 December 2019**

Documents Approved:

Date Uploaded	Version Number	Document Name
23/11/2018	Version 2	Appendix 2 Health4LifeStudent Questionnaire Amended Clean
23/11/2018	Version 2	Appendix 4 Health4Life Student Follow-Up Procedure
22/11/2018	Version 2	Appendix 3 Health4Life Duty of Care Procedure
22/11/2018	Version 1	Appendix 5 Health4Life App Example
22/11/2018	Version 1	Appendix 6 Health4Life Example Activities
22/11/2018	Version 1	Appendix 7 Health4Life Program Key Messages
22/11/2018	Version 2	Appendix 8 Health4Life Summary of scales with rationale
22/11/2018	Version 2	Appendix 11 Health4Life PIS CF_Student (Control Group)_Amend
22/11/2018	Version 2	Appendix 13 Health4Life PIS & CF_Teacher (Intervention Group
22/11/2018	Version 2	Appendix 14 Health4Life PIS & CF_Teacher (Control Group)
22/11/2018	Version 2	Appendix 10 Health4Life PIS CF_Student (Intervention Group)
06/11/2018	Version 1	Researcher qualifications
01/11/2018	Version 1	Clinical Trial Protocol
01/11/2018	Version 1	Risk Management Plan
25/10/2018	Version 1	Appendix A Health4Life Letter for school recruitment
25/10/2018	Version 1	Appendix F Health4Life Control school logbook
25/10/2018	Version 1	Appendix I Health4Life Teacher Evaluation
25/10/2018	Version 1	Appendix J Health4Life Student Evaluation
25/10/2018	Version 1	Appendix K Health4Life References

Special Condition/s of Approval

- 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 (http://www.anzctr.org.au/).
- 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 clinical-trials.research@sydney.edu.au.

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 clinical-trials.research@sydney.edu.au
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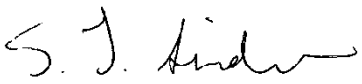
Condition/s of Approval

- 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 Stephen Assinder
Chair
Human Research Ethics Committee (HREC 1)

cc. Clinical Trial Governance (only where relevant)

The University of Sydney HRECs are constituted and operate in accordance with the National Health and Medical Research Council's (NHMRC) National Statement on Ethical Conduct in Human Research (2007) and the NHMRC's Australian Code for the Responsible Conduct of Research (2007).