# Informed consent for research study

# IMPEDE-PKD

## Testing whether metformin, an existing medicine for diabetes, can prevent decreases in kidney function for people with Autosomal Dominant Polycystic Kidney Disease

Kia ora ……………………………………

We understand that making a choice to take part in any research study can be complex.
We appreciate that you are thinking about taking part in this research.

This guide to informed consent can help you to make your choice by explaining what you can expect in this research study, also known as a clinical trial.

Please keep this information and research guide for your own reference.

Taking part in a research study is completely your own choice. You can take as long as you need to make your own decision. You can include other people in your decision such as your family and whānau, your GP, your specialist doctors and others who support you.

You can always change your mind about whether you want to take part in this research. If you decide not to take part, this choice will have not have any effect on the care that you receive from your health team.

Before you agree to take part in this research study, it is important that you read and understand the information in this guide. If you choose to take part in this research study, you must sign the consent form to let your research study team know about your decision.

The research study team will work with you to answer any questions that you may have about the study.

This document provides you with more detailed information about clinical trials to assist with your decision. Your research team will work through this guide with you when you are ready.

This guide and consent form is 22 pages.

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Study doctor

# Table of contents

To help you work through the information, this guide has been separated into **Part 1: Overview**, **Part 2: In greater detail** and **Part 3: Consent to participate.** Make sure to read through all parts of the guide before making your decision to participate.

## PART 1: OVERVIEW

## PART 2: IN GREATER DETAIL

## PART 3: CONSENT TO PARTICIPATE

# Study contact details

This sheet contains the contact information for members of your research team and other people who may be available to help you.

People involved in your care during the research:

| Study Coordinator | Study Doctor |
|---|---|
| Name:<br>Email:<br>Phone: | Name:<br>Email:<br>Phone: |

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

| Independent advocate |
|---|
| Phone: 0800 555 050<br>Email: advocacy@advocacy.org.nz |

For Māori health support please contact:

| Kaitohutohu Rangahau Hauora Māori |
|---|
| Name:<br>Email: |

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

| HDEC |
|---|
| Phone: 0800 400 569 (Ministry of Health general enquires)<br>Email: hdecs@health.govt.nz |

# Part 1: Overview of the research

This section provides you with information about the study and what will be asked of you if you take part.

# Part 1: Overview

## Key points about this research study

### What is this study about?

This research study is called IMPEDE-PKD. The research study (also known as a clinical trial) is testing whether metformin, a medicine used for diabetes and other conditions, can slow the decrease in kidney function for people with Autosomal Dominant Polycystic Kidney Disease (ADPKD for short). We know from previous smaller studies that metformin is safe in people with ADPKD. We are now testing whether metformin is helpful to protect kidney function. Please go to page 18 of this document more information about how ADPKD develops.

### How might metformin work to protect kidney function

People with ADPKD experience cysts (fluid-filled sacs) growing in both kidneys and, sometimes, the liver. These cysts put pressure on healthy tissue and cause damaged kidneys. The cysts can become blocked and cause infection, or cause pain or bleeding. People with ADPKD can develop kidney failure when the damaged kidneys can no longer work properly.

Kidneys clean the blood of unwanted toxins and fluid. When this no longer happens, toxins can build up in the blood stream and need to be removed. Toxins can be removed by kidney dialysis (using a machine or fluid to clean the blood) or a kidney transplant (a kidney from someone else).

Metformin may change the way cysts form for people with ADPKD. In research studies, metformin is shown to slow the growth of cysts through specific body cell changes. We now need to test whether metformin protects kidney function in people with ADPKD in a clinical trial.

## Why am I being asked to take part in this research study?

You are being asked to take part because you have ADPKD, and you may be at risk of decreased kidney function. You are between 18 and 70 years old.

