UNIVERSITY OF CANBERRA

Human Research Ethics Committee

Application for Approval

1. ABOUT THE PROJECT

Project Title:	Fatigue resistance index of inspiratory muscles – what is normal in a healthy population?					
Type of Project:	○ Teaching	◉ Research	○ Clinical Trial	**Is your Project:**	◉ New	○ Continuing
Proposed Start Date:	1/12/2015			**Anticipated Completion Date:**	31/7/16	

Please note: The Committee cannot grant retrospective approval!

Is this project related to a previous application?	○ Yes	◉ No	**If yes, original project number:**	
Does this project repeat a previous study?	○ Yes	◉ No		
If yes, please explain why repetiton is necessary:				

1.1. ABOUT THE CHIEF INVESTIGATOR

Family Name:	Bissett	**Given Name:**	Bernie	**Title:**	Asst/Prof
Email - *Please provide a staff or student email address only:*	Bernie.Bissett@canberra.edu.au				
Faculty / University Research Centre:	Faculty of Health				
Staff ID:	s425818	and/or	**Student ID:**		
Course of study (if a student):					

1.2. UNIVERSITY OF CANBERRA SUPERVISOR (if Chief Investigator is a student)

Family Name:		**Given Name:**		**Title:**	
Faculty / University Research Centre:					
Phone:		and	**Email:**		

1.3. QUALIFICATIONS AND EXPERIENCE OF CHIEF INVESTIGATOR

Qualifications:	Bachelor of Applied Science (Physiotherapy) (Hons1)
Relevant Research Experience:	Completing PhD through University of Queensland Published 8 papers Grant Acquisition: > $79 000 since 2006 Currently conducting 2 randomised trials of inspiratory muscle training in intensive care at Canberra Hospital. Winner of People's Choice Award 'Pitch for Funds' competition, UC 2015

1.3.1. FOR STUDENTS ONLY

Degree and Training in Research:	

1.4. CO-INVESTIGATOR 1

Family Name:	Freene	**Given Name:**	Nicole	**Title:**	Dr
Faculty / University Research Centre:	Faculty of Health				
Name of external organisation:					
Phone:		and		**Email:**	Nicole.Freene@canberra.edu.au
Qualifications:	BSc (Hons), BAppSc(Physiotherapy), PhD				
Relevant Experience:	Completed PhD 2014, published 5 papers 2011 - 2015, awarded $22400 grant funding 2014-2015, presented at 3 international conferences 2012 - 2015				

1.4. CO-INVESTIGATOR 2

Family Name:		**Given Name:**		**Title:**	Asst/Prof
Faculty / University Research Centre:	Faculty of Health				
Name of external organisation:					
Phone:		and		**Email:**	
Qualifications:					
Relevant Experience:					

1.4.1. CO-INVESTIGATOR 3

Family Name:		**Given Name:**		**Title:**	Dr
Faculty / University Research Centre:	Faculty of Health				
Name of external organisation:					
Phone:		and		**Email:**	
Qualifications:					
Relevant Experience:					

1.4.2. CO-INVESTIGATOR 4

Family Name:		**Given Name:**		**Title:**	Dr
Faculty / University Research Centre:	UC Health Research Institute				
Name of external organisation:					
Phone:		and		**Email:**	
Qualifications:					
Relevant Experience:					

1.5. DETAILS OF ANY OTHERS INVOLVED IN THE RESEARCH (IF KNOWN)

Name(s):	Elizabeth Kilpatrick
Role(s):	Physiotherapy Honours Student
Qualifications:	Nil
Relevant Experience:	Involvement in data collection as part of Honours project

1.6. SITE(S) WHERE THE RESEARCH WILL BE CONDUCTED

Address 1:	Faculty of Health Clinical Research Laboratories
Address 2:	University of Canberra
Address 3:	Bruce, ACT, 2617
Address 4:	

1.7. FUNDING AND REVIEW

Source of funds and amount:	$925 - Faculty of Health Research Support Grant
RM Number (if applicable):	Nil

Do the funding and/or commercial and intellectual property arrangements place you in a conflict of interest as a researcher? If so, please provide details below.

Details:	Nil
Constraints on publication if any:	Nil
Describe any peer review of the proposed research:	Nil

2. RESEARCH DESIGN AND METHODOLOGY

This section is to provide members of the HREC with clear understanding about the need for the research and the approach adopted. Please use language that can be understood by those outside of the discipline or profession.

2.1. RATIONALE AND LITERATURE REVIEW

The purpose here is to understand how the problem being investigated fits with other research in the area (see NS 1.1(c)).

