



31/10/2024

Associate Professor Michelle Kennedy  
University of Newcastle

Dear Associate Professor Michelle Kennedy,

**RE: 2328/24: Which Way? Gulibaa Project.**

I am pleased to advise you that the above research project meets the requirements of the National Statement on Ethical Conduct in Human Research (2007 updated 2023) and ethical approval for this research project has been granted by AH&MRC Human Research Ethics Committee.

This approval is valid from 31/10/2024 until 31/10/2025, with ongoing approval subject to the receipt and approval of an annual report.

The documents listed below are approved:

CathChamberlain\_CV\_2pages.docx  
CV\_Amanual\_Getnet\_Mersha\_2023.docx  
CV\_Booth\_2page.docx  
CV\_Jessica\_Bennett.docx  
CV\_KRB\_2page.docx  
CV\_Zabowie\_Mills\_2\_page.docx  
Felicity\_Collis\_CV.docx  
Joley\_Foster\_CV\_2\_page.docx  
Maddox\_Academic\_CV\_Jan\_2022.docx  
Martiniuk\_Curriculum\_Vitae.docx  
Raymond\_Kelly\_CV.pdf  
Short\_Curriculum\_Vitae\_Dr\_Jamie\_Bryant\_Sep\_2023.docx  
Short\_CV\_Dr\_Michelle\_Kennedy\_1\_page.docx  
Sian\_Maidment\_CV\_2023.docx  
Tameka\_McFadyen\_CV\_2023.docx  
Tanika\_CV\_2\_page.pdf  
Doran\_2\_pager.doc  
Burchill\_CV\_2page.docx  
MaryBelfrageCV.docx  
AHMRC\_LoS.pdf  
HREA\_Gulibaa\_V1.rtf  
Protocol\_Gulibaa\_V1.docx  
Appendix\_1.A\_Information\_Sheet\_Services\_V1.docx  
Appendix\_2.C\_Information\_Sheet\_Governance\_Yarns\_V1.docx  
Appendix\_3.B\_Information\_Sheet\_Training\_V1.docx  
Appendix\_4.C\_Information\_Sheet\_Group\_Participants\_V1.docx  
Appendix\_4.J\_Information\_Sheet\_Post\_Program\_Yarns\_V1.docx



Appendix 1.A Information Sheet Services\_V1.docx  
Appendix 1.B Brochure Services\_V1.docx  
Appendix 1.C Text Templates Services\_V1.docx  
Appendix 1.D Site Implementation\_Log\_V1.docx  
Appendix 2.A Research Agreement Services\_V1.docx  
Appendix 2.B Consent Services\_V1.doc  
Appendix 2.C Information Sheet Governance Yarns\_V1.docx  
Appendix 2.D Yarning Guide Governance Yarns\_V1.docx  
Appendix 2.E Terms of Reference.docx  
Appendix 3.A Text Template Training\_V1.docx  
Appendix 3.B Information Sheet Training\_V1.docx  
Appendix 3.C Survey Training\_V1.docx  
Appendix 3.D Yarning Guide Training\_V1.docx  
Appendix 4.A Promotional Flyer Group Participants\_V1.docx  
Appendix 4.B Brochure Group Participants\_V1.pdf  
Appendix 4.C Information Sheet Group Participants\_V1.docx  
Appendix 4.D Text Template Group Participants\_V1.docx  
Appendix 4.E Survey Group Participants Baseline\_V1.docx  
Appendix 4.F Survey Group Participants 6-week\_V1.docx  
Appendix 4.G Survey Group Participants 3-month\_V1.docx  
Appendix 4.H Survey Group Participants 6-month\_V1.docx  
Appendix 4.I Facilitator\_Log\_V1.docx  
Appendix 4.J Information Sheet Post Program Yarns\_V1.docx  
Appendix 4.K Yarning Guide Post Program Yarns\_V1.docx  
Appendix 4.L Survey Service Maintenance\_V1.docx  
Appendix 4.M Grant Application\_Form.docx

The amended documents listed below that were submitted as a result of the AH&MRC HRECs request for further information are approved.

#### **0. Response Letter.docx**

Appendix 1.A Information Sheet Services\_V2.docx  
Appendix 1.A Information Sheet Services\_V2\_Tracked.docx  
Appendix 1.B Brochure Services\_V2.docx  
Appendix 1.B Brochure Services\_V2\_Tracked.docx  
Appendix 2.C Information Sheet Governance Yarns\_V2.docx  
Appendix 2.C Information Sheet Governance Yarns\_V2\_Tracked.docx  
Appendix 2.E Terms of Reference\_V2.docx  
Appendix 2.E Terms of Reference\_V2\_Tracked.docx  
Appendix 3.B Information Sheet Training\_V2.docx  
Appendix 3.B Information Sheet Training\_V2\_Tracked.docx  
Appendix 3.C Survey Training\_V2.docx  
Appendix 3.C Survey Training\_V2\_Tracked.docx  
Appendix 4.A Promotional Flyer Group Participants\_V2.docx  
Appendix 4.A Promotional Flyer Group Participants\_V2\_Tracked.docx  
Appendix 4.B Brochure Group Participants\_V2\_Tracked.pdf  
Appendix 4.C Information Sheet Group Participants\_V2.docx  
Appendix 4.C Information Sheet Group Participants\_V2\_Tracked.docx



**Appendix\_4.E\_Survey\_Group\_Participants\_Baseline\_V2.docx**  
**Appendix\_4.E\_Survey\_Group\_Participants\_Baseline\_V2\_Tracked.docx**  
**Appendix\_4.F\_Survey\_Group\_Participants\_6-week\_V2.docx**  
**Appendix\_4.F\_Survey\_Group\_Participants\_6-week\_V2\_Tracked.docx**  
**Appendix\_4.G\_Survey\_Group\_Participants\_3-month\_V2.docx**  
**Appendix\_4.G\_Survey\_Group\_Participants\_3-month\_V2\_Tracked.docx**  
**Appendix\_4.H\_Survey\_Group\_Participants\_6-month\_V2.docx**  
**Appendix\_4.H\_Survey\_Group\_Participants\_6-month\_V2\_Tracked.docx**  
**Appendix\_4.J\_Information\_Sheet\_Post\_Program\_Yarns\_V2.docx**  
**Appendix\_4.J\_Information\_Sheet\_Post\_Program\_Yarns\_V2\_Tracked.docx**  
**Distress\_Protocol\_V1.docx**  
**Nathan\_Taylor\_CV\_2024.pdf**  
**Protocol\_Gulibaa\_V2.docx**  
**Protocol\_Gulibaa\_V2\_Tracked.docx**

[Note: The amended documents supersede the original document version].

Approval of this project from the AH&MRC HREC is subject to the following conditions being met:

- The Coordinating Principal Investigator will immediately report anything that might warrant a review of the ethical approval of the project.
- The Coordinating Principal Investigator will notify the AH&MRC Ethics Committee of any event that requires a modification to the protocol or other project documents and submit any required amendments in accordance with the instructions provided by the HREC. These instructions can be found at [www.ahmrc.org.au/ethics](http://www.ahmrc.org.au/ethics).
- The Coordinating Principal Investigator will submit any necessary reports related to the safety of research participants in accordance with the AH&MRC Ethics Committee policy and procedures. These instructions can be found at [www.ahmrc.org.au/ethics](http://www.ahmrc.org.au/ethics).
- The Coordinating Principal Investigator will report to the AH&MRC Ethics Committee annually in the specified format and notify the HREC when the project is completed at all sites.
- The Coordinating Principal Investigator will notify the AH&MRC Ethics Committee if the project is discontinued at a participating site before the expected completion date, with reasons provided.
- The Coordinating Principal Investigator will notify the AH&MRC Ethics Committee of any plan to extend the duration of the project past the approval period listed above and will submit any associated required documentation. Instructions for obtaining an extension of approval can be found at [www.ahmrc.org.au/ethics](http://www.ahmrc.org.au/ethics).
- The Coordinating Principal Investigator will notify the AH&MRC Ethics Committee of his or her inability to continue as Coordinating Principal Investigator including the name of and contact information for a replacement.



