

HREC/2024/QCH/101501 (Feb ver 6) - 1747
Application Approved
02.22 AD:df
Telephone: (07) 4226 5513
Email: FNQ_HREC@health.qld.gov.au



Queensland
Government
Far North Queensland
Human Research Ethics Committee

2 April 2024

Email: Gillian.Gould@scu.edu.au; isistaquit@scu.edu.au

Professor Gillian Gould
Faculty of Health
Southern Cross University
Coffs Harbour NSW 2450

Dear Professor Gould,

Review Reference: HREC/2024/QCH/101501 (Feb ver 6) - 1747

Project Title: iSISTAQUIT (Implementing Supporting Indigenous Smokers to Assist Quitting) scale-up in Indigenous populations of Australia.

Thank you for submitting the above research project for ethical and scientific review. This project was considered by the Far North Queensland Human Research Ethics Committee (FNQ HREC) (EC00157) as a new application on the 19 October 2023 and further reviewed by the Committee on 21 March 2024.

I am pleased to advise you that the above research project meets the requirements of the National Statement on Ethical Conduct in Human Research (2023) and **ethical approval for this research project has been granted** by FNQ HREC.

The nominated participating Queensland Health sites in this project are:

- Cairns and Hinterland Hospital and Health Service (CHHHS)
- Torres and Cape Hospital and Health Service (TCHHS)

Note: If additional sites are engaged or withdrawn prior to the commencement of, or during the research project, the Coordinating Principal Investigator is required to submit an amendment to the FNQ HREC.

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.

Please contact: CHHHS Research Governance Officer

A: William McCormack Place, Level 7, 5B Sheridan Street, Cairns
E: RGO_Cairns@health.qld.gov.au | T: (07) 4226 5512

TCHHS Research Governance Officer

A: William McCormack Place, Level 6, 5B Sheridan Street, Cairns
E: Torres-Cape-Research-Governance@health.qld.gov.au | T: (07) 4226 5966

The documents include:

<i>Ethically approved documents</i>	<i>Version</i>	<i>Date</i>
HREA	Feb ver 6	06 February 2024
Protocol (clean and tracked)	3.0	27 November 2023
Health Service Information Sheet (FNQ-HS-PIS) (clean and tracked)	3	21 November 2022
Health Professional Participant Information Sheet (iSQ scale-up health providers PIS) (clean and tracked)	3.0	29 November 2023
iSISTAQUIT Scale-Up Study Information Sheet for interested health services (clean and tracked)	2	12 December 2023



Participant Information Sheet (Stage 1 qualitative interviews/focus groups/survey) (clean and tracked)	3	27 November 2023
Participant Information Sheet (Stage 6 qualitative interviews/focus groups) (clean and tracked)	3	27 November 2023
Delphi Study Participant Information Sheet (clean and tracked)	2	12 December 2023
Master iSISTAQUIT Scale-up Organizational Information Sheet	1.0	26 September 2022
Consent Form - Health Service (iSISTAQUIT HS consent form) (clean and tracked)	3	21 November 2023
Participant Consent Form – Health Professional (iSISTAQUIT HP consent form) (clean and tracked)	3	21 November 2023
Participant Consent Form (Stage 1 qualitative interviews/focus groups/survey) (clean and tracked)	3	21 November 2023
Participant Consent Form (Stage 6 qualitative interviews/focus groups) (clean and tracked)	3	21 November 2023
iSISTAQUIT scale-up Delphi Study Consent Form	1.0	26 September 2022
iSISTAQUIT Scale-up Health Professional 1- month post training survey	1	28 August 2023
iSISTAQUIT Scale-up Health Professional 3-month post training survey	1	28 August 2023
iSISTAQUIT Scale-up Health Professional 6-month post training survey	1	28 August 2023
SISTAQUIT Scale-up baseline survey (clean and tracked)	2	28 August 2023
iSISTAQUIT Scale-up Health Professional immediate post training survey (clean and tracked)	2.0	28 August 2023
iSISTAQUIT scale-up Stage 1 interview guide/survey	1.0	26 September 2022
iSISTAQUIT scale-up Delphi Study interview guide	1.0	26 September 2022
iSISTAQUIT scale-up HP 6- & 12-months post-training survey	1.1	30 January 2023
iSQ Scale-up CPD Accredited Activity Evaluation form	1	30 January 2023
FNQ Flyer	1	14 December 2023
National Aboriginal and Torres Strait Islander iSISTAQUIT Scale-up Advisory Committee Terms of Reference (clean and tracked)	2	03 January 2024
Expression of Interest in the iSISTAQUIT Community Advisory Committee	1.0	11 September 2023
Documents noted	Version	Date
Cover letter	N/A	05 October 2023
Reply to HREC queries v2	N/A	06 February 2024
Reply to HREC queries v1	N/A	08 January 2024
National Association of Aboriginal and Torres Strait Islander Health Workers and Practitioners Ltd (NAATSIHWP) – Support Letter	N/A	23 November 2023
NSW Health Royal Prince Alfred Hospital, Women and Babies – Support Letter	N/A	04 December 2023
SA Health Southern Adelaide Local Health Network, Flinders Medical Centre (Women’s and Children Division) – Support Letter	N/A	29 January 2024
Darling Downs Health Human Research Ethics Committee –	N/A	10 October 2023