Background:

Poor respiratory muscle endurance is a consequence of invasive mechanical ventilation for patients in intensive care (1,2). Over the past 10 years, researchers including ourselves (2,3) have used the 'Fatigue Resistance Index' (FRI) method to quantify the endurance of the respiratory muscles of intensive care patients. This involves inhaling through a hand-held device for 2 seconds, then breathing against resistance for 2 minutes, and then inhaling maximally through the hand-held device again. The FRI is a feasible alternative to more complex invasive methods of analysing diaphragmatic endurance.
However, to our knowledge, this method of quantifying endurance has not been tested in a normal population. Following our publication in 2015 (1), we wish to measure FRI in normal healthy subjects to allow us to compare our data from intensive care patients with age and gender matched healthy participants.

REFERENCES:
1. Bissett B, Ledtischke IA, Boots R & Paratz J. Weaned but weary: one third of adult intensive care patients mechanically ventilated for 7 days or more have impaired inspiratory muscle endurance after successful weaning. Heart and Lung. 2015; 44: 15 – 20.
2. Chang AT, Boots RJ, Brown MG, Paratz J, Hodges PW. Reduced inspiratory muscle endurance following successful weaning from prolonged mechanical ventilation. Chest. 2005; 128: 553 – 559.
3. Bissett BM, Leditschke IA, Paratz JD, Boots RJ. Protocol: inspiratory muscle training for promoting recovery and outcomes in ventilated patients (IMPROVe): a randomised controlled trial. BMJ Open. 2012:2e000813.

2.2. AIMS OF THE RESEARCH

Aim:
To quantify inspiratory muscle endurance, through the Fatigue Resistance Index method, in healthy people.

2.3. RESEARCH APPROACH, METHODS AND INSTRUMENTS

Please note that the National Statement requires additional ethical matters to be considered in particular types of research such as clinical trials, the collection of human samples, genetic testing, cellular therapy, ionising radiation, research on gametes or the creation of embryos (see NS 3.3-3.6).

Methods

Participants
Participants will be healthy volunteers from the Canberra community. Flyers advertising the project will be distributed through the UC campus and electronically through existing professional networks. Participants will be included if they are adults free from existing lung disease, who are able to provide consent and are able to follow instructions to complete the testing. Participants will be excluded it they cannot provide consent, already suffer from lung disease (eg Chronic Obstructive Lung Disease, Asthma or Cystic Fibrosis), already participate in any form of inspiratory muscle training or cannot communicate sufficiently to perform testing. Each participant will be provided with a Patient Information Sheet and written informed consent will be obtained.

Procedure

The procedure is identical to that performed in the previous studies in intensive care at Canberra Hospital. To perform the testing, participants will need to 'empty their lungs', then inhale maximally through a hand-held device (MircoRPM Respiratory Pressure Metre) for 1 to 2 seconds. This will be repeated 3 times to ensure reliability. The participant will then breathe through an inspiratory muscle trainer (Threshold IMT) for 2 minutes at a resistance equivalent to 30% of their maximum effort. The participant will then repeat the 3 maximum inhalations through the hand-held MicroRPM machine. Thus a total of 6 maximal breaths is required for testing, i.e. 3 breaths either side of the 2 minute resistance challenge.

Participants will be monitored closely and testing ceased if not tolerated at any point. Total testing time should take less than 15 minutes allowing for explanation and rest time.
This testing procedure is very low risk as we have performed it without a single incident in intensive care patients in Canberra Hospital over the past 5 years3. Exercise testing will be performed in the Faculty of Health research offices available in Building 12 or an alternative venue mutually convenient to the researcher and participant.

Sample size

To allow comparison with our previous sample1, we will aim to recruit 45 participants aged 20 – 90, recruiting both males and females to allow age and gender matching to our intensive care patients as much as possible. The time frame for data collection is January to March 2016, with potential to extend by 1 to 2 months if necessary.

2.4. RESEARCH PRODUCTS *(please select)*

○ Book(s)	○ Commercial Product(s)	◉ Conference Paper(s)	○ Exhibition(s)	◉ Journal Article(s)
○ Performance(s)	○ Report(s)	○ Therapeutic Product(s)	○ Thesis	○ Other

If Other, please explain:	

2.5. BENEFITS AND OTHER IMPACTS OF THE RESEARCH

The results of this study will have implications for interpreting the data from previous studies which have used FRI as a measure of respiratory muscle endurance. Furthermore, this preliminary study may indicate that a more in-depth study is required if the patterns of fatigue resistance obtained show wide variation with age, gender etc.

