

Departments of Defence and Veterans' Affairs Human Research Ethics Committee CP3-7-038, Campbell Park Offices, PO Box 7912, Canberra BC ACT 2610

DDVA HREC/OUT/2019/BN2481007

21 January 2019

Dr Melissa CroweInstitute of Sport and Exercise Science
James Cook University
Townsville QLD 4811

Copy: Ms Faith Alele

Dear Dr Crowe

074-18 Investigating heat tolerance in females

Thank you for providing the additional documentation in support of your resubmission of the above research project. The Chair of the Departments of Defence and Veterans' Affairs Human Research Ethics Committee (DDVA HREC) has reviewed the additional information out-of-session.

I am pleased to advise you that the DDVA HREC has granted ethical approval of this research project.

The nominated participating site for this project is James Cook University.

Note: If additional sites are engaged prior to the commencement of, or during the research project, the Coordinating Principal Investigator is required to notify DDVA HREC. Notification of withdrawn sites should also be provided to the DDVA HREC in a timely fashion.

Please note that the version control details have been revised since the initial ethical approval letter was inadvertently sent out prior to clearance by the Assistant Director Research Ethics. The approved documents include:

Document	Version	Date
Human Research Ethics Application	7	3 January 2019
Project Description		Received 10 January 2019
Participant Information Sheet – Cases	4	31 December 2018
Consent Form – Cases	4	31 December 2018
Participant Information Sheet – Controls	4	31 December 2018
Consent Form – Controls	4	31 December 2018
Medical Pre-screening Questionnaire		Received 5 December 2018

Document	Version	Date
Recruitment flyer controls		Received 17 January 2019
Recruitment email		Received 17 January 2019

Approval of this project from DDVA HREC is valid from 15 January 2019 to 14 January 2022 subject to the following conditions being met:

- The Principal Investigator will immediately report anything that might warrant review of ethical approval of the project. Project Description
- The Principal Investigator will notify the DDVA HREC of any event that requires an amendment/modification to the protocol or other project documents and submit any required amendments in accordance with the instructions provided by the HREC.
- The Principal Investigator will submit any necessary reports related to the safety of research participants in accordance with DDVA HREC policy and procedures.
- The Principal Investigator will submit progress reports to the DDVA HREC annually and notify DDVA HREC when the project is completed at all sites in the specified formats.
- The Principal Investigator will notify the DDVA HREC if the project is discontinued at a participating site before the expected completion date, with reasons provided.
- The Principal Investigator will notify the DDVA HREC of any plan to extend the duration of the project past the approval period listed above and will submit any associated required documentation.
- The Principal Investigator will notify the DDVA HREC of their inability to continue and indicate the name of and contact information for a replacement.
- The return of the Principal Investigators Assurance (Attachment A) signed by all Principal Investigators prior to the commencement of the research.

<u>This letter constitutes ethical approval only</u>. This project cannot proceed at any site until separate research governance authorisation has been obtained from the CEO or Delegate of the institution under whose auspices the research will be conducted at that site.

Should you have any queries about the DDVA HREC's consideration of your project please contact the DDVA HREC Secretariat on (02) 6266 3807 or ddva.hrec@defence.gov.au.

The DDVA HREC wishes you every success in your research.

Yours sincerely

Ms Terri Davis

Assistant Director Research Ethics

For

Mr Ian Tindall

Chair, Departments of Defence and Veterans' Affairs Human Research Ethics Committee

Attachment:

A. Principal Investigator's Assurance

The Departments of Defence and Veterans' Affairs Human Research Ethics Committee is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research*.