Animal-Assisted Therapy in the Intensive Care Unit

SHORT TITLE: ***AAI ICU***

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Aims/Objectives

To evaluate the effect of an existing standardized Quality Improvement (Q.I.) process of “Delta Therapy Dogs” in the Canberra Hospital Intensive Care Unit (ICU) on patient and family member’s anxiety.

Background

Delta Therapy Society is a national, not for profit organisation devoted to bringing therapy dog teams to hospitals and care facilities. Their core belief is that the human and animal bond remarkably improves quality of life for patients. “Delta Therapy Dogs” were implemented into the Canberra Hospital ICU in June 2018. The aim of this initiative was to improve the overall mental well-being of long-term patients and their families and to help create a humanized environment and decrease patient and family anxiety whilst in ICU.

Anxiety is a common complication of critical illness (Chahraoui, Laurent, Bioy & Quenot, 2015). It has been found that anxiety and depression are more prevalent in ICU patients when compared to the general population (Chahraoui et al., 2015). Anxiety is estimated to occur in 70% to 87% of Intensive Care patients (Gustad, Chaboyer & Wallis, 2005). It has also been suggested the highly stressful ICU environment can have severe impacts on patients’ psychological health. These complications can have a significant negative impact on the patients’ physical rehabilitation, mental and social health, leading to a substantial reduction in quality of life (Chahraoui et al., 2015) and contribute to an increase in mortality and morbidity (Wake & Kitchiner, 2013).

When patients are admitted to the ICU with critical, life threatening illnesses, clinicians often direct full medical attention to the physical ailments of patients and may neglect patients’ mental health status or overall mental well-being (Chivukula, Hariharan, Rana, Thomas & Andrew, 2017). ICU patients often encounter stressors which can be exacerbated by the feeling of loneliness and separation from family and loved ones and may potentially impact their experience and recovery (Chivukula et al., 2017). Sedatives frequently administered to assist patients with symptoms associated with their illness can significantly increase rates of delirium, resulting in an increased

anxiety level and diminished health outcomes (Reade & Finfer, 2014). Given this evidence, it is important to identify and evaluate non-pharmacological interventions that can help to create a therapeutic and healing environment, decrease stress and improve patients' experience (Reade & Finfer, 2014).

Published literature also suggests that a high proportion of family members of Intensive Care patients present with varying psychological symptoms of anxiety. Possible precipitating factors include concern for the illness necessitating admission to the ICU; the prospect of the death of a loved one, discussion and decisions regarding end-of-life and the prospect of providing continuing care to survivors.

Therapy dogs have significantly benefited patients in health care settings such as geriatrics, pediatrics, mental health and palliative care environments (Hosey, Jaskulski, Wegener, Chlan & Needham, 2018). Literature suggests that integrating pet therapy into the health care setting reduces symptoms of anxiety, depression and feelings of loneliness and isolation (Hosey et al., 2018). Research also demonstrates the extensive benefits of Animal Assisted Therapy in providing comfort, confidence and companionship to patients (Cherniack & Cherniack, 2014). Hoffmann et al (2009) suggest that a dog sitting in a patient's lap significantly eases suffering and builds motivation in ways that medical interventions may not achieve. A literature review from 2001-2010 completed by Munoz Lasa, Ferriero, Brigatti, Valero & Franchignoni (2011) found that therapeutic outcomes associated with Animal Assisted therapy included enhancement of socialisation, reduction of stress and anxiety, improvement in mood and general well-being, further supporting the significant benefit of therapy dogs.

Summary

Data regarding Animal Assisted Therapy in the ICU are scant, with narratives suggesting that animal presence is beneficial to patients. To date, there are no Australian studies that have examined the use of therapy dogs in an ICU. Further research is required to adequately assess the potential benefits of dog therapy in this specialised environment. Given the absence of research to support therapy dogs in the ICU setting, this study will provide evidence that could demonstrate the effects of

dog therapy on anxiety in ICU patients and their family members. The data collected could assist with scientific evidence to support this as a non-pharmacological intervention to reduce anxiety in the ICU environment.

Hypothesis

Delta Therapy dogs in the ICU setting will assist in reducing anxiety for the patient and family members who meet the inclusion criteria for this study.

Outcome

Primary Outcome:

- To compare anxiety levels in ICU patients and their families prior to and after the therapy dog visit.