3. PARTICIPANTS, RELATIONSHIPS, FEEDBACK AND CONSENT

Please note that the National Statement focuses on the principle of respect for persons. In addition to the participants recruited for the research, there is a need to consider the impact on others who may be affected by the research (see NS 1.1 (d), 1.6-1.9, 1.10, Chapter 2.1).

3.1. PLEASE DESCRIBE WHAT PARTICIPANTS WILL BE REQUIRED TO DO OR AGREE TO HAVE DONE TO THEM.

Demographic Data:
Participants will fill out a simple 1 page questionnaire which will capture participant data (see attachment), including age, gender, weight, usual exercise and physical activity levels. These will be stored in a deidentified manner.

Procedure

To perform the testing, participants will need to breathe out fully ('empty their lungs'), then inhale maximally through a hand-held device (MircoRPM Respiratory Pressure Metre) for 1 to 2 seconds. This manoeuvre requires effort, but is not painful in any way. This measurement will be repeated 3 times to ensure reliability.
The participant will then breathe through an inspiratory muscle trainer (Threshold IMT) for 2 minutes at a resistance equivalent to 30% of their maximum effort. This will feel like the participant is breathing against resistance, and should feel challenging but not impossible. Again, it is not painful in any way. If participants feel they cannot continue breathing against resistance for any reason, they simply stop and rest for the remainder of the 2 minute period.
The participant will then repeat the 3 maximum inhalations through the hand-held MicroRPM machine. Thus a total of 6 maximal breaths is required for testing, i.e. 3 breaths either side of the 2 minute resistance challenge. The whole testing procedure is easily achievable within 10 minutes.

3.2. PLEASE OUTLINE THE RISK OF ANY POSSIBLE DISCOMFORT OR HARM FOR PARTICPANTS AND YOUR STRATEGIES FOR MINIMISING THIS RISK.

If patients report discomfort, shortness of breath or dizziness, or wish to cease the test at any time, they simply remove the device from their mouth and either rest until they choose to continue, or testing is abandoned. This is consistent with the testing approach used in intensive care patients where it has been well-tolerated.

3.3. PLEASE OUTLINE ANY POSSIBLE RISK TO YOU AS THE RESEARCHER AND YOUR STRATEGIES FOR MINIMISING THIS RISK.

The conduct of this research provides minimal (if any) risk to the research team.

Research team members can access the free counselling services offered to University of Canberra employees by Converge (1800 337 068).

3.4. PLEASE OUTLINE ANY POSSIBLE RISKS TO OTHERS ARISING FROM THIS RESEARCH.

No anticipated risks to others.

3.5. PLEASE DESCRIBE HOW YOU WILL SELECT, RECRUIT AND CONTACT PARTICIPANTS.

Participants will be healthy volunteers from the Canberra community. Flyers advertising the project will be distributed through the UC campus and electronically through existing professional networks (see attached).
Participants will be included if they are adults free from existing lung disease, who are able to provide consent and are able to follow instructions to complete the testing.
Participants will be excluded it they cannot provide consent, already suffer from lung disease (eg Chronic Obstructive Lung Disease, Asthma or Cystic Fibrosis), already participate in any form of inspiratory muscle training or cannot communicate sufficiently to perform testing.
Each participant will be provided with a Participant Information Sheet and written informed consent will be obtained.

3.6. IF APPLICABLE, PLEASE DESCRIBE HOW YOU WILL OBTAIN APPROVAL TO ACCESS PARTICIPANTS.

No approval required, as these will be healthy volunteers.

3.7. HOW MANY PARTICIPANTS WILL YOU RECRUIT? WHAT IS THE RATIONALE FOR THIS NUMBER?

To allow comparison with our previous sample (1), we will aim to recruit 45 participants aged 20 – 90, recruiting both males and females to allow age and gender matching to our intensive care patients as much as possible. The time frame for data collection is January to March 2016, with potential to extend by 1 to 2 months if necessary.

