Participant Information and Consent Form

Short Name of Project	Impede-PKD
Full Name of Project	Implementation of metformin therapy to ease decline of kidney function in Polycystic Kidney Disease (PKD)
Principal Investigator	Professor Andrew Mallett
Project Sponsor	The University of Queensland, Brisbane

What am I being invited to do?

We, the project team, invite you to take part in a project that looks at a drug called metformin – 'the study drug'. We want to find out whether the study drug can slow kidney disease in people with Autosomal Dominant Polycystic Kidney Disease (ADPKD). You have been invited to take part because you have been diagnosed with ADKPD.

If you take part, we will ask you to be in the project for 2 years and 3 months. During this time, you will need to visit the clinic for tests, take the study drug or placebo medication, and talk to us on the phone.

Around 250 people will take part in this project. They will be from different hospitals in Australia.

Please read this information and ask us any questions. You can also talk to someone you trust, like a family member, friend, or your doctor. You can take some time to make up your mind. You get to decide whether this project is right for you.

What is the purpose of this project?

In this project, we will explore ways to treat ADPKD. Now, there is only one drug available to treat ADPKD. Not everyone can take this drug because it is expensive and has unwanted side effects.

In this study, we will look at how the study drug can be used in people with ADPKD. This drug is inexpensive and may have fewer side effects than the current treatment.

The study drug is not new. It has been licensed for many years and is taken by millions of people world-wide. This drug is usually used to treat type 2 diabetes. However, there is some evidence that it can slow the growth of cysts in people who have ADPKD.

The study drug is not approved to treat ADPKD. Because of this, the study drug is considered an experimental treatment for ADPKD. This means that it must be tested in a clinical trial to see if it is a safe and effective treatment for ADPKD.

Do I have to take part and can I change my mind?

Taking part is up to you

You get to decide whether you take part in this project. You can say yes or no.

Your decision will not affect your relationship with your doctor or the hospital.

If you choose not to take part, your doctor will discuss other options with you. This may include tolvaptan.

You can change your mind at any time

If you do take part, you can stop at any time. If you want to stop, please tell someone in the project team. You do not have to tell us the reason.

Once you stop taking part, we will not do any more project visits or collect additional information from your medical records. We will keep the information we have already collected about you. This is so we can measure the project results properly. Please only join this project if you are happy with this approach.

The project might stop for other reasons

We might need to stop the project while you are taking part. If this happens, we will explain the reasons to you.

We may also ask you to stop taking part in the project if it is no longer in your best interests. If this happens, we will discuss this with you.

What do I have to do if I take part?

If you take part in this study, you will be in it for 2 years and 3 months.

Be aware that some medications should not be taken at the same time as the trial medication. Your doctor will tell you which medications you can and cannot take while you are taking part in this study. A list is also available in supplementary materials. If you are female, you need to take steps not to become pregnant while participating in the trial.

This table below outlines what you need to do in this project. For more information, please ask a member of the project team.

This study has 2 parts:

- In part 1, we will check if the study drug is right for you. This part will go for about 3 months.
- If the study drug is right for you, we will invite you to join part 2. Part 2 will go for 2 years.

The table below details what you can expect from this study.

What part of the project?	**What do I have to do?**
When you start the project	You will come into the clinic and a doctor will do some tests: • Measure your weight • Take your blood pressure • Measure your heart rate • Collect blood and urine • Check whether you have diabetes • Check your cholesterol level If the project is suitable for you, we will give you the study drug to take for 10 weeks. We will also give you some questionnaires to complete.
When you are in Part 1 of the project	We will contact you by phone 4 times to see how you are going with taking the study drug. You will come into the clinic 2 times to see a member of the study team and get a blood test.
At the end of Part 1	After 10 weeks of taking the study drug, you will stop taking the study drug. You will come into the clinic and the doctor will do the same tests as at the start of part 1. If these tests show that the study drug is suitable for you, we will invite you to join part 2. If the study drug is not suitable for you, you will stop taking part in this study.
When you start Part 2 of the project	In Part 2 of the project, you will be randomised two groups. • The treatment group – you will take the study drug for 2 years • The placebo group – you will take a placebo for 2 years, which is a medication with no active ingredients. Randomisation means that you are put into a group by chance, like flipping a coin. We put people into groups

