PARTICIPANT INFORMATION SHEET – Pathways App

Pathways for Aboriginal & Torres Strait Islander Hearing Health: The Pathways App Pilot Study

Chief Investigator
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Introduction
We would like to invite you to participate in the research project, Pathways for Aboriginal & Torres Strait Islander Hearing Health: The Pathways App Pilot Study.

You have been invited because you are a parent or carer of an Aboriginal and/or Torres Strait Islander child aged 0–8 years who has had ear health issues at some time in the past, and you have access, personally or through a family member, to a compatible smartphone (iPhone or Android).

This Participant Information Sheet tells you about the research project. It explains the processes involved in taking part. Please read this information carefully. Ask questions about any parts you don't understand or want to know more about.

Participating in this research is voluntary. If you do not want to take part, you do not have to. If you decide you would like to take part, you will need to sign a Consent Form. You will be given a copy of this Participant Information Sheet to keep.

By providing consent you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to the use of your information as described

This research project has been approved by Flinders University's Human Research Ethics Committee (Project ID 9922) and the Aboriginal Health Research Ethics Committee (#04-26-1244). If you have any complaints or reservations about the ethical conduct of this study, you may contact Flinders University's Research Ethics & Compliance Office via telephone on 08 8201 2543 or by email human.researchethics@flinders.edu.au or Aboriginal Health Research Ethics Committee via telephone on (08) 8273 7200 or by email research@ahcsa.org.au

What is this research about?

Ear disease, and its associated hearing loss, are much more prevalent in Aboriginal and Torres Strait Islander children. However, while ear and hearing health services are available, families can face significant challenges navigating a complex care system and maintaining continuity of care across multiple providers and services. We have developed a mobile phone application (app) called the Pathways App to help families manage their child's ear health. This app was co-designed with Aboriginal families and communities. The purpose of this pilot study is to test how easy the app is to use, whether families find it helpful, and whether it supports families in managing their child's ear health and staying connected with health services.

What will I be asked to do?

Participation in this project involves downloading and using the Pathways App for at least 3 months. If you have not had much chance to use the app's features in that time, you can ask to keep using it for longer before completing the survey.

When you first open the app, you will be asked to accept the app's Terms and Conditions and Privacy Policy, like you would with any app. This explains how the app works and how your information is protected. After accepting these, you will be asked to register yourself and your child. As part of registration, you will provide your name, and for each child's profile, your child's name, your child's date of birth, your child's postcode, and your child's Aboriginal and/or Torres Strait Islander status. Your child's postcode helps us understand regional patterns and advocate for better services in your area. When we report on the research, postcodes are grouped together into larger areas (like council areas or regions) and are never reported individually to protect your privacy.

The app has features that can help you manage your child's ear health, including:

- Tracking your child's ear health appointments, symptoms, and treatments
- Setting reminders for follow-up appointments and medication
- Accessing ear health information and resources

You can use whichever features are most helpful for you and your family. The app will also collect usage data (such as which features you use most often) to help us understand how the app is being used. This data is stored under a study ID number rather than your name, and only the lead researcher can link it back to you.

When you finish using the app for the study, you will be asked to complete a short survey about your experience with the app (approximately 15–20 minutes). At the beginning of the survey, you will be asked some basic demographic questions including: the number of children you use the app for, the ages of those children, and their Aboriginal and/or Torres Strait Islander status. We do not collect personal demographic or health information about you (the parent or guardian). If you are invited to participate in a yarning interview, the same demographic questions will be asked at the beginning of that interview.

You may also be invited to participate in a yarning interview with a researcher about your experience (approximately 40 minutes). This is optional and you can choose whether or not to participate. If you are invited to and choose to participate, the conversation will be audio recorded. The recording will be transcribed (typed up) either through an automated transcription service (such as Microsoft Teams) or by an

external transcription agency (such as DAATS Pty Ltd, South Australia), with the transcript then reviewed and corrected as needed by a member of the research team.

After your yarning interview, you will have the opportunity to review the written transcript to check it accurately reflects what you said and make any changes you feel are needed. We will contact you to arrange this in whatever way suits you best, such as by email or a printed copy, and you will have two weeks to review it. You can also choose not to review the transcript if you prefer. If we do not hear from you within two weeks, we will assume you are happy for it to be used as is. Only the investigators listed on this information sheet will have access to recordings and transcripts.