You may have:

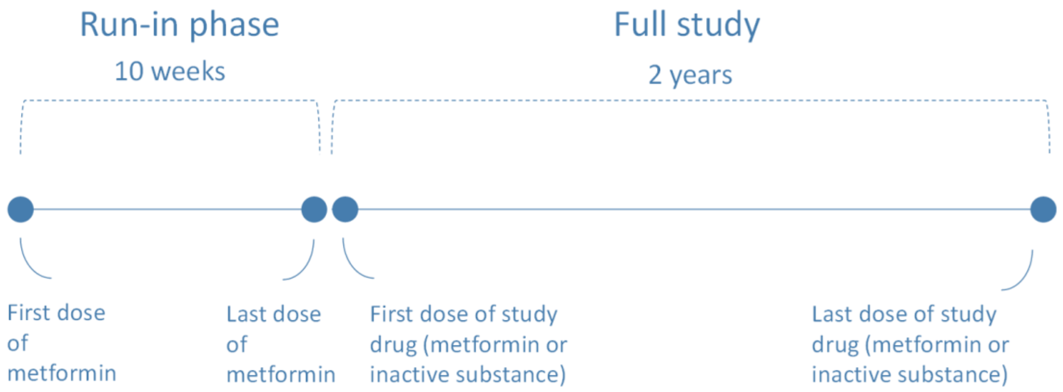
- kidneys that are larger than 16.5 cm each (seen on a scan) or
- your kidney function has changed at least 5 percent over the previous year (measured on blood tests) or
- your kidney function has changed at least 3 percent each year for the last 5 years (measured on blood tests)

Your current kidney function is required to be between 38 per cent and 90 per cent of full function to take part in the study.

## What is involved in the research study?

The research study takes 2 years and 3 months to complete. This document will provide you with more information about the level of time commitment in more detail.

The research study IMPEDE-PKD is in two parts, a **run-in phase**, and a **full study phase.**



① The first part is a **run-in phase that lasts 12 weeks**. If you give your consent to take part, you will be assessed at a clinic visit by the research team. If you meet the criteria to take part in the study, you will start the run-in phase. In this phase, you will start taking metformin treatment for 10 weeks.

② If you can take metformin at least 1000 mg a day (2 tablets) for 10 weeks during the run-in phase, you will be asked to start the **full study phase**, which lasts for 24 months (two years).

### Run-in phase (12 weeks)

If you take part in the study, you will be asked to take metformin for 10 weeks starting at 1000 mg a day, two tablets and increasing the dose up to 2000 mg a day (4 tablets) with the support of the research study doctor. The run-in phase will test whether you can tolerate metformin at a dose that is high enough to be in the full study (1000 mg a day or more, two tablets). Some people experience diarrhoea (loose bowel motions) or stomach bloating when metformin is started, which can go away after a few weeks. Starting at a smaller dose can help.

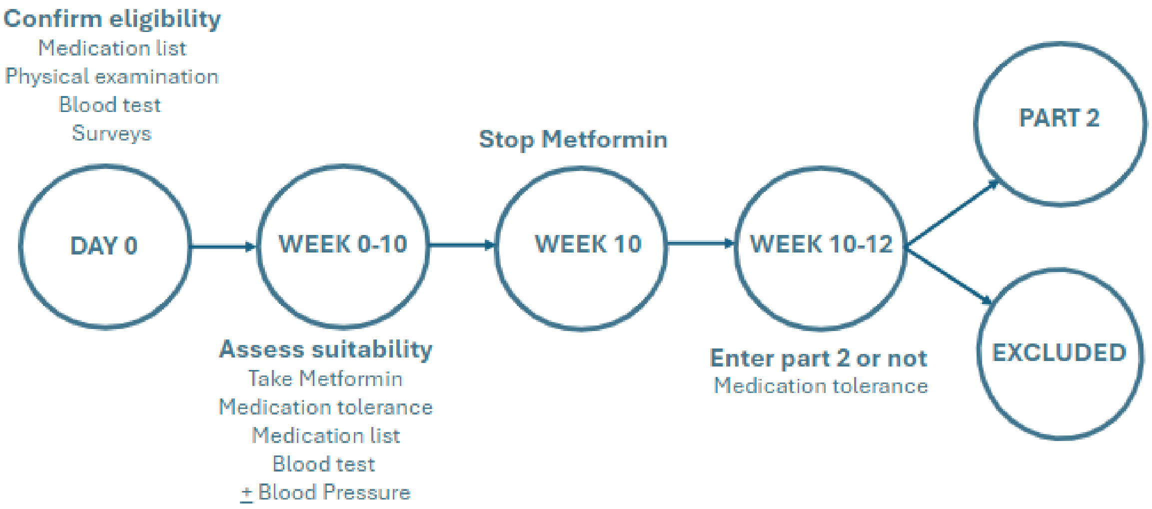
### Full-study phase (2 years)

If you can take metformin at 1000 mg a day (two tablets) or more at 10 weeks, you can enter the full study, where you are placed (by random chance) in a group taking metformin for 2 years or a group taking placebo (inactive substance) for 2 years. During these 2 years, you have two in-person visits (1 hour) and three health checks by phone or video call. Kidney function is monitored by blood tests once a year.