Secondary Outcomes:

- To assess whether the change in level of anxiety experienced is sustained in long term patients and their relatives/immediate families who have received multiple therapy dog visits throughout their ICU stay.
- To assess physiological change in patients before and after therapy dog visit (e.g. pain levels, vital signs, minute ventilation, etc.)

Study Design/ Procedure

Assessment tools:

- Anxiety: Visual Analogue Scale for Anxiety; pre and post therapy dog visit (See Appendix 1).
- Pain: Numerical Pain Rating Scale (0-10 pain score); pre and post therapy dog visit (See Appendix 2).
- Physiological assessment: change in heart rate, blood pressure, respiratory rate and minute ventilation; change in sedation and analgesia requirements.

This study utilises a prospective, single center, observational cohort survey design.

Potential participants will be screened using ‘Metavision’ (the ICU online patient portal system) to determine patient eligibility. Eligible patients are those who have been admitted longer than 72 hours and likely to stay within the ICU for a further 24 hours. Screening will occur prior to the therapy dog visit, with researchers assessing patient eligibility. Visitation of the therapy dogs is scheduled to occur weekly, with the specific day depending on the availability of the Delta volunteer.

Eligible patients and family members (as determined by the inclusion/exclusion criteria) will be invited to participate in the research. Participant involvement will be voluntary, and completion of the assessment tools will be taken as consent. The participant will be given an explanation of the study by the researcher, provided with the Participant Information Sheet (See Appendix 5) and asked if they wish to be involved. Participants agreeing to be involved in the study will be asked to complete the Visual Analogue Scale for Anxiety (VAS-A) prior to the therapy dog visit, and immediately after the therapy dog visit occurs. Researchers, or the bedside nurse, will assist participants in completing the scale where required. Participants will continue to have weekly therapy dog visits and will be required to complete the VAS-A each week, prior to and after the therapy dog visit until discharge from ICU or up to 90 days. Patient care will not be affected and all procedures and care will be able to continue as normal.

In addition to the VAS-A, the patients will be asked to complete the Numerical Pain Rating Scale. A CRF has been created to collect a de-identified data set of patients, which consists of questions regarding to age, sex, length of ICU stay, ventilation status (ventilated/not ventilated), heart rate, blood pressure, respiratory rate and minute ventilation; sedation and analgesia requirements and pain score. The physiological assessment will be recorded on the CRF pre and post the therapy dog visit (See Appendix 3). It is important to note that this physiological data is routinely and continuously monitored for all ICU patients. A CRF has been created for family members to identify their age, sex and length of stay for their family member (See Appendix 4).

Assessment Tools

The Visual Analogue Scale for Anxiety

This study will be using the VAS-A to assess anxiety before and after the therapy dog visits for patients and family members. The VAS-A is a valid and free, single-item, self-report measure of anxiety in hospitalised patients (Hornblow, 1976; Williams, Morlock & Feltner, 2010). It is easy to complete and imposes minimal burden to participants. It has shown to be a useful tool for assessing anxiety by clinicians and for research into the reduction of anxiety in this vulnerable population (Hernandez-Palazon et al, 2015). The VAS-A consists of a scale from 0, where no anxiety is present to 10, representing extreme anxiety. The patient is asked how much anxiety is felt at the moment of the assessment and the answer may be by a verbal or non-verbal response. For example, they can point to the relevant number. Given this, the patient requires minimal effort to complete the survey.

The Numerical Pain Rating Scale

The Numerical Pain Rating Scale is a validated and free tool used to measure the intensity of pain in adults in the ICU (Hjermstad et al., 2011). In the ICU, best practice for pain assessment is direct reporting from the patient, as pain is a subjective experience. Therefore, it is currently already regularly used to measure pain in the Canberra Hospital ICU. The patients will self-report their level of pain with a score of 0 representing no pain and 10 representing the worst pain imaginable.

Study Population

The setting for the trial will be in the Canberra Hospital ICU. The Delta Therapy dog visitations will take place at the patient bedside or the ICU balcony. The ICU balcony is an external, covered space that is fully equipped for ventilated patients and is accessible from the ICU. We aim to recruit 80-100 patients and 80-100 family members within a six-month timeframe. This number is realistic for this study as the therapy dog's visit on average 5-10 patients per week. This number takes into consideration the Delta Therapy Dog visitation guidelines that the dog must not exceed a 1.5-hour visit. Canberra Hospital ICU currently has funding (independent of this research) for 1 visit from a therapy dog per week.

