THE UNIVERSITY OF SYDNEY

Research Integrity & Ethics Administration
HUMAN RESEARCH ETHICS COMMITTEE

Wednesday, 28 June 2023

Dr Lexine Stapinski
Matilda Centre; Faculty of Medicine and Health
Email: lexine.stapinski@sydney.edu.au

Dear Lexine,

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:	**2023/348**
Protocol Title:	**Nipping it in the bud: RCT of the Inroads self-guided early intervention for anxiety and drinking among young adults.**
Sites Approved:	
Authorised Persons:	**Stapinski Lexine; Prior Katrina; Chatterton Mary Lou; Deady Mark; Hudson Jennifer; Kay-Lambkin Frances; Lee Yong Yi; Mihalopoulos Cathrine; Rapee Ronald; Teesson Maree; Guckel Tara; Haber Paul; Newton Nicola; Baillie Andrew; Slade Timothy;**
Approval Period:	**28/06/2023** to **28/06/2027**
First Annual Report Due:	**28/06/2024**

Documents Approved:

Date Uploaded	Version Number	Document Name
19/06/2023	Version 2	2-month follow-up survey_clean
19/06/2023	Version 2	6, 12, 24-month follow-up survey_clean
19/06/2023	Version 2	Advertising materials_posters
19/06/2023	Version 2	Baseline survey_clean
19/06/2023	Version 2	clinical_trial_protocol_clean
19/06/2023	Version 2	Eligibility survey_clean
19/06/2023	Version 2	PIS_clean
19/06/2023	Version 1	Summary of measures
02/05/2023	Version 1	C. PCF_v1
02/05/2023	Version 1	H. Advertising materials_social media_v1
02/05/2023	Version 1	J. CTSO Decision_TGA medical device
03/05/2023	Version 1	CM_declaration
03/05/2023	Version 1	J.Hudson_declaration
03/05/2023	Version 1	M.Deady_declaration
03/05/2023	Version 1	ML.Chatterton_declaration
03/05/2023	Version 1	R.Rapee_declaration
03/05/2023	Version 1	YY.Lee_declaration
03/05/2023	Version 1	FKL_declaration
05/06/2023	Version 1	Declaration - Paul Haber

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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

- 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/).

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,

Helen Mitchell

Associate Professor Helen Mitchell
Chair, Human Research Ethics Committee (HREC 1)

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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 (2018) and the NHMRC's Australian Code for the Responsible Conduct of Research (2018).