

**Subject:** FW: 2023/ETH00929: Application HREA - Approved

**Date:** Thursday, 10 August 2023 at 4:03:57 pm Australian Eastern Standard Time

**From:** Ritesh Chimoriya (Sydney LHD)

**From:** no\_reply@regis.health.nsw.gov.au [mailto:no\_reply@regis.health.nsw.gov.au]

**Sent:** Friday, 28 July 2023 10:55 AM

**To:** Sarah Aitken <sarah.aitken@sydney.edu.au>

**Cc:** Sophie JAMES (Western Sydney LHD) <Sophie.JAMES@health.nsw.gov.au>

**Subject:** 2023/ETH00929: Application HREA - Approved

Date of Decision Notification: **28 Jul 2023**

Dear A/Professor Aitken,

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

**2023/ETH00929:** Multidisciplinary Team-based approach to guide secondary risk prevention for cardiovascular and limb outcomes in patients with Peripheral Artery Disease (TEAM-PAD): A Randomized Controlled Trial

This Application was reviewed as a **Greater than low risk review pathway** and was initially considered by the Scientific Sub-Committee at its meeting of 10 May 2023 and by the **Sydney Local Health District Human Research Ethics Committee - Concord Repatriation General Hospital** at its meeting held on 25 May 2023.

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

**Please find attached ethics approval with conditions for the study. 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:

- **Concord Repatriation General Hospital**

[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: 27 Jul 2023

The approval is for a period of 5 years from the date of this e-mail (**28 Jul 2023**)

The Committee granted a waiver of the usual requirement of consent for the use of re-identifiable information held by NSW agencies, in line with the State Privacy Commissioner's Guidelines for Research and the Health Records and Information Privacy Act 2002 (NSW).

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://secure->

[web.cisco.com/1lWa45\\_wj7VdjkhhlwP7S35XZv0vB0JG\\_RUnGNtFqFsbVKox6MHDnwQoGo6VCQrwa3tpvvtGy9SmMIREyU\\_hSXi2G4fuMVO4sB72wmaoLErOoztHQIPIZriDbUXHkWs5SrcSONaiew7\\_jpdsij5wvM2v2yy3FYvXhgXRv06PIUOykROIL-EY0WO9LbJomBEM8DG2hqD3kjpgc9CWTEWcvRasuu25AorJNZtP94x8\\_UenItXnBn8DwKxclZzyiQ12OiGdSIGObX0lw7wSV3dB4IBZBhFV5-oXUkD6rw0nJ0cgQ5uT-l9l5qdl\\_L2\\_bM8eaC0VF\\_WwTcPCQ41IQgKTlls-5RhTv\\_eOvzaombyi-xh3aSEqHxb3w4Q9S9kJnfAEdvJ7jiXhkdfgL2ao9wG\\_3VOkpGp7aPgXusCU\\_fQFp6mXg\\_FIAvESWMI0I27w0QUqqF4nKKUuaGtfvBnQLckCDd8bSn1ICwxHFo0U\\_II9kuCw/https%3A%2F%2Fwww.anzctr.org.au](https://web.cisco.com/1lWa45_wj7VdjkhhlwP7S35XZv0vB0JG_RUnGNtFqFsbVKox6MHDnwQoGo6VCQrwa3tpvvtGy9SmMIREyU_hSXi2G4fuMVO4sB72wmaoLErOoztHQIPIZriDbUXHkWs5SrcSONaiew7_jpdsij5wvM2v2yy3FYvXhgXRv06PIUOykROIL-EY0WO9LbJomBEM8DG2hqD3kjpgc9CWTEWcvRasuu25AorJNZtP94x8_UenItXnBn8DwKxclZzyiQ12OiGdSIGObX0lw7wSV3dB4IBZBhFV5-oXUkD6rw0nJ0cgQ5uT-l9l5qdl_L2_bM8eaC0VF_WwTcPCQ41IQgKTlls-5RhTv_eOvzaombyi-xh3aSEqHxb3w4Q9S9kJnfAEdvJ7jiXhkdfgL2ao9wG_3VOkpGp7aPgXusCU_fQFp6mXg_FIAvESWMI0I27w0QUqqF4nKKUuaGtfvBnQLckCDd8bSn1ICwxHFo0U_II9kuCw/https%3A%2F%2Fwww.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 **Sydney Local Health District Human Research Ethics Committee - Concord Repatriation General Hospital** is constituted in accordance with the National Statement on Ethical 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,

**Sarah Truong**

**Acting Executive Officer & Research Governance Officer**  
**Research & Ethics Office | Concord Repatriation General Hospital**  
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