Patient Participant Inclusion Criteria

- Happy for a therapy dog visit
- 18 years and over
- Admission over 72 hours ago
- Conscious and co-operative with a RASS score of 0-1
- Able to communicate verbally or non-verbally
- Understand English

Patient Participant Exclusion Criteria

- Allergies to dogs
- Phobias / fear of dogs
- Patients with burns
- Open wounds
- Recent splenectomy
- Immunosuppressed patients
- Neutropenic patients
- Delirious or aggressive patients
- Patients with planned procedures during the therapy dog visit

Family Member Participant Inclusion Criteria

- Happy for a therapy dog visit
- 18 years and over
- Has a family member admitted into the ICU over 72 hours ago
- Family member interested in a dog visit
- Able to communicate verbally or non-verbally
- Understand English

Family Member Participant Exclusion Criteria

- Allergies to dogs
- Phobias / fear of dogs

Participant information and consent:

Participant involvement in this study is voluntary and completion of the survey will be taken as consent for participation. An information sheet about the study will be given to each participant involved and explained by the researcher. This information sheet will provide sufficient information for participants to adequately understand both the proposed research and the implications of their participation. Patient care will not be affected if they decline to participate in the research project and the patient will still be able to access dog visitation as normal.

Withdrawal from the study

Patients and family members will be able to withdraw from the study at any stage and will have no obligation to complete the survey if they change their mind. However, if participants agree, the surveys already collected will be retained to ensure that the result of the research project can be measured properly. Participant data will be disposed of appropriately if the participant is opting to completely withdraw from the study, where they do not wish any previously collected information to be used. Withdrawal from the study will be explained in the participant information sheet.

Escalation plan

If a patient is identified to be at a moderate to high risk of anxiety or displaying behavior that would indicate concern for their mental well-being, the researchers will notify the ICU treating team immediately to ensure regular processes are followed.

If a family member is identified to be at moderate to high risk of anxiety or displaying behavior that would indicate concern for their mental well-being, the researchers will notify the ICU treating team, Clinical Nurse Consultant, and Social Worker to provide increased support, to ensure regular processes are followed.

Ethical Issues

The study will not commence until relevant Human Research Ethics Committee approval is gained. This study is a no / negligible risk research study.

Data Analysis

Key categorical and ordinal variables will be reported using frequencies and proportions. Continuous variable will be reported using means or medians and standard deviations (SD). Categorical variables will be compared using the chi-square or exact Fisher test. Continuous variables will be compared using t-tests or Mann-Whitney U tests. Univariate logistic regression will be used to determine predictors (age, sex, length of ventilation) of decrease in anxiety and pain scores. Statistical analysis will be performed using SPSS version 25.

Data Management

Paper copies of completed surveys and CRF's will be kept in the Critical Care Research and Service Development (RSDU) office at the Canberra Hospital. This office is locked and secured at all times with access limited to Research staff.

Participant confidentiality and privacy will be maintained. An enrolment log including the patient's name, date of birth, hospital identification number, date of enrolment and unique study number will be compiled. Subsequent data will be identified by the unique study number only. The enrolment and study log and study data will be kept separately. The enrolment log will be kept on a secure, password protected computer at the Canberra Hospital.

Funding

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Acknowledgements

Two ICU patients and their families, Mr. and Mrs. Taylor and Mr. and Mrs. Mielke, were consulted regarding this study and we would like to acknowledge this. Both families have provided consent for their acknowledgement in this study.

