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| Participant Information Sheet  | Logos - both.  |
| Study title: | Genetic and Biochemical Predictors of Pelvic Organ Prolapse |
| Locality:  | Southern District Health Board | Ethics committee ref.: |  |
| Lead investigator: | Dr Emma Wade | Contact phone number:  | 0221 75 6315 |

You are invited to take part in a study on how your genes may influence whether or not you experience a pelvic organ prolapse. Whether or not you take part is your choice. If you don’t want to take part, you don’t have to give a reason, and it won’t affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you’d like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 7 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

## What is the purpose of the study?

The purpose of the study is to discover if certain types of variation in a person’s genes can influence whether or not they experience a pelvic organ prolapse (POP). We want to understand if your genes can change the composition of the supportive pelvic floor tissue and make it more likely that you will experience a prolapse.

The study involves laboratory testing on tissue(s) removed from the body including blood, urine and a tissue biopsy in some cases. The study does not affect your care or healing in any way.

The new knowledge gained will help scientists and doctors better understand if women are predisposed to pelvic organ prolapse based on their genetics. This could allow future research to discover new treatments or to target particular women for preventative care.

This study is funded by the University of Otago. The study is approved by a research ethics committee to ensure the safety of those in the study.

The results of the study may be published or presented in scientific journals or at conferences. No information will be disclosed that could cause you to be identified. Portions of the information collected may be used in a thesis used for the purposes of gaining a research qualification by a student researcher. You will not be able to be identified from any of this information.

**What will my participation in the study involve?**

You may have been invited to participate in the study as you have a gynecological surgery scheduled, either to repair a pelvic organ prolapse or for a non-prolapse related reason (control group). Or your primary care provider has nominated you to participate in the genetics study only as a POP candidate or a non-POP control.

The following three paragraphs apply to all study participants

If you choose to be involved in this study, a researcher will organise a time to meet you and give you the opportunity to provide informed consent and give a blood sample. A second visit will be arranged for you to give a blood sample if you wish. Some health information will be collected from you. This includes information about your height, weight, ethnicity, and if applicable, number of pregnancies and mode of delivery. These visits could be at your primary care provider, your home, or at the Dunedin Medical School. If you are scheduled for surgery, blood will be taken while you are in the hospital. This is the only contact you are required to have with a researcher.

We will use your blood to discover if you have certain changes in your DNA. These changes are found in many people and do not have a profound effect on your health. We do not expect to discover disease-causing changes in your DNA because of the methods we have chosen to use. In rare cases we may discover that your genetics predisposes you and/or your children to certain connective tissue problems. If we find this in your genome you will be contacted by a clinical geneticist to discuss the finding.

All data generated ultimately belongs to you as the study participant and you get to make the decisions about what happens to it. The researchers undertaking the study recognize their responsibility as custodians of these samples and data. Tissue samples that remain after laboratory testing will be destroyed using a biologically safe method of tissue destruction. Karakia can be arranged for this process if you desire.

The following three paragraphs only apply if you have a scheduled surgery

If you are scheduled for surgery and choose to be enrolled in this study, you will be asked to give a urine sample as well as the blood sample for research prior to your surgery and while you are in the hospital

During your surgery a small (4-10 gram) piece of fascia and ligament (connective tissue) will be removed from your vagina. This tissue is often removed routinely as part of this surgery and discarded. This tissue will be removed either by your surgical team or by one of the study investigators. This means that there could be one additional person in the operating theatre for your procedure. If you are not in the study, no tissue sample would be removed. The removal of this tissue will not alter how your surgery is carried out, or how you recover.

The time involved in the study will be for 15 – 30 minutes whilst a blood and urine sample are collected, and only a minute or two while the tissue sample is removed during surgery. Once your samples are collected and the tissue is removed, it will be tested in a laboratory. No further contact with you will be required. The only involvement for you is to have your samples collected prior to, and during, surgery.

**What are the possible benefits and risks of this study?**

No risks, side effects nor discomfort is expected from your participation in the study. Your blood sample will be collected by a trained individual and only a small amount is needed for this study. The tissue sample removed for the study is small, and will not affect your healing. You will be under anaesthesia for your surgery, so there will be no pain from the sample collection. There may be a small amount of bleeding form the biopsy site (a few milliliters). This is easily stopped by either holding pressure against the bleeding area, or using electrical cautery, or placing a stitch.

