

Office of Research and Development

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14-Mar-2018

Name: Sharyn Burns

Department/School: School of Public Health Email: S.Burns@curtin.edu.au

Dear Sharyn Burns

RE: Ethics Office approval

Approval number: HRE2018-0101

Thank you for submitting your application to the Human Research Ethics Office for the project A formative intervention research study to develop and trial a school-based "Whole Person ovulatory-menstrual (OM) health literacy program" for 13-16 year old (Year 9-10) females in Perth WA.

Your application was reviewed through the Curtin University Low risk review process.

The review outcome is: Approved.

Your proposal meets the requirements described in the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research* (2007).

Approval is granted for a period of one year from 14-Mar-2018 to 13-Mar-2019. Continuation of approval will be granted on an annual basis following submission of an annual report.

Personnel authorised to work on this project:

Name	Role
Roux, Felicity	Student
Burns, Sharyn	CI
Hendriks, Jacqui	Supervisor
Chih, Jun	Supervisor

Approved documents:

Document

Standard conditions of approval

- 1. Research must be conducted according to the approved proposal
- 2. Report in a timely manner anything that might warrant review of ethical approval of the project including:
 - proposed changes to the approved proposal or conduct of the study
 - unanticipated problems that might affect continued ethical acceptability of the project
 - major deviations from the approved proposal and/or regulatory guidelines
 - serious adverse events
- 3. Amendments to the proposal must be approved by the Human Research Ethics Office before they are implemented (except where an amendment is undertaken to eliminate an immediate risk to participants)
- 4. An annual progress report must be submitted to the Human Research Ethics Office on or before the anniversary of approval and a completion report submitted on completion of the project
- 5. Personnel working on this project must be adequately qualified by education, training and experience for their role, or supervised
- 6. Personnel must disclose any actual or potential conflicts of interest, including any financial or other interest or affiliation, that bears on this project
- 7. Changes to personnel working on this project must be reported to the Human Research Ethics Office
- 8. Data and primary materials must be retained and stored in accordance with the Western Australian University Sector Disposal Authority (WAUSDA) and the Curtin University Research Data and Primary Materials policy
- 9. Where practicable, results of the research should be made available to the research participants in a timely and clear manner
- 10. Unless prohibited by contractual obligations, results of the research should be disseminated in a manner that will allow public scrutiny; the Human Research Ethics Office must be informed of any constraints on publication
- 11. Approval is dependent upon ongoing compliance of the research with the <u>Australian Code for the Responsible Conduct of Research</u>, the <u>National Statement on Ethical Conduct in Human Research</u>, applicable legal requirements, and with Curtin University policies, procedures and governance requirements
- 12. The Human Research Ethics Office may conduct audits on a portion of approved projects.

Special Conditions of Approval

None.

This letter constitutes low risk/negligible risk approval only. This project may not proceed until you have met all of the Curtin University research governance requirements.

Should you have any queries regarding consideration of your project, please contact the Ethics Support Officer for your faculty or the Ethics Office at hrec@curtin.edu.au or on 9266 2784.

Yours sincerely

Amy Bowater

Acting Manager, Research Integrity