

Dr Kiran Gudivada
Intensive Care Unit
Building 5, Level 5
Canberra Hospital
Garran ACT 2605

ACT Reference	2024.LRE.00128
REGIS Reference	2024/ETH00159
Study Title	Assessment of Voice disorder among mechanically ventilated adult ICU survivors – A single-centre observational study (VOICE study)

Dear Dr Gudivada,

The ACT Health Human Research Ethics Committee's Low Risk Sub-Committee considered the above referenced proposal at its meeting of 26 June 2024.

I am pleased to inform you that, following further correspondence, the committee agreed the proposal satisfied the requirements for ethically acceptable research as per the National Statement on Ethical Conduct in Human Research and as such the application has been approved out of session.

Approval includes:

- Human Research Ethics Application, created 25 January 2024
- VOICE Study Protocol, version 2, dated 21 September 2024
- Adverse Event Protocol, version 1, dated 21 September 2024
- Case Record Form (CRF), version 1, dated January 2024
- Voice Handicap Index (VHI-10), dated 2004
- Voice-Related Quality of Life (V-RQOL) Measure, version undated
- Participant Information Sheet, version 1, dated September 2024
- Consent Form, version 1, dated September 2024
- Minor Grant Acceptance Letter, dated 15 April 2024
- CVs and GCP certificates for the following personnel, maintained on file:
 - Professor Imogen Mitchell
 - Dr Sumeet Rai
- Response to request for further information, dated 21 September 2024

The ACT Health Human Research Ethics Committee is constituted according to the National Statement on Ethical Conduct in Human Research 2023 and is certified for single review of multi-centre health and medical research. ACT Health HREC operates in compliance with applicable regulatory requirements and the principles of the International Conference on Harmonization Guidelines on Good Clinical Practice.

Please see attached Conditions of Approval

Approved Sites

Ethical approval is given for this research project to be conducted at the following sites:

- Canberra Health Services – Dr Kiran Gudivada, Principal Investigator

Site-Specific Assessment (SSA)

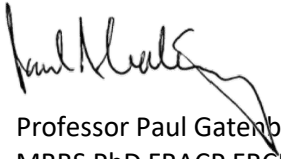
Site specific Approval is given for this research project to be conducted at the following sites:

- Canberra Health Services – Dr Kiran Gudivada, Principal Investigator

SSA authorisation is required at all sites participating in the study. Research activity must not commence at any site until appropriate authorisation is given. Please contact each proposed site directly for guidance on its SSA requirements. Provide a copy of this ethics approval letter with each SSA request.

If this project is being conducted at the Australian National University or the University of Canberra, please include this letter with your application for expedited review.

Yours sincerely,



Professor Paul Gatenby AM
MBBS PhD FRACP FRCPA
Chairman
ACT Health Human Research Ethics Committee

25 September 2024

Conditions of Approval

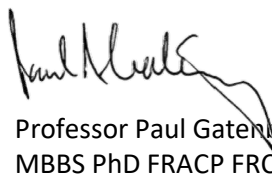
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Principal Investigator	Dr Kiran Gudivada
Date of Approval	25 September 2024

This project was considered by the ACT Health Human Research Ethics Committee's Low Risk Sub-Committee and approved for a period of three years from 25 September 2024 to 25 September 2027.

First Annual Report due: 1 September 2025

Reporting requirements:

- Amendments to the protocol or project plan
- Changes to project personnel
- Breaches of security of records
- Breaches of compliance with approved consent procedures and documentation
- Breaches of compliance with other approved procedures
- Unexpected adverse effects on participants
- Unforeseen events that might affect continued ethical acceptability of the project.
- All published reports are to carry an acknowledgement stating:
 - Approved by ACT Health Human Research Ethics Committee on 25 September 2024



Professor Paul Gatenby AM
MBBS PhD FRACP FRCPA
Chairman
ACT Health Human Research Ethics Committee

25 September 2024