

Enquiries to: Metro North HREC
Telephone: 07 3646 5280
Email: MetroNorthResearch-Ethics@health.qld.gov.au
File Ref: ERM: 101033 Approval

Metro North Health

19 December 2023

Dr Nicolas Smoll
Sunshine Coast Hospital and Health Service
E: nicolas.smoll@health.qld.gov.au

Dear Dr Nicolas Smoll

Re: Project ID: 101033; HREC/2023/MNHB/101033; Rectal swabs vs Bulk Faeces Sampling

Thank you for submitting the above research project for ethical review. This project was considered by the Metro North Health Human Research Ethics Committee (HREC) B (EC00168) at its meeting held on 21 September 2023.

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 HREC granted final ethical approval of this research project.

Note: If additional sites are engaged prior to the commencement of, or during the research project, the Coordinating Principal Investigator is required to notify the HREC. Notification of withdrawn sites should also be provided to the HREC in a timely fashion.

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 reviewed and approved documents include:

Document	Version	Date
Form Reference: HREA	Aug ver 2	31 August 2023
Letter of Support	-	29 August 2023
Pathology Request Form	13101PU	-
Operational Process	1.1	7 September 2023
CV – Nicolas Smoll	-	-
Pathology Queensland – Request	V131018PU	-
Responses to further information requested - Form Reference: HREA	Oct ver 3	6 October 2023
Responses to further information requested - Form Reference: HREA	Nov ver 4	17 November 2023
Responses to further information requested - Form Reference: HREA	Dec ver 5	4 December 2023

Response letter	-	4 December 2023
Protocol	1.17	4 December 2023
Master Patient Information Sheet & Consent Form	1.06	4 December 2023

This information will be tabled for noting at the next HREC meeting to be held on 22 February 2024.

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 and a final report is to be submitted on completion of the study.
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:
www.health.qld.gov.au/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:**
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/hiiro/html/regu/regu_home

The nominated participating sites for this project are:

No.	Site
1.	Sunshine Coast Hospital and Health Service
2.	Forensic Scientific Services
3.	Central Queensland Hospital and Health Service
4.	Pathology Queensland

The Metro North Health HREC wishes you every success in your research.

Yours sincerely,

Dr Lynn Woodward
Chairperson, Metro North Health Human Research Ethics Committee B (EC00168)
Metro North Office of Research
Metro North Health

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 \(2007\)](#), NHMRC and Universities Australia [Australian Code for the Responsible Conduct of Research \(2007\)](#) and the CPMP/ICH Note for Guidance on Good Clinical Practice.