JOINT HEALTH COMMAND

Australian Defence Human Research Ethics Committee
CP3-6-036, Campbell Park Offices, PO Box 7912, Canberra BC ACT 2610

2013/1195601

ADHREC/OUT/2014/R18910579

10 July 2014

Professor Carolyn Mountford
The University of Newcastle

Dear Professor Mountford

Protocol number: 732-13
Project title: ***Biomarkers for Mild Traumatic Brain Injury, Blast Injury and Post Traumatic Stress Disorder***

Thank you for submitting the above project amendments for ethical review. I am pleased to advise you that the ADHREC has granted ethical approval of this research project.

The nominated participating site/s in this project is/are:

- HMRI / University of Newcastle

- The University of Adelaide

- Brigham and Women's Hospital, Harvard Medical School, USA

- Charles Stuart Draper Laboratories

- University of Manitoba, Canada

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 Notification of withdrawn sites should also be provided to the ADHREC in a timely fashion.

The approved documents include:

Document	Version	Date
Information/Consent form version number: Version	3	07/07/14
Research Protocol submission for scientific and ethical approval	2	23/04/14

Approval of this project from ADHREC is valid from 10 July 2014 to 9 July 2017 subject to the following conditions being met:

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

This letter constitutes ethical approval only. 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 ADHREC's consideration of your project please contact ADHREC Secretariat, on 02 6266 3807 or ADHREC@defence.gov.au.

The ADHREC wishes you every success in your research.

Yours sincerely

Terri Davis
A/ADHREC Executive Officer

For
MAJGEN Jeffrey Rosenfeld
Chair, Australian Defence Human Research Ethics Committee

Attachment:
A. Research Agreement

Enclosure:
A. Guidelines for Volunteers

Australian Government
Department of Defence

RESEARCHERS' AGREEMENT

The Australian Defence Human Research Ethics Committee (ADHREC) requires your agreement to the following conditions in order to secure its endorsement of your project.

Please Initial

☐ **1** **You must quote your ADHREC number and title of your protocol in all correspondence:**

ADHREC PROTOCOL 732-13 BIOMARKERS FOR MILD TRAUMATIC BRAIN INJURY, BLAST INJURY AND POST TRAUMATIC STRESS DISORDER

☐ **2** If you do not commence data collection within twelve months of this approval, the protocol will need to be resubmitted.

☐ **3** The approval of your protocol is for a period of three years. If your research is to continue beyond the three-year approval time, an extension is to be sought in writing.

☐ **4** You are required to submit six-monthly progress reports, the first of which is due **01 December 2014**

☐ **5** The Committee requires confirmation that your project has begun, or notification that it has been delayed or abandoned.

☐ **6** The Committee requires that a copy of the ADHREC *Guidelines for Volunteers* be given to every participant when they are recruited for the protocol.

☐ **7** Committee approval **must** be sought before any modifications to the protocol are instituted.

☐ **8** The Committee **must** be informed of any deviations from the approved protocol and immediately informed of any protocol deviations with real or potential ethical implications.

☐ **9** The Committee **must** be informed immediately of unforeseen event that might affect the continued ethical acceptability of this project.

☐ **10** The Committee **must** be informed immediately of any untoward effects with respect to the medical, personal or administrative management of participants, or which may have ethical and / or publicity implications.

☐ **11** ADHREC gives it ethical approval subject to your explicit agreement to an *intention to publish*. Publication should be in a refereed journal or other source open to public audit. It would be appropriate to include in your submission for publication the phrase "Ethical clearance for this project was provided by the Australian Defence Human Research Ethics Committee". Should a security classification make publish in an open source inappropriate, ADHREC is to be notified in writing.

☐ **12** ADHREC requires a comprehensive **Final Report** which details the conduct of the project and its findings. This report is to be submitted as soon as possible after the project has

finished.

☐ **13** The ADHREC Secretariat requires that you provide notification of any change in your contact details. Point of Contact is the Executive Secretary at ADHREC@defence.gov.au .