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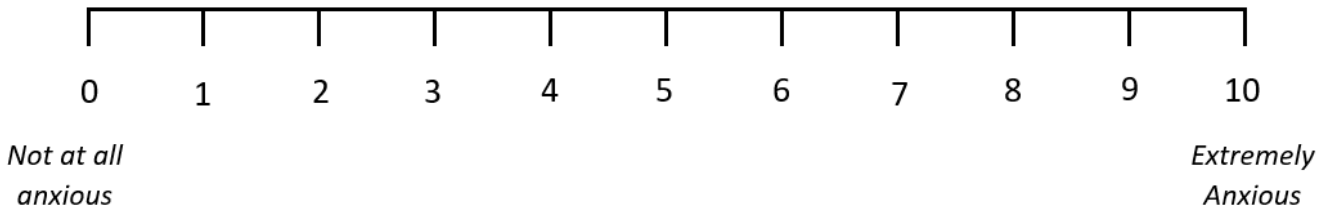
APPENDIX 1:

Visual Analogue Scale for Anxiety

Figure 1: The VAS-A

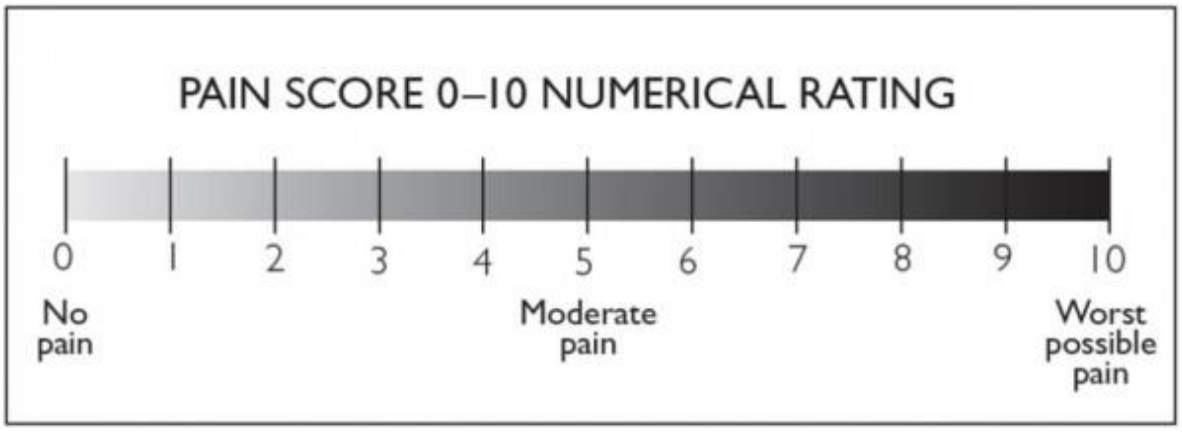
Note how anxious (on average) you feel with a mark on the line below at this current moment.



(Williams, Morlock & Feltner, 2010)

APPENDIX 2:

Numerical Pain Rating Scale



(Hjermstad et al., 2011)

APPENDIX 3:

Animal-Assisted Therapy in the Intensive Care Unit

1. Patient Demographics

1.1 Age _____

1.2 Sex _____

2. Patient Length of ICU Stay

2.1 Length of ICU Stay _____

3. Patient Inclusion Criteria *(Must answer YES to each question for patient to be eligible)*

3.1	Happy for a therapy dog visit	☐ Yes	☐ No
3.2	18 years and over	☐ Yes	☐ No
3.3	Admission over 72 hours ago	☐ Yes	☐ No
3.4	Conscious and co-operative with a RASS score of 0-1	☐ Yes	☐ No
3.5	Able to communicate verbally or non-verbally	☐ Yes	☐ No
3.6	Understand English	☐ Yes	☐ No

4. Patient Exclusion Criteria *(Must answer NO to each question for patient to be eligible)*

4.1	Allergies to dogs	☐ Yes	☐ No
4.2	Phobias / fear of dogs	☐ Yes	☐ No
4.3	Patients with burns	☐ Yes	☐ No
4.4	Open wounds	☐ Yes	☐ No
4.5	Recent splenectomy	☐ Yes	☐ No

4.6	Immunosuppressed patients	☐ Yes	☐ No
4.7	Neutropenic patients	☐ Yes	☐ No
4.8	Delirious or aggressive patients	☐ Yes	☐ No
4.9	Patients with planned procedures during the therapy dog visit	☐ Yes	☐ No

