# Participant Information Sheet

## Study title: The Pipelle for Pregnancy in Unexplained Infertility (PIP-UE) study

Lead investigator: Prof Cindy Farquhar Ethics committee ref.: 14/NTA/62

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You are invited to take part in the PIP-UE study

## WHAT IS THE PURPOSE OF THE STUDY?

The PIP-UE study is a trial in couples with unexplained infertility who are attempting to conceive through natural conception (sexual intercourse).

**Purpose of the PIP-UE study**

Endometrial pipelle sampling (also known as endometrial biopsy, injury or scratching) is a common procedure often used to collect endometrial samples from women with heavy periods. A thin plastic sampler (pipelle) is passed through the cervix and into the womb where a sample is then obtained by rotation.

Researchers have found that taking a sample from the womb in women who had unsuccessful IVF cycles increased their chance of pregnancy in the next IVF cycle. However, it is not known whether sampling is also helpful for couples with unexplained infertility who are trying to get pregnant. It is possible that pipelle sampling may be beneficial for these patients too.

The PIP-UE study aims to determine whether pipelle sampling improves pregnancy and live birth rates in couples who are attempting to get pregnant. The PIP-UE study is recruiting couples who have been diagnosed with unexplained infertility.

It is believed that endometrial sampling may increase the chance of pregnancy because it disturbs the lining of the womb and causes a small inflammatory response. Biological factors which are then released due to this response are thought to be helpful for implantation of an embryo into the lining of the womb.

**Randomisation and Blinding**

Couples who agree to take part in the PIP-UE study will be randomly allocated to either pipelle sampling or no sampling. If you decide to take part in the study you will not be able to choose to have sampling or no sampling, a computer will randomly allocate you to a group.
Couples in the PIP-UE study will not be told whether they have been allocated to the pipelle sampling or placebo procedure. This is known as double-blinding and is important for the integrity of the study design.

The PIP-UE study is being led by clinicians and researchers who are at the University of Auckland, Repromed and Fertility Plus. Funding for the study has been provided by the Auckland District Health Board.

The PIP study has received ethics approval from the National Health and Disability Ethics Committee.

## WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

You have been invited to participate in this study because you are, or have recently been, a patient at one of the clinics involved in the study.

**Endometrial Biopsy Procedure**

If you agree to participate in the PIP-UE study you will have one procedure in addition to usual care (either the pipelle sampling or the placebo procedure, though you will not know which procedure you have been allocated to).

The pipelle procedure is similar to having a smear test done. The speculum is inserted into your vagina. Then the pipelle will be inserted gently through the cervix and into your uterus. The pipelle procedure takes 1-2 minutes and involves gently moving the pipelle back and forth to obtain a sample. In approximately 5% of women is it necessary to dilate the cervix, and some of these women may prefer to have local anesthetic. Rarely, sampling is not possible. Participants are often recommended to have a chaperone present during the procedure, who is often another member of staff. You may also wish to have your partner or a family member present.

If you are in the placebo group you will undergo a similar procedure, however the pipelle will not actually enter your uterus.