What are the possible benefits of taking part?

The app may help you better manage your child's ear health by providing reminders, tracking information, and easy access to resources. The information we gather in this study will help improve the app and contribute to better ear and hearing health care services that meet the needs of Aboriginal families and communities. Participants will also be reimbursed for their time. You will receive a $25 voucher after four weeks of using the app, and a further $25 voucher when you complete the survey at the end of the study. If you participate in the optional yarning interview, you will receive an additional $50 voucher.

What are the possible risks of participating in the study?

The possible risks of taking part in this study are described below:

- Emotional distress: Recording information about your child's health or discussing their ear health experiences may cause some emotional distress. You can stop using the app or withdraw from the study at any time. Research team members can provide initial support and help you access more specific support if needed. You will also be provided with a Support Services flyer listing services you can contact at any time.
- Privacy concerns: While we have strong security measures in place, there is always a small risk when storing health information digitally. All data will be stored securely and encrypted, and we follow strict privacy protocols (see below).
- Time commitment: Using the app may take some of your time, though it is designed to be quick and easy to use.

Important: This app is a research tool and is not a substitute for professional medical advice or emergency care. If you have concerns about your child's health, please contact your health care provider. In an emergency, call 000.

Do I have to take part in this research project?

Participation in this project is completely voluntary. If you took part in an earlier stage of the Pathways Project, this does not mean you are expected or obliged to take part in this study, the decision is entirely yours. If you do not wish to participate you do not have to, and you can stop participating at any time. Whatever decision you make will not affect the care that you or your child(ren) receive.

If you choose to withdraw from the study, you can do so by contacting the Aboriginal Community Engagement Officer or any member of the research team using the contact details in this sheet. You can request that any data already collected about you be removed from the study, up until the point that it has

been de-identified and combined with other participants' data for analysis. Once data is de-identified and aggregated, it is no longer possible to identify and remove your individual contribution.

Please note that if you simply stop using the app without contacting us, we may think that you are still part of the study. If you stop using the app with the intention of withdrawing, we will not know that you have withdrawn, and any data already collected through the app will continue to be included in the study as evaluation data. If you want to withdraw, please let us know so we can remove your data.

What will happen to the information about me?

By giving your consent, you agree to the research team collecting and using information from you for this study. All information that could identify you will be kept confidential.

Information collected through the app will include:

- Health information you enter about your child (appointments, symptoms, treatments)
- Your child's postcode (used to identify broader regional areas, not specific locations)
- App usage data, stored under your study ID (which features you use, how often)
- Survey responses at the end of the study
- Audio recordings and transcripts from yarning interviews (if you choose to participate)

All information will be stored securely and confidentially. Data stored on the app will be encrypted and protected by password. App usage data collected through the Pathways App is stored on REDCap Platform, which provides secure, encrypted data storage. Only the approved investigators listed on this information sheet will have access to identifiable data.

All research data collected during this study, including app usage data, survey responses, and interview recordings and transcripts will be stored on secure, password-protected Flinders University servers for five years after the date of any publication arising from this study, or after conclusion or abandonment of the project (whichever occurs first), after which it will be securely destroyed.

When research findings are published or presented, no information that could identify you or your family will be included. All information included in publications will either be de-identified so that it cannot be linked back to you or combined with responses from other participants so that no individual can be identified.

Because the study is being conducted with a small number of families in the Far West South Australia region, there is a small possibility that someone familiar with the community may recognise a participant from details such as where they live or the experiences they describe, even when names are not used. To reduce this risk, we will carefully review what is included in any publications, group information into broader regional areas rather than specific locations, and the Aboriginal Advisory Group will review qualitative themes before they are shared to identify and address any material that could inadvertently identify individuals.

