

Joanna Williams (Western Sydney LHD)

From: WSLHD-ResearchOffice
Sent: Monday, 24 September 2018 4:29 PM
To: Joanna Williams (Western Sydney LHD)
Subject: 5352 Amendment Approved
Attachments: HREA Amendment Form 220818.pdf; 5352 S7 Daniel Pellen Signed site addition.pdf; 5352 Section 7 Add Headspace+Roger Gurr.pdf; 5352 Section 7 Addition BJ_lappin_ethics.pdf; 5352 Section 7 addition NSLHD.PDF

Dear Joanna,

Research Proposal: Is there a synergistic effect of adding social cognition remediation to cognitive remediation therapy in young people? A Randomised Controlled Trial. Short Title: ADVANTAGE Trial

I am pleased to advise approval has been granted for the Request for Amendment / Modification for this single/multicentre research project being conducted at:

- Westmead Hospital –Chief Investigator A/Prof Anthony Harris
- Department of Psychiatry, Prevention Early Intervention Recovery Service (PEIRS)- Principal Investigator Ms Carlie Dodds
- Royal North Shore Hospital Principal Investigator Dr Nick O'Connor
- Nepean Hospital Principal Investigator Dr Daniel Pellen
- Concord Hospital Principal Investigator Dr Jean Starling

The following documentation has been reviewed and approved.

- Study Protocol, version 5, dated 15 August 2018
- Master PICF version 4, dated 15 August 2018
- Site Specific PICF version 2, dated 15 August 2018
- PICF Parent/ Guardian version 3, dated 15 August 2018
- Site Specific PICF Parent/ Guardian version 2, dated 15 August 2018

Your request to add Dr Roger Gurr, Beverly Moss, Julia Lappin as an investigator and adding site as Child and Youth Mental Health Service Principal Investigator Dr Daniel Pellen to the study was reviewed and approved by Research Ethics and authorised by Research Governance. We note Dr Nick O' Connor removal from the study at Nepean Hospital.

This amendment has also been reviewed and authorised by the Research Governance Officer for Western Sydney Local Health District. For non-Western Sydney Local Health District sites please ensure that the Research Governance Officer for each site named on this study receives the updated approved documentation in relation to this amendment.

HREC approval is granted for a period of 12 months and ongoing approval is contingent upon annual submission. Annual Reports for all studies should be submitted in November, they will be review, approved, and notified to the HREC. A copy of the Annual / Final Research Report Form can be obtained electronically from the Research Office on request.

We appreciate your keeping us informed and look forward to receiving your next annual report.

Yours sincerely



Mrs Pat Fa

Secretary
WSLHD Human Research Ethics Committee

From: Joanna Williams (Western Sydney LHD)
Sent: Wednesday, August 22, 2018 2:30 PM
To: WSLHD-ResearchOffice; Kellie Hansen (Western Sydney LHD)
Subject: FW: 5352 HREC/17/WMEAD/427 - Request for Amendment

Dear Kellie

Please accept our attached HREC request for Amendment form regarding further changes to the Advantage Trial (5352).

Attachments include:

- Signed HREC Request for Amendment form 220818
- Section 7 of HREC form for each new investigator and their sites (CVs attached)
- Advantage Protocol Version 5 150818 (clean and tracked)
- Master Adult PICF Version 4 150818 (clean and tracked)
- Master Parent/Guardian PICF Version 3 150818 (clean and tracked)
- WSLHD Adult PICF Version 2 150818 (clean and tracked)
- WSLHD Parent/Guardian PICF Version 2 150818 (clean and tracked)

If we have missed anything please don't hesitate to get in contact.

Kind Regards,

Joanna Williams
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Cognitive Remediation | Advantage Trial
Available Wednesday and Friday
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