## Study flow and time commitment

### Run-in phase

The **run-in phase** lasts for 12 weeks. You will be asked to visit the research doctor and coordinator twice during this phase (for about one hour each visit). You will be asked to take metformin tablets (starting at 2 tablets (1000 mg) a day) and increase the dose gradually to 2000 mg a day.



### Step 1 of Run-in phase – Screening Visit – Day 0

The first step in the run-in phase is the screening visit.

1. You will be asked to visit your local hospital team for about one hour to find out whether you are eligible to take part in the study. You can bring a family member or support person with you.
2. You will be asked to sign this consent form. The research coordinator will work through this consent form with you.
3. We will measure your weight, waist, blood pressure, and heart rate.
4. We will ask about the medicines you are taking.
5. We will ask you to have a blood test (about 3 tablespoons of blood) and urine test including to check whether you have diabetes.
6. We will ask you to complete some surveys about your wellbeing, any pain related to your kidney cysts and any bowel symptoms you may have (such as slow bowel habit or loose bowel motions).
7. We may ask you to have a kidney scan to measure the size of your kidneys. This is an ultrasound scan which is painless and will be no cost to you. The scan will be at a different visit to your screening visit. This scan may be done at a different hospital or radiology centre.

### Step 2 of Run-in phase – Confirm taking part in the study (week 0)

If the measurements in your screening visit show:

You have ADPKD

Your kidney function is between 38 and 90 percent

You do not have diabetes

Your kidney size is larger than 16.5 cm or you have had decreasing kidney function

You can take metformin two tablets a day

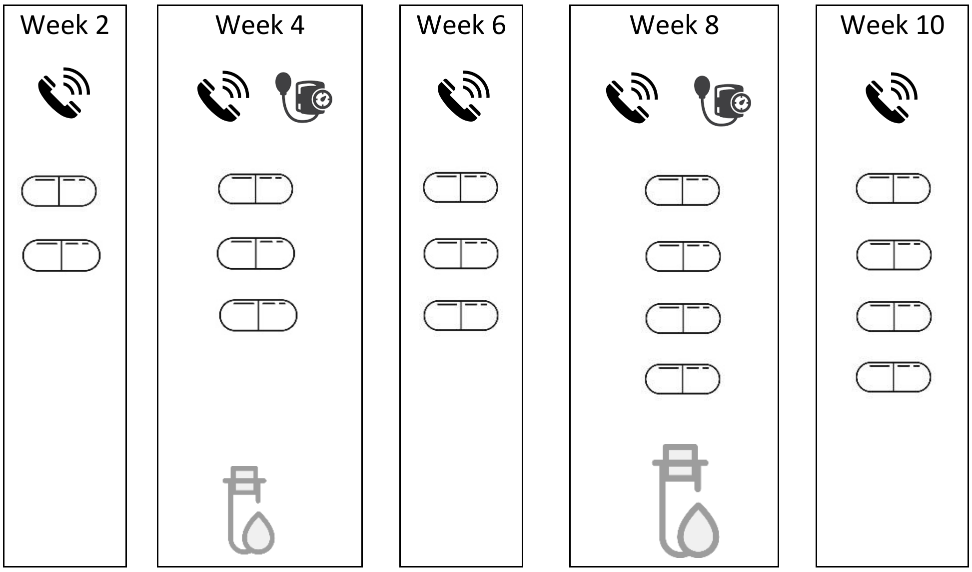
You are not low in vitamin B12

You will be asked to take part in the run-in phase of the research study.

### Step 3 of the Run-in phase – Start taking metformin (weeks 0 to 10)

You will be asked to start taking metformin at 1000 mg a day. This is two tablets every evening with food. You will be sent the medicine by courier.

- Your research study coordinator will contact you every 2 weeks by phone or video call to ask you about your wellbeing and about any side effects.
- You will be asked to take your blood pressure every 4 weeks and let us know what it is.
- You will have a blood test at week 4 and week 8 at your local testing centre.
- Every 4 weeks, you may be asked to increase your metformin dose by one extra tablet a day until you are taking up to 4 tablets a day (2000 mg). If you have side effects, you may be asked to reduce the number of tablets you take each day. You can contact the coordinator if you have any questions or concerns.
- You will stop taking metformin at 10 weeks in the run-in phase.