5. VAS-A Score

5.1 Pre-Therapy Dog Visit _____

5.2 Post-Therapy Dog Visit_____

6. Ventilation Status

6.1 Ventilated/ Not Ventilated *(Please Circle)*

7. Physiological Status Pre-Therapy Dog Visit

7.1 Pain Score (0-10) _____

7.2 Blood pressure_____

7.3 Heart Rate _____

7.4 Respiratory Rate _____

7.5 Minute Ventilation _____

7.6 Sedation/ Analgesia Currently Running

- Fentanyl (mcg/hour)_____
- Propofol (mg/hour)_____

- Midazolam (mg/hour) _____
- Morphine (mg/hour)_____

Other_____

8. Physiological Status Post-Therapy Dog Visit

8.1 Pain Score (0-10) _____

8.2 Blood pressure_____

8.3 Heart Rate _____

8.4 Respiratory Rate _____

8.5 Minute Ventilation _____

8.6 Sedation/ Analgesia Currently Running

- Fentanyl (mcg/hour)_____
- Propofol (mg/hour)_____
- Midazolam (mg/hour) _____
- Morphine (mg/hour)_____

Other_____

Appendix 4

Animal-Assisted Therapy in the Intensive Care Unit

1. Family Members Demographics

1.1 Age _____

1.2 Sex _____

2. Length of ICU Stay *(For your Family Member in ICU)*

2.1 Length of ICU Stay _____

3. Family Member Inclusion Criteria *(Must answer YES to each question for patient to be eligible)*

3.1	Happy for a therapy dog visit	☐ Yes ☐ No
3.2	18 years and over	☐ Yes ☐ No
3.3	Family member admitted into ICU over 72 hours ago	☐ Yes ☐ No
3.4	Able to communicate verbally or non-verbally	☐ Yes ☐ No
3.5	Understand English	☐ Yes ☐ No

4. Patient Exclusion Criteria *(Must answer NO to each question for patient to be eligible)*

4.1	Allergies to dogs	☐ Yes ☐ No
4.2	Phobias / fear of dogs	☐ Yes ☐ No

5. VAS-A Score

5.1 Pre-Therapy Dog Visit _____

5.2 Post-Therapy Dog Visit_____

Appendix 5

Animal Assisted Therapy in the Intensive Care Unit Participant Information Sheet

The Canberra Hospital

Title	Animal Assisted Therapy in the Intensive Care Unit
Protocol Number	
Coordinating Principal Investigator/ Principal Investigator	Clare Robertson
Associate Investigator(s)	Kathleen Cook Sumeet Rai Shakira Spiller
Location	The Canberra Hospital Intensive Care Unit

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project. This is because you have been admitted longer than 72 hours to the Intensive Care Unit (ICU) or are a relative/immediate family member of a patient within the ICU. The project team is investigating if “Delta Therapy Dog” visits within the ICU assist with reducing anxiety in ICU patients and their families.

“Delta Therapy Dogs” were implemented into the Canberra Hospital ICU in June 2018 and is now a standardised process within this unit. Delta Therapy Society is a national, not for profit organisation devoted to bringing therapy dog teams to hospitals and care facilities. Their one core belief is that the human animal bond remarkably improves quality of life. The aim of the introduction of therapy dogs for ICU patients was to improve the overall mental well-being of long-term patients and their families. Additionally, the therapeutic intervention of therapy dogs aimed to create a humanized environment, positive patient experience and reduction in the patients and family’s feelings of fear and anxiety during their ICU stay.

To date, there are no Australian studies that have examined the use of dog therapy in an ICU and further research is needed to assess the potential benefits of dog therapy in this specialised environment. Given the absence of research to support therapy dogs in the ICU setting, this study aims to evaluate if a therapy dog visit reduces anxiety in the ICU patients and relatives/immediate family members.

This Participant Information Sheet tells you about the research project. Your participation in this study is entirely voluntary. By completing the survey you are voluntarily agreeing to participate. You are free to decline to answer any particular question you do not wish to answer for any reason. You can also choose to withdraw from the study at any time without any consequences. You will receive the best possible care whether or not you take part. You can still receive a Delta Therapy dog visit if you do not wish to participate in this survey.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

If you decide you want to take part in the research project, you will be provided with the survey to complete and assisted where required.

2 What is the purpose of this research?

The purpose of this study is to:

- To evaluate the standardised process "Delta Therapy Dogs" in the Canberra Hospital ICU in reducing patient and relative/immediate family member's anxiety.
- To measure the level of anxiety in ICU Patients before and after a Delta Therapy Dog visit.
- To measure the level of anxiety in ICU Patient relatives/immediate family members before and after a Delta Therapy Dog visit.