	and give each group a different treatment to see if one is better. You will have an equal chance of being placed in either group. Neither you, your doctor, or the project staff will know what group you are in.
When you are in Part 2 of the project	**After one month** We will contact you by phone to see how you are going. This will take 5 to 10 minutes. **From 3 months after you start taking your medication until 2 years** You will visit the clinic 5 times for one hour each time. You will not be ablet to eat for 9 to 12 hours before these visits. At these visits, we will: • Take your weight and waist measurement • Measure your blood pressure and heart rate • Ask you about your medications • Collect a blood and urine sample • Do a pregnancy test if you could become pregnant • Ask you to fill in questionnaires about your pain When you come in after one year and 2 years, we will also ask you to fill in some questionnaires about how you feel and your gut symptoms.
At the end of your project participation	You will stop taking the study drug or placebo medication after 2 years. Your doctor will discuss the options you have with regards to the continuing treatment of your kidney disease. You will have nothing else to do as part of this study.
After the project completes	We will send you a plain language summary of the results of the project.

Your time and expenses

There are no additional costs associated with participating in this research project, nor will you be paid. All medication, tests and medical care required as part of the research project will be provided to you free of charge.

What are the benefits of taking part?

By taking part, you will help the researchers understand more about ADKP. This knowledge may help people in the future.

What are the risks and discomforts of taking part?

There are potential risks to you from taking part in this project because of the possible side effects of metformin.

Risks of study drug

All medicines have side effects. The possible known side effects from taking metformin are listed in the table below. Most of the side effects are rare. Some rare side effects may be serious. There may also be side effects that are unknown. Many side effects go away after you stop taking a medicine. Others can last a longer time or forever.

You should talk to a doctor urgently if you start to feel unwell during this project.

Very Common side effects More than one in 10 people will experience these side effects	**Rare side effects** One in 10,000 people will experience these side effects	**Rare side effects** People will only experience these side effects in unusual cases
• Nausea and vomiting • Diarrhoea • Stomach pain	• Trouble breathing, shortness of breath • Feeling weak or generally unwell • Unusual muscle pain • Sleepiness • Dizziness or feeling light-headed • Shivering and feeling very cold • Slow heartbeat	• Yellowing of the skin and eyes and dark coloured urine • Fever

Risks for unborn and newborn babies

The effects of the study drug on unborn and newborn babies are unknown.

You cannot participate if you are pregnant, breastfeeding, or if you or a partner are trying to become pregnant. You should take action to avoid pregnancy while taking the study drug and for one month after completion. This includes not donating sperm or eggs.

If childbearing is a possibility, you will be required to undergo pregnancy tests throughout the research project. Tell us if you or a partner has conceived during this time frame so that we can help you manage any risks.

Risks if you are taking other medicines

There are some medicines and treatments that you cannot have while taking part in this project. You need to tell us about any medicines and treatments you are taking. These include:

- prescription medicines, such as antibiotics
- over-the-counter medicines, such a paracetamol
- vitamins or herbal medicines, such as echinacea
- alternative treatments, such as acupuncture.

We will tell you if you need to stop taking any.

How will my information and samples be used for this project?

This section tells you how this project will collect, store, use, and share and/or dispose of your information and samples. If you do not want us to collect this information, you cannot participate in this project. If you would like to know more, see our Data Management Plan.

Collecting your information

We will collect information for the project from your medical record and directly from you.

We will also collect information from other services, which will be linked to information from this project. To correctly link different sources of data about you, we may need to use identifiers such your name, address, or date of birth.

We will only share your identifiers to accurately link information about you from different sources. For all other data sharing purposes, we will replace your identifiers with a unique code.

Where will we collect your information from	What kind of information we will collect
Medicare Benefits Schedule held by the Australian Government	Your usage of health services
Pharmaceutical Benefits Scheme held by the Australian Government	Your usage of health services

Keeping your information and samples safe

To keep your information and samples safe, we will:

- follow all relevant privacy requirements
- store information securely in a secure electronic format or locked filing cabinet at ABC Hospital.
- store blood and urine samples securely at ABC hospital or local pathology lab.