3.8. WILL YOU TARGET PARTICIPANTS FOR WHOM THERE ARE SPECIFIC ETHICAL CONSIDERATIONS?

- ◯ Children and young people
- ◯ People in dependent or unequal relationships
- ◯ Women who are pregnant and the human foetus
- ◯ People unable to give consent for health or other reasons
- ◯ People with a cognitive impairment, intellectual disability or mental illness
- ◯ Aboriginal and Torres Strait Islanders
- ◯ People in other countries
- ◯ People who are incarcerated
- ◯ People for whom English is a second language
- ◯ People who may be involved in illegal activities

3.8.1. IF SO, HOW ARE THE SPECIFIC ETHICAL CONSIDERATIONS BEING ADDRESSED?

N/A

3.9. ARE ANY CATEGORIES OF PARTICIPANT SPECIFICALLY EXCLUDED? IF SO, PLEASE PROVIDE A RATIONALE.

Participants will be excluded it they already suffer from lung disease (eg Chronic Obstructive Lung Disease, Asthma or Cystic Fibrosis). These pathologies are likely to affect the strength and endurance of inspiratory muscles, and would therefore contaminate the sample of healthy participants.

Participants will also be excluded if they already participate in any form of inspiratory muscle training as this is likely to affect the Maximal Inspiratory Pressure manoeuvre used in the FRI test, and would not represent usual respiratory muscle activity for a healthy person (i.e. they are likely to have supra-normal results).

Participants will be excluded if they cannot communicate sufficiently to provide consent or perform testing.

3.10. PLEASE DESCRIBE ANY PAYMENT OR COMPENSATION TO PARTICIPANTS.

Nil

3.11. PLEASE DESCRIBE ANY PRE-EXISTING RELATIONSHIP WITH PARTICIPANTS AND ANY ETHICAL CONSIDERATIONS THAT NEED TO BE ADDRESSED AS A RESULT OF THIS RELATIONSHIP.

Nil

3.12. HOW WILL YOU OBTAIN PARTICIPANTS' CONSENT TO PARTICIPATE? HOW WILL YOU ENSURE THAT CONSENT IS VOLUNTARY? HOW WILL YOU ENSURE THEIR RIGHT TO WITHDRAW FROM THE RESEARCH WITHOUT PENALTY AND WITHOUT FEELING DISCOMFORT?

Written informed consent will be obtained from each participant, and the participant information sheet will clearly state that they may cease participation at any time.

Prior to commencing testing, participants will be reminded that they may cease testing and rest, or cease testing altogether at any point without having to provide a reason.

3.13. DO YOU INTEND TO WITHHOLD OR DISGUISE THE PURPOSE OF THE RESEARCH IN ANY WAY? IF SO, PLEASE PROVIDE REASONS.

No.

3.14. WILL YOU PROVIDE ANY FEEDBACK TO PARTICIPANTS ABOUT THE RESULTS OF THE RESEARCH? IF SO, PLEASE ADVISE IN WHAT FORM FEEDBACK WILL BE PROVIDED.

Participants will be provided with their inspiratory muscle strength values (eg 75 cmH2O) and a brief explanation as to how this corresponds to those values that would be expected given the participant's age and gender.
If there are any concerns that these values vary from normal, they will be offered a personal consultation with an experienced respiratory physiotherapist (BB) who can offer advice and treatment if indicated.

4. DATA

It is important that privacy and respect are the principles underlying the collection, storage and use of data. Data should be reliable, retrievable and replicable if necessary. (See Section 2 of the Australian Code for the responsible Conduct of research)

4.1. HOW WILL YOU PROTECT THE CONFIDENTIALITY AND PRIVACY OF PARTICIPANTS?

All results will be non-identifiable, as all data will be collected and stored in a deidentified manner.

4.2. WILL OTHERS BE ABLE TO IDENTIFY RESEARCH PARTICIPANTS FROM PUBLISHED DATA OR OTHER SOURCES (E.G. INTERPRETERS, TRANSLATORS, OBSERVERS)?

No.

4.3. WILL THE DATA BE INDIVIDUALLY IDENTIFIABLE, NON-IDENTIFIABLE *(COLLECTED IN A WAY THAT NO ONE KNOWS THE NAME OF THE PARTICIPANTS)* OR RE-IDENTIFIABLE *(CODED IN SOME WAY SO THAT ONLY THE RESEARCH TEAM CAN CONNECT THE DATA TO SPECIFIC PARTICIPANTS)*?

All data will be collected in a non-identifiable manner.

4.4. HOW WILL YOU ENSURE THE SECURITY OF THE DATA?

Only non-identifiable data will be collected. Data will be secured in electronic format and stored on password-protected computers based at the University of Canberra.

4.5. IN WHAT FORM WILL THE DATA BE STORED?

Data will be secured in electronic format and stored on password-protected computers based at the University of Canberra, in a non-identifiable format.

4.6. WHERE WILL THE DATA BE STORED?

Data will be secured in electronic format and stored on password-protected computers based at the University of Canberra. The data will be archived at the University of Canberra for at least five years.

