



Māori and Pacific Women's Views of Endometrial Cancer Microbiome Research

2023 Participant Information Sheet

Tēnā koe and warm greetings,

We are a team of health professionals and researchers who would like to invite you to kōrero or talanoa (be interviewed) as part of a study about Māori and Pacific women's views on:

- Research about endometrial cancer (cancer of the womb) and
- Testing samples for a bacteria called *P. somerae* and pH levels to see if they are indicators of Endometrial cancer.

Māori and Pacific women have a much higher likelihood of being diagnosed with endometrial cancer. We are exploring reasons for this and looking for ways to find cancer early.

This participant information sheet sets out why we are doing the study, what being part of the study involves, what the benefits and risks to you might be and what happens after the study ends.

We will go through this information with you and answer any questions you have. You do not have to decide right now whether you will participate in this study. Before you decide, please feel free to talk about the study with other people, such as whānau, friends or your healthcare provider.

If you decide to participate you will be given a copy of this participant information sheet to take home and a consent form which you will be asked to sign.

Do I have to take part in this study?

It is your choice to participate in this study. If you do not want to take part, you do not have to give a reason, and it will not affect any future health care you receive. If you choose to take part but later change your mind, you can withdraw by letting us know.

What is the purpose of this study?

The purpose of this research is to understand the views of Māori and Pacific women about taking different kinds of samples from their womb or vagina to see if we can identify endometrial cancer earlier. The findings of this study will help inform future endometrial cancer microbiome research involving bacterial testing, swabs, blood samples and storing of tissue samples. We hope to find ways to test for endometrial cancer that work for women. A microbiome is a community of tiny organisms like bacteria, which live in specific areas of the human body. Changes to this can sometimes lead to disease.

How will we do the study?

We will invite Māori and Pacific women to kōrero or talanoa with a researcher (one-to-one interviews). You may like to bring a support person(s) as well.

We would be privileged to hear your views about endometrial cancer microbiome research, including:

- Your experiences with recent treatment and health services
- Your views about the research and the kinds of tests we might do in the research
- Your ideas about engaging well with Māori and Pacific women for the Endometrial Cancer Microbiome Study
- Your thoughts on storing blood or other tissue for further cancer research
- Your thoughts about how we can best ask questions about your current health and nutrition
- Your thoughts on biobanking and tissue banking (these are processes where bodily fluid and tissue are collected and stored for research).

Who can take part in the study?

You are invited to take part in the study if you:

- Are a Māori and/or Pacific women aged 18 years or older
- Reside in Auckland
- Within the last 12 months have
 - had a hysterectomy (surgical removal of the womb/uterus) related to endometrial cancer OR another reason
 - are currently having tests after seeing a doctor for bleeding

What will I have to do?

Kōrero or talanoa (interviews) will take one to two hours and will be arranged at a time and place that is convenient to you. The interview can happen at a hospital clinic or another location (this may include your own home). If you wish it can also be done by Zoom video call.

Interviews can be held in Te Reo Māori, most Pacific languages or English; please let us know which language you would prefer. We can arrange a language interpreter. Please feel free to have family or other support with you for the interview. There will be kai and refreshments provided during the interview if it is in person.

You will have the option to receive a summary of the study results before it is used in the study.



ROIMATA TIPENE
Research Manager (*Ngāpuhi, Ngāti Wai*)



ANASTACIA OLOAPU
Pacific Research Assistant



KAZMAIRE BAUTISTA
Research Assistant

What are the risks and benefits to this study?

We acknowledge that this health topic may be sensitive for some people, and so there is a chance that you may become upset during or after the discussion. You can pause or stop the interview at any time or decline to answer any question. We have a list of supports that we will hand out to all participants if you feel like you want to talk to someone during or after the interview.

The benefits of this study will be that these interviews will help inform future research on endometrial cancer. In particular, how to ensure Māori and Pacific women will not only benefit from the research but that the research itself will be culturally appropriate and responsive.

There is no cost for you to participate in this study. In recognition of your time and contribution to this research, you will receive a koha (\$50 voucher) as a small token of our gratitude. Parking and travel cost reimbursements can also be arranged for you and your support person(s).