No direct benefit to you is expected from your participation.

The research team has a medical monitor who will review chart notes to ensure that no participant has study related harm. If the study monitor has concern about study related harm, you will be contacted by the research team to ensure that you are provided with appropriate follow-up medical care.

**Who pays for the study?**

This study is funded by the University of Otago.

There will be no costs for being in the study.

You will not be paid to be in the study.

**What if something goes wrong?**

If you were injured in this study, you would be eligible to apply for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

In the very unlikely event, that ACC determines that their cover did not apply to your injury, then the University of Otago’s clinical trial insurance would apply. This cover would provide you with compensation equivalent to that you would otherwise have been entitled to under the Accident Compensation Act 2001. By signing the Consent Form for this study, should ACC decline cover, you are explicitly agreeing that compensation for any injury will be as per the terms of University’s then current clinical trials insurance cover, the full terms and conditions of which are freely available on request. The research team will support you in making such a claim for compensation.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.

## What will happen to my information?

During this study the researchers or doctors will record information about you and your study participation. This includes the results of any study assessments and laboratory tests. If needed, information from your hospital records and your GP may also be collected. You cannot take part in this study if you do not consent to the collection of this information.

Identifiable Information

Identifiable information is any data that could identify you (e.g. your name, date of birth, or address). Only lead researchers will have access to your identifiable information. In the very unlikely event that we discover a connective tissue problem from your genetic data, your identifiable information will be shared with a clinical geneticist and your GP to ensure you are notified.

De-identified (Coded) Information

To make sure your personal information is kept confidential, information that identifies you will not be included in any report generated by the researcher or in any study information sent to the sponsor. 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.

The following groups may have access to your coded information:

* The sponsor, for the purposes of this study.
* People and companies working with or for the sponsor, for the purposes of this study (this may include approximately 10 people).

The results of the study may be published or presented, but not in a form that would reasonably be expected to identify you.

Security and Storage of Your Information.

Your identifiable information is held at the University of Otago during the study. After the study it is transferred to a secure archiving site and stored for at least 2 years, then destroyed. Your coded information will be entered into electronic case report forms and sent through a secure server to the sponsor. Coded study information will be kept by the sponsor in secure, cloud-based storage indefinitely. All storage will comply with local and/or international data security guidelines.

Risks

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with coded and anonymised information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information (e.g. making it harder for you to get or keep a job or health insurance) is currently very small, but may increase in the future as people find new ways of tracing information.

Rights to Access Your Information.

You have the right to request access to your information held by the research team. You also have the right to request that any information you disagree with is corrected.

Please ask if you would like to access the results of your screening and safety tests during the study.

If you have any questions about the collection and use of information about you, you should contact the lead researcher.

Rights to Withdraw Your Information.

You may withdraw your consent for the collection and use of your information at any time, by informing the lead researcher.

If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you.

If you agree, information collected up until your withdrawal from the study will continue to be used and included in the study. You may ask for it to be deleted when you withdraw, unless you withdraw after the study analyses have been undertaken.

Ownership Rights.

Information from this study may lead to discoveries and inventions or the development of a commercial product. The rights to these will belong to the lead researchers, Cure Kids and the University of Otago. You and your family will not receive any financial benefits or compensation, nor have any rights in any developments, inventions, or other discoveries that might come from this information.

Māori Data Sovereignty

Māori data sovereignty is about protecting information or knowledge that is about (or comes from) Māori people. We recognise the taonga of the data collected for this study. To help protect this taonga:

* We have consulted with Hine Forsyth, Ōtākou Runaka about the collection, ownership, and use of study data.
* We allow Māori organisations to access de-identified study data, for uses that may benefit Māori.

**What are my rights?**

Your involvement in the study is voluntary. You are free to decline to enroll and can withdraw from the study at any time. The contact information at the end of this information sheet should be used if you wish to withdraw. This decision will not affect your medical care in any way. If you withdraw your tissue and any data will be destroyed, or if possible, returned to you if you so wish.

