



Southern Cross University
Human Research Ethics Committee (SCU HREC)

Notification
Human Research Ethics Application Approval

To: Lauche Romy; Schloss Janet
From: Professor Colleen Cartwright
Chair, Human Research Ethics Committee (HREC)
Project name: A Phase II Randomised Double-Blind, placebo-controlled clinical trial evaluating the efficacy of Happy Hormones in menopausal women.
Approval Date: 19/04/2021
Approval Number: 2021/036
Expiry Date: 18/04/2024

Dear Investigator/s,

Thank you for the Human Research Ethics Application (HREA). The Application was considered by the SCU HREC and is approved. Please note the ethics approval number above.

The nominated participating site/s in this project is/are: Not applicable (online)

This approval is subject to the following conditions being met:

The Chief Investigator will:

1. immediately report anything that might warrant review of ethical approval of the project on the Adverse Events form;
2. immediately notify the SCU HREC, on the appropriate form, of any change in protocol;
3. report to the SCU HREC annually in the specified format and notify HREC when the project is completed;
4. notify the SCU HREC if the project is discontinued at a participating site before the expected completion date, with reasons provided;
5. notify the SCU HREC of any plan to extend the duration of the project past the approval period listed above and will submit any associated required documentation

A copy of this ethical approval letter must be submitted by all site Principal Investigators to the Research Governance Office or equivalent body or individual at each participating institution in a timely manner to enable the institution to authorise the commencement of the project at its site/s.

This letter constitutes ethical approval only. This project cannot proceed at any site until separate research governance authorisation has been obtained from the CEO or Delegate of the institution under whose auspices the research will be conducted at that site.

Should you have any queries about the SCU HREC's consideration of your project please contact ethics.lismore@scu.edu.au. The SCU HREC Terms of Reference, membership and standard forms are available from <https://www.scu.edu.au/research/forms-and-downloads-document-downloads/>.

SCU HREC wishes you every success in your research.

Kind Regards,



for
Professor Colleen Cartwright
Chair, Human Research Ethics Committee