Will this cost me anything?

It will not cost you any money to take part in this study. The cost to you is your time. Your time is valuable and to recognise the time that you have spent to be part of this study, you will receive a koha (\$50 voucher).

What will happen to my information?

During this study, the researchers and other study staff will record information about you and the information you share with them. An audio recording will be made of the interview. The only people that will have access to this recording are the research team members and staff working on this study. The audio recording will be transcribed and deleted once the analysis is complete. Although all efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed, even with coded information. The risk of people accessing and misusing your information is small.

IDENTIFIABLE INFORMATION

Identifiable information is any data that could identify you (e.g., your name, date of birth, or address). The following people may have access to your identifiable information:

- Members of the research team (approximately 6 people).
- The Te Whatu Ora sponsor, ethics committees, or government agencies from New Zealand or overseas, if the study or site is audited. Audits are done to make sure that participants are protected, the study is run properly, and the data collected is correct.
- The record of your consent and information from the interview with you will be held at the Waitematā locality of Te Whatu Ora during the study. After the study, it will be held securely for at least ten years. After that, it will be destroyed. A karakia will be performed at this time.

DE-IDENTIFIED (CODED) INFORMATION

To make sure your personal information is kept confidential, information that identifies you will not be included in any report written by the researchers. Instead, you will be identified by a code. The researcher will keep a list linking your code with your name, so that you can be identified by your coded data if needed.

When the results of the study are published or presented, we may use direct quotes from the interview. It is important to let you know that **no information that could identify you** (like your name or date of birth) will be included in these reports or publications.

FUTURE RESEARCH USING YOUR INFORMATION

Your coded information will not be used for any other research.

YOUR RIGHTS

You have the right to request a copy of your interview transcript held by the research team. You also have the right to request that any information you disagree with is corrected or removed.

MĀORI DATA SOVEREIGNTY

Māori data sovereignty is about protecting information or knowledge that is about

(or comes from) Māori. We recognise the taonga of the data collected for this study. To help protect this taonga we have consulted with the study's Māori advisors about the collection, ownership, and use of the study data.

If you have any questions about the collection and use of information about you, you can ask the research team member discussing this information sheet with you or contact Roimata Tipene (Research Manager).

What happens after the study or if I change my mind?

You may withdraw your participation from this study at any time by informing a research team member. Their details are below and on your consent form.

If you withdraw your participation, the study team will stop collecting information from you. Please note, your information can be withdrawn up to two weeks following your interview, at which time the analysis will begin, and data is unable to be withdrawn from that point on.

Can I find out the results of the study?

A summary of the study results will be made available to you. Kōrero with you and anyone you wish to attend can also be arranged to provide opportunity for a face to face and verbal presentation of results. Kōrero can be held in Te Reo Māori, most Pacific languages or English; please let us know which language you would prefer. An interpreter can also be arranged to present the results back to you (if you wish) and the full published results will be available mid-2024 on the Waitematā Te Whatu Ora website.

Who is funding the study?

The study is funded through the Māori Health Pipeline at Te Whatu Ora (Service Innovation and Improvement). The researchers for this study work for Te Whatu Ora.

Who has approved the study?

Health and Disability Ethics Committee (HDEC) 16657 and localities approved.



Who do I contact for more information or if I have concerns?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Roimata Tipene, Research Manager

P: 021 415 266

E: roimata.tipene@waitematadhb.govt.nz

If you want to talk to someone who is not involved with the study, you can contact an independent health and disability advocate:

P: 0800 555 050

E: advocacy@advocacy.org.nz

W: www.advocacy.org.nz

You can also contact the Health and Disability Ethics Committee (HDEC) who approved this study:

P: 0800 4 ETHIC

E: hdecs@health.govt.nz

For Māori cultural and health support please contact He Kamaka Waiora Māori Health Services:

P: (09) 486 8324 ext 43553

M: 021 822 576

For Pacific cultural and health support please contact Waitematā Pacific Cultural and Pastoral Support Services:

P: (09) 837 8836 ext 6836

M: 021 225 0016

For more info, scan to visit our study website:



Te Whatu Ora
Health New Zealand