

Ms Clare Robertson Research and Data Office Building 2, Level 3, Canberra Hospital. Garran ACT, 2605

ACT	2019/LRE/00015
REGIS	2019ETH00046
Title	Animal-Assisted Therapy in the Intensive Care Unit

## Dear Ms Robertson

Thank you for your submission of the above referenced research proposal. The ACT Health Human Research Ethics Committee's Low Risk Sub-Committee received notification of the proposed study at its meeting of 30 January 2019.

I am pleased to inform you that, following further correspondence, your application has been approved out of session.

The Sub-Committee agreed that the application is for low risk research and determined that the research meets the requirements of the National Statement on Ethical Conduct in Human Research and is ethically acceptable.

I attach for your records an Outcome of Consideration of Protocol form.

I confirm that 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 International Conference on Harmonization Guidelines on Good Clinical Practice.

Yours sincerely

Professor Paul Gatenby

MBBS PhD FRACP FRCPA

Chairman

ACT Health Human Research Ethics Committee

Low Risk Sub-Committee

12 March 2019



## **Outcome of Consideration of Protocol**

ACT	2019/LRE/00015
REGIS	2019ETH00046
Title	Animal-Assisted Therapy in the Intensive Care Unit
Principal Investigator	Ms Clare Robertson
Date of Approval	12 March 2019

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 12 March 2019 to 12 March 2020.

**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 This means ethical approval is no longer current and work must not continue on this project.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.

As the project will close automatically you are not required to submit a final report. For the duration of the approval period you will be required to report any amendments and breaches as per the reporting requirements below.

## **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 to carry an acknowledgement stating:
  - Approved on 12 March 2019 by the ACT Health Human Research Ethics Committee's Low Risk Sub-Committee.

Professor Paul Gatenby

MBBS PhD FRACP FRCPA

Chairman

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