- take steps to prevent anyone from accessing information or samples that identifies you unless they are authorised to do so, such as the project sponsor.
- give information and samples a code and keep them separate from your name or contact information.

You can ask us to tell you what information we have collected about you as part of this project. If your information is not correct, you can also ask us to change it. If you have any complaints about how we are managing your personal information, you can contact Hospital ABC Privacy Officer.

We will keep your information for at least 15 years after the study is finished. We will keep your samples for at least 10 years.

After this, we will destroy the information and samples.

Sharing your information with others

We will share some of your information with these people:

- **Your doctor**: We will tell your doctor that you are taking part in this project. They may add this information to your medical records. If we find out information relevant for your ongoing care, we will share this information with your doctor so you can receive the care you need.
- **Analysing samples**: We may send your samples to Australian laboratories to be analysed.

Publishing project information

We will share certain information from this project so that others can use it and understand the study findings. This project information does not identify you individually. We will make this project information available through journal articles and presentations. **By being in this project, you agree to us sharing project information for these purposes**.

How will my information and samples be shared for future research?

Sharing your individual data may help improve new research projects in the future. **We will also ask you to consider sharing your individual data, including your blood samples, for 'future research'**. When we share your individual data and blood samples, we will take steps to make it difficult for anyone to link this data back to you. This includes removing information that could easily identify you, like your name or contact information. There is still a small chance that someone could identify you again.

If you agree, we will share your individual data and samples for research that is very similar to this project or research that is very different. The researchers may be in Australia or

overseas. They may work for a commercial organisation like a pharmaceutical company or medical device company.

If you agree to share your individual data and samples, you will not be told about the future research projects or any results from these projects.

If you change your mind, you have the option to ask us to stop sharing your individual data and samples. However, if your individual data or samples have already been shared, it may not be possible to retrieve or destroy them.

More information about how we will share your individual data and samples for future research is in our Data Sharing Policy.

Who is running and paying for this project?

This project is being run by ABC Hospital.

This project is being organised by the University of Queensland.

The site is receiving funding from a government grant to run this project.

What happens if something goes wrong?

In an emergency, you should call 000 or go to the emergency department at your nearest hospital. If your injury is not urgent, you should contact us. We can help you organise medical care.

If you are harmed because of taking part in this project, contact Professor Andrew Mallett on XXXXXXXXX. We will talk about treatment options with you and your doctor. You may also be able to take action through the courts. You may wish to seek independent legal advice. If you are eligible for Medicare, you can receive the treatment you need to treat the harm free of charge as a public patient in any Australian public hospital.

Who has reviewed and approved this project?

The ABC ethics committee has approved this project. This is an independent committee that makes sure that this project meets Australian ethical standards for research that involves people.

Comments or complaints about how this project is being run

If you have any comments or complaints about this project, please contact:

Margaret Smith	Ethics Manager	03 5555 7777

Where can I find more information?

Thank you for taking the time to read this information about our project. You can contact a member of the project team at any time to ask questions.

Dr Kimberley Jones	Study Doctor	03 6666 8888
Michael Lee	Research Nurse	03 3333 5555

Signature Page

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Project Sponsor	The University of Queensland, Brisbane

Consent to take part in this project: This means you can say NO		
By signing this consent form, I acknowledge that: • I freely agree to take part in this project • I understand that I can stop taking part in the project at any time • I have read, or have had read to me, the information provided about this project and understand what is involved including the use of my personal information • I have had the opportunity to consider the information, ask questions and am satisfied with the answers I received • I give permission for my medical records to be accessed for the purposes of this project		
Consent to future use of information and samples	**Yes**	**No**
I agree to my individual data and samples being collected, stored and shared for **any** future research	☐	☐

Person taking part in the project

Signature: _____ Date: _____

Name: _____

Person conducting the informed consent discussion

I have explained the research project, its procedures and risks to the potential participant and I believe they have understood that explanation.

Signature: _____ Date: _____

Name: _____

Each person must sign and personally date this consent form