



Queensland  
Government

Royal Brisbane & Women's Hospital  
Human Research Ethics Committee

Metro North  
Hospital and Health Service

Enquiries to: Ann-Maree Gordon  
Coordinator  
Telephone: 07 3647 1007  
File Ref: HREC/2021/QRBW/73854  
Email: [RBWH-Ethics@health.qld.gov.au](mailto:RBWH-Ethics@health.qld.gov.au)

Prof Dan Siskind  
Clinical Academic Psychiatrist  
Mobile Intensive Rehabilitation Team (MIRT)  
Metro South Hospital and Health Service  
228 Logan Road  
Woolloongabba Qld 4102

Dear Prof Siskind,

**Re: Ref N<sup>o</sup>: HREC/2021/QRBW/73854: Clozapine Obesity and Semaglutide Treatment (COaST). A randomised controlled multi-centre trial of semaglutide versus placebo for people with schizophrenia on clozapine with obesity inadequately responsive to metformin**

Thank you for submitting the above research project for single ethical review. This project was considered by the Royal Brisbane & Women's Hospital Human Research Ethics Committee (RBWH HREC) (**EC00172**) at its meeting held on 08 March 2021.

I am pleased to advise that this research project meets the requirements of the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007)* and that the RBWH Human Research Ethics Committee has granted ethical approval of this research project.

**This letter constitutes ethical approval only.** This project cannot proceed at any site until separate research governance authorisation has been obtained from the CEO or Delegate of the institution under whose auspices the research will be conducted at that site.

The approved documents include:

<i>Document</i>	<i>Version</i>	<i>Date</i>
CADENCE COaST Protocol	1.0	30 January 2021
Clinical Investigator's Brochure COaST	1.0	22 February 2021
Case Report Form	1.0	30 January 2021
Curriculum Vitae of Dan Siskind		
Response to request for further information		12 March 2021
HREA	Mar ver 2	12 March 2021

<i>Document</i>	<i>Version</i>	<i>Date</i>
Participant Information Sheet & Consent Form	1.1	12 March 2021
Response to request for further information		15 March 2021

Ongoing approval is for the duration of the project, conditional on:

1. In accordance with Section 5.5.6 (b) of the National Statement, the Principal Investigator will report to the HREC annually (**Due by 30 April each year**) in the specified format with a final report to be submitted on completion of the study.  
<https://www.health.qld.gov.au/metronorth/research/ethics-governance/post-approval-reporting/default.asp>
  2. The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project, in the specified format, including:
    - a. Unforeseen events that might affect continued ethical acceptability of the project.
    - b. Serious Adverse Events that materially impact on the continued ethical acceptability of the project.
  3. Amendments to the research project are to be submitted to the HREC for review. Amendments should be reflected in a cover letter from the Principal Investigator, providing a description of the changes, the rationale for the changes, and their implications for the ongoing conduct of the study. Further advice on submitting amendments is available from:  
<https://metronorth.health.qld.gov.au/research/ethics-and-governance/post-approval-reporting>
  4. The Principal Investigator will notify the HREC if the project is discontinued at the participating site(s) with reasons provided.
  5. If additional sites are engaged prior to the commencement of, or during the research project, the Principal Investigator is required to notify the HREC. Notification of the withdrawn sites should also be provided to the HREC in a timely fashion accompanying a close out report for that site.
- **Please advise the HREC of the date you commence the research project for the approved site(s) using the Notification of Commencement Form:**  
<https://www.health.qld.gov.au/metronorth/research/ethics-governance/post-approval-reporting/default.asp>
  - The HREC's Terms of Reference, Standard Operating Procedures, membership and standard forms are available from:  
<https://www.health.qld.gov.au/metronorth/research/ethics-governance/hrec->

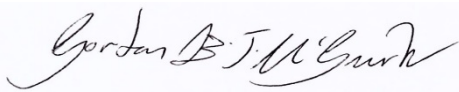
[approval/membership/default.asp](#).

**The nominated participating sites for this project are:**

- Metro North Mental Health
- Metro South Mental Health Services
- West Moreton Mental Health Services

The Royal Brisbane & Women's Hospital Human Research Ethics Committee wishes you every success in your research.

Yours sincerely,



Dr Gordon McGurk  
**Chairperson RBWH Human Research Ethics Committee**  
[Metro North Hospital and Health Service](#)  
17 March 2021

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007)*. The processes used by this HREC to review multi-centre research proposals have been certified by the National Health and Medical Research Council.