



Approval Date: 26 October 2015

**Dr Maggie Killington**  
**SA Brain Injury Rehabilitation Services**  
**HAMPSTEAD REHABILITATION CENTRE**

Dear Dr Killington

HREC reference number: **HREC/15/RAH/183**

Project Title: **“Prevalence of a history of acquired brain injury in South Australian prisoners and significance of this for prisoners and prison system.”**

**RAH Protocol No: 150507**

Thank you for submitting the above project for ethical and scientific review. This project was first considered by the Royal Adelaide Hospital Human Research Ethics Committee at its meeting held on 28 May 2015.

I am pleased to advise that your protocol has been granted full ethics approval and meets the requirements of the *National Statement on Ethical Conduct in Human Research*. The documents reviewed and approved include:

- **NEAF Submission: Sites covered by this approval:**
  - SA Prison Facilities:**
    - Remand Centre
    - Yatala
    - Pre-release
    - Cadell
    - Port Augusta
    - Port Lincoln
    - Mount Gambier
    - Adelaide Womens
    - Mobilong
  - CPI – Dr Maggie Killington**
- **Protocol, Version 3, dated 23 October 2015**
- **Participant Information Stage 1, Version 3, dated 23 October 2015**
- **Participant Information Stage 2, Version 3, dated 23 October 2015**
- **Participant Information Stage 3, Version 3, dated 23 October 2015**
- **Participant Consent Form Stage 1, Version 1, dated 23 October 2015**
- **Participant Consent Form Stage 2, Version 1, dated 23 October 2015**
- **Participant Consent Form Stage 3, Version 1, dated 23 October 2015**
- **Phase 3 interview guide, Version 1**
- **Demographic information questionnaire**
- **Acquired Brain Injury screening questionnaire**
- **Frontal Systems Behaviour Scale**

Please quote the **RAH Protocol Number, 150507** and the **HREC number, HREC/15/RAH/183** allocated to your study on all future correspondence.

#### **GENERAL TERMS AND CONDITIONS OF ETHICAL APPROVAL:**

- For all clinical trials, the study must be registered in a publicly accessible trials registry prior to enrolment of the first participant.
- Adequate record-keeping is important. If the project involves signed consent, you should retain the completed consent forms which relate to this project and a list of all those participating in the project, to enable contact with them in the future if necessary. The duration of record retention for all clinical research data is 15 years.
- You must notify the Research Ethics Committee of any events which might warrant review of the approval or which warrant new information being presented to research participants, including:
  - (a) serious or unexpected adverse events which warrant protocol change or notification to research participants,
  - (b) changes to the protocol,
  - (c) premature termination of the study

- The Committee must be notified within 72 hours of any serious adverse event occurring at each approved site.
- Confidentiality of the research subjects shall be maintained at all times as required by law.
- Approval is valid for **5 years** from the date of this letter, after which an extension must be applied for. Investigators are responsible for providing an annual review to the RAH REC Executive Officer each anniversary of the above approval date, within 10 working days, using the Annual Review Form available at: <http://www.rah.sa.gov.au/rec/index.php>
- The REC must be advised with a report or in writing within 30 days of completion.

***You are reminded that this letter constitutes ethical approval only. You must not commence this research project at any site until separate authorisation from the Chief Executive or delegate of that site has been obtained.***

This Committee is constituted in accordance with the NHMRC's *National Statement on the Ethical Conduct of Human Research (2007)* incorporating all updates.

Should you have any queries about the HREC's consideration of your project, please contact Mrs Heather O'Dea, Executive Officer on 08 8222 4139, or [Health.CALHNResearchEthics@sa.gov.au](mailto:Health.CALHNResearchEthics@sa.gov.au).

The HREC wishes you every success in your research.

Yours sincerely,



for

**A/Prof A Thornton  
CHAIRMAN  
RAH HUMAN RESEARCH ETHICS COMMITTEE**