**AH&MRC**  
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Supported by the NSW Ministry of Health

ABN 66 085 654 397

- The Coordinating Principal Investigator will submit the final draft report from the research, and any publication or presentation where data or findings are presented, to the AH&MRC Ethics Committee to be reviewed for compliance with ethical and cultural criteria prior to:
- Any submission for publication; and/or
- Any dissemination of the report

Should you have any queries about the AH&MRC HREC's consideration of your project please login to Submittable, contact [ethics@ahmrc.org.au](mailto:ethics@ahmrc.org.au) or phone (02) 9212 4777.

Yours faithfully,

Associate Professor Michael Doyle  
**Co-Chair**  
AH&MRC Ethics Committee

# Human Research Ethics Application

## Application Management Information

**Application ID:** MK03533

**Created date:** 12/09/2024

**Originating Application ID:**

*\*This is the earliest application from which this application (MK03533) was copied.*

**Parent Application ID:**

*\*This is the immediate predecessor from which this application (MK03533) was copied.*

**Version Number:** 1

**Application submitted to:** Aboriginal Health & Medical Council of NSW; Aboriginal Health & Medical Research Council Ethics Committee.

The applicant has requested that this ethics application be considered under the Greater than low risk review pathway.

## Section 1 – Core Information

### Pre-application conditions

The applicant/s have acknowledged that:

1. The HREA has been designed for ethics review of human research, as defined in the [National Statement](#).
2. Adequate resources must be available to conduct this research project.
3. All relevant institutional policies pertaining to the conduct of this research project should be considered and adhered to.
4. Research activities must not commence until ethics approval (and site authorisation, if appropriate) has been provided.

### Project Overview

**Q1.1 Project Title:**

Gulibaa Project- Implementing and evaluating a state-wide, co-designed model of care to support Aboriginal and Torres Strait Islander women to be smoke and vape free

**Q1.2 Summary of the research project:**

The Gulibaa project is an Indigenous-led and community embedded project to co-design, implement and evaluate a model of care to support Aboriginal and Torres Strait Islander women to be smoke and vape-free. The aim of the Gulibaa project is to reduce the prevalence of smoking among Aboriginal and Torres Strait Islander women by developing and implementing group-based smoking cessation care within Aboriginal Community Controlled and Non-Government Health Services.

**Q1.3 Which category/ies of research best describes the project?**

Health Services Research

**Q1.4 In what environments will the research be conducted?**

Aboriginal Community Controlled Health Services and non-Government Health Services

**Q1.5 What organisation/entity has overall responsibility for this project?**

The University of Newcastle

**Application ID:** MK03533

**Created date:** 12/09/2024

**Q1.6 Describe how this research project is currently, or will be, funded.**

This project is funded by an MRFF Maternal and Health Lifestyles Grant.

**Q1.7 Anticipated starting date of the research project:**

As soon as ethics and any other relevant approvals have been provided.

**Q1.8 Anticipated duration of the research project:**

3 Years

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## **Project Team**

**Name:** A/Prof Michelle Kennedy

**Q1.9.4 Email Address:**

michelle.kennedy11@newcastle.edu.au

**Q1.9.5 Is this person the contact person for this application?**

Yes

<b>Q1.9.5.1 Email Address:</b>	michelle.kennedy11@newcastle.edu.au
<b>Q1.9.5.2 Telephone Number:</b>	0413950744
<b>Q1.9.5.3 Mailing Address</b>	University of Newcastle, IDC Building, University Drive, Callaghan NSW 2308

**Q1.9.6 Is this person a student on this project?**

No

**Q1.9.7 Institutional affiliation and position:**

The University of Newcastle, Research Fellow

**Q1.9.8 Staff ID (optional):**

**Q1.9.9 ORCID Identifier (optional):**

**Q1.9.10 Position on the research project:**

Chief Investigator/Researcher

**Q1.9.11 Does this person have authorisation to sign the application on behalf of all members of the research team?**

Yes

**Q1.9.12 Research activities A/Prof Michelle Kennedy will be responsible for:**

Project lead. All aspects of the research, community governance, reporting and knowledge translation.

**Q1.9.13 Expertise relevant to the research activity:**

A/Prof Kennedy has extensive experience developing and implementing community-led research. Further details on Kennedy's expertise can be found in the attached CV.

**Name:** A/Prof Raglan Maddox

**Q1.9.4 Email Address:**

Raglan.Maddox@anu.edu.au

**Q1.9.5 Is this person the contact person for this application?**

No

**Q1.9.6 Is this person a student on this project?**

No

**Q1.9.7 Institutional affiliation and position:**

Australian National University, Research Fellow

**Q1.9.8 Staff ID (optional):**

**Q1.9.9 ORCID Identifier (optional):**

**Q1.9.10 Position on the research project:**

Investigator/Researcher

**Q1.9.11 Does this person have authorisation to sign the application on behalf of all members of the research team?**

No

**Q1.9.12 Research activities A/Prof Raglan Maddox will be responsible for:**

Co-lead data sovereignty and governance, data analysis and reporting. Research investigator: Oversee and contribute to research implementation, data collection, analysis, and reporting.

**Q1.9.13 Expertise relevant to the research activity:**

A/Prof Maddox has extensive experience in leading Aboriginal Health Research, further details of Maddox's expertise can be found in the attached CV.

**Name: Prof Alexandra Martiniuk**

**Q1.9.4 Email Address:**

alexandra.martiniuk@sydney.edu.au

**Q1.9.5 Is this person the contact person for this application?**

No

**Q1.9.6 Is this person a student on this project?**

No

**Q1.9.7 Institutional affiliation and position:**

University of Sydney, Professor

**Q1.9.8 Staff ID (optional):**

**Q1.9.9 ORCID Identifier (optional):**

**Q1.9.10 Position on the research project:**

Investigator/Researcher

**Q1.9.11 Does this person have authorisation to sign the application on behalf of all members of the research team?**

No

**Q1.9.12 Research activities Prof Alexandra Martiniuk will be responsible for:**

Research investigator: Oversee and contribute to research implementation, data collection, analysis, and reporting.

**Q1.9.13 Expertise relevant to the research activity:**

Prof Martiniuk has extensive experience in leading Aboriginal Health Research, further details of Martiniuk's expertise can be found in the attached CV.

**Name: Prof Catherine Chamberlain**

**Q1.9.4 Email Address:**

cacham@unimelb.edu.au

**Q1.9.5 Is this person the contact person for this application?**

No

**Q1.9.6 Is this person a student on this project?**

No

**Q1.9.7 Institutional affiliation and position:**

University of Melbourne, Head, Indigenous Health Equity Unit /NHMRC Leadership Fellow

**Q1.9.8 Staff ID (optional):**

**Q1.9.9 ORCID Identifier (optional):**

**Q1.9.10 Position on the research project:**

Investigator/Researcher

**Q1.9.11 Does this person have authorisation to sign the application on behalf of all members of the research team?**

No

**Q1.9.12 Research activities Prof Catherine Chamberlain will be responsible for:**

Research investigator: Oversee and contribute to research implementation, data collection, analysis, and reporting.

