

Ethics Status – Approved

Research Governance Status – Approved

8 May 2017

Dr Victoria Manning
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Via Email – victoriam@turningpoint.org.au

HREC Reference Number: HREC/17/EH/7
Eastern Health Site Reference Number: E03-2017

Study Title: Can novel computerised brain-training reduce relapse among methamphetamine users?

Further to the HREC correspondence sent 28 March 2017, thank you for the response dated 11 April 2017 with amendments and clarifications. The response and all documents have been reviewed and approved by the Chair of the HREC.

Therefore I am pleased to advise that the above study has received full ethical approval from the Eastern Health Human Research Ethics Committee (HREC). In addition the study has received full governance approval from the Office of the Chief Executive Officer at Eastern Health and may commence at the nominated site.

The HREC confirms that your proposal meets the requirements of the National Statement on Ethical Conduct in Human Research (2007) (**National Statement**). This HREC is organised and operates in accordance with the National Health and Medical Research Council's (**NHRMC**) National Statement and all subsequent updates.

HREC Final Approval Date: 21 April 2017
Research Governance Approval: 08 May 2017
Ethical approval for this project applies at the following Eastern Health campus: Wellington House

Approved Documents:

The following documents have been reviewed and approved by the HREC:

Document	Version	Dated
NEAF Application	AU/1/ED2D212	11/04/2017
Site Specific Assessment	AU/5/DD2D28	11/04/2017
Victorian Specific Module	v1 9.2.17	27/02/2017
Protocol	2	31/03/2017

Document	Version	Dated
Questionnaire - Measures to be administered during inpatient withdrawal including methamphetamine use disorder module of the Structured Clinical Interview for DSM-5 Disorders Research-Version (SCID-5-RV)	2	05/04/2017
Participant Information Sheet/Consent Form	3	29/03/2017

Other Documents related to the Study:

Document	Version	Dated
Eastern Health Foundation Grant Letter		
Budget \$29,914	1	06/02/2017
CV for Investigators: V Manning, A Verdejo-Garcia, D Lubman, J Garfield, K Mroz, P Thorn, I Zhang, J Lum, T Tolliday.		

Approval is subject to:

1. The Principal Researcher is to ensure that all associate researchers are aware of the terms of approval and to ensure the project is conducted as specified in the application and in accordance with the National Statement on Ethical Conduct in Human Research (updated March 2014).
2. Immediate notification to the Research Governance Unit of any serious adverse events on participants.
3. Immediate notification of any unforeseen events that may affect the continuing ethical acceptability of the project.
4. Notification of any changes to personnel on the study.
5. Notification and reasons for ceasing the project prior to its expected date of completion.
6. Notification of approved amendments to the study.
7. Submission of an annual report due on 14 February each year for the duration of the study (report template is [here](#)).
8. Submission to the HREC of any proposed modifications to the project or documents as approved by the HREC and noted above.
9. Submission of a final report and papers published on completion of the project.
10. Projects may be subject to an audit or any other form of monitoring by the Research Governance and Ethics Office at any time.

Confidentiality, Privacy & Research:

Research data stored on personal computers, USBs and other portable electronic devices must not be identifiable. No patients' names or UR numbers must be stored on these devices. Electronic storage devices must be password protected or encrypted. The conduct of research must be compliant with the conditions of ethics approval and Eastern Health policies.

Publications:

It is very important that the role of Eastern Health is acknowledged in publications.

Composition of the HREC

We confirm at the meetings at which the above project was considered, the Committee fulfilled the requirements of the NHMRC National Statement in that it contained men and women encompassing different age groups and included people in the following categories:

HREC Members

Chairperson

Lay Man

Lay Woman

Lawyer

Person/s fulfilling a Pastoral Care Role

Person/s with Counselling Experience

Person/s with Current Research Experience

Please quote the reference number **E03-2017** in all future correspondence.

Eastern Health HREC wishes you and your colleagues every success in your research.

Yours sincerely



Natasha Savvides

Research Governance and Ethics Officer

Direct Line: 03 9895 3380

On behalf of

1. Eastern Health Human Research Ethics Committee (Ethics Approval)
2. Executive Director Research and Medical Services (Site Authorisation)

cc Associate Professor Antonio Verdejo-Garcia – antonio.verdejo@monash.edu
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