For Clinical Trials Only

☐ **14** ADHREC requires that the nominal roll of participants, for the purpose of future tracing, is to be kept for the requisite time by you, according to the NHMRC *National Statement on Ethical Conduct in Human Research.*

☐ **15** The Committee must be informed of any 'adverse events' and immediately informed of any 'serious adverse events' (SAE) which are considered by the Principal Investigator (PI) to be possibly drug related **within 72 hours of their occurrence.**

☐ **16** You must retain records of your volunteers' details, any who withdraw, the reasons for that withdrawal (if known) and provide such on request.

I agree to abide by the conditions above:

Signature ……

Surname……

First Name……

Position/Rank ……

Contact No Work:…… Work Mobile……

Email……

Date……

Executive Secretary
Australian Defence Human Research Ethics Committee
CP3-6-036
PO Box 7912
CANBERRA BC ACT 2610
AUSTRALIA
Tel (02) 6266 3807
E-mail: ADHREC@defence.gov.au

Useful Information

Useful information may be obtained from the following website:
http://www.defence.gov.au/health/research/adhrec/i-adhrec.htm

AUSTRALIAN DEFENCE HUMAN RESEARCH ETHICS COMMITTEE— GUIDELINES FOR VOLUNTEERS

Thank you for taking part in Defence Research; your involvement is very much appreciated. This pamphlet explains your rights as a volunteer.

What is the Australian Defence Human Research Ethics Committee?

- ADHREC is the Australian Defence Human Research Ethics Committee. It was established in 1988, to make sure that Defence complied with accepted guidelines for research involving human beings.
- After World War II (WWII), there was concern around the world about human experimentation. The Declaration of Helsinki was made in 1964, which provided the basic principles to be followed wherever humans were used in research projects.
- The National Health and Medical Research Council (NHMRC) in Australia has published the *National Statement on Ethical Conduct in Human Research* (NHMRC 2007). This *Statement* describes how human research should be carried out.
- ADHREC follows both the *Declaration of Helsinki* and the NHMRC *Statement*.

What Australian Defence Human Research Ethics Committee approval means

- If you are told that the project has ADHREC approval, what that means is that ADHREC has reviewed the research proposal and has agreed that the research is ethical.
- ADHREC approval does not imply any obligation on commanders to order or encourage their Service personnel to participate, or to release personnel from their usual workplace to participate. Obviously, the use of any particular personnel must have clearance from their commanders but commanders should not use ADHREC approval to pressure personnel into volunteering.

Voluntary participation

- As you are a volunteer for this research project, you are under no obligation to participate or continue to participate. You may withdraw from the project at any time without detriment to your military career or to your medical care.
- At no time must you feel pressured to participate or to continue if you do not wish to do so.
- If you do not wish to continue, it would be useful to the researcher to know why, but you are under no obligation to give reasons for not wanting to continue.

Informed consent

- Before commencing the project you will have been given an information sheet which explains the project, your role in it and any risks to which you may be exposed.
- You must be sure that you understand the information given to you and that you ask the researchers about anything of which you are not sure.
- Before you participate in the project you should also have been given a consent form to sign. You must be happy that the consent form is easy to understand and spells out what you are agreeing to. Again, you should keep a copy of the signed consent form.

Clinical trials.

- The NHMRC requires that the researcher provide a nominal roll of study participants where the study is a clinical trial (eg when the researchers are trialling a new treatment or device). For trials conducted by large Defence institutions like the Defence Science and Technology Organisation, the Submarine and Underwater Medicine Unit, the Army Malaria Institute, the Institute of Aviation Medicine or the Centre for Military and Veterans' Health, this roll is kept by them on ADHREC's behalf. These records will not be used to consider your medical employment standard or for compensation purposes.
- All ADHREC protocol files are secured in a locked filing cabinet and only the Secretariat has access to these. ADHREC will not pass your contact information to a third party without your permission.

Complaints

- If at any time during your participation in the project you are worried about how the project is being run or how you are being treated, then you should speak to the researchers.
- If you don't feel comfortable doing this, you can contact the Executive Secretary of ADHREC. Contact details are:

Executive Secretary
Australian Defence Human Research Ethics Committee
CP3-6-036
PO Box 7912
CANBERRA BC ACT 2610
AUSTRALIA

Tel (02) 6266 3807
E-mail: ADHREC@defence.gov.au

More information

If you would like to read more about ADHREC, please visit the ADHREC website at: **http://www.defence.gov.au/health/research/adhrec/i-adhrec.htm**