**Q1.9.13 Expertise relevant to the research activity:**

Prof Chamberlain has extensive experience in leading Aboriginal Health Research, further details of Chamberlain's expertise can be found in the attached CV.

**Name: Dr Jamie Bryant**

**Q1.9.4 Email Address:**

jamie.bryant@newcastle.edu.au

**Q1.9.5 Is this person the contact person for this application?**

No

**Q1.9.6 Is this person a student on this project?**

No

**Q1.9.7 Institutional affiliation and position:**

The University of Newcastle, Senior Fellow

**Q1.9.8 Staff ID (optional):**

**Q1.9.9 ORCID Identifier (optional):**

**Q1.9.10 Position on the research project:**

Investigator/Researcher

**Q1.9.11 Does this person have authorisation to sign the application on behalf of all members of the research team?**

No

**Q1.9.12 Research activities Dr Jamie Bryant will be responsible for:**

Research investigator: Oversee and contribute to research implementation, data collection, analysis, and reporting.

**Q1.9.13 Expertise relevant to the research activity:**

Dr Bryant has extensive experience in leading Aboriginal Health Research, further details of Bryant's expertise can be found in the attached CV.

**Name: Prof Sandra Eades**

**Q1.9.4 Email Address:**

sandra.eades@unimelb.edu.au

**Q1.9.5 Is this person the contact person for this application?**

No

**Q1.9.6 Is this person a student on this project?**

No

**Q1.9.7 Institutional affiliation and position:**

University of Melbourne, Professor

**Q1.9.8 Staff ID (optional):**

**Q1.9.9 ORCID Identifier (optional):**

**Application ID:** MK03533

**Created date:** 12/09/2024

**Q1.9.10 Position on the research project:**

Investigator/Researcher

**Q1.9.11 Does this person have authorisation to sign the application on behalf of all members of the research team?**

No

**Q1.9.12 Research activities Prof Sandra Eades will be responsible for:**

Research investigator: Oversee and contribute to research implementation, data collection, analysis, and reporting.

**Q1.9.13 Expertise relevant to the research activity:**

Prof Eades has extensive experience in leading Aboriginal Health Research, further details of Eades' expertise can be found in the attached CV.

**Name: A/Prof Luke Burchill**

**Q1.9.4 Email Address:**

Burchill.Luke@mayo.edu

**Q1.9.5 Is this person the contact person for this application?**

No

**Q1.9.6 Is this person a student on this project?**

No

**Q1.9.7 Institutional affiliation and position:**

University of Melbourne, Research Fellow/ Mayo Clinic Cardiologist

**Q1.9.8 Staff ID (optional):**

**Q1.9.9 ORCID Identifier (optional):**

**Q1.9.10 Position on the research project:**

Investigator/Researcher

**Q1.9.11 Does this person have authorisation to sign the application on behalf of all members of the research team?**

No

**Q1.9.12 Research activities A/Prof Luke Burchill will be responsible for:**

Research investigator: Oversee and contribute to research implementation, data collection, analysis, and reporting.

**Q1.9.13 Expertise relevant to the research activity:**

A/Prof Burchill has extensive experience in Aboriginal Health Research and is a practicing Cardiologist. Further details can be found in the attached CV.

**Name:** Dr Mary Belfrage

**Q1.9.4 Email Address:**

Mary.Belfrage@racgp.org.au

**Q1.9.5 Is this person the contact person for this application?**

No

**Q1.9.6 Is this person a student on this project?**

No

**Q1.9.7 Institutional affiliation and position:**

Clinical Lead, RACGP NACCHO Partnership Project/ RACGP Aboriginal & Torres Strait Islander Health

**Q1.9.8 Staff ID (optional):**

**Q1.9.9 ORCID Identifier (optional):**

**Q1.9.10 Position on the research project:**

Investigator/Researcher

**Q1.9.11 Does this person have authorisation to sign the application on behalf of all members of the research team?**

No

**Q1.9.12 Research activities Dr Mary Belfrage will be responsible for:**

Research investigator: Oversee and contribute to research implementation, data collection, analysis, and reporting.

**Q1.9.13 Expertise relevant to the research activity:**

Dr Belfrage as extensive experience in Aboriginal health research and clinical guideline development. Further details are provided in the attached CV.

**Name:** Mrs Jessica Bennett

**Q1.9.4 Email Address:**

jessica.bennett@newcastle.edu.au

**Q1.9.5 Is this person the contact person for this application?**

No

**Q1.9.6 Is this person a student on this project?**

No

**Q1.9.7 Institutional affiliation and position:**

The University of Newcastle, PhD Candidate

**Application ID:** MK03533

**Created date:** 12/09/2024

**Q1.9.8 Staff ID (optional):**

**Q1.9.9 ORCID Identifier (optional):**

**Q1.9.10 Position on the research project:**

**Q1.9.11 Does this person have authorisation to sign the application on behalf of all members of the research team?**

**Q1.9.12 Research activities Mrs Jessica Bennett will be responsible for:**

**Q1.9.13 Expertise relevant to the research activity:**

**Name: Dr Tameka McFadyen**

**Q1.9.4 Email Address:**

**Q1.9.5 Is this person the contact person for this application?**

**Q1.9.6 Is this person a student on this project?**

**Q1.9.7 Institutional affiliation and position:**

**Q1.9.8 Staff ID (optional):**

**Q1.9.9 ORCID Identifier (optional):**

**Q1.9.10 Position on the research project:**

**Q1.9.11 Does this person have authorisation to sign the application on behalf of all members of the research team?**

**Q1.9.12 Research activities Dr Tameka McFadyen will be responsible for:**

Research investigator- Oversee and contribute to research implementation, data collection, analysis, and reporting.

**Q1.9.13 Expertise relevant to the research activity:**

Dr McFadyen has extensive experience in leading Aboriginal Health Research, further details of McFadyen's expertise can be found in the attached CV.

**Disclosure of interests**

**Q1.10 Do any members of the research team (including persons not listed in this application), have any financial or non-financial interests related to this research?**

No

**Restrictions**

**Q1.11 Are there any restrictions or limits on publication of data or dissemination of research outcomes of this project?**

No

**Evaluations**

**Q1.12 Has the scientific or academic merit of the research project been evaluated?**

Yes

**Q1.12.1 What was the review process and what was the outcome?**

The scientific merit of this research was firstly conducted by the Aboriginal Community Panel at the University of Newcastle. Once this review and approval was granted the research was submitted to the MRFF Maternal and Healthy Lifestyles Grant round receiving external peer review and assessment by experts in the field.

