The Royal Melbourne Hospital

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Ethical Approval

Royal Melbourne Hospital Human Research Ethics Committee

A/Prof Kelly Allott
Orygen, The National Centre of Excellence in Youth Mental Health

16 February 2023

Dear A/Prof Kelly Allott,

HREC Reference Number: HREC/89942/MH-2022
Royal Melbourne Hospital Site Reference Number: 2022.275
Project Title: CogScreen: Validating cognitive screening in young people with first-episode psychosis

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I am pleased to advise that the above project has **received ethical approval** from the Royal Melbourne Hospital 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). This HREC is organised and operates in accordance with the National Health and Medical Research Council's (NHRMC) National Statement on Ethical Conduct in Human Research (2007), and all subsequent updates, and in accordance with the Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95), the Health Privacy Principles described in the Health Records Act 2001 (Vic) and Section 95A of the Privacy Act 1988 (and subsequent Guidelines).

HREC Approval Date: 15 February 2023

Ethical approval for this project applies at the following sites:

Site
• Orygen Specialist Program, Royal Melbourne Hospital VIC • headspace Early Psychosis - (Alfred Health) VIC • headspace Early Psychosis – (Adelaide) SA • Western/Eastern/Northern/North Eastern Community Mental Health Adelaide (formerly summarised as North Adelaide Local Health Network and Central Adelaide Local Health Network) • Prevention Early Intervention and Recovery Service (PEIRS) – (Western Sydney Local Health District) NSW • headspace Early Psychosis Service – (Parramatta and Mt Druitt) NSW • Bondi Early Psychosis Program (EPP) - (South-Eastern Local Health District) NSW

Approved Documents:

The following documents have been reviewed and approved:

Document	Version	Date
Protocol	2.1	15 February 2023
Brief Study Summary	2.0	01 February 2023
Master Self Participant Information Sheet/Consent Form	2.1	15 February 2023
Master Parent/Guardian Participant Information Sheet/Consent Form	2.1	15 February 2023
Master Self Implementation Participant Information Sheet/Consent Form	2.1	15 February 2023
Master Parent/Guardian Implementation Participant Information Sheet/Consent Form	2.1	15 February 2023

Master Self Withdrawal Form	1.0	20 September 2022
Master Parent/Guardian Withdrawal Form	1.0	20 September 2022
Mandatory Decision Making Flow Chart VIC	1.0	31 January 2023
Cognitive Test Results Summary 12-15	2.0	31 January 2023
Cognitive Test Results Summary 16+	2.0	31 January 2023
Example SMS	1.0	15 November 2022
Guidelines for Interpreters Completing Research Assessments	1.0	31 January 2023
Guidelines for Researchers Completing Research Assessments with Interpreters	1.0	31 January 2023
Cog Screen Inclusion/Exclusion	2.0	01 February 2023
Managing Disclosures of Abuse or Neglect	2.0	31 January 2023
Safety Management Plan	2.0	25 January 2023
Post-study Survey	1.0	01 November 2022
CogScreen SOA	2.0	01 February 2023
Montreal Cognitive Assessment (MoCA)	7.2	-
Screen for Cognitive Impairment in Psychiatry (SCIP) 1	-	-
Screen for Cognitive Impairment in Psychiatry (SCIP) 2	-	-
SCID-5 Diagnoses	1.0	09 May 2018
Acceptability Questionnaire	1.0	20 October 2022
ACE	1.0	23 November 2022
AQ	1.2	19 June 2018
ASRS	1.0	01 February 2023
ASSIST	1.0	02 August 2016
BPNS	1.0	21 December 2016
CSS	1.0	18 October 2022
Demographics	1.0	01 November 2022
Functioning Probes	1.0	01 February 2023
GAD-7	1.0	18 July 2017
GF Role	1.0	01 February 2023
GF Social	1.0	01 February 2023
GSES	1.0	01 February 2023
Implementation Interview Guide	1.0	20 October 2022
K10	1.1	21 August 2017
NSSR-VF	1.0	01 February 2023
PANSS	1.1	26 May 2016
PCL-5	1.1	29 November 2022
PDQ-D	1.1	18 January 2018
RSES	1.0	01 February 2023
SCID5 Overview	1.2	29 January 2018
Strengths Use Scale	1.0	01 February 2023
VIA-72	1.0	26 July 2022
WHODAS 2.0	1.0	15 January 2018
WHOQOL-BREF	1.1	17 January 2017

Governance Authorisation:

Governance Authorisation is required at each site participating in the study before the research project can commence at that site.

You are required to provide a copy of this HREC approval letter to the principal investigator for each site covered by this ethics approval for inclusion in the site specific assessment application.

Conditions of Ethics Approval:

- You are required to submit to the HREC:
    - An Annual Progress Report (that covers all sites listed on approval) for the duration of the project. This report is due by 31 March each year. Continuation of ethics approval is contingent on submission of an annual report being submitted by 31 March each year. Failure to comply with this requirement may result in suspension/withdrawal of the project by the HREC.
    - A comprehensive Final Report upon completion of the project.
- Submit to the reviewing HREC for approval any proposed amendments to the project including any proposed changes to the Protocol, Participant Information and Consent Form/s and the Investigator Brochure.
- Notify the reviewing HREC of any adverse events that have a material impact on the conduct of the research in accordance with the NHMRC's Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods (2016) guideline.
- Notify the reviewing HREC of your inability to continue as Coordinating Principal Investigator.
- Notify the reviewing HREC of the failure to commence the study within 12 months of the HREC approval date or if a decision is taken to end the study at any of the sites prior to the expected date of completion.
- Notify the reviewing HREC of any matters which may impact the conduct of the project.
- If your project involves radiation, you are legally obliged to conduct your research in accordance with the Australian Radiation Protection and Nuclear Safety Agency Code of Practice 'Exposure of Humans to Ionizing Radiation for Research Purposes' Radiation Protection series Publication No.8 (May 2005)(ARPANSA Code).

Please note: Template forms for reporting Amendments, safety reporting, Annual/Final reports, etc. can be accessed from: https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/monitoring-reporting

NSW sites:

If your trial includes participants in NSW who may be incapable of providing valid consent to participate for themselves, the HREC suggest that you make yourself aware of the provisions of the *Medical Treatment Planning and Decisions Act 2016.* Prior to commencing your trial in NSW, you may need to make an application to the NSW Civil and Administrative Tribunal (NCAT) for approval for your trial to proceed as well as to provide direction on the appropriate consent mechanism. Please note that the Act contains serious penalties for conducting clinical trial research on non-competent participants without proper authorisation.

The HREC may conduct an audit of the project at any time.

Yours sincerely,

Prof Peter Colman
Chair – Royal Melbourne Hospital Human Research Ethics Committee (HREC)