

St Vincent's Hospital (Melbourne) Limited ABN 22 052 110 755

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30 November 2017

Dr Victoria Manning Eastern Health Clinical School Monash University

Dear Dr Manning,

SERP HREC Reference Number: HREC/17/SVHM/239 St Vincent's HREC Ref: HREC 207/17

'Can novel computerised brain training reduce relapse among methamphetamine users?'

I am pleased to advise that the above project has received <u>ethical approval</u> from the St Vincent's Hospital Melbourne Human Research Ethics Committee (HREC)

HREC Approval Date: 30 November 2017

This HREC is accredited by the Consultative Council for Human Research Ethics under the single ethical review system. The HREC has ethically approved this research according to the Memorandum of Understanding between the Consultative Council and the participating organisations conducting the research.

Approval is given in accordance with the research conforming to the National Health and Medical Research Council Act 1992 and the National Statement on Ethical Conduct in Human Research 2007 (updated May 2015)

Ethical approval for this research project has been given at the following sites.

St Vincent's Hospital Melbourne (DePaul House)

Please note that each participating site will require governance approval (SSA approval) prior to commencement of this research project.

Site-Specific Assessment (SSA)

SSA authorisation is required at all sites participating in the study. SSA must be authorised at a site before the research project can commence.

You are now required to forward this HREC approval letter with an electronic copy of the approved documents named above to the Principal Investigator(s) and the Research

Facilities St Vincent's Hospital Melbourne Caritas Christi Hospice St George's Health Service Prague House Governance Officer (s) at each participating site covered by this HREC approval. Each participating site must issue governance approval of the project before the study can commence at individual sites.

Approval is subject to:

- An Annual Progress Report (that covers all sites listed on approval) for the duration
 of the project. This report is due on the 01 May each year for the duration of the
 project. Continuation of ethics approval is contingent on submission of an annual
 report. Failure to comply with this requirement may result in suspension of the
 project by the HREC.
- 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 2007 (updated May 2015)
- Immediate notification to the Research Governance Unit of any serious adverse events on participants.
- Immediate notification of any unforeseen events that may affect the continuing ethical acceptability of the project;
- Notification and reasons for ceasing the project prior to its expected date of completion;
- Submit to the reviewing HREC for approval of any proposed amendments to the project including any proposed changes to the Protocol, Participant Information and Consent Form/s, Investigator Brochure and other study materials.
- Submission of reviewing HREC approval for any proposed modifications to the project.
- Submission of a final report and papers published on completion of project.
- Projects may be subject to an audit or any other form of monitoring by the Research Governance Unit at any time.

The following documents have been reviewed and approved:

Approved documents:

Document	Versio n	Date
Human Research Ethics Application (JG01468)	-	04/09/2017
Victorian Specific Module	Aug 2017	04/10/2017
Brain Training for methamphetamine dependence protocol	4	06/11/2017
Measures for methamphetamine dual training 2-week follow-up	1	03/02/2017
Measures for methamphetamine dual training 3-month follow-up	1	03/02/2017
Measures during inpatient withdrawal, methamphetamine CBM training	3	31/07/2017
Methamphetamine CBM Participant Information and Consent Form SVHM	2	06/11/2017
Meth dual training study budget	1	26/09/2017
CV Victoria Manning	-	_
CV Martyn Lloyd-Jones	-	-
CV Yvonne Bonomo	-	

CV Joshua Garfield	-	-
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Protocol number:

The HREC wishes you and your colleagues every success in your research.

Yours sincerely,

Ms Leanne Clinch HREC Secretary

Research Governance Unit

St Vincent's Hospital (Melbourne)