Optional future research consent

Your de-identified information may also be used in future research that is closely related to this study, such as research about the Pathways App or ear and hearing health in Aboriginal and Torres Strait Islander

communities. It will only ever be used in de-identified form and will not be shared outside the research team without separate ethics approval. As part of the Consent Form, and again when you first open the Pathways App, you will be asked to indicate whether you agree to two optional permissions:

- Permission to use your de-identified, aggregated app data for future research beyond this pilot study
- Permission to contact you about future research opportunities

These are completely optional and you can choose yes to one, both, or neither. You can change or update these preferences at any time through the app settings. These permissions are separate from your consent to participate in this pilot study and do not affect your participation.

What will happen to the results of the study?
During the consent process you will be given the opportunity to provide your contact details if you wish to receive a copy of the final report and any articles that are published. Results of the study may be published in peer-reviewed journals, presented at conferences or other forums, and shared back with the community.

Who is organising and funding the research project?
The project is led by Associate Professor Jacqueline Stephens at Flinders University and is being conducted in partnership with Far West Community Partnerships. The Pathways Project has received a total of $1,155,685 funding for 3 years through the National Health and Medical Research Council.

Who has reviewed the research project?
The project has been approved by the following ethics committees:

- SA Aboriginal Health Research Ethics Committee (#04-26-1244)
- Flinders University's Human Research Ethics Committee (Project ID 9922).

Further information and who to contact.
If you have any further questions or want more information about this project, please contact:

Associate Professor Jacqueline Stephens
Chief Investigator
College of Medicine and Public Health, Flinders University
Email: pathways@flinders.edu.au

If you have any complaints about any aspect of this research project and wish to talk with an independent person, you may contact any of the people listed below. Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.

Flinders University's Research Ethics & Compliance Office Tel: (08) 8201 2543 E: human.researchethics@flinders.edu.au	Aboriginal Health Research Ethics Committee Tel: (08) 8273 7200 E: research@ahcsa.org.au

Thank you for taking the time to read this information sheet which is yours to keep. If you accept our invitation to be involved, please sign the enclosed Consent Form.

This research project has been approved by Flinders University's Human Research Ethics Committee (Project ID 9922) and the Aboriginal Health Research Ethics Committee (#04-26-1244). If you have any complaints or reservations about the ethical conduct of this study, you may contact Flinders University's Research Ethics & Compliance Office via telephone on 08 8201 2543 or by email human.researchethics@flinders.edu.au or Aboriginal Health Research Ethics Committee via telephone on (08) 8273 7200 or by email research@ahcsa.org.au

CONSENT FORM – Pathways App

Pathways for Aboriginal & Torres Strait Islander Hearing Health: The Pathways App Pilot Study

Chief Investigator
Associate Professor Jacqueline Stephens, College of Medicine and Public Health, Flinders University, Tel: (08) 8201 3972

Co-investigators
Dr Celine Northcott, College of Medicine and Public Health, Flinders University
Samantha Rattos, College of Medicine and Public Health, Flinders University
Lisa Callahan, Paediatric Audiologist, Women's and Children's Health Network

CONSENT STATEMENT

- ☐ I have read the Participant Information Sheet. I understand what the Information Sheet says about the project and what I am being asked to do.
- ☐ I understand my rights as a participant.
- ☐ This information has been discussed with me, and my questions have been answered.
- ☐ I have been given a copy of the information sheet to keep for future reference.
- ☐ I agree to download and use the Pathways App for at least 3 months, or longer if agreed, and understand that during registration I will provide my name and, for each child's profile, my child's name, date of birth, postcode, and Aboriginal and/or Torres Strait Islander status.
- ☐ I understand that for research evaluation, the research team will collect app usage data (which features I use, how often) along with my child's date of birth, postcode, and Aboriginal and/or Torres Strait Islander status. Names will not be used for analysis.
- ☐ I understand that any health information I enter about my child through the app (such as appointments, symptoms, and treatments) is for my own family's use, and that the research team will not collect or access this information for the study.
- ☐ I understand and consent to app usage data being stored on the REDCap Platform.
- ☐ I agree to complete a survey about my experience with the app when I finish using it.
- ☐ I understand that at the beginning of the survey I will be asked basic demographic questions about the number of children I use the app for, their ages, and their Aboriginal and/or Torres Strait Islander status.

