

27 March 2023

Ms Dhiraj Dwivedi
 Monash Health
 Department of Infectious Diseases/ICU
 246 Clayton Road
 Clayton Vic 3168

Dear Researcher,

Project Title: A study to compare two approaches of remote monitoring used for BALANCE trial

ERM Reference Number: 95676

Monash Health Reference Number: RES-23-0000-173Q

The above proposal has been reviewed by the Chair of the Monash Health HREC, the Director, Research Operations and the HREC Executive Officer, who advised that this is negligible risk research and may be exempted from ethical review. The proposal has therefore been reviewed and approved via an alternate pathway.

The proposal is consistent with the NHMRC Ethical Considerations in Quality Assurance and Evaluation Activities (2014) guideline. The project is authorised to commence on the provision that the Head of Department has provided you with approval to undertake the activity.

Approval Date: 27 March 2023*

****Please note the project is approved up to two years. Progress (or final) reports are not required for negligible risk research, clinical audits or quality activity projects.***

Approved Documents:

The following documents have been reviewed and approved:

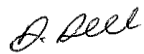
Document	Version	Date
Quality Assurance Application	HREC/95676/MonH-2023-361399(v1)	22/03/2023
V 1 Protocol A study to compare remote monitoring approaches	1	14/02/2023
One page info re Remote monitoring study	1	22/02/2023

Conditions of Approval:

- The project must adhere to the NHMRC Ethical Considerations in Quality Assurance and Evaluation Activities (2014) guideline.
- Notify the reviewing research office of your inability to continue as Coordinating Principal Investigator.

- Notify the reviewing research office of any matters which may impact the conduct of the project.
- The reviewing research office, authorising institution and/or their delegate/s may conduct an audit of the project at any time.
- This study will last no longer than two years past the above approval date; at this time a new application will be required.
- Projects submitted via this pathway cannot be amended once approved; amendments must be submitted as a new application.
- The data must be kept for 7 years following completion of the Negligible Risk/Quality Assurance (QA) Activity.

Yours sincerely,



DEBORAH DELL

Director, Research Operations
Research Support Services

Cc: Ross Major - HIS