



A/Professor Bernie Bissett
University of Canberra Hospital CERC
Office 8, Level 2, Guraguma Street
Bruce ACT 2617

ACT Reference	2022.LRE.00038
REGIS Reference	2022/ETH00369
Study Title	The feasibility and patient-acceptability of a novel multidisciplinary COVID-19 Recovery Service in the ACT

This submission has been assessed under the usual guidelines for research ethics and site governance. Australian, State and Territory Government and relevant institution COVID-safety guidelines must be followed.

Dear A/Professor Bissett,

The ACT Health Human Research Ethics Committee’s Low Risk Sub-Committee considered the above referenced proposal at its meeting of 3 February 2022.

I am pleased to inform you that, following further information, 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.

Approval includes:

- Human Research Ethics Application, created 2 March 2022
- Protocol, version 1, dated 2 March 2022
- Participant Information Sheet, version 2, dated 3 March 2022
- Consent Form, version 2, dated 3 March 2022
- Acceptability of CR Clinic Questionnaire, version 1, dated 24 February 2022
- Interview Topic Guide, version 1, dated 3 March 2022
- The PICUPS Community, version 7, dated 17 September 2020
- Response to request for further information, dated 25 March 2022

The ACT Health Human Research Ethics Committee is constituted according to the National Statement on Ethical Conduct in Human Research 2007 and is certified for single review of multi-centre clinical trials. 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 Hospital and Health Services – A/Professor Bernie Bissett, Principal Investigator

Site-Specific Assessment (SSA)

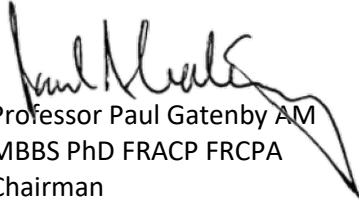
Site specific Approval is given for this research project to be conducted at the following sites:

- Canberra Hospital and Health Services – A/Professor Bernie Bissett, 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 March 2022



Conditions of Approval

ACT Reference	2022.LRE.00038
REGIS Reference	2022/ETH00369
Study Title	The feasibility and patient-acceptability of a novel multidisciplinary COVID-19 Recovery Service in the ACT
Principal Investigator	A/Professor Bernie Bissett
Date of Approval	25 March 2022

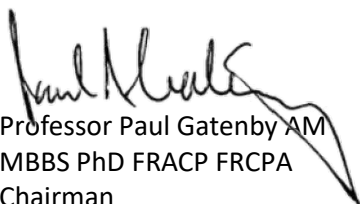
This submission has been assessed under the usual guidelines for research ethics and site governance. Australian, State and Territory Government and relevant institution COVID-safety guidelines must be followed.

This project was considered by the ACT Health Human Research Ethics Committee’s Low Risk Sub-Committee and approved for a period of one year from 25 March 2022 to 25 March 2023.

NOTE: Projects approved for one year will be automatically marked as ‘closed’ by the secretariat office on the anniversary of the approval date. This means ethical approval is no longer current and work must not continue on this project. If additional time is required you will need to submit a request for extension of the ethical approval period prior to the anniversary date.

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 March 2022



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

25 March 2022