3 What does participation in this research involve?

To participate in this study, you need to be 18 years of age and over, and you or your family members length of admission to the ICU is 72 hours or greater.

You will be given an explanation of the study by the researcher, provided with this Participant Information Sheet and asked if you wish to be involved. If you agree to be involved in the research study, you will be asked to complete the Visual Analogue Scale for Anxiety (VAS-A) prior to the therapy dog visit and immediately after the therapy dog visit occurs. The VAS-A consists of a scale from 0, where no anxiety is present to 10, representing extreme anxiety. You asked how much anxiety is felt at the moment of the assessment and the answer may be by a verbal or non-verbal response. You will continue to have weekly therapy dog visits and will be required to

complete the VAS-A each week, prior to and after the therapy dog visit until discharge from ICU or up to 90 days. Patient care will not be affected, and all procedures and care will be able to continue as normal.

In conjunction with the VAS-A, we will be collecting some information regarding your vital signs, pain score, length of ICU stay, ventilation status, age and sex. Paper copies of completed surveys and all information collected will be kept in the Critical Care Research and Service Development office at the Canberra Hospital. This office is locked and secured at all times with access limited to Research staff.

Participant confidentiality and privacy will be maintained. Your name, date of birth, hospital identification number, date of enrolment will be collected and entered onto an enrollment log, however confidentiality processes will be strictly followed. The enrolment log will be kept on a secure password protected computer at the Canberra Hospital with access limited to Research staff. Your survey responses will be stored for the purposes of analysis and combined with those from other participants and analyzed as a group.

There are no additional costs associated with participating in this research project, nor will you be paid.

4 Other relevant information about the research project

This study is being conducted at the Canberra Hospital ICU which provides both Intensive Care and High Dependency Care for patients accessing the ACT Health service. A total of 80-100 patients will be participating in this study.

5 Do I have to take part in this research project?

You do not have to take part in this research if you do not wish to. Involvement is entirely voluntary. Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with Canberra Hospital.

6 What are the possible benefits of taking part?

There may be no immediate benefit to you from participating in this study. You will still receive a therapy dog visit if you do not wish to participate in the study.

7 What will happen to my test samples?

The data collected on the surveys will be reviewed by the lead investigator and compared to the results of other participants. This information will be kept secure on a password protected computer on a hard drive that has restricted access. Your

personal information will not be recorded on this data. All data collected in the course of this study will be kept for a period of 15 years and securely stored within the Synergy Research Centre and destroyed thereafter.

8 Can I have other treatments during this research project?

Your participation in this research project will not impact on your ability to receive treatments or medications**.**

9 What if I withdraw from this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any time.

110 What will happen to information about me?

The findings of this study may provide the foundation for future research aimed at improving the quality and delivery of clinical care. The summary of the research findings will be presented to clinicians in the ICU via seminars and forums to aid in enhancing clinical care.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified.

11 Who is organising and funding the research?

This research project is being conducted Clare Robertson and Kathleen Cook, Registered Nurses in the Canberra Hospital ICU. Intensive Care Staff Specialist Sumeet Rai and Research and Data Manager Shakira Spiller are research team members assisting with the project. The Academic Mentor for this project is Senior Lecturer and Academic Representative on University of Canberra Council, Holly Northam. This project is funded by the SYNERGY Nursing and Midwifery Centre.

12 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of ACT Health.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

If you would like any further information concerning this project please contact the principal investigator (see below).

Clinical contact person

Name	*Clare Robertson*
Position	*Intensive Care Registered Nurse*
Email	*Clare.robertson@act.gov.au*

Complaints

If you had any complaints about any aspect of the study or the way in which it is being conducted you could contact the Patient Liaison Officer at Canberra Hospital on Telephone: (02) 6244 2222. You will need to tell the Patient Liaison Officer the name of the Principle Investigator: Clare Robertson

Concerns about the conduct of this study

This study has been reviewed and approved by the ACT Health Directorate Human Research Ethics Committee. Should you wish to discuss the study in relation to the rights of a participant, or should you wish to make an independent complaint, you may contact the ACT Health Directorate Human Research Ethics Committee, which is authorised to deal with concerns regarding the protection of participants. You may reach the Committee office, Monday through Friday, by phone, 02 61747968 or email; acthealthhrec@act.gov.au or in writing: PO Box 11,Woden, ACT 2606.