**Q 1.12.2 Attach evidence of the outcome of the scientific or academic review process.**  
*(optional)*

**Q1.13 Has this research project had prior ethics review?**

No

**Q1.14 Will any further or additional specialised review of this application be sought?**

Yes

<b>Q1.14.1 Name of entity conducting specialist review</b>	<b>Q1.14.2 When review will be sought</b>
AH&MRC Ethics Committee	September 2024

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## **Setting of research**

**Q1.15 Will this project be conducted at multiple sites?**

Yes

**Q1.16 Will separate institutional approvals or authorisations be required prior to commencing research at each site?**

No

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## Section 2 – Research Details and Participants

**Q1.17** The following research methods will be used in the research project:

Research Method	Status
Action research	X
Biospecimen analysis research	X
Data linkage research	X
Ethnographic research	X
Epidemiological research	X
Interventional/Clinical Trials research	✓
Observational research	X
Survey/Interview/Focus Group research	✓
Textual analysis research	X
None of the above	X

**Q1.18** The research will be conducted with the following:

Participation	Status
Human beings (via active participation), including their associated biospecimens and/or data.	✓
Human biospecimens only	X
Data associated with human beings only (i.e. as the primary object of research)	X

**Q1.19** The research will involve the following participants:

Participants	Status
Women who are pregnant and the human fetus	✓
Children and young people	X
People highly dependent on medical care who may be unable to give consent	X
People with a cognitive impairment, intellectual disability or mental illness	X
People in dependent or unequal relationships	X
People who may be involved in illegal activities	X
People in other countries	X
Aboriginal and Torres Strait Islander peoples	✓

## Method Specific Questions

### Interventional/Clinical Trials Research

#### **M6.1 Briefly describe the intervention/s that you will be using.**

A group-based smoking and vaping cessation model of care will be implemented and evaluated for reach, effectiveness, adoptions, implementation and maintenance.

**The Group-based program:** The program covers key content including the harms of smoking and vaping, benefits of quitting, overcoming challenges to quitting, education on nicotine dependence, cessation supports available, how to make a quit plan, motivations, and social supports. Group-based sessions embed cultural practices and cover topics of the health effects of smoking and vaping, setting a quit date, identifying triggers, behavioural tools to resist cravings, importance of healthy lifestyle, relapse, and celebrating successes. The has been designed to be flexible so that services can deliver the six sessions in a way that is responsive and appropriate to their community and service (i.e., across 6 weeks, condensed across two days, half-day event etc.). The sessions are designed as follows.

#### **Session 1: Benefits of Quitting the Smokes and Vapes**

- Understand the potential health risks associated with smoking.
- Understand the multitude of health benefits that can be gained by quitting smoking.
- Discuss practical approaches to minimise exposure to passive smoke.

#### **Session 2: Overcoming Challenges to Quitting**

- Reflect on personal motivations and reasons for quitting smoking, exploring the potential benefits and positive changes that can be experienced.
- Reflect and understand motivations behind smoking, which may include social influences, stress relief, habit formation, peer pressure, or psychological factors.
- Understand the difficulties and obstacles often encountered when attempting to quit smoking.

#### **Session 3: Support to Quit**

- Understand how nicotine affects the brain and creates a physiological and psychological dependency.
- Understand how NRT and other cessation supports in the journey of quitting smoking.
- Understand strategies for effectively addressing the challenges that may have arisen during previous attempts to quit smoking.
- Initiate the process of creating a comprehensive quit plan to enhance successfully quitting.
- Combination NRT will be offered based on preference and participants will be instructed to start using the NRT on their quit day.

#### **Session 4: Changing Behaviours and Developing a Quit Plan**

- Discuss replacement behaviours for managing smoking urges and cultivating new habits.
- Discuss relapse prevention including strategies and techniques to anticipate, manage, and ultimately avoid returning to smoking after quitting.
- Finalize the quit plan and share with the group.

#### **Session 5: Celebrating success and staying on track**

- Learning about motivation, building habits and self-rewards.
- Participants will share stages to talk about change after quitting.
- Discuss and explore strategies for social support to stay smoke-free.

## Session 6: Graduation

- Empower participants.
- Discuss future plans beyond the six sessions.

### **M6.2 Is your intervention related to the prevention, diagnosis, treatment or management of a health condition?**

Yes

### **M6.2.1 Do you consider that you are conducting a clinical trial?**

No

### **M6.2.2.1 In what context and with whom will you be conducting your interventional research?**

This research will be conducted in partnership with Aboriginal Health Services and Non-Government health services, their health service staff and Aboriginal and Torres Strait Islander women who utilise their service who smoke or vape and want to quit. This interventional research is preventative in nature, quitting smoking and vaping prevents a range of diseases, including but not limited to, cancers.

A group-based smoking cessation model has been co-designed with Aboriginal Health Services and will be offered to Aboriginal and Torres Strait Islander women who use the service in a delivery mode of the services choosing. The services can implement the interventional research is a way that is appropriate to their service and community. Partnering services will be reimbursed through a small grants program to support the staffing costs of running the program (details on this can be found in the protocol from page 30). Communities will be able to use the program resources as much as they wish beyond the research component of the program.

All community partners in the research are full owners of the project and data collected. The study has been co designed with them and based on the interests and needs of Aboriginal and Torres Strait Islander women. The study implementation has been designed to minimise the burden placed on communities, for example communities are not required to recruit and follow up women, this is managed externally.

Further details are provided in the methods section of the protocol.

### **M6.3 With regard to your answers above, describe any ethical considerations related to your use of the intervention/s in this research project and your plans for addressing these issues.**

The potential ethical implications of this study are deemed minimal; however the safety of NRT (if chosen by participants) has been given carefully consideration. The smoking cessation support will adhere to the RACGP guideline. The RACGP guideline recommends the use of smoking pharmacotherapies in addition to behavioural support for all Aboriginal and Torres Strait Islander people who want to quit smoking. Participants will not be offered NRT as part of the intervention but may request this following the educational component. The intervention has been designed to uphold ethical choice of participants and access to culturally responsive cessation care during pregnancy and beyond. Initially, a randomized approach was considered to generate effectiveness measures. However, due to the high rates of smoking among Aboriginal and Torres Strait Islander individuals and the significance of providing support to all those who wish to quit, this method was deemed unethical. Instead, this research design is an implementation trial with a broad scope for delivery based on individual community needs and interests, which we believe is a more ethically sound approach.

## Survey/Interview/Focus Group Research

Application ID: MK03533

Created date: 12/09/2024

**M8.1 What process/es will your research project use?**

Surveys  
Interviews  
Focus groups

**M8.2 How will you engage with your participants?**

Face to face  
Via telephone, texting or messaging services, or online collaboration tools

**M8.3 How will personal identifiers be retained or removed over the course of your project?**

To uphold community rights to data and place-based reporting throughout the life of the project, as well as individual participants rights to in process personal tracking, identifiers will be used. Identifiers will be collected and used in the research for personal follow up and reporting on individual changes through the intervention.  
Once all research follow up is completed, prior to formal analysis, identifiers will be removed and only anonymous data used in analysis and reporting.  
Regarding qualitative yarning interviews, participants will receive a copy of their transcript and have the opportunity to edit/remove any content they wish. No identifying information will be used and the process will be overseen by the Research Governance Committee.  
All data collected will be held on password protected University of Newcastle software. Only research staff will have access to all data. No data will be shared outside the research project team.

**M8.4 Will participants have the opportunity to review or edit their responses or contributions prior to data analysis or publication?**

Yes

**M8.4.1.1 Indicate the relevant section/s of your Project Description that detail this opportunity.**

Survey items will not have the opportunity for review once submitted, as there is no functionality in the REDcap system to have participants review their answers. They can cease completing the survey at any time and start again if they are not confident in their responses. Participants will also have contact details for the research team who can support them to change their responses at any time over the phone. Only full and complete surveys will be used for analysis. As described in M8.3 participants contributing qualitative data will be able to review their transcripts and edit responses prior to analysis of this data.

