Research Integrity & Ethics Administration
Human Research Ethics Committee

Friday, 11 May 2018

Assoc Prof David Hawes
Psychology; Faculty of Science
Email: david.hawes@sydney.edu.au

Dear David

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.

Approval is granted for a period of four years from **11 May 2018** to **11 May 2022**

Project Title: **Does a One Month Brief Behavioural Treatment Improve Sleep for Adolescents in High School (ages 12-17): An Open Label Pilot Study**

Project No.: **2018/091**

First Annual Report Due: **11 May 2019**

Sites Approved: The School of Psychology, University of Sydney, Camperdown NSW 2006

Authorised Personnel: **Hawes David; Quartly-Scott Gregory; Miller Christopher;**

Documents Approved:

Date Uploaded	Version number	Document Name
24/04/2018	Version 2	Participant Information Sheet - Revised (clean copy)
24/04/2018	Version 1	Roles and Experience of Investigators
24/04/2018	Version 1	Clinical Risk and Trial Site Assessment
24/04/2018	Version 2	BBTi Avertisement - Revised
13/04/2018	Version 2	Revised Data Package
21/01/2018	Version 1	Study Protocol
14/01/2018	Version 1	Participant Consent
14/01/2018	Version 1	Parent/Caregiver Consent
14/01/2018	Version 1	Parent/Caregiver Information
14/01/2018	Version 1	Daily Sleep Diary

Special Condition/s of Approval

- It is a condition of approval that verbal consent will be obtained from both parent/carer and adolescent prior to the sleep diary activity. Please ensure that verbal consent is recorded in researchers' notes and written consent is obtained at the first face to face consultation.

THE UNIVERSITY OF SYDNEY

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

Glen Davis

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Professor Glen Davis
Chair
Human Research Ethics Committee (HREC 2)
Chair

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).