

## 2022/ETH00396: Application HREA - Approved

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Fri 3/06/2022 1:40 PM

To: Yasser@carefirstortho.com.au <Yasser@carefirstortho.com.au>

Cc: Femi Ayeni <femi.ayeni@sydney.edu.au>

Date of Decision Notification: 03 Jun 2022

Dear Dr Yasser Khatib,

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

**2022/ETH00396:** Robotic assisted vs instrumented total knee replacement: a single-blind randomized clinical trial

This Application was reviewed as a **Greater than low risk review pathway** and was initially considered by the **Nepean Blue Mountains Local Health District HREC** at its meeting held on 22/3/2022 .

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. Please ensure to comply with any specific Research Governance requirements at Nepean Private Hospital prior to study start.

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

- Nepean Private Hospital - Kingswood NSW
- Dr Yasser Khatib - 2 Hopse Street Penrith NSW
- A/Prof Rami Sorial - 60A Derby Street Penrith NSW
- Dr Eli Oleschewski Suite 7 Level 3/ 84-88 Parker Street Kingswood NSW
- Dr Pav Sunner - Suite 13B Level 3 1A Barber Avenue Penrith NSW

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

- Data collection sheet V2 \_ 3 June 2022 (1)
- Application, HREA
- Investigator GCP certificates - Femi Ayeni, Rami Sorial, Yasser Khatib, Ian Harris and Juntine Naylor
- Investigator GCP certificates-Olschewski
- Master delegation log template V1 dated 10.4.2022
- Master delegation log template\_Signed
- Master Study sheet V1 \_ 2 Feb 2022
- Participant Information Sheet, PISCF\_V5\_ 3.6.2022
- Institutional Radiation Safety Approval, or letter from PI stating that radiation exposure is part of normal clinical management/care, Radiation safety form
- SAE FORM v1 21.4.2020

- Study Participant log\_V1 dated 2.2.2022
- Study Protocol, Study protocol\_ROSA\_V9\_ dated 3.6.2022\_ Clean

### Special Conditions:

- The HREC Only Indemnity is to be fully executed prior to the study commencing at Nepean Private Hospital. HREC Only Indemnity to be submitted for full execution by NBMLHD. Please submit via the HREC Ethics Officer.
- Study Sponsor confirmed as Healthscope.

[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: 1.03

Date: 31 May 2022

The approval is for a period of 5 years from the date of this e-mail (**03 Jun 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 **Nepean Blue Mountains Local Health District HREC** 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,

Penny Mahairas  
Executive Officer | **Research Office (Ethics)**  
Level 5, South Block, Nepean Hospital  
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