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Our Ref: HREC/2023/QTDD/101376



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10 October 2023

Professor Gillian Gould
Southern Cross University
Coffs Harbour NSW 2450
c/o Nicole Ryan

Dear Professor Gould,

HREC Reference number: HREC/2023/QTDD/101376

Project title: iSISTAQUIT (implementing Supporting Indigenous Smokers To Assist Quitting) scale-up in Indigenous populations of Australia

Thank you for submitting the above project for ethical and scientific review, which has been undertaken by the Darling Downs Health Human Research Ethics Committee (HREC).

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, 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*.

I am pleased to advise that the Human Research Ethics Committee has granted approval of this greater than low risk research project at the following site/s:

- Australia wide recruitment, including Hospital and Health Services and General Practitioners.

Please note: This letter constitutes ethical approval only. A copy of this approval must be submitted to the HHS Research Ethics and Governance Officer (REGO) along with a completed Site-Specific Assessment (SSA) Application and applicable documents for authorisation from the CE or delegate to conduct this research within the HHS.

The documents reviewed and approved include:

Document	Version	Date
Ethics submission		30 August 2023
Cover letter		28 August 2023
iSQ scale-up Protocol (clean)	1.1	30 January 2023
iSQ scale-up Delphi interview guide	1	26 September 2022



National Safety
and Quality Health
Service Standards
Second Edition
QUALITY CERTIFIED
ORGANISATION

iSQ scale-up Stage 1 interview guide survey	1	26 September 2022
iSQ scale-up HP baseline survey	1	30 January 2023
iSQ scale-up HP immediate post training survey	1	30 January 2023
iSQ scale-up 6 and 12 month post training survey	1	30 January 2023
iSQ scale-up stage 1 consent form	1	26 September 2022
iSQ scale-up stage 1 PIS	1	26 September 2022
iSQ scale-up Delphi consent form	1	26 September 2022
iSQ scale-up Delphi PIS	1	26 September 2022
iSQ scale-up HP consent form	1	26 September 2022
iSQ scale-up HP PIS	1	26 September 2022
iSQ scale-up organisational consent form	1	26 September 2022
iSQ scale-up organisational PIS	1	26 September 2022
iSQ scale-up stage 6 qual interviews focus groups consent form	1	26 September 2022
iSQ scale-up stage 6 PIS	1	26 September 2022
CPD Accredited Activity Evaluation Form eLearning	1	18 January 2023
Response to HREC	1	30 January 2023
TOR iSISTAQUIT National Aboriginal Advisory	1	27 January 2023
Support Letter Aboriginal advisory committee	1	26 September 2022
Minimisation of Duplication Approval Notification	1	30 April 2023
Submittable Approval	1	7 March 2023
List of submittable files	1	30 January 2023
CVs – M Tane, M Kennedy, G Gould, J Boyle, K Briscoe, M Jones, A Baker, B Oldenburg, Prof Doran, F McMillan, T Calma, C Oldmeadow, M Clarke, R Kumar.		

Please note the following conditions of approval:

1. The Principal Investigator (PI) 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. Serious Adverse Events must be notified to the Committee as soon as possible. In addition, the PI must provide a summary of the adverse events, in the specified format, including a comment as to suspected causality and whether changes are required to the Patient Information and Consent Form. In the case of Serious Adverse Events occurring at the local site, a full report is required from the PI, including duration of treatment and outcome of event.
2. Amendments to the research project which may affect the ongoing ethical acceptability of a project must be submitted via Ethical Review Manager (ERM) to the HREC for review.
3. Amendments to the research project which only affect the ongoing site acceptability of the project are not required to be submitted to the HREC for review. These amendment requests should be submitted directly to the REGO via ERM (by-passing the HREC).
4. Proposed amendments to the research project which may affect both the ethical acceptability and site suitability of the project must be submitted firstly to HREC for review and, once HREC approval has been granted, then submitted to the REGO.

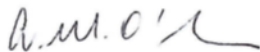
5. Amendments which do not affect either the ethical acceptability or site acceptability of the project (e.g., typographical errors) should be submitted via ERM to the HREC Coordinator. These should include a cover letter from the PI providing a brief description and rationale for the changes and accompanied by all relevant updated documents with tracked changes.
6. The HREC will be notified, giving reasons, if the project is discontinued at a site before the expected date of completion.
7. The PI will provide an annual report to the HREC by 30th April each year and a final report at completion of the study in the specified format.
8. The District administration and the HREC may inquire into the conduct of any research or purported research, whether approved or not and regardless of the source of funding, being conducted on hospital premises or claiming any association with the Hospital; or which the Committee has approved if conducted outside Darling Downs Health.

HREC approval is valid for 3 years from the date of this letter.

Should you have any queries about the HREC's consideration of your project please contact the Chair of the Darling Downs Health Human Research Ethics Committee. Queensland Health HREC information is available from http://www.health.qld.gov.au/ohmr/html/regu/regu_home.asp.

The HREC wishes you every success in your research.

Yours sincerely



Angela O'Shea
Chair
Darling Downs Health
Human Research Ethics Committee

10/10/2023