4.7. WHO WILL HAVE ACCESS TO THE RAW DATA?

Only the researchers will have access to the raw data. One scanned and stored electronically, the original paper-based data collection forms will be disposed of as secure waste.

4.8. DO YOU ANTICIPATE USING THE DATA IN A FUTURE PROJECT?

Yes.

4.9. WILL THE DATA BE ARCHIVED OR DESTROYED? IF DESTROYED, PLEASE PROVIDE A DATE.

The data will be archived at the University of Canberra for at least five years.

4.10. IF THE DATA WILL BE ARCHIVED, WHO WILL HAVE ACCESS TO IT AND WHAT CONDITIONS WILL BE ATTACHED?

Only the researchers will have access to the raw data, as it will be stored in a password protected file on the University of Canberra computers.

5. DECLARATIONS AND SIGNATURES *(please print this page and ensure that all researchers, supervisors and the ADR sign it, please do not insert any electronic signatures)*

I/we certify that:

- All information is truthful and as complete as possible.
- I/we have had access to and read the *National Statement on Ethical Conduct in Human Research*, and that the research will be conducted in accordance with the national Statement and in accordance with the ethical arrangements of the organizations involved.
- I/we have consulted any relevant legislation and regulations, and the research will be conducted in accordance with these.
- I/we will immediately report to the HREC anything which might warrant review of the ethical approval of the proposal (NS 5.5.3).
- I/we will inform the HREC, giving reasons, if the research project is discontinued before the expected date of completion (NS 5.5.6, 5.5.8b).
- I/we will adhere to the conditions of approval stipulated by the HREC and will cooperate with HREC monitoring requirements, including the provision of annual progress reports and final reports as required.

Chief Investigator/Co-Investigator(s)/ Supervisor name:	BERNIE BISSETT / NICOLE FREENE
Signature:	
Date:	1st September 2015

I certify that:

- I am familiar with this project and endorse its undertaking;
- the resources required to undertake this project are available;
- the researchers have the skill and expertise to undertake this project appropriately or will undergo appropriate training as specified in this application.

Associate Dean Research or nominee (name):	
Signature:	
Date:	

6. ATTACHMENTS CHECKLIST

- ◉ Participant Information Form(s) and Consent Form(s)
- ◉ Recruitment Material
- ◉ Questionnaires, surveys, interview questions, test items
- ◯ Organisational and/or institutional approvals
- ◯ Relevant agreements or contracts
- ◯ Other relevant information or documentation

NOTES FOR APPLICANTS

When completing this Application Form, you should always refer to the Human Research Ethics Manual. Please go to http://www.canberra.edu.au/research/ucresearch/ethics/human-ethics-manual to download a copy.

INSTRUCTIONS TO APPLICANTS

- Please answer all questions. If a question is not applicable then please state "not applicable" in the relevant box.
- Please save the form when you have finished and, if approved by your supervisor and/or ADR, forward an electronic copy to the Research Ethics & Compliance Officer.
- Please print the signature page only and ensure that all researcher(s), your supervisor (if applicable) and the Associate Dean Research sign it. A scanned copy of the signature page should then be sent to the Research Ethics & Compliance Officer.
- To be considered at a particular meeting, completed application forms must be submitted to the Research Ethics and Compliance officer by the scheduled closing date listed on the Research Services Office website.
- University insurance must be arranged for each project involving clinical trials (definition: http://www.nhmrc.gov.au/health-ethics/human-research-ethics/clinical-trials]. Complete the Clinical Trials Insurance Data Collection Form and return to insurance@canberra.edu.au.
- MAC users - Please complete the form using Adobe Reader and please do not use Mac Preview. If you use Mac Preview then your entered form data may disappear.

CHECKLIST FOR SUBMISSION OF APPLICATION

Having completed the application form please check the following:

- Full details of Chief Investigator and Supervisor have been provided.
- All questions have been answered and the language used can be understood by a layperson.
- Attachments are clearly identified, numbered and included with the application.
- Does your Participant Information Form conform to UC Guidelines?
- Letters of approval from cooperating institutions, e.g. schools and government agencies, have been included (if applicable).
- Storage of data has been stated as being at the University of Canberra.
- Private addresses and phone numbers have not been used as means for participants to contact the Researcher.
- Follow-up counselling has been identified if necessary, and the counselling service identified.
- Application has been signed by Researcher/s, Supervisor and Associate Dean Research (or nominee).
- Starting date of the research postdates the meeting at which the application will be considered.
- The relevant closing date for receipt of applications has been noted.