ADDRESS FOR ALL CORRESPONDENCE
RESEARCH ETHICS AND GOVERNANCE OFFICE
ROYAL PRINCE ALFRED HOSPITAL

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EMAIL: SLHD-RPAEthics@health.nsw.gov.au
REFERENCE: X22-0042 & 2022/ETH0072

NSW GOVERNMENT Health
Sydney Local Health District

12 May 2022

This letter constitutes ethical approval only. You must NOT commence this research project at ANY site until you have submitted a Site Specific Assessment Form to the Research Governance Officer and received separate authorisation from the Chief Executive or delegate of that site.

Dear Professor Hickie,

Re: Protocol no. X22-0042 & 2022/ETH0072 - "A large-scale clinical effectiveness (health services) trial to determine whether personal-ised health care packages, combined with digitally-supported measurement-based care, improve functional outcomes in young people with mood disorders"

The Executive of the Ethics Review Committee, at its meeting of 12 May 2022 considered your correspondence of 26 April 2022. In accordance with the decision made by the Ethics Review Committee, at its meeting of 9 March 2022, ethical approval is granted.

I am pleased to advise that final ethical approval has been granted on the basis of the following:

- The research project meets the requirements of the *National Statement on Ethical Conduct in Human Research*.

This approval includes the following:

- HREA (Version number 1, dated 20 April 2022)
- Protocol (Version 6, 26 April 2022)
- Participant Information Sheet/Consent Form – Adult (Version 3.0, 26/04/2022)
- Participant Information Sheet/Consent Form – Parent/Guardian (Version 3.0, 26/04/2022)
- Conflict Management Plan
- Research Data Management Plan (V1, 26 April 2022)

- ASRM
- ASSIST alcohol
- ASSIST cannabis lite
- ASSIST tobacco lite
- AUDIT-C plus
- BMC sleep-wake cycle
- BMI and waist
- B-NSSI-AT adapted
- Demographics
- EDE adapted
- IPAQ
- K10 plus
- Work and Education
- OASIS
- PQ-16
- PTSD5
- QIDS
- Schusters SSS
- SIDAS and C-SSRS
- WSAS
- C-SSRS
- PSP
- QIDS-A17-C
- SOFAS

You are asked to note the following:

The Committee noted that authorisation will be sought to conduct the study at the following sites:

- Brain and Mind Centre, The University of Sydney, NSW
- Mind Plasticity, Sydney, NSW

- It is a requirement of ethics approval that, before its commencement, this clinical trial is registered on a publicly accessible register, such as the Australian New Zealand Clinical Trials Registry or another appropriate international register. The Committee therefore sought details of the Register in which the study has been included and its registration number.

- This approval is valid for **five years**, and the Committee requires that you furnish it with annual reports on the study's progress beginning in **May 2023.** This will be through the submission of a milestone in REGIS.

- This human research ethics committee (HREC) has been accredited by the NSW Department of Health as a lead HREC under the model for single ethical and scientific review and is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*.

- **Partnering with Consumers:** As per Standard 2 of The National Clinical Trials Governance Framework, you are asked to provide an annual update with your annual progress report (milestone) on the ongoing involvement of consumers in the planning, design, delivery, measurement and evaluation of the trial.

- **Good Clinical Practice (GCP):** When adding additional sites, it is a condition of approval that the GCP Certificate of Completion be submitted for the principal investigator responsible for the new site.

- You must immediately report anything which might warrant review of ethical approval of the project in the specified format, including unforeseen events that might affect continued ethical acceptability of the project.

- You must notify the HREC of proposed changes to the research protocol or conduct of the research in the specified format.

- You must notify the HREC and other participating sites, giving reasons, if the project is discontinued at a site before the expected date of completion.

Should you have any queries about the Committee's consideration of your project, please contact me. The Committee's Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the Sydney Local Health District website.

<u>If you are not using REGIS, a copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.</u>

The Ethics Review Committee wishes you every success in your research.

Regards,

Sanaa Thomas
Executive Officer
Clinical Trials Sub-committee

For:

Rosemary Carney
Executive Officer
Ethics Review Committee (RPAH Zone)

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