**M8.5 Is it foreseeable that your project will explore topics that may cause distress for participants?**

No

## Participant Specific Questions

### Women who are pregnant and the human fetus

#### **P1.1 Who will the research involve?**

Women who are pregnant and the fetus in utero

#### **P1.2 Is there a foreseeable impact on the fetus in utero?**

No

#### **P1.3 How will the wellbeing of the pregnant woman and fetus be managed?**

While the research sample is not targeting pregnant people specifically, eligible participants are of reproductive age and therefore potentially pregnant. This research will likely support Aboriginal and Torres Strait Islander mothers who are pregnant to quit smoking and vaping through an Indigenous-led evidence based model of care. The care will be provided from the woman health service who will ensure the wellbeing of the mother and fetus is upheld.

#### **P1.4 Describe any arrangements for counselling that will be provided or made available to the women.**

Smoking and vaping cessation counselling is part of the intervention. Further to this participant information sheets refer women to the use of 13YARN should they require additional supports.

#### **P1.5 How will you ensure that the research meets the guidance provided in [National Statement 4.1.20](#) regarding the information that should be provided to female participants?**

All participants will give informed consent before any research activities are conducted, and will be notified that they are able to withdraw from the study at any time without any impact to their health care treatment.

#### **P1.6 Will the research involve the removal of organs or tissues from fetuses that have been delivered dead?**

No

#### **P1.7 Will fetal cells be derived from fetal tissue and stored or propagated, or will the tissue or cells be used for human transplantation?**

No

### Aboriginal and Torres Strait Islander peoples

#### **P8.1 How have you considered and addressed local Aboriginal and Torres Strait Islander cultural values in the design and conduct of this research?**

This project was designed by Aboriginal and Torres Strait Islander women and community partners over a 5-year period. The project was developed in partnership with Waminda South Coast Women's Health and Wellbeing Aboriginal Corporation and the Aboriginal Health and Medical Research Council. Further local expert review and guidance to the project was offered by the Wukul Yabang Aboriginal Health Research Community Panel prior to grant submission. A/Prof Michelle Kennedy, a Wiradjuri woman and research fellow at the University of Newcastle who will lead the project in partnership with a team of Aboriginal and Torres Strait Islander researchers and the Aboriginal Health & Medical Research Council. The project is a continuation of a long term, co-owned research to develop an Indigenous-led evidence base for smoking cessation care. Details of the research and publications that have informed this application can be found in the Study Protocol from page 6.

This project has been designed in partnership and co-ownership with Peak Bodies for

Aboriginal Community Controlled Health Services; and Aboriginal Health and Medical Research Council (AH&MRC). The research will be conducted with utmost culturally sensitive and ethical consideration. This research project adheres to the guideline set fourth in Ethical Conduct in Health Research with Aboriginal and Torres Strait Islander peoples and communities: Guidelines for researchers and stakeholders NHMRC 2018. The project recognises and upholds the six core values of: Spirit and Integrity, Cultural Continuity, Equity, Reciprocity, Respect and Responsibility are acknowledged as follows.

**Spirit and Integrity:** The project aims to evaluate the impact of a group-based smoking and vaping cessation supports with evidence generated from a prior study that Aboriginal and Torres Strait Islander women wants to support their quitting journey with community support. The project acknowledges the significant impact tobacco use has on the health and wellbeing of Aboriginal and Torres Strait Islander people. A Research Governance committee made up research team and representatives from partnering organisations will continue to oversee the project. Community guidance is at the forefront of the research and any local requirements or processes will be followed with the upmost respect.

**Cultural continuity:** As an Aboriginal researcher, CIA Kennedy's Indigeneity is at the forefront of the research conducted with application of Indigenous Research methodologies. The conduct of research is governed by Kennedy's cultural values of; respect, humility and trust. Kennedy acknowledges her privileged position as a researcher and is committed to the conduct of transparent research conduct in honour and recognition of the communities involved. Aboriginal data sovereignty plan has been established. Data will be governed by the Research Governance Committee. The research team acknowledges the rights of Aboriginal and Torres Strait Islander peoples to govern the creation, collection, ownership, and application of the data.

**Equity:** An acknowledgement of Aboriginal and Torres Strait Islander peoples as the knowledge holders is the foundations for the project. This is evidenced throughout the Research protocol and it's Indigenous leadership via researchers and community partners.

**Reciprocity:** Reciprocity is articulated throughout the Research Protocol as being a core cultural value of CIA A/prof Michelle Kennedy. The research has been designed in consultation with Aboriginal communities and senior researchers, with an acknowledgement that consultation is an ongoing process, organic in nature and at the centre of the research practice. Partners in the project are long-term and building on established respectful relationships. Although this research poses limited foreseen potential risks to participants all possible risks and discomforts have been addressed and will continue to be at the forefront of research design. The project will provide training and employment opportunities for Aboriginal and Torres Strait Islander community researcher (sometimes referred to as research assistants) and PhD student placements ensuring the research implemented has continual benefit to Aboriginal communities. CIA Kennedy is passionate about training, supporting and mentoring Aboriginal and Torres Strait Islander people in research (both formally and informally) and will continue to seek opportunities to do this.

**Respect:** The project will be conducted with upmost respect to Aboriginal communities and their women. The Recruitment strategy in the Research Protocol outlines the developed culturally respectful approach to safe research developed in consultation with partnering communities that has been carefully developed with Aboriginal and Torres Strait Islander community researchers, Investigators and community partners. Participants to will always be informed that participation in the research is voluntary and they have the right to withdrawal at any time without being asked 'why'. Participants will be fully informed on the research process and use of their data before provided full informed consent to the study. Aboriginal communities have full engagement, negotiation and decision making in the conduct of this research.

**Responsibility:** The project is a community led, culturally safe research project led by a team of Aboriginal and Torres Strait Islander researchers in full partnership and co-ownership with Aboriginal communities. All research design and delivery is developed with the guidance of the Aboriginal communities. The research team will ensure all communities and participants have

all relevant information required to consent to the research and appropriate processes in place to report back to communities. This practice will require ongoing consultation and guidance from communities involved. All publications and reporting of this research will undertake several rounds of community consultation and approvals through the Research Governance Committee. This is outlined in detail throughout the Study Protocol.

**P8.2 Describe the process that will be used to satisfy the requirements for community consultation, engagement and governance that apply to your research?**

This project is co-owned by the community and has been for over 5 years. The CIA A/Prof Kennedy has undertaken over 2 years of knowledge translation work across the country, sharing findings from earlier research from the Which Way? study. The knowledge translation activities have informed the co-design of this group-based model which has undergone feasibility and acceptability testing before implementing across NSW.

To appropriately design this research for Aboriginal Health Services, Kennedy continued for the past 2 years to consult peak organisation (AH&MRC & NACCHO) and undertake a series of co-design workshops with community partners. Workshops have covered areas of: Behaviour Change Techniques needed in the program, what resources are required and beneficial, content of the program, development of video and graphical resources, program design and research methods (particularly recruitment and follow up approaches) and research questions and survey content.

Aboriginal Governance is central to the running of the Which Way? research project. Each site involved in the research is a full partner and co-owner of the research process. Research Governance is established to oversee the research process including research design, implementation, analysis and reporting this will be expanded as new sites consent to the study. No data will be used without full consultation, plan, review and approval by all Research Governance Committee members. A/Prof Kennedy will continue to engage, share preliminary findings and seek feedback from the Research Governance Committee and community partners in meaningful ways as directed by the community. This has been conducted this way for 5 years and will continue. The AH&MRC have provided a letter of support which has been attached for reference.

**P8.3 List any relevant ethics guidelines that you have consulted during the development of your research project.**

All activities will be guided by principles outlined in the:

1. National Statement on ethical conduct in Human research, 2007 (updated 2018);
2. NHMRC Road Map II- A Strategic Framework for Improving the Health of Aboriginal and Torres Strait Islander People through Research;
3. AH&MRC Values and Ethics- Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research;
4. AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research
5. Keeping research on track- A guide for Aboriginal and Torres Strait Islander peoples about health research ethics.

