Date of Decision Notification: 18 Apr 2023

Dear Professor Ramon Shaban,

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

2023/ETH00523: Nurse-Led Improvements to the Quality and Safety of Residential Aged Care - HIRAID Aged Care

This Application was reviewed as a Greater than low risk review pathway and was initially considered by the Western Sydney Local Health District Human Research Ethics Committee at its meeting held on 4 April 2023.

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

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

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

- Template P2 Health Variables V1.0 2023 Feb 22
- Template P2 D-Catch Tool V1.0 2023 Feb 22
- Survey P2 ResidentsCarers V1.0 2023 Feb 21
- Survey P2 Nurses V1.0 2023 Feb 21
- Survey P2 Medical Staff V1.0 2023 Feb 21
- Survey P1 Delphi V1.0 2023 Feb 21
- Participant Information Sheet/s, PICF P2 ResidentsCarers V1.0 2023 Feb 22
- Participant Information Sheet/s, PICF P2 Nurses Survey V1.0 2023 Feb 22
- Participant Information Sheet/s, PICF P2 Nurses Interview V1.0 2023 Feb 22
- Participant Information Sheet/s, PICF P2 Medical Staff V1.0 2023 Feb 22
- Participant Information Sheet/s, PICF P2 Facilitators V1.0 2023 Feb 22
- Participant Information Sheet, PICF P2 CarersResponsible V1.0 2023 Feb 22
- Participant Information Sheet, PICF P1 Delphi V1.0 2023 Feb 22
- Letter of Invitation, Invitation P2 Surveys V1.0 2023 Feb 22
- Letter of Invitation, Invitation P2 Interview V1.0 2023 Feb 22
- Letter of Invitation, Invitation P1 Delphi V1.0 2023 Feb 22
- InterviewGuide P2 ResidentsCarers V2.0 2023 Apr 14
- InterviewGuide P2 Nurses V2.0 2023 Apr 14
- HIRAID_Aged_Care_Protocol_2023_03_14

- COVID-19 Safety Plan V1.0 2023 Feb 23
- Agreement PrivacyConfidentiality V1.0 2023 Feb 22
- Template P2 Implementation Fidelity V1.0 2023 Feb 22
- Template P2 Implementation Log V1.0 2023 Feb 22

<u>Application Documents</u> - (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: 1.01 Date: 14 Apr 2023

The approval is for a period of 5 years from the date of this e-mail (18 Apr 2023)

The Committee granted a waiver of the usual requirement of consent for the use of reidentifiable 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) and the Guidelines approved under Section 95/95A of the Privacy Act 1988. If Waiver of Consent

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 <u>REGIS website</u>.

It is noted that the Western Sydney Local Health District Human Research Ethics Committee 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,

Research Office

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