

26 February 2024

Professor Gillian Gould
Southern Cross University
gillian.gould@scu.edu.au
CC: Karen.McFadyen@scu.edu.au; isistaquit@scu.edu.au
Via Email

Dear Professor Gould,

NT HREC Reference Number: 2023-4701

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

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Thank you for letter dated 10/01/2024 and taking the time to respond to the issues of concern identified by the Human Research Ethics Committee of Northern Territory Health and Menzies School of Health Research (NT HREC) at its meeting held on the 29/11/2023.

This project was considered by the NT HREC including the Aboriginal Ethics Sub-Committee (AESC) and assessed against guidelines for human research including the NHMRC *National Statement on Ethical Conduct in Human Research 2007*.

I am pleased to advise that **full ethical approval** of this research project has been granted following assessment by representatives of both the AESC and the HREC. Please note that approval applies only to research conducted after the date of this letter and continued approval is dependent on annual reporting.

Approval Date: 26/02/2024

Approval is granted for the above research project until the next report due date.

Annual progress report due: 26/02/2025

Approved timeframe (subject to compliance and annual reporting): 26/02/2024 – 31/12/2027

The nominated sites/s participating in this project that have been approved by this HREC are:

- Department of Health Northern Territory Government
- Wurlu Wurlinjang Health Service
- *Other sites to be identified and an amendment sought from the HREC*

Please note:

- * Researchers must comply with site specific governance regulations, data custodian and other stakeholder requirements.
- * For site-specific authorisation for NT Health sites including access to NT Health data, please liaise with the NT Health Research Governance office, nthealth.rgo@nt.gov.au

The documents listed below are approved:

NT-HP-PIS-V3-iSQ-Scale-Up-29Nov23-clean.docx
NT-HP-PIS-V3-iSQ-Scale-Up-29Nov23-tracked
NT-HP-CF-V3-iSQ-Scale-Up-21Nov23-clean.doc
NT-HP-CF-V3-iSQ-Scale-Up-21Nov23-tracked.doc
NT-Stage 1-PIS-V3-iSQ-Scale-Up-27Nov23-clean.docx
NT-Stage 1-PIS-V3-iSQ-Scale-Up-27Nov23-tracked.docx
NT-Stage 1-CF-V3-iSQ-Scale-Up-21Nov23-clean.docx
NT-Stage 1-CF-V3-iSQ-Scale-Up-21Nov23-tracked.docx
NT-Stage 6-PIS-V3-iSQ-Scale-Up-27Nov23-clean.docx
NT-Stage 6-PIS-V3-iSQ-Scale-Up-27Nov23-tracked.docx

NT-Stage 6-CF-V3-iSQ-Scale-Up-21Nov23-clean.docx
NT-Stage 6-CF-V3-iSQ-Scale-Up-21Nov23-tracked.docx
Protocol-V3-iSQ Scale-Up-27Nov23-clean.docx
Protocol-V3-iSQ Scale-Up-27Nov23_tracked.docx
Info sheet-V2-iSQ-Scale-Up-14Dec23-clean.docx
Info sheet-V2-iSQ-Scale-Up-14Dec23-tracked.docx
Flyer-iSQ-Scale-up-Oct-2023.pdf
iSISTAQUIT scale-up protocol v3.0 Dated: 27/11/2023
Application Form 08/11/2023

APPROVAL IS SUBJECT TO the following conditions being met:

1. The Coordinating Principal Investigator will **immediately report anything that might warrant review** of ethical approval of the project.
2. The Coordinating Principal Investigator will notify the NT HREC of any event that requires a **modification or amendment to the protocol or other project documents** and submit any required amendments in accordance with the instructions provided by the NT HREC. These instructions can be found on the Menzies' website.
3. The Coordinating Principal Investigator will submit any necessary reports related to the **safety of research participants (e.g. protocol deviations, protocol violations)** in accordance with the NT HREC's policy and procedures. These guidelines can be found on the Menzies' website.
4. The Coordinating Principal Investigator will **report** to the NT HREC **annually** and notify the NT HREC when the project is completed at all sites using the specified forms. Forms and instructions may be found on the Menzies' website.
5. The Coordinating Principal Investigator will notify the NT HREC if the project is **discontinued at a participating site before the expected completion date** and provide the reason/s for discontinuance.
6. The Coordinating Principal Investigator will notify the NT HREC of any plan to **extend the duration of the project past the approval period listed above** and will submit any associated required documentation. The preferred time and method of requesting an extension of ethical approval is during the **annual progress report**. However, an extension may be requested at any time.
7. The Coordinating Principal Investigator will notify the NT HREC of his or her **inability to continue as Coordinating Principal Investigator**, including the name of and contact information for a replacement.
8. The safe and ethical conduct of this project is entirely the responsibility of the investigators and their institution(s).
9. Researchers should immediately report anything which might affect continuing ethical acceptance of the project, including:
 - Adverse effects of the project on participants and the steps taken to deal with these;
 - Other unforeseen events;
 - New information that may invalidate the ethical integrity of the study; and
 - Proposed changes in the project.
10. Approval for a further twelve months, within the original proposed timeframe, will be granted upon receipt of an annual progress report if the NT HREC is satisfied that the conduct of the project has been consistent with the approved protocol. Report templates are available on the Menzies ethics webpage.
11. Confidentiality of research participants should be maintained at all times as required by law.

12. The Patient Information Sheet and the Consent Form shall be printed on the relevant site letterhead with full contact details.
13. The Patient Information Sheet must provide a brief outline of the research activity including: risks and benefits, withdrawal options, contact details of the researchers and must also state that the Human Research Ethics Administrators can be contacted (telephone and email) for information concerning policies, rights of participants, concerns or complaints regarding the ethical conduct of the study.
14. You must forward a copy of this letter to all Investigators and to your institution (if applicable).

This letter constitutes ethical approval only.

This project, including amendments to the research protocol or conduct of the research which may affect the site acceptability of the 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, if not already obtained.

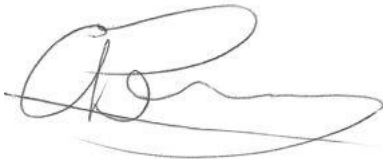
Any transfer of data is subject to institutional research governance arrangements for data ownership, data custodianship, and data transfer agreements.

Please forward this approval letter to the relevant research governance office.

Should you wish to discuss the above research project further, please contact the Ethics Administrators via email: NTHREC@menzies.edu.au

The Human Research Ethics Committee of Northern Territory Health and Menzies School of Health Research wishes you every continued success in your research.

Yours sincerely,



Mr Chris Perry
Acting Chair
Human Research Ethics Committee
of NT Health and Menzies School of Health Research
<http://www.menzies.edu.au/ethics>

NT HREC is registered and certified for multi-site review with the Australian National Health and Medical Research Council (NHMRC) and operates in accordance with the NHMRC *National Statement on Ethical Conduct in Human Research (2007)*. NHMRC Reg no. EC00153