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

TELEPHONE: (02) 9515 6766
EMAIL: SLHD-RPAEthics@health.nsw.gov.au
REFERENCE: X22-0146 & 2022/ETH00969

NSW GOVERNMENT Health Sydney Local Health District

7 July 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 Sanders,

Re: Protocol no. X22-0146 & 2022/ETH00969 - "Managing Delirium with Fluvoxamine Treatment for Non-Cardiac Surgery (MD FluNCS): A double-blind, placebo-controlled, randomised, controlled pilot study"

The Executive of the Ethics Review Committee, at its meeting of 7 July 2022 considered your correspondence of 21 June 2022. In accordance with the decision made by the Ethics Review Committee, at its meeting of 8 June 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 3, dated 21 June 2022)
- Protocol (Version 2, 21 June 2022)
- Consumer Medicine Information - APO-Fluvoxamine (updated January 2021)
- Patient Information Consent Form (Version 2, dated 21 June 2022)
- Master Code Sheet MD FluNCS (Version 1 dated 20.5.2022)
- Case Record Form (Version 1, dated 30.09.2021)
- Training Log (Version 1, 5 May 2021)
- Research Data Management Plan (28 June 2022)
- Delegation Log

- DRS Scoring Guidelines (updated 2022)
- Letter to GP

You are asked to note the following:

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

- Royal Prince Alfred Hospital

It is a condition of approval that the study sites listed in this approval letter, and any subsequent additional sites added in future through the amendment process, will be sponsored by their own local health district or institution and will take on all sponsor-related liabilities.

- **This study requires notification to the Therapeutic Goods Administration (TGA) under the Clinical Trials Notification (CTN) Scheme.**
- 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 **quarterly reports** on the study's progress beginning in **October 2022.** 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*.
- In accordance with the National Statement, Chapter 4.7, you are reminded that you must seek ethical approval from the HREC of the Aboriginal Health and Medical Research Council (AHMRC) if you intend to use Aboriginal or Torres Strait Islander status in any presentation or publication.
- **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.

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.

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)

HERC\EXCOR\22-06