Approval Letter		
Western Australian Aboriginal Health Ethics Committee (WAAHEC) – Approval Letter	N/A	9 February 2024
Human Research Ethics Committee of NT Health and Menzies School of Health Research – Approval Letter	N/A	26 February 2024
Aboriginal Health Research Ethics Committee – Approval Letter	N/A	22 February 2024
Aboriginal Health & Medical Research Council (AH&MRC) Human Research Ethics Committee – Approval Letter	N/A	07 March 2023
Southern Cross University Human Research Ethics Committee (SCU HREC) Notification Minimisation of Duplication Application Approval	N/A	30 April 2023
Torres and Cape Hospital and Health (AHREC) Service – Email Support Evidence	N/A	31 January 2024
Flinders Medical Centre Expression of Interest	N/A	Undated
Northern Adelaide Local Health Network, Lyell McEwin Hospital Expression of Interest	N/A	Undated
CV – Mr Rod Reeve	N/A	Undated
CV – Professor Gillian Gould	N/A	Undated
CV – Professor Brian Oldenburg	N/A	Undated
CV – Professor Tom Calma	N/A	Undated
CV – Dr Michelle Kennedy (Bovill)	N/A	Undated
CV – Dr Marilyn Clarke	N/A	Undated
CV – Dr Ratika Kumar	N/A	Undated
CV – Professor Christopher M Doran	N/A	Undated
CV – A/Professor Christopher Oldmeadow	N/A	Undated
CV – A/Professor Faye McMillan	N/A	Undated
CV – Dr Moana Pera Tane	N/A	Undated
CV – Dr Nicole M Ryan	N/A	Undated
CV – Dr Mark Jones	N/A	Undated
CV – A/Professor Jacqueline Boyle	N/A	Undated
CV – Mr Karl Briscoe	N/A	Undated

Ethical approval of this project from the Far North Queensland Human Research Ethics Committee is valid from the 2 April 2024 to 2 April 2029 subject to the following conditions being met:

- In accordance with Section 5.4.8 of the National Statement, the Principal Investigator will submit a progress report annually by **30 April** and a final report on completion of the study in the specified format. Please contact the HREC Coordinator for post approval reporting advice.
- The Principal Investigator will immediately report anything that 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) Complaints made by study participants regarding the conduct of the project.

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- c) Serious Adverse Events, safety issues and safety measures that materially impact on the continued ethical acceptability of the project.

Please contact the HREC Coordinator for advice.

- The Principal Investigator will notify the FNQ HREC of any event that requires a modification to the protocol or other project documents or Investigator changes and submit any required amendments in accordance with the instructions provided by the HREC. Please contact the HREC Coordinator for amendment submission advice.
- The Principal Investigator will notify the FNQ HREC of his or her inability to continue as Principal Investigator including the name of and contact information for a replacement.
- A copy of this ethical approval letter together with completed Site-Specific Assessment (SSA) and any other requirements must be submitted by all site Principal Investigators to the Research Governance Office at each participating Queensland Health institution within 12 months of ethical approval being granted to obtain authorisation to commence the project at its site/s.

Should you have any queries about the FNQ HREC's consideration of your project please contact the HREC Coordinator on 07 4226 5513.

The FNQ HREC wishes you every success in your research.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'A. Diedricks'.

Dr Angelo Diedricks

Acting Chair, Far North Queensland Human Research Ethics Committee

Cairns and Hinterland and Torres and Cape Hospital and Health Services

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 (2023).