We expect that during the run-in phase, between 3 and 5 patients in every 100 patients will not be able to tolerate metformin. If this happens, you will be asked to stop your metformin medication. You will not continue in the research study if this happens. If you are not able to take two or more tablets of metformin at 10 weeks after starting it, you will not continue in the full study.

### Step 4 – End of Run-in phase (week 12) – In-person assessment

If you are taking 2 or more metformin tablets at week 10 of the run-in phase, you will be asked to visit the hospital for about one hour to check if you are able to continue in the **full study**. This visit will also count as your visit 1 for the **full study**.

① You will be asked to visit your local hospital team for about one hour to find out whether you are eligible to take part in the full study. You can bring a family member or support person with you.

② We will measure your weight, waist, blood pressure, and heart rate.

③ We will ask about the medicines you are taking.

4. We will ask you to have a blood test (about 3 tablespoons of blood) and urine test.
5. We will ask you to complete some surveys about your wellbeing, any pain related to your kidney cysts and any bowel symptoms you may have (such as slow bowel habit or loose bowel motions).

When the research team has the results of the blood tests, they will contact you to let you know if you can take part in the **full study**.

## Full study phase (2 years)

In the full study phase, you will be asked to take metformin or placebo (inactive substance) for 24 months (about 2 years). You will be placed in the metformin group or the placebo group by chance. You will be asked to visit the clinic two times (once a year). We will also ring you for health checks four times (for 5-10 minutes).

### Step 1 of the Full Study – Intervention

The research team will perform randomization. This is when you are placed into one of the two intervention groups by chance. You have an equal chance of taking either the metformin or taking the inactive placebo. You, your family, your doctors and clinical team and the research team will not know which intervention you are receiving. The metformin and the placebo tablets look and taste the same. We will always be able to find out which intervention you are taking in an emergency if we need to.

### Step 2 of the Full Study – Health checks

1. We will ring you at **1 month** after starting your medication to check on your health and any side effects.
2. We will ring you at **3 months** after starting your medication to check on your health and any side effects.
3. We will ring you at **6 months** after starting your medication to check on your health and any side effects.
4. We will ask you to visit us at the clinic **at 1 year** after starting your medication. This visit includes a health check, surveys, and a blood test. You will be asked to bring in any medication you have. We will give you more metformin tablets when you need them.
5. We will ring you at **18 months** after starting your medication to check on your health and any side effects.

6. We will ask you to visit us at the clinic **at 2 years** after starting your medication. This visit includes a health check, surveys, and a blood test. You will be asked to bring in any medication you have. This is the end of the study. You will stop taking metformin or placebo.

### What else are we asking you to do during the research study?

- Continue your usual activities.
- Take the study medicines in the evening with food.
- Let your study coordinator or your GP know if you are unwell. We will give you important advice about your medicines. You may need to stop taking your study medicine for a few days.
- Check with your GP, pharmacist, or research study team if you need to start a new medicine. We will need to check if it is still okay to take your study medicine at the same time.

## Risks and benefits

### What are the possible benefits of taking part?

Being part of this research study may not be of any benefit to you. You will be asked to take medicines and have extra health checks and blood tests.

If you do take part, you will be helping to improve our understanding of how to treat ADPKD.

### What are the possible risks of taking part?

#### Common side effects

Metformin has common side effects that happen in more than 1 in 100 people.

These include:

- feeling sick (nausea)
- being sick (vomiting)
- loose bowel motions (diarrhoea)
- stomach discomfort
- loss of appetite
- a metal taste in the mouth

If these side effects continue to bother you, tell your research coordinator or your GP.

#### Low blood sugar

Metformin does not usually cause low blood sugar on its own. Low blood sugar can happen when you take metformin with other diabetes medications. Tell your research coordinator if you have been advised to start a diabetes medicine.

#### Serious side effects

Serious side effects are rare and happen in less than 1 in 10,000 people.

A rare side effect is called lactic acidosis. Call your doctor or 111 straight away if you have:

- a feeling of being unwell with severe tiredness, fast or shallow breathing
- shivering, feeling very cold
- dizziness or light-headedness
- a slow heartbeat
- unusual muscle pain
- feeling sick, vomiting, and tummy pain
- sleepiness

## Costs and reimbursements

This research study is funded by the New Zealand government.