## **Recruitment Questions**

### **Q2.1.1 Indicate how you will identify and recruit participants for your research, referencing any relevant sections of your Project Description/Protocol as appropriate.**

See page 14 of the protocol for the study flow for recruitment. Details of individual stages of the project recruitment are below and articulated in alignment with the study stages.

**Site Recruitment:** All ACCHS' and non-government Health Services who implement the Tackling Indigenous Smoking programme will be sent a hard copy and digital (emailed) information brochure that outlines key details on the program (see appendix). This will direct the service to the Which Way? website and include the study team contact details to sign-up as a participating site. Information regarding the program will be disseminated by the research team and AH&MRC to member organisations. Further advertisement of the program will be conducted by AH&MRC through newsletters, advertisement at AH&MRC events and face to face updates with member organisations. Current partnering sites will also support the development of short videos and information on the program to be uploaded to the Which Way? website for accurate information of the program. This content will not focus on recruitment, but rather provide detailed information on the project and communities experiences delivering the pilot version of the group-based program. Lead researcher A/Prof Michelle Kennedy will continue to present the program as invited at key events across NSW such as the Tackling Indigenous Smoking workshops and AH&MRC Health Summit, providing the context of the project and answering any questions services might have. The project will also be promoted through social media on the established Which Way? Facebook page, AH&MRC, and partnering services/organisations. Services will be directed to the Which Way? website to express their interest in participating, relevant photographs of the research team and phone and email information will also be provided to ensure services can engage in a way that is meaningful to them. Services will nominate a 'site champion' to facilitate communication between the service staff and research team. All participating services will be offered face to face or zoom discussions regarding the project and will provide organisational consent prior to any engagement of staff or community members for individual consent (see stage 2).

**Recruitment Service representative Indigenous leadership and oversight:** Service representatives will be recruited on an ongoing basis throughout the duration of the project. This will be at the discretion of the service based on their role and involvement in the implementation of the program and training. Service representatives will be nominated by the CEO, site champion, manager, or senior staff member of the participating site at relevant time intervals. Contact details will be provided by the site champion. When services undertake the organisational consent and research agreement making process, they will be able to opt-in to participate in the Governance Yarns. Before Yarning interviews are conducted, the researcher will ask if the representative consents to a recording or note taking of the discussion. If consent to recording is granted, verbal consent will be collected at the beginning of the interview.

**Health provider Recruitment:** Health Service Staff will be invited to participate after the organisation has consented to participating in the Gulibaa project. Services will invite staff in a way that is suitable to their service and community. It is anticipated that the CEO or manager will share the relevant training opportunity. The research team will provide an email for services to use if they wish (see appendix). The research team will also offer to connect in person or via zoom and attend staff meetings to explain the study and training content on offer. At the training registration process, staff will be able to access the detailed information statement and asked to provide informed online consent for participation in the pre and post training surveys which are embedded in training modules. During the survey, the participant will be able to select to opt-in to an additional yarn to share their perception of the training after completion.

**Post-program Yarns:** Appropriate representatives will be nominated by the CEO, manager, senior staff members, and site champions to share their perceptions of the program, resources and facilitation. **Maintenance Survey:** An appropriate representative will be nominated by the CEO, manager, senior staff members, or site champion to complete a short survey 6-months

post-implementation. The survey will be sent team to the appropriate contact provided (i.e., email or phone).

**Aboriginal and Torres Strait Islander participant Recruitment:** Aboriginal and Torres Strait Islander women will be recruited to join the smoking and vaping cessation groups by self-referral or referral by health service staff at participating services. Recruitment approaches will be led by the health service and may include face-to-face engagement, posters, social media advertisements or brochures. Examples of the promotional materials that will be offered from the research team for communities to adapt can be found in appendix. Participants can access further relevant information on the Gulibaa project and the broader Which Way? programme via the live website [www.whichway.info](http://www.whichway.info).

Health service staff will provide a detailed participant information statement to all group participants who can take all the time required to consider involvement. Consent will be gathered either prior to the first session or at the first session before the group commences via QR link to survey. During the first session, group participants will be given the opportunity to ask any questions about the program prior to consenting. Services will be advised that if a group program participant does not want to consent to the research component, they are still welcome to participate in the groups, and no information will be collected. At the 6-week follow-up survey, participants will have the opportunity to opt-in via a tick box in the survey to participating in an audio-recorded yarn or yarning circle to share their perceptions and experiences with the program. Group Program Participants will also be invited to Yarns or Yarning Circles by the Health Service Staff.

See pages 15-27 of the Study Protocol for more details.

### **Q2.1.2 How will your recruitment strategy take account of the ethical considerations relevant to the specific people you are recruiting?**

The approach to recruit participants has been directed by the partnering Aboriginal communities and informed by previous research led by A/Prof Kennedy with acknowledgement of community needs and appropriate policies and practices. Our previous research "Koori Quit Pack Mailout Smoking Cessation" (#1894/21) found remote recruitment to be relevant and appropriate for Aboriginal and Torres Strait Islander people. In addition, we have included community driven recruitment approaches to uphold place-based ethical research practices. Participant recruitment and consent will be conducted in a respectful and culturally responsive manner by partnering service staffs with a range of informational materials and links to self-referral. Full informed consent will be gathered from the research team with participants being advised they can withdraw at any time without question.

## **Consent Questions**

### **Q2.2.1 Indicate by reference the relevant section/s of your Project Description/Protocol that address/es consent.**

A detailed information sheet will be provided to all potential participants in addition to informational brochures with access via QR codes to spoken version of the content developed by the research team (video content is not yet available and will be made following written content approval by the ethics committee). Consent will be obtained online using REDCap without coercion and by audio recording ahead of qualitative interviews. Participants will be informed of their right to decline to participate and that their decision will not affect them in anyway. Participants will also be notified of their right to withdraw at anytime, without giving a reason or without penalty. Participants can take as much time as they want before consenting and can open and close the portal unlimited times.

If the service experiences women who do not wish to participate in research, but want to attend groups, the service can opt to run a "no research group-based program". Meaning Aboriginal

and Torres Strait Islander women who do wish to participate in group based smoking cessation care but do not wish to participate in research, will not miss out on access to evidence-based smoking cessation care.

**Q2.2.2 Will you be obtaining consent from some or all participants to participate in the research?**

Yes for all participants

**Q2.2.2.1 What is the scope of consent that you will be seeking?**

Specific

**Q2.2.2.2 How will consent be obtained?**

Written  
Verbal

**Q2.2.2.3 Are you proposing to obtain consent using limited disclosure?**

No

**Q2.2.3 Are family members, authorised representatives or any others involved in the participants' decision to participate in the research?**

No

(Pregnant women and the human fetus specific question)

**Q2.2.P1.1 Will the process of providing information and obtaining consent from the participants be separate from clinical care and consent for non-research purposes?**

Yes

(Pregnant women and the human fetus specific question)

**Q2.2.P1.1.1 How will you ensure that these processes are separate?**

The intervention is not aligned with usual clinical care.

**Q2.2.4 Will there be an opportunity to confirm or re-negotiate consent during the research project?**

No

**Q2.2.6 Describe any ethical considerations related to the approach to consent that you will be seeking and your strategies for addressing and managing these issues.**

Participant consent form is prepared in a way that can be understood at any level of literacy and evaluated for cultural responsiveness and clarity. While no re-negotiation of consent is possible, women can withdrawal at anytime including the withdrawal of their data.

