
2020/ETH03194: Application HREA - Approved

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To: tdevoy12@gmail.com
Cc: rso-ethics@uow.edu.au, kristy.pierce@health.nsw.gov.au

Thu, Jan 21, 2021 at 10:20 AM

Date of Decision Notification: **21 Jan 2021**

Dear Tamblyn Devoy,

Thank you for submitting the following Human Research Ethics Application (HREA) for HREC review;

2020/ETH03194: Effect of sugammadex on the serum plasma levels of circulating oestrogens and progesterones in healthy females who take hormone contraception in the perioperative setting

This Application was reviewed as a **Low risk review pathway** and was initially considered by the **Joint University of Wollongong and Illawarra Shoalhaven Local Health District Health and Medical Human Research Ethics Committee** at its meeting held on 19/01/2021

The project was determined to meet the requirements of the National Statement on Ethical Conduct in Human Research (2007) and was **APPROVED**.

This email constitutes ethical and scientific approval only.

This project cannot proceed at any site until separate research governance authorisation has been obtained from the Institution at which the research will take place.

This project has been Approved to be conducted at the following sites:

- **The Wollongong Hospital - Illawarra Shoalhaven Local Health District**

The following documentation was reviewed and is included in this approval:

- Application, HREA
- Project Registration
- Research Protocol 25112020.docx
- Cover Letter for 12012021 changes-1-12-Jan-2021
- Participant Consent Form-1-25-Nov-2020
- Participant Information Sheet-1-25-Nov-2020
- Participant Questionnaire-1-25-Nov-2020
- Application, Submission_Original

[Application Documents](#) - (link will only be active for 14 days from the decision date. The approved documents are also available to download from forms section of this project in REGIS)

The Human Research Ethics Application reviewed by the HREC was:

Version: 1.02

Date: 12 Jan 2021

The approval is for a period of 1 year from the date of this e-mail (**21 Jan 2021**)

The Coordinating Principal Investigator will:

- provide the HREC with an annual report and the final report when the project is completed at all sites. This will be through the submission of a milestone in REGIS.
- immediately report anything that might warrant review of ethical approval of the project.
- submit proposed amendments to the research protocol, including; the general conduct of the research, changes to CPI or site PI, an extension to HREC approval, or the addition of sites to the HREC before those changes can take effect. This will be through a notification of an amendment in REGIS
- will notify the HREC if the project is discontinued at a participating site before the expected completion date, with reasons provided.

Submission of annual progress/final reports (milestone), amendments and safety reports should be done through the forms provided in REGIS. Guidance on these processes can be found on the [REGIS website](#).

It is noted that the **Joint University of Wollongong and Illawarra Shoalhaven Local Health District Health and Medical Human Research Ethics Committee** is constituted in accordance with the National Statement on Human Conduct in Research, 2007 (NHMRC).

Please contact rso-ethics@uow.edu.au if you would like to discuss any aspects of this process further. We look forward to managing this study with you throughout the project lifecycle.

Yours Sincerely,

Susan Thomas

Dr Susan Thomas,

Chair, UOW & ISLHD Health and Medical Human Research Ethics Committee

The University of Wollongong and Illawarra and Shoalhaven Local Health District Health and Medical HREC is constituted and functions in accordance with the NHMRC National Statement on Ethical Conduct in Human Research. The processes used by this HREC to review multi-centre research proposals have been certified by the National Health and Medical Research Council.