There are no payments for taking part in this study.

Any treatment you receive related directly to this study will not cost you anything. You will be asked to provide your own transport to the clinic four times during this study.

Any treatment by your GP during this study will cost you the usual amount.

Any ultrasound scan requested as part of this study will not cost you.

## Compensation for research-related injury

### What if something goes wrong?

- In the event of injury directly because of taking part in this study, you will be able to apply for compensation from the Accident Compensation Corporation (ACC). You will have to lodge a claim and ACC may take some time to assess.
- In an unlikely event that ACC does not apply, then the University of Otago clinical trial insurance would apply. Full terms and conditions are available on request.
- If you have private health or life insurance, you may wish to check with your insurer to understand if taking part in this study will affect your current or future insurance.

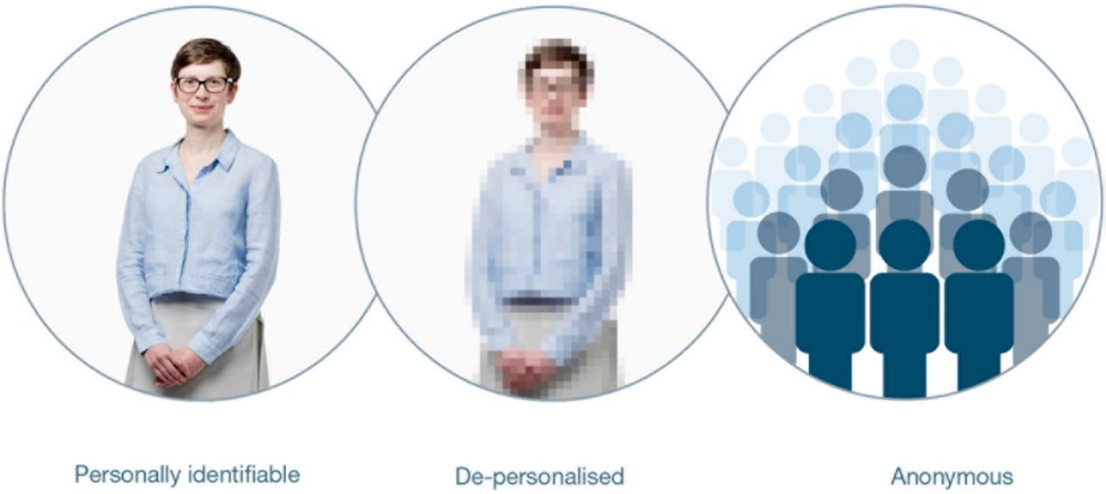
## Privacy and data collection

You will have information collected about you during the research study. This will include your personal information and your health-related information.

We will always keep your information private in a secure network that is protected by passwords. Your information will only by available to people who have a right to access your information to verify the proper conduct of the research study as required by law.

Your information is one of 3 different types:

1. **Personally identifiable**
2. **De-identified**
3. **Anonymised**



## Personally identifiable information

Personally identifiable information is information that could be used to identify, contact, or locate you. This information includes your:

- Full name
- Date of birth
- Physical address
- Email address
- National health identification (NHI) number

The research study team and your usual healthcare team at *[Name of hospital]* will have access to the minimum amount and type of information that is necessary to provide healthcare and conduct the research study safely.

The Ethics Committee that approved this study will allow authorised people who are bound by the Privacy Act 2020 as well as representatives of domestic and/or foreign health authorities and competent ethics committees, to inspect the personally identifiable data if this is necessary to check the proper conduct of the research study or as required to by law.

By signing this consent form, you authorise release of, or access to, this confidential information to these authorised people. Any information obtained in connection with this research that can identify you will remain confidential. After enrolment, you will be given a unique study identification number.

## De-identified (de-personalised) information

De-identified information is information that has had all personally identifiable information removed from it. It cannot be used to identify, locate, or contact you.

Any information that can identify you will be removed before your data is entered into the research study database. This information will be replaced by a unique study identification number. Your personally identifiable information will not be sent out of New Zealand or held in any database other than locally by your research team.

Your de-identified information will be stored in Australia and the United States (at the University of Queensland in Brisbane, Australia, and at Vanderbilt University in Nashville, Tennessee). The research study systems have strong protections against unauthorised access.

