Date of Decision Notification: **03 Feb 2023**

Dear Dr Sim

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

2022/ETH02470: Identifying the effect of air purifiers in reducing the incidence of Acute Respiratory Infections (ARIs) among residents in Australian Residential Aged Care Facilities (RACFs): A Randomised Control Trial.

This Application was reviewed as a **Greater than low risk review pathway** and was initially considered by the **Hunter New England Human Research Ethics Committee** at its meeting held on **14 December 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 site/s:

- **Bushland Health Group - PI: Bismi Thottiyil Sultanmuhammed Abdul Khadar**

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

- **HREA** (Version 3 created 16 January 2023)
- **Hunter New England Human Research Ethics (HNEHREC) Response to Committee Form** (undated)
- **Research protocol** (Version 2.0 dated 24 January 2023)
- **Participant Information Sheet** (Version 3 dated 30 January 2023)
- **Participant Consent Form** (Version 1 dated 28 November 2022)
- **Participant Information Statement (Guardian)** (Version 2 dated 30 November 2022)
- **Enduring Guardian Consent Form** (Version 1 dated 28 November 2022)

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 **(03 Feb 2023)**

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 registeries 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 **Hunter New England Human Research Ethics Committee** is constituted in accordance with the National Statement on Ethical Conduct in Human Research, 2007 (NHMRC).

The processes used by the HREC to review multi-centre research proposals have been certified by the National Health and Medical Research Council.

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.

Kind regards

Debbie Madden
Ethics Administration Officer
Research Office
Hunter New England Local Health District
Ph: 02 49855929
Email: Debbie.madden@health.nsw.gov.au