

13 June 2024

Dr Kerry Hancock PO Box 576 Glenelg SA 5045

kerryh194@gmail.com

Dear Dr Hancock,

## **Project Title:**

NREEC 24-202 A Lung Health Calculator in Primary Care: Pilot of "PRECURSOR" HREA Application ID KH02554

Thank you for your amended submission of the above proposal. The NREEC considered it at its 27 May 2024 meeting.

The NREEC reviewed the following:

Document	Date received
24-202_NREEC Response _280424	6 May 2024
24-202_SOP_v5.1_Appendix G_clean_010524	6 May 2024
24-202_SOP_v5.1_AppendixG_tracked_010524	6 May 2024

The NREEC thank you for your satisfactory response to its request for further information.

It has **granted ethical approval** of the revised submission for a 5-year period, from **13 June 2024 until 13 June 2029**, subject to the following before commencement:

• forwarding of your amended documentation to clarify whether data storage is for 5 or 15 years.

The NREEC also advise that, despite it not being mandatory, it is good practice to register your app with the TGA.

## NREEC standard conditions of approval are that:

- The Coordinating Principal Investigator will immediately report anything that might warrant review of ethical approval of the project, including *any* adverse events or proposed changes to the protocol, including data management and/or data custodianship.
- The Coordinating Principal Investigator will notify the NREEC of any event that requires modification to the protocol or other project documents and submit any required amendments in accordance with the instructions provided.



- The Coordinating Principal Investigator will report to the NREEC 12-monthly on 13 June or as requested, by completing the appropriate reporting template and providing any additional information requested. Reporting templates are available on the RACGP ethics webpage at RACGP Ethics.
- The Coordinating Principal Investigator will notify the NREEC via a final report on the appropriate reporting template on completion of the project.
- The Coordinating Principal Investigator will notify the NREEC of discontinuation of the project at a participating site before the expected completion date, with reasons provided.
- The Coordinating Principal Investigator will notify the NREEC of any plan to extend the duration of the project past the approval period listed above and will submit any associated documentation.
- The Coordinating Principal Investigator will notify the NREEC of his or her inability to continue as Coordinating Principal Investigator including the name of and contact information for a replacement.

Please note that further amendments to your application must be in accordance with the National Statement on Ethical Conduct in Human Research 2023. The following is a guide for future correspondence about this project:

- 1) A cover letter should outline any proposed changes to the original application
- Please name files succinctly, commencing with the NREEC the project number e.g., '24-202\_Output form\_ v2\_tracked\_ DDMMYY'
- 3) Please number all pages sequentially
- 4) Each document submitted for review MUST have an updated version number and date
- 5) Please submit a 'tracked' and 'clean' copy of each amended document.
- 6) Please do not resubmit unamended documents.
- 7) To facilitate an efficient review process, please tabulate your responses to NREEC review

The NREEC wish you success with your project.

Should you wish to discuss the Committee's review of your project, please contact Ms Gail Roberts, RACGP Research Ethics Manager on 03 8699 0385 or at ethics@racgp.org.au.

Yours sincerely,

**Emeritus Professor Siaw-Teng Liaw** 

Chair, RACGP National Research & Evaluation Ethics Committee

This HREC is constituted and operates in accordance with the National Statement on Ethical Conduct in Human Research 2023. The processes used by this HREC are certified by the National Health and Medical Research Council.