Enquiries to: Metro South Research Ethics
MSH-Ethics@health.qld.gov.au
Telephone: 07 3443 8047 or 07 3443 8049
Our Ref: 79000
Date: 23/11/2021

Queensland Government

Metro South Health

Research

Mr Nicholas Tutticci
Gastroenterology Department
QEII Jubilee Hospital

Dear Mr Tutticii,

HREC Reference number: HREC/2021/QMS/79000
Project Title: Assessing the safety of routine snare tip soft coagulation (STSC) in patients undergoing cold endoscopic mucosal resection for large polyps during colonoscopy

Thank you for submitting the above research protocol to the Metro South Human Research Ethics Committee for ethical and scientific review. This protocol was first considered by the Human Research Ethics Committee (HREC) at the meeting held on 5th October 2021.

I am pleased to advise you that the research protocol meets the requirements of the *National Statement on Ethical Conduct in Human Research (2007, updated 2018)* and ethical clearance has been granted. This HREC clearance is valid from 23rd November 2021.

You are reminded that this letter constitutes ethical approval only. You must not commence this research protocol at a site until separate authorisation from the Hospital Health Service Chief Executive (CE) or Delegate of that site has been obtained.

A copy of this approval must be submitted to the Research Governance Office(r)/Delegate of the relevant institution with a completed Site Specific Assessment (SSA) Form for authorisation from the CE or Delegate to conduct this research at the sites listed in the Appendix.

If this study currently receives grant funding, please remember to forward a copy of this approval letter to the relevant Grants Office of the Administering Institution(s) for the grant.

The documents reviewed and approved include:

ERM Document Name	Version	Date
HREA Form submitted via Ethical Review Manager (ERM)	Nov ver 2	
CV_Tutticci 18 AUG 2021	1.0	18/08/2021
Study Protocol - STSC	2.0	26/10/2021
Consent form - STSC	2.0	26/10/2021
XB_CV_QHealth	1.0	01/09/2021
qeii-colonoscopy-30-day-survey	1.0	26/10/2021
STSC_CoverLetter_01	1.0	03/11/2021

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

1. In accordance with Section 5.5.6 (b) of the National Statement, to maintain ongoing ethical clearance for the duration of the project 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.

   The Annual Safety Report is due alongside the Annual Progress Report by 30 April each year.

2. The Principal Investigator will immediately report anything which might warrant review of ethical approval of the protocol in the specified format, including unforeseen events that might affect continued ethical acceptability of the protocol as per the National Health and Medical Research Council's (NHMRC) guidance on *Safety Monitoring and Reporting in Clinical Trials involving Therapeutic Goods (2016)* and its supplementary documents.
3. Amendments to the research protocol which may affect the ongoing ethical acceptability of a protocol must be submitted to the HREC for review electronically via Ethical Review Manager (ERM). Major amendments should be reflected in revised study documentation and a cover letter from the principal investigator, providing a brief description of the changes, the rationale for the changes, and their implications for the ongoing conduct of the study.
4. Amendments to the research protocol which only affect the ongoing site acceptability of the protocol are not required to be submitted to the HREC for review. These amendment requests should be submitted directly to the Research Governance Office/r.
5. Proposed amendments to the research protocol which may affect both the ethical acceptability and site suitability of the protocol must be submitted firstly to the HREC for review and, once HREC approval has been granted, then submitted to the Research Governance Office/r.
6. Amendments which do not affect either the ethical acceptability or site acceptability of the protocol (e.g. typographical errors) do not need to be submitted to the HREC. Rather the Principal Investigator or Study Co-ordinator should maintain a study log of any such changes made to study documentation.
7. The HREC will be notified, giving reasons, if the protocol is discontinued at a site before the expected date of completion.
8. Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes (WHO / ICMJE 2008 definition) should be registered, including early phase and late phase clinical trials (phases I-III) in patients or healthy volunteers (WHO Recommendation / ICMJE policy). If in doubt, registration is recommended. All studies must be registered prior to the study's inception, i.e. prospectively. http://www.anzctr.org.au/

Please note: The Metro South 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, updated 2018), NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2018)* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. The composition of the Metro South HREC is attached on the final page of this letter.

Should you have any queries about the HREC's consideration of your protocol please contact Ethics Secretariat on 07 3443 8049.

The Metro South HREC wishes you every success in your research.

Yours sincerely,

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Dr Mary Boyde
Chair

Metro South Hospital and Health Service
Human Research Ethics Committee (EC00167)
Metro South Research
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Appendix: List of Participating Sites

No.	Sites
1.	QEII Jubilee Hospital

TO WHOM IT MAY CONCERN

The following is the current composition of the Metro South Human Research Ethics Committee as at 4 May 2021. It is advised that the Committee abides by the guidelines of the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research (2007, updated 2018)*.

COMPOSITION OF METRO SOUTH HUMAN RESEARCH ETHICS COMMITTEE	MEMBER
Category A – Chairperson	Mary Boyde
Category B - Lay Female	Beverley Kurkowski
Category B - Lay Male	Callum Gordon
Category B – Lay Female	Judith Wardell
Category B - Lay Male	David Milne
Category C - Knowledge of Professional Care	Kelly Perkins
Category C - Knowledge of Professional Care	Jenny Jones
Category C – Knowledge of Professional Care	Bena Brown
Category C – Knowledge of Professional Care	Megan McKerrow
Category C – Knowledge of Professional Care	Andrew Wheaton
Category C – Knowledge of Professional Care	Melissa Arneil
Category C – Knowledge of Professional Care	Vera Meeusen
Category D – Pastoral Care Role in Community	Cindy Sinclair
Category D – Pastoral Care Role in Community	David McEwan
Category D – Pastoral Care Role in Community	Trevor Jordan
Category E – Lawyer	John Bennett
Category E – Lawyer	Susan Gardiner
Category F - Knowledge of Research	Adam La Caze
Category F - Knowledge of Research	Marianne Wyder
Category F – Knowledge of Research	Theo Theodoros
Category F - Knowledge of Research	Ayesha Shah
Category F – Knowledge of Research	Nicole Warrington
Category F – Knowledge of Research	Aideen McInerney-Leo
Category F – Knowledge of Research	Dariusz Korczyk
Category F – Knowledge of Research	Rahul Ladwa
Category F – Knowledge of Research	Victoria Atkinson
Category F – Knowledge of Research	Tatiane Yanes
Category F – Knowledge of Research	Shivanand Hebbandi
Category F – Knowledge of Research	Rachel Phillips

Should you require further information, please do not hesitate to contact our office on the telephone number listed above. Attendance at the Committee meeting was in accordance with Guidance of the National Statement 5.2.30.