This research project has been approved by Flinders University's Human Research Ethics Committee (Project ID 9922) and the Aboriginal Health Research Ethics Committee (#04-26-1244). If you have any complaints or reservations about the ethical conduct of this study, you may contact Flinders University's Research Ethics & Compliance Office via telephone on 08 8201 2543 or by email human.researchethics@flinders.edu.au or Aboriginal Health Research Ethics Committee via telephone on (08) 8273 7200 or by email research@ahcsa.org.au

- ☐ I understand that no personal information that could identify me personally will be intentionally used in the reporting of information collected from this study, and I have read the section in the Participation Information Sheet explaining the small residual risk of identification due to the size of participating communities
- ☐ I understand I can stop being in the study at any time without it affecting myself or my family and that it will not affect my health care in any way.
- ☐ I understand that I do not have to answer questions in the survey if I do not want to.
- ☐ I understand that all information provided by me will be treated as confidential and will not be released to a third party unless required to do so by law.
- ☐ I understand that this app is a research tool and not a substitute for professional medical advice, and I will continue to seek appropriate medical care for my child as needed.
- ☐ ***Optional –*** I agree to my de-identified, aggregated app usage data being used for future research closely related to this study, such as research about the Pathways App or ear and hearing health in Aboriginal and Torres Strait Islander communities.
- ☐ ***Optional –*** I agree to being contacted by the research team about future research opportunities related to this study.
- ☐ ***Optional –*** I would like to receive a summary of project outcomes.

  Email: _____

PARTICIPANT

Signed: _____ Date: _____

Name: _____

CONTACT DETAILS

Please provide your contact details so we can stay in touch with you during the study (for example, to arrange the survey at the end of the pilot period, invite you to participate in an optional yarning interview, and arrange your electronic gift card).

Phone: _____ Email: _____

RESEARCHER

I have fully explained to _____ the nature and purpose of the research, the procedures to be employed, and the possible risks involved. I have provided the participant with a copy of the Information Sheet.

Researcher Signed: _____ Date: _____

Researcher Name: _____

CONSENT FORM – Pathways App Yarning Interview

Pathways for Aboriginal & Torres Strait Islander Hearing Health: The Pathways App Pilot Study

Chief Investigator
Associate Professor Jacqueline Stephens, College of Medicine and Public Health, Flinders University, Tel: (08) 8201 3972

Co-investigators
Dr Celine Northcott, College of Medicine and Public Health, Flinders University
Samantha Rattos, College of Medicine and Public Health, Flinders University
Lisa Callahan, Children's Audiology Service, Women's and Children's Health Network

CONSENT STATEMENT

- ☐ I have been invited to participate in an optional yarning interview as part of the Pathways App Pilot Study. I have already read and signed the main Participant Information Sheet and Consent Form for this study.
- ☐ I understand the yarning interview will be conducted by a researcher and will take approximately 40 minutes.
- ☐ I understand that at the beginning of the yarning interview I will be asked basic demographic questions about the number of children I use the app for, their ages, and their Aboriginal and/or Torres Strait Islander status.
- ☐ I agree to the yarning interview being audio recorded and understand the recording will be transcribed and stored securely for five years, after which it will be destroyed.
- ☐ I understand that only the investigators listed on the Participant Information Sheet will have access to recordings and transcripts.
- ☐ I understand that I do not have to answer any questions I do not want to, and I can stop the interview at any time without it affecting my participation in the rest of the study or my access to services.
- ☐ I understand that no personal information, including my name or anything that could identify me, will be used in any reporting or publications arising from the interview.

This research project has been approved by Flinders University's Human Research Ethics Committee (Project ID 9922) and the Aboriginal Health Research Ethics Committee (#04-26-1244). If you have any complaints or reservations about the ethical conduct of this study, you may contact Flinders University's Research Ethics & Compliance Office via telephone on 08 8201 2543 or by email human.researchethics@flinders.edu.au or Aboriginal Health Research Ethics Committee via telephone on (08) 8273 7200 or by email research@ahcsa.org.au

PARTICIPANT

Signed: _____ Date: _____

Name: _____

RESEARCHER

I have fully explained to _____ the nature and purpose of the research, the procedures to be employed, and the possible risks involved. I have provided the participant with a copy of the Information Sheet.

Researcher Signed: _____ Date: _____

Researcher Name: _____