**Q2.2.7 Are you proposing to use an opt-out approach with respect to some or all of the participants?**

No

**Q2.2.8 Are you requesting a waiver of the requirement for consent with respect to some or all participants?**

No

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**Risk Questions**

**Q 2.3.1 Describe the risks and burdens associated with your research, referencing any relevant sections of your Project Description as appropriate.**

There is no anticipated risk to the participants. The approach to recruitment and follow up have been developed to avoid any burden placed on participants and partnering services.

**Q 2.3.2 Describe how these risks will be minimised, mitigated or managed.**

Upholding Indigenous leadership and governance will ensure that any risks identified are managed in a responsive and appropriate manner.

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## **Benefit Questions**

**Q2.4.1 Describe the benefits associated with your research, referencing any relevant sections of your Project Description as appropriate.**

The Which Way? programme has been designed for and by Aboriginal and Torres Strait Islander people to uphold individual and community level benefit of involvement. This is evidenced in our continued partnership with a growing body of work. The Gulibaa project has been co-designed to ensure there is reduced burden of communities participating in the study and an appropriate short, middle and long-term benefit for participating.

**Benefit to Services**

Services will have a range of benefits for participating in the Gulibaa project. Firstly, the study will embed a range of training and capacity building processes that will be offered for free including: smoking and vaping cessation training and data sovereignty training (not included in any research element of the program). Services will receive resources for staff and women to deliver the core smoking and vaping cessation group content and will have access to downloadable versions of all content for use both in the Gulibaa project or for other programs. All data collected will be owned by the service and shared with the research team (as outlined in the draft Research Agreement). Services will be offered ongoing opportunities for the research team to report back findings and data in a way that is meaningful to the service for use beyond research. Research staff will establish ongoing relationships with the services, community and staff which can extend to other work that is of interest to the community. For example, this relationship the Which Way? programme has with Waminda has resulted in Waminda requested partnership to develop and deliver Tackling Indigenous Smoking projects. To recognise the time and resources required to participate in this project services will have access to small grants to implement the groups. Grants will be provided based on the mode of group-based program delivery and include a \$5,000 project launch grant (all sites offered once the launch event is confirmed to support purchasing any resources). Further to this, ongoing small grants will be offered as follows with base payments paid up front and participant payments at the conclusion of their chosen program delivery method:

**Half day event:** applicable for services who deliver the program in one day. Total amount available: \$1,000 for 1-5 eligible group participants. \$100 per additional eligible group participant.

**Compressed program:** applicable for services who conduct the compressed version of the program over 2-4 days. Total amount available: \$2,000 for 1-5 eligible group participants. \$200 per additional eligible group participant.

**6 Week program:** applicable for services who deliver the program across 6 weeks. Total amount available: \$3,000 for 1-5 eligible group participants. \$500 per additional eligible group participant.

All payments will be made via invoice payment system to the service in a way that is appropriate for them. If a service requires payments before programs commence, the research team will work with the service to ensure this can occur. The payments are not intended to be

an incentive, they will support any catering, travel support, resource purchasing and staff time to deliver the program. A budget of \$250,000 has been allocated for small grants, which will allow recruitment of 500 Aboriginal and Torres Strait Islander women. The grant application form can be found in appendix X.

The project has been designed with a plan for sustainability in community settings. Once services have access to the training and resources, we hope they will benefit from continuing to implement this evidence-based program in their community in a way that suits them and their community's needs.

#### **Benefit to Service Staff**

Staff at participating services will have access to smoking and vaping cessation training that has been developed based on their reported requests and needs. The training has been developed by Indigenous people and community partners to meet the needs of the community-controlled sector. This training is unlike any other available training and meets a current gap in what staff have access to. Staff will receive a certificate upon completion of the training which is currently in the process to receive CPD points and endorsement across the AHW/P and Tobacco Control sector.

Staff will also have support and guidance to implement the group-based program by a Tobacco Treatment Specialist and Worimi woman, Mrs Joley Foster. Staff will be able to join an online group facilitated by Joley to support ongoing learning and support. The Which Way? team also build reciprocal relationships, staff will have a responsive and empowering support provided by the team.

The staff will be offered a range of different merchandise to acknowledge their work and commitment to delivering the group-based program throughout the study. This does not form part of the research component but rather our celebration of tobacco resistance.

#### **Benefit to Aboriginal and Torres Strait Islander women**

The Gulibaa project was established because Aboriginal and Torres Strait Islander women nationally told us they want access to group based programs to support and empower them to be smoke and vape free. Women will be accessed a world first, group-based smoking and vaping cessation care has never been developed or implemented for and by Indigenous people. Women will have the immediate benefit for participating in this study as they will receive Indigenous-led, community driven and evidence based smoking and vaping cessation support and access to a range of resources to support their quitting journey. With minimal data being collected from women and all data collected remote to their service, we have developed the study to have minimal impact and burden on women. Women will have access to a range of resources developed by the Which Way? team including our women's journal and resources available on our website through involvement in the program. Women will be able to go in the draw for a monthly Clothing the Gaps merchandise pack upon registration and go in the draw for one of 3 Airpod Max headphones for completing the 6-week, 3-month and 6-month survey. The Which Way? team believe women will benefit from receiving culturally responsive smoking and vaping cessation care. Our Quit Pack study found 34% of participants were smoke and vape-free at 6 months, we anticipate our women's program being as, if not more successful based on the face to face and comprehensive content offered to women.

#### **Q2.4.2 Explain how benefits of this research justify any risks of harms or discomfort and any burdens or inconvenience associated with the research.**

As described there are no risk of harm, discomfort or inconvenience. The study has been developed in close partnership with Aboriginal and Torres Strait Islander people and communities to ensure this.

#### **Q2.4.3 How will you manage participants' expectations of the perceived benefit of participating in the research?**

The potential benefits of this for participants are detailed on the respective 'Participant

Information Statements', which the participant will be able to read and retain before they consent to participation. Participants will have the opportunity to ask any questions, including their expectations of the benefits of the research and program. Participants will be informed of the extent to which the smoking and vaping cessation supports will help in quitting in addition to details on the quitting journey utilising developed resources.

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# Section 3 – Data and Privacy

## Data Characteristics

**Q3.1 Indicate the type of information/data you will be collecting for this project.**

Personal information  
Not personal information

**Q3.2 Indicate the type of information/data you will be using in this project:**

Personal information  
Not personal information

**Q3.3 Indicate the degree of identifiability of information/data you will be collecting for this project.**

Individually identifiable information

**Q3.4 Indicate the degree of identifiability of information/data you will be using in this project.**

Individually identifiable information

**Q3.5 Describe any ethical considerations relating to the collection and/or use of the information/data in this project.**

The research team acknowledges the rights of Aboriginal and Torres Strait Islander peoples to govern the creation, collection, ownership, and application of their data and has an established Research Governance Committee to uphold Indigenous data sovereignty throughout the project. We acknowledge the partnering services as the knowledge holders and as such the co-owners of all data collected. The partnering services will continue to lead the Research Governance Committee with the CIA A/Prof Michelle Kennedy. The committee directs all use of research data including, but not limited to, the framing and oversight of data analysis and reporting. This strong, long term governance is reflected in the investigator team and previously co-authored publications (Doing “deadly” community-based research during COVID-19: the Which Way? study, Michelle Kennedy and Hayley Longbottom Med J Aust 2022; 217 (2): 86-87. || doi: 10.5694/mja2.51624)

No reference group is applied to this study, rather all partnering services are named investigators and co-owners of the project.