If you change your mind and decide to withdraw from (leave) this study, please let someone from the study team know. You do not have to give a reason, and it will not affect the medical care or treatment you receive. **You should be aware that data collected by the research study team up to the time you withdraw will form part of the research project results.** We may ask you for your consent to continue to collect some information about you following your withdrawal from the study. However, you do not have to agree to this if you do not wish to.

## Anonymised information

Anonymised information is information that has had all person identifiers removed and cannot be used to identify, contact, or locate you. Any reports of this study that are made public will only have anonymized information.

You have the right to access the data collected about you and to correct any errors you might discover, provided this does not affect the conduct of the trial.

## Data linkage - Additional consent form

**If you provide specific consent,** the study team will collect personal information about your health, kidney disease and on how many health services you use during the study. This information is already collected as part of your usual hospital treatment.

This information includes:

- Information on medical visits, hospital admissions, tests, and procedures.
- Information on prescription medicines.
- Information on any adverse events.

This information is stored with the NZ Ministry of Health in the Integrated Data Infrastructure (IDI). We will request your information contained in the IDI from the Ministry of Health only for the purposes of the economic analysis of the IMPEDE-PKD study. We will request access to this information using your unique National Health Index (NHI) number. This information will allow us to calculate the cost of your healthcare for over 1 year. Any information about you will remain confidential and will only be used for the purposes we have told you about.

You can choose not to have your personal information collected/linked with the Ministry of Health and still participate fully in the research study.

## Data storage and destruction

Identifiable data source documents will be stored at local sites in locked cabinets or electronically in secure networks. Electric copies will be stored in password protected computers and shared via secure online platforms. The electronic database for identifiable will be hosted by the University of Otago REDCap secure database. The data and information will be stored for 15 years after the publication.

De-identifiable data will be stored in the IMPEDE-PKD trial database (REDCap system at Vanderbilt University based in Nashville, Tennessee). The data and information will be stored for 15 years after the publication.

The duration of the storage of your data is also regulated by legal provisions.

## Future unspecified study – Additional consent form

Additionally, data from the study may be shared confidentially with external researchers in New Zealand, Australia, or other countries for future unspecified research projects.

- This data sharing will not include your personal information and researchers will not be able to use this information to identify you.
- These projects will be assessed by the Australasian Kidney Trials Network for sound science, benefit/risk balancing and team expertise.
- No report of study data will be presented in a way that would identify you, except with your permission, and as required by law.
- We don’t know how long data will be stored and you won’t be informed of the results of these tests.

You can choose not to have your information stored for future use and still participate fully in the research study.

## Māori participants

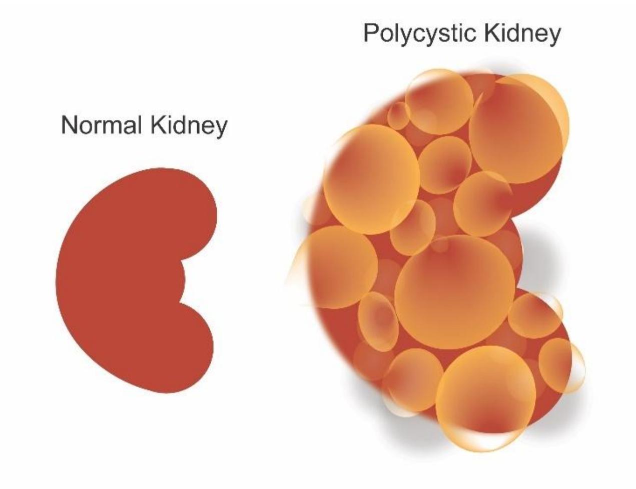
For Māori participants, there may be cultural considerations associated with the collection and storing of your information for future research studies. These considerations should be discussed with your family/whānau as appropriate, citing the protection of whakapapa. Controlling access to your data and limiting unauthorised use of your information are important questions that you may need to think about before consenting to research. It is also acknowledged that individuals have the right to choose whether they participate or not in a research study. You may also like to think about the direct benefits that this research will have for yourself, your whānau and for Māori as a people. We advise participants to consult with their whānau prior to consenting to participate in a research study and suggest that your family/whānau are involved with you at all stages of the research.