You have the right to access the information collected from youas part of the study.

Your information will be kept private by using a study code that unlinks your study information from your identity. Only the study staff have access to the key to break the code that protects your identity. This code is kept secure in a locked office on a password protected computer.

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

The data generated by the study will be kept for up to 12 years. Any information about you that is private will be kept for up to two years beyond study completion. Study information will be stored on a password protected computer in a locked office. This information will be coded so that your identity will not be known. The study roster that links identity to the information will be destroyed by electronically “shredding” the computer files containing the information.

DNA that is extracted from your blood and any tissue samples will be destroyed using heat and steam at the end of data collection (approximately 2 years). Your tissue will not be made available to other researchers nor other research projects. If you decide to withdraw from the study after your tissue has been collected, we will destroy your tissue sample using heat and steam if you request for us to do so.

At the end of the study participants who want to know the information learned will be sent a summary of the findings. We will need to for you to provide your contact details for us to provide you with this information at the end of the study.

**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:

Dr Emma Wade (PhD)

Telephone 0221 75 6315

Email: emma.wade@otago.ac.nz

If you want to talk to someone who isn’t involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@advocacy.org.nz

For Māori cultural support please contact :

SDHB Māori Health Support

03 474-0999 ext 8649

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

 Phone: 0800 4 ETHICS

 Email: hdecs@moh.govt.nz

**Department of Women’s and Children’s Health**

**Te Tari Hauora Wāhine me te Tamariki**

**Laboratory for Genomic Medicine**

An interpreter is available upon request.

**Genetic and Biochemical Predictors of Pelvic Organ Prolapse**

**CONSENT FORM**

**Full Name:…………………………………………...………………………..**

**Please tick to indicate you consent to the following**

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| I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.  | Yes 🞏 | No 🞏 |
| I understand that I will be given a copy of the information sheet to keep | Yes 🞏 | No 🞏 |
| I have been given sufficient time to consider whether or not to participate in this study. | Yes 🞏 | No 🞏 |
| I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study. | Yes 🞏 | No 🞏 |
| I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet. | Yes 🞏 | No 🞏 |
| I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care. | Yes 🞏 | No 🞏 |
| I consent to the research staff collecting and processing my information, including information about my health and ethnicity | Yes 🞏 | No 🞏 |
| I am aware that this study will involve extensive analysis of my genetic makeup | Yes 🞏 | No 🞏 |
| I am aware that this genetic analysis may produce unexpected results of potential health significance  | Yes 🞏 | No 🞏 |
| I consent to providing a blood, urine and tissue sample for this study | Yes 🞏 | No 🞏 |
| I am aware that the study will store and examine my DNA (genetic makeup) for this research project and I consent to such analysis being performed | Yes 🞏 | No 🞏 |
| I understand that if I consent to such analysis, no rights will be created for the researcher to my genetic information  | Yes 🞏 | No 🞏 |
| I understand that I can request to have my samples and data destroyed at any time | Yes 🞏 | No 🞏 |
| I have read the ‘What if Something Goes Wrong’ section in the Participant Information Sheet. I agree that in the unlikely event that ACC declines cover for any injury to me arising from this study, the compensation available will be as per the terms of University’s then current clinical trials insurance cover. | Yes 🞏 | No 🞏 |
| I would like any remaining samples to be disposed of at the end of the study (please tick one):  🞏 Using standard disposal methods  🞏 Disposed with appropriate karakia  |  |  |
| I agree to an approved auditor appointed by the New Zealand Health and Disability Ethic Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study. | Yes 🞏 | No 🞏 |
| I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study. | Yes 🞏 | No 🞏 |
| I know who to contact if I have any questions about the study in general. | Yes 🞏 | No 🞏 |
| I wish to receive a summary of the results from the study. | Yes 🞏 | No 🞏 |
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**Declaration by participant:**

I hereby consent to take part in this study.

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| Participant’s name: |
| Signature: | Date: |

**Declaration by member of research team:**

I have given a verbal explanation of the research project to the participant, and have answered the participant’s questions about it.

I believe that the participant understands the study and has given informed consent to participate.

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| Researcher’s name: |
| Signature: | Date: |