No data will be used without full consultation, plan, review, and approval by Governance Committee members.

Data will be managed confidentially at all times. Data will be kept confidential by the research team. No third party will have access to the data at any time during the data collection, data analysis and after the completion of the study. No data will be published that identifies individuals participating in this research. The REDCap (Research Electronic Data Capture) to collect the survey data. The REDCap is located at the Hunter Medical Research Institute secure servers (<https://redcap.hmri.org.au/>) which are both physically and virtually secured to access. Data is stored in a user password protected server. The server is in a locked and closed-circuit television (CCTV) monitored area at the HMRI. Any kind of communication utilises a Secure Socket Layer encryption. The HMRI REDCap Information and Governance Policy is available at: <https://redcap.hmri.org.au/surveys/?s=CJJ8XC384R>. Data will be managed in accordance with the AH&MRC data management guideline (<https://www.ahmrc.org.au/publication/ahmrcguidelines-for-research-into-aboriginal-health-2020/>) and any successor Guidelines.

We will be collecting participants names and phone numbers for follow up and personal progress reporting. This information will NOT be used for any other purpose and not linked to the data used in analysis. This information will be only tracked by the Aboriginal and Torres Strait Islander community researchers using password protected online filing that is only accessible by the team.

Ethical approval will be obtained from the Aboriginal Health & Medical Research Council Ethics Committee of NSW, and the University of Newcastle. The study will be conducted in accordance with relevant ethical guidelines such as the five key principles of the Aboriginal Health & Medical Research Council guideline: Net benefits for Aboriginal people and communities, Aboriginal community control of research, cultural Sensitivity, reimbursement of costs, and enhancing Aboriginal skills and knowledge. Data will be collected, stored, and used in accordance with the National Health and Medical Research Council (NHMRC) data management policy. Informed consent will be obtained from all participants included in this study. Participates information will be always kept confidential. No data will be published that identifies individual participants.

**Q3.6 Identify the source/s of the information/data that you will be collecting and/or using in this project.**

Individual participants and/or relatives or associates of participants

**Q3.7 Describe any ethical considerations relating to the source of information/data as indicated in the response to the previous question.**

Consent and data collection will be obtained from the individuals themselves and if required via telephone with Aboriginal and Torres Strait Islander researchers.

The research team will uphold Indigenous data sovereignty throughout the implementation and implementation of the project. The research team understands the importance and acknowledges the rights of Aboriginal and Torres Strait Islander peoples to govern the creation, collection, ownership, and application of their data. The team acknowledges the partnering services as the knowledge holders and as such the owners of all data collected. No data will be used without full consultation, plan, revision, and approval by Governance Committee members. The gathered data will be kept in a strictly confidential manner and no third party will have access to the data at any time during the data collection, data analysis and after the completion of the study. Interview records and transcripts will be kept confidential in a de-identified form, accessed by researchers only. Audio-recorded interviews will be transcribed verbatim by a professional transcribing company.

**Q3.8 Was the information/data that you are using previously collected for a purpose other than research?**

No

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**Activities Planned for/with Data**

**Q3.9 Do you plan to disclose any personal information/data in this project to a third party?**

No

**Q3.10 How will you protect the privacy of participants and non-participants in any notes and/or publications arising from your research?**

Publications arising from the data collected will only contain summary statistics, no individuals

will be able to be identified. ACCHSs will be asked if they would like to be named on any publications prior to their dissemination. All publications will be provided to the Research Governance Committee for review, prior to dissemination.

**Q3.11 Are there any restrictions on your ability to assure the confidentiality of participants?**

No

**Q3.12 Do you plan to share any individual research results obtained during this research to the participants?**

No

**Q3.13 Describe how you will handle any secondary or incidental findings that arise from the analysis of personal information/data.**

It is not expected that any issues will arise from the analysis of personal information.

**Q3.14 Describe how the information/data will be stored, accessed, archived and/or destroyed.**

The gathered data will be kept in a strictly confidential manner and no third party will have access to the data at any time during the data collection, data analysis and after the completion of the study. All hard copies of study documentation will be stored in a locked filing cabinet at the University of Newcastle. All electronic data will be stored password protected files on the University of Newcastle secure network. Identifying data (i.e. names and contact details) will be stored separately. Only the key research personnel will have access to this data. Study-specific information will be stored for a minimum of 7 years in line with University of Newcastle policy. The investigators and research team are responsible for maintaining a centralised and comprehensive filing system of all study-related documentation, suitable for inspection at any time by the approving HREC or applicable regulatory authorities.

**Q3.15 Describe any ethical considerations relating to the storage of, access to or destruction of information/data in this project.**

The procedures described above will ensure that data is stored securely with access limited to named members of the research team.

**Q3.16 Will the outcomes of this project be disseminated to the participants?**

Yes

**Q3.16.1.1 Describe how the outcomes of the project will be disseminated to the participants, or refer to the relevant section/s of your Project Description/Protocol which deals with this matter.**

**Returning Results and research findings**

Findings from the project will be disseminated via partner organisations, such as AH&MRC as well as through social media. Participants will be asked if they wish to receive results from the study during the recruitment process. We will work with the Aboriginal Governance Committee to develop meaningful knowledge translation activities. Our broader Which Way? team will continue to engage regularly at community events, develop social media updates and content as well as host webinars to share results during the study process, not just at the end.

**Q3.16.1.2 Describe any ethical considerations relating to any dissemination of outcomes to the participants.**

No data will be published or shared that identifies individual participants.

**Q3.17 Describe any foreseeable future activities for which information/data collected and/or used in this project may be made available.**

The result of the study will be presented in relevant local, national and international conferences inviting and funding Which Way? project team, including community researchers and community partners to do this (not just CIA Kennedy). This approach is evidenced in both the World

Indigenous Cancer Conference with community researcher/undergraduate student Kayden Roberts-Barker presenting Quit Pack findings, and the Which Way? project supporting two staff at Waminda to travel to the upcoming Oceania Tobacco Control Conference to share findings from the pilot study. A comprehensive dissemination plan will be developed with the Aboriginal Governance Committee and the Policy Committee to ensure community level and policy level translation and impact. We anticipate several manuscripts will be co-authored with the Aboriginal Governance Committee and research team and submitted to relevant journals. A range of community-led dissemination strategies will be informed by partnering communities and conducted by the research team, these may include but will not be limited to; face to face presentations to community, infographics, webinars, short videos and brief reports.

**Q3.18 Describe any ethical considerations relating to the planned or possible future use of information/data in this project.**

Any planned or future use of data will present data only in de-identified and summary form. No data sharing will be provided.

## Section 4 – Attachments and Declarations

### Attachments

The following documents have been attached to this HREA.

#### Project Description/Protocol

See attachment

#### Other attachments

Attachment File Name	Attachment Description

### Investigator Team Declarations

The research team has certified that:

- All information in this application and supporting documentation is correct and as complete as possible;
- I have read and addressed in this application the requirements of the National Statement and any other relevant guidelines;
- I have familiarised myself with, considered and addressed in this application any relevant legislation, regulations, research guidelines and organisational policies;
- All relevant financial and non-financial interests of the project team have been disclosed; and
- In the capacity of a supervisor, as applicable, I have reviewed this application and I will provide appropriate supervision to the student(s) in accordance with the arrangements specified in this application and those associated with the student's educational program.

**A/Prof Michelle Kennedy**

Sign here: *M. Kennedy 17/09/2024*