**If you have any questions about the handling of your data in this trial, please contact your local study team first.**

# Part 2: In greater detail

This section gives you more information about polycystic kidney disease, clinical trials, and taking metformin.

## More about Autosomal Dominant Polycystic Kidney Disease



Autosomal Dominant Polycystic Kidney Disease (known as ADPKD) is the most common kidney condition caused by a change in your DNA sequence. Your DNA sequence gives your cells all the information they need to perform their functions.

A **genetic** condition happens when part of your DNA is in a different place, isn't complete, or has been damaged.

ADPKD is caused by a change in your DNA inherited from one of your biological parents. You have a 1 in 2 chance of receiving the gene change. Your brothers or sisters may also have the genetic change and have the condition. About 1 in every 2500 people have ADPKD.

### What happens in ADPKD

Kidneys have little filters that remove unwanted material and fluid from your blood stream. This material builds up when your body digests your food, and your cells are functioning to make energy and repair themselves. This material needs to be removed from your body and your blood stream for you to be well.

In ADPKD, fluid filled cysts grow in your kidneys (both kidneys) and sometimes in your liver. These cysts grow from when you are very young and squeeze your normal kidney tissue, stopping your kidneys from working properly.

About half of people with ADPKD need support for kidney function at around 60 years of age. This is when their kidney function is less that ten percent of a healthy kidney. For some people, kidney function is supported by kidney dialysis which removes the excess materials and fluid in the blood. For some people, kidney function is supported by a kidney transplant, from another person.

### Common complications of ADPKD

| Kidney pain | Urine infection | Bleeding cysts | High blood pressure | Reduced kidney function | Tummy bloating | Kidney stones |
|---|---|---|---|---|---|---|
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# More about clinical trials

Clinical trials are research studies that explore whether medicines are safe and beneficial for humans.

## What do clinical trials do?

Clinical trials help to find out whether a new intervention:

- Is safe to use
- Has any side effects
- Is better than standard intervention
- Helps you to feel better
- Helps prevent complications of disease

Each trial is required to follow a careful study plan. This plan must be approved by an ethics committee who make sure that the study participants are not exposed to unnecessary risks.

The **head researcher** is required to make sure that the study plan is followed exactly.

Each trial has a **sponsor** that has the responsibility to make sure the study is completed in an ethical and proper way.

A trial also has a special committee called a **Data Safety Monitoring Committee**. This committee is made up of experts who are separate from the trial. They look at the study results regularly. If they find that the study interventionis not working or is harmful, they will recommend that the trial be stopped straight away.

The research team is required to explain the study to all people who take part, including the possible side effects and risks of intervention. You are given this consent form to sign. By signing this form, you are showing that you have received the information and you want to be part of the study.

A clinical trial uses **randomization**. This is when people taking part are placed into different groups that are given different interventions. The process is by chance, meaning that neither the researcher nor the participant chooses which intervention they will receive. Using chance means that we can understand any differences between interventions more fairly.

## Medicines to take care with when taking metformin

Study doctors will assess your eligibility and if you are on any of the drugs that interfere with metformin the study doctor may decide to exclude you or adjust your dosage or monitor you. We encourage you to keep a copy of this list.

**Tell your doctor or pharmacist if you are taking any other medicine or starting any new medicine during trial.**

### Medicines that may interfere with metformin

- Diabetes medicines
- Iodinated contrast (dyes)
- Medicines that contain alcohol such as cough and cold syrups
- Corticosteroids, such as prednisolone, prednisone, and cortisone
- Tetracosactrin (used in people with multiple sclerosis)
- Danazol for treatment of endometriosis
- Medicines to treat high blood pressure and some heart conditions such as beta-blockers (metoprolol), calcium channel blockers (nifedipine, amlodipine, verapamil) and ACE inhibitors (captopril, enalapril, fosinopril, lisinopril, perindopril, ramipril, quinapril, and trandolapril)
- Some medications to treat asthma such as salbutamol and terbutaline
- Diuretics (also called fluid or water tablets) such as amiloride, bumetanide, frusemide, hydrochlorothiazide, and spironolactone
- Chlorpromazine (used for treatment of schizophrenia and other mental health conditions)
- Non-steroidal anti-inflammatory medicines used to relieve pain, swelling, and other symptoms of inflammation including arthritis, for example aspirin, diclofenac, meloxicam, naproxen, and piroxicam
- Some medicines used to treat ulcers and acid reflux, e.g., cimetidine
- Some medicines used to treat blood clots, e.g., warfarin
- Medicines that are substrates or inhibitors of organic cation transporters – OCT1 e.g., dolutegravir (antiretroviral medications); OCT 2 e.g., crizotinib, olaparib, vandetanib (cancer treatment) and daclatasvir (hepatitis treatment)
- Medicines that can induce OCT 1, e.g., rifampicin (antibiotic)
- Medicines that may increase the risk of lactic acidosis when used with metformin, e.g., topiramate (migraine prevention), and other carbonic anhydrase inhibitors, e.g., zonisamide (seizure treatment) and acetazolamide or dichlorphenamide (glaucoma treatment).

