

Sharon Lee (Western Sydney LHD)

From: no_reply@regis.health.nsw.gov.au
Sent: Tuesday, 23 August 2022 11:30 AM
To: Jennifer King
Cc: Sharon Lee (Western Sydney LHD)
Subject: 2022/PID01324 - 2022/ETH01170: Application HREA - Approved

Date of Decision Notification: 23 Aug 2022

Dear Dr J King,

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

[2022/PID01324 - 2022/ETH01170: Efficacy of tadalafil therapy in women with refractory idiopathic detrusor overactivity.](#)

Thank you for your correspondence addressing the matters raised in the HREC's letter following the WSLHD Drug Committee on 4 July 2022, WSLHD Scientific Advisory Committee (SAC) on 4 July 2022, and by the WSLHD Human Research Ethics Committee (HREC) on 5 July 2022. 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:

- Westmead Hospital – Principal investigator Dr Jenny King

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

1. HREA Application
2. Protocol Tadalafil in detrusor overactivity, version 2 dated 14th August 2022
3. Participant Information and Consent Form, version 2 dated 14 August 2022
4. Study bladder diary version 1 dated 6th April 2022
5. Tadalafil product information
6. Screening bladder diary version 1 dated 6th April 2022
7. Tadalafil study I-QOL questionnaire version 1 dated 6th April 2022
8. Tadalafil CT - 10mg capsules Optima Quote JUN 2022
9. TADALAFIL 10mg STUDY HREC Info
10. GMP Licence - Accord Trust Rampart Trust TA Optima Ovest - MI-2012-LI-00060-3 - authorised 22 March 2022
11. Template Engine PIPDF
12. DSMB charter Investigator initiated trials, version 1 dated 6 April 2022
13. Image Tally counter

[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 approval is for a period of 5 years from the date of this e-mail (23 Aug 2022)

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.
- submit any necessary reports related to the safety of research participants in accordance with NHMRC Safety and Reporting Guidance. This will be through the Significant Safety Issue or Third Party Breach form in REGIS.
- Interventional trials must be registered on one of the clinical trial registries e.g. <https://www.anzctr.org.au>.

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 **Western Sydney Local Health District Human Research Ethics Committee** is constituted in accordance with the National Statement on Human Conduct in Human Research, 2007 (NHMRC).

Please contact us if you would like to discuss any aspects of this process further, as per the contact details below. We look forward to managing this study with you throughout the project lifecycle.

Regards,
WSLHD Research Office