



**ST VINCENT'S
HOSPITAL**

MELBOURNE

A FACILITY OF ST VINCENT'S HEALTH AUSTRALIA

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09 March 2017

Dr Victoria Manning
Turning Point
Eastern Health

Dear Dr Manning

SERP HREC Reference Number: HREC/17/SVHM/21
St Vincent's HREC Ref: 030/17

'A randomised controlled trial of Cognitive Bias Modification training during early recovery from alcohol dependence'

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

Approval Status: FINAL

Period of Approval: 09 March 2017 – 09 March 2021

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.

- De Pal House (St Vincent's Hospital Melbourne)
- Wellington House
- Windana Drug & Alcohol Recovery 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 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:

- 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 an annual report, due on the anniversary date of approval, for the duration of the study. Failure to comply with this requirement may result in suspension of the project by the HREC.
- 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	Version	Date
National Ethics Application Form (AU/1/374C24)	2.2 (2014)	06/03/2017
Victorian Specific Module	-	09/02/2017
Alcohol CBM Protocol	2	03/03/2017
Master Participant Information and Consent Form	2	03/03/2017
Measures administered during inpatient withdrawal	1	01/02/2017
Measures to be administered for alcohol CBM 2-week follow-up	1	01/02/2017
Measures for 3,6, and 12-month follow-ups or alcohol CBM study	1	01/02/2017
Alcohol CBM project budget	1	31/01/2017
Application Assessment Summary	-	-
CV Joshua Garfield	-	-

CV Kate Hall	-	-
CV Pinar Thorn	-	-
CV Petra Staiger	-	-
CV John Reynolds	-	-
CV Antonio Verdejo-Garcia	-	-
CV David Lloyd-Jones	-	-
CV Daniel Lubman	-	-
CV Victoria Manning	-	-
CV Jarrad Lum	-	-
CV Ingrid Zhang	-	-
CV Anthony Harris	-	-
CV Yvonne Bonomo		-
CV Katherine Mroz	-	-

Noted

Document	Version	Date
Grant Proposal – 2016 project grants	-	-

<p>HREC Reference Number: HREC/17/SVHM/21 St Vincent’s HREC Ref: HREC 030/17 Protocol number:</p>
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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)