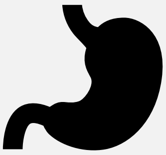
**If you develop a condition needing one or more of these medications, you must inform the trial doctor as soon as possible and let the person prescribing your new treatment know that you may be taking metformin.**

## Side effects of metformin in greater detail

All medicines have side-effects. Sometimes they are serious. Most of the time, they are not.

If you notice any of these symptoms, tell your study coordinator or doctor as soon as possible.

Do not be alarmed by the following list of side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.



**Stomach – very common (about 1 in 10 people)**

The more common side effects should disappear after the first few weeks:

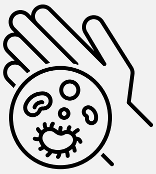
- Stomach upset such as nausea (feeling sick) or vomiting (being sick)
- Diarrhoea (loose bowel motions)
- Stomach pain

Taken metformin with food can help reduce nausea and diarrhoea.

**Lactic acidosis – very rare (about 1 in 10,000 people)**

This is caused by lactic acid building up in the blood. Although very rare, this is very serious and needs urgent medical attention.

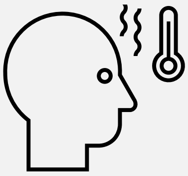
- Nausea, vomiting, stomach pain
- Trouble breathing
- Feeling weak, tired, or unwell
- Unusual muscle pain
- Sleepiness
- Dizziness or light-headedness
- Shivering, feeling extremely cold
- Slow heartbeat



**Allergy – very rare (about 1 in 10,000 people)**

Symptoms may include:

- Cough, shortness of breath, wheezing or difficulty breathing
- Swelling of face, lips, tongue, throat, or other parts of the body
- Rash, itching, or hives or pain



**Liver disease (extremely rare)**

- Nausea
- Vomiting
- Loss of appetite
- Feeling unwell
- Fever
- Yellowing of skin, eyes, and urine

**Pregnancy**

It is important that you do not take part in the research if you are pregnant or trying to get pregnant. It is important to use effective contraception during the study and 1 month after the study is finished. If you become pregnant, please advise your research team straight away.

# CONSENT FORM

## The IMPEDE-PKD Trial

**If you need an INTERPRETER, please tell us.**

*An interpreter is available on request.*

***I understand and agree with the following statements:***

I have read or have had read to me in my first language, and I understand the Participant Information Sheet.

I have been given sufficient time to consider whether to participate in this study.

I have had the opportunity to use a legal representative, whānau/ family support, or a friend to help me ask questions and understand the study.

I am satisfied with the answers I have been given regarding the study and I have a copy of this information sheet and consent form.

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.

I consent to the research staff collecting and processing my information, including information about my hospital admissions, mortality, prescriptions, laboratory samples and outpatient visits from the Ministry of Health, Te Whatu Ora, and Community and Hospital Clinical Laboratories.

If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.

I agree to my de-identified data being sent overseas.

I consent to my GP or current provider being informed about my participation in the study and of any significant abnormal results obtained during the study.

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.

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|---|---|---|
| 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. | | |
| I understand the compensation provisions in case of injury during the study. | | |
| I know who to contact if I have any questions about the study in general. | | |
| I understand my responsibilities as a study participant. | | |
| I wish to receive a summary of the results from the study. | Yes ☐ | No ☐ |

**Additional consent**

| | | |
|---|---|---|
| I give permission for my data to be linked to the New Zealand Integrated Data Infrastructure. | Yes ☐ | No ☐ |
| I agree to my de-identified data used for future research. | Yes ☐ | No ☐ |

**Declaration by participant:**

I consent to take part in this study.

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.

Researcher's name:

Signature: Date: