easternhealth

Office for Research and Ethics
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7 January 2020

A/Prof Victoria Manning
Turning Point
110 Church Street
Richmond VIC 3121

Dear A/Prof Victoria Manning,

Study Title: 'A pilot randomised controlled trial (RCT) of personalised approach bias modification for patients undergoing residential treatment for methamphetamine use disorder (MAAT)'

Eastern Health Site Reference Number: E19/022/58264
Principal Investigator: A/Prof Victoria Manning
Associate Investigators: Dr Shalini Arunogiri, Prof Malcolm Hopwood, Dr Eli Kotler, Dr Joshua Garfield, Prof Dan Lubman, Mr Jeffrey Gavin, Ms Suzanne George, Dr Goke Okedara, Mr Hugh Piercy, Ms Katherine Mroz, Dr Paul Sanfilippo, Mr Samuel Campbell
ERM Project ID: 58264

Further to HREC correspondence sent 12 December 2019 and responses received 17 December 2019 including a final series of amendments and clarifications.

I am pleased to advise that the above study has received full ethical approval from the Eastern Health Human Research Ethics Committee (HREC).

The HREC confirms that your proposal meets the requirements of the National Statement on Ethical Conduct in Human Research 2007 (all updates inclusive) (**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, and in accordance with the Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95), the Health Privacy Principles (HPP's) described in the Health Records Act 2001 (Vic)

HREC Final Approval Date: 07 January 2020
Eastern Health Research Governance Authorisation: Pending
Ethical approval for this project applies at the following site(s): Eastern Health - Turning Point & Wellington House, Malvern Private Hospital, Ramsay Health Care

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

Document	Version	Dated
Human Research Ethics Application (HREA)	HREC/58264/EH-2019-192548(v1)	01 November 2019
Protocol	1	26 August 2019
Master Participant Information Sheet/Consent Form (PICF)	2	12 December 2019
MAAT Baseline Questionnaires	1	13 September 2019
MAAT 4-week Follow-up Questionnaires	1	16 September 2019
MAAT 3-month Follow-up Questionnaires	1	16 September 2019
MAAT Trial Locator Form	1	02 October 2019
Victorian Specific Module (VSM)	-	31 October 2019

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 (2007).
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 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 Eastern Health Office of Research & Ethics at any time.

Research Governance Authorisation

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

A copy of this ethics approval letter and all relevant documents must be submitted to site for authorisation by the Chief Executive or delegate. This applies to each site participating in the research.

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 **E19/022/58264** in all future correspondence.

Yours sincerely

Robert Reid
Eastern Health
2020.01.07
10:18:19 +11'00'

Robert Reid
Ethics Governance and Project Officer
Eastern Health Office of Research and Ethics

On behalf of

1. Eastern Health Human Research Ethics Committee (Ethics Approval)