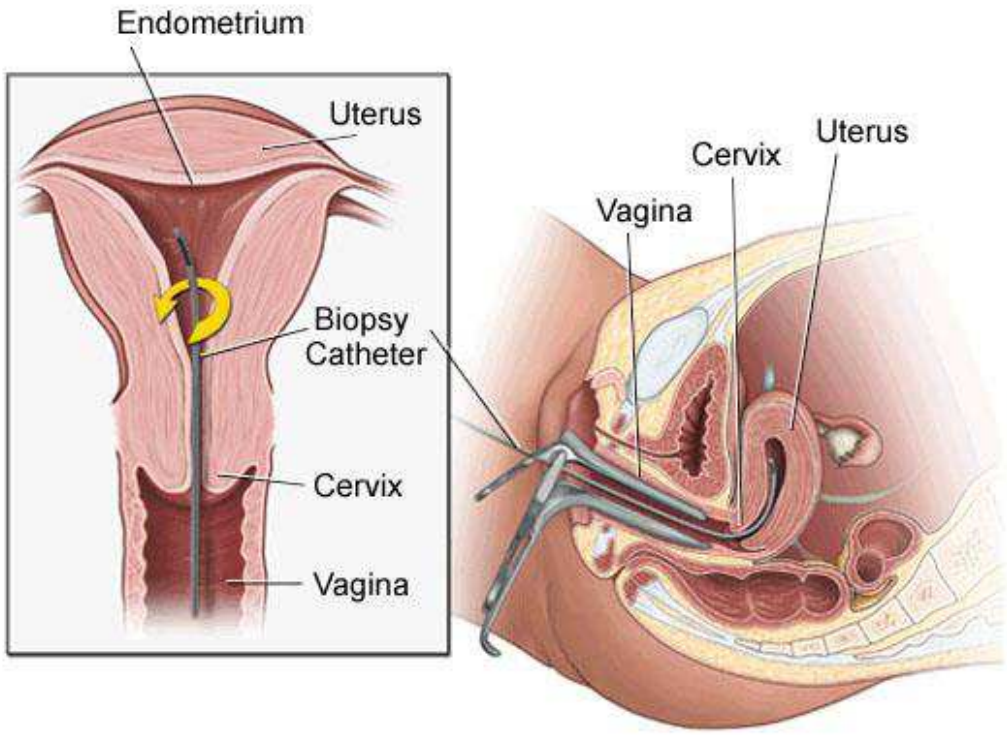


**Figure: Endometrial pipelle sampling**

Figure kindly provided by: Krames StayWell, 780 Township Line Road, Yardley, PA, 19067, 267-685-2500

Participants are expected to have regular, unprotected intercourse for up to three months following the procedure.

**Data collection**

We will also collect some additional information from you than is routinely collected during fertility treatment, including the costs involved in your treatment, your sexual intercourse frequency and the pain or discomfort you experience during the procedure.

## WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

Research on pipelle sampling has shown that it may increase the chance of pregnancy in both IVF and natural conception cycles. If you agree to participate in the PIP-UE study you may benefit from a higher chance of pregnancy.

Endometrial pipelle sampling is a safe procedure that is usually well-tolerated by patients. However, if you take part in this study there are a number of small risks you should be aware of:

1. Spotting or bleeding after the procedure (for less than 1 hour)
2. Crampy period-like discomfort (which is usually short lived)

There is also an extremely small risk of infection or uterine perforation. If this happens, antibiotics and observation for fever may be recommended.

## WHO PAYS FOR THE STUDY?

Couples who agree to participate in the PIP-UE study will not incur any costs or significant inconveniences above normal care.

## WHAT IF SOMETHING GOES WRONG?

If you were injured in this study, which is unlikely, you may be eligible for compensation from ACC just as you would be if you were injured in an accident at work or at home.

## WHAT ARE MY RIGHTS?

Participation in the PIP-UE study is completely voluntary and you are free to decline to participate or withdraw from the study at any time, and you do not need to provide a reason. If you do not choose to participate or you withdraw from the study, this will not affect the care or treatment you receive from your fertility clinic.

As a participant in the PIP-UE study you have a right to access all information collected about you for the purposes of the study. All information collected about you will be stored in a secure electronic system which is only accessible by investigators on the study and staff at participating clinics. No identifiable information about any PIP-UE participants will be published or provided to anyone outside of the PIP-UE study.

## WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

Data collected about you for the PIP-UE study will be stored electronically for 10 years and then destroyed. When the PIP-UE study is completed you will receive information about results of the study in a brief publication sent to the email address you provide.

## 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:

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| Sarah Lensen<br>PIP study coordinator | pipue@auckland.ac.nz | 09 923 9487 |
| Professor Cindy Farquhar<br>PIP study lead investigator | c.farquhar@auckland.ac.nz | 09 923 9493 |
| Dr Devashana Gupta<br>PIP study doctor | devashanag@adhb.govt.nz<br>dgupta@repromed.co.nz | 09 524 1232 |
| Dr Sarah Armstrong<br>PIP study doctor | s.armstrong@auckland.ac.nz | 09 923 3874 |

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

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

If you require Māori cultural support, you can talk to your whānau in the first instance. Alternatively you may contact the administrator for He Kamaka Waiora (Māori Health Team) by telephoning 09 486 8324 ext 2324

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

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| Phone: | 0800 4 ETHICS |
| Email: | hdecs@moh.govt.nz |