Participant Information Sheet

Study title:	**TRANSDIAB**		
Locality:	**AUCKLAND CITY HOSPITAL**	Ethics committee ref.:	
Lead investigator:	**Helen Pilmore**	Contact phone number:	**09 379 7440**

You are invited to take part in a study looking at diabetes development after kidney transplantation. 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 6 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

WHAT IS THE PURPOSE OF THE STUDY?

Diabetes occurs in up to 50% of patients after kidney transplantation and is associated with an increased risk of dying and failure of the kidney transplant. We are undertaking a pilot study of a commonly used drug in diabetes called Metformin compared with usual treatment (dietician review and information about diet and exercise) in patients who develop blood tests suggesting a higher chance of developing diabetes after their kidney transplant. In this study we are going to check the safety of Metformin, how well people are able to tolerate Metformin (by looking at whether people get side effects) and the effect of Metformin on

body weight at 12 months after transplantation. We will also look at how commonly diabetes occurs after transplantation in our population of kidney transplant recipients.

Metformin has been shown to prevent the development of diabetes in people with a high risk of diabetes in the general population. Additionally it does not cause hypoglycaemia (low blood sugars) and has beneficial effects on survival. In the Auckland Renal Transplant Group we have been using Metformin in patients who develop diabetes after their kidney transplantation. There is evidence that people who are pre-diabetic will benefit from Metformin and that this drug will prevent diabetes from occurring. This has not been tested after kidney transplantation.

All consenting patients will undergo an oral glucose tolerance test when they are well with stable blood tests at 4 – 12 weeks after kidney transplantation. This involves fasting and then getting a blood test followed by a sugary drink. Patients then have 2 more blood tests each an hour apart. Patients who have an elevated fasting glucose, or impaired glucose tolerance will be randomised to Metformin in addition to standard advice regarding diet and exercise, or standard advice alone. This means you have a 50% chance of being given Metformin if you consent to the study and have blood tests suggesting you have a higher chance of diabetes. We will also check your kidney function and your blood sugars for 12 months.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

All patients who are over the age of 18 and not already diabetic who have a kidney transplant done but the Auckland Renal Transplant Group will be asked to participate in the study. Being in the study will involve an oral glucose tolerance test and then if you have a high glucose and are pre-diabetic in that test, you will be randomised (chosen by a random computer generated program) to have either standard advice on diet and exercise or Metformin in combination with advice on diet and exercise. You will also have a questionnaire on potential side effects of Metformin to answer at 1 month and 12 months after starting the study. If you are no longer in Auckland at this time we will contact you by phone to do the questionnaire. All other blood tests done will be your usual blood tests done at standard time.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

Potential risks of being in the study are the possible side effects of Metformin.

Very Common -occurring in more than 10% (10/100) people taking Metformin

- Nausea
- Vomiting
- Diarrhoea
- Abdominal pain
- Loss of appetite

Common - affecting between 1 to less than 10% (1/ 10 to 1 /100) people taking Metformin

- Taste disturbance, usually a metallic taste

Very rare - affecting under 0.01% (1 in 10,000) people taking Metformin

- Elevated levels of lactic acid in the blood (lactic acidosis)
- Decreased absorption of vitamin B12 during long-term use
- Skin reactions such as rash, itching or flushing

Metformin can rarely cause a serious disorder called lactic acidosis. This results in too much acid in the blood and occurs in about 5 out of 100 000 people on this medication and can be very serious resulting in admission to intensive care units, dialysis and even death. Lactic acidosis may occur more commonly in people with poor kidney function. Hence we will only use this medication in people who have at least 30% of normal kidney function. People with lactic acidosis feel very unwell, short of breath and notice rapid breathing. It can occur if people become unwell for any other reason such as having a bad flu or other infection. If you feel very unwell and are on Metformin you need to seek medical help urgently. Additionally all patients who become unwell with a fever or require admission to hospital will have the use of Metformin re-evaluated.

Potential benefits of Metformin are that patients on this medication may have a lower risk of developing diabetes and a lower risk of heart disease and cancer. Additionally Metformin has been shown to prevent weight gain in most populations. Weight gain is very common after kidney transplantation and associated with more diabetes and worse outcomes.

All patients who have a glucose tolerance test will be followed for 12 months to check to see if they have developed diabetes over that period. All of the data collected on you will be stored safely and you will not be identified in any way.

WHO PAYS FOR THE STUDY?

This study is funded by the A+ Trust. All of your study visits will be done during usual clinic visits. If you are no longer in Auckland for your follow up after transplantation we will contact your caring team to find out your blood results.

WHAT IF SOMETHING GOES WRONG?

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

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 ARE MY RIGHTS?

Entry into this study is entirely voluntary. Choosing not to take part in this study will not affect your treatment or care in any way. The doctors will continue to treat you with the best means available.

If you agree to participate in this study you will be asked to sign a consent form. However you may withdraw from the study at any time without giving a reason. This will not affect your treatment or care in any way.

All the information collection in the study will be kept confidential.

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

After the study we will send you information about the results of the study. Any patient can take Metformin if it is prescribed by their doctor so if the medication is working for you, you will be able to remain on Metformin.

All study data will be stored for at least 15 years and will be stored on a password locked computer by the primary investigator.

It is anticipated that the results of the study will be available by 2017 and we will send you the results. We hope to publish the results in a peer reviewed journal. You will not be identifiable in any publication.

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:

Name, **Associate Professor Helen Pilmore; Renal Physician**

Telephone number **09 379 7440**

Email **hpilmore@adhb.govt.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@hdc.org.nz

If you require Māori cultural support 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

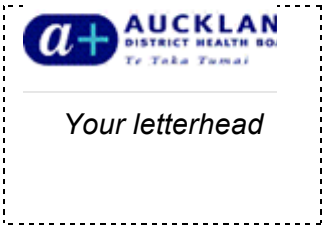
If you have any questions or complaints about the study you may contact the Auckland and Waitematā District Health Boards Māori Research Committee or Maori Research Advisor by telephoning 09 4868920 ext 3204

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

Consent Form



If you need an INTERPRETER, please tell us.
If you are unable to provide interpreters for the study, please clearly state this in the Participant Information Sheet

Please tick to indicate you consent to the following *(Add or delete as appropriate)*

I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.	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.	Yes ☐	No ☐
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.	Yes ☐	No ☐
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.	Yes ☐	No ☐
I understand that there may be risks associated with the treatment	Yes ☐	No ☐

in the event of myself or my partner becoming pregnant. I undertake to inform my partner of the risks and to take responsibility for the prevention of pregnancy.		
I agree to my (type of tissue) samples being sent overseas and I am aware that these samples will be disposed of using established guidelines for discarding biohazard waste.	Yes ☐	No ☐
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 understand the compensation provisions in case of injury during the study.	Yes ☐	No ☐
I know who to contact if I have any questions about the study in general.	Yes ☐	No ☐
I understand my responsibilities as a study participant.	Yes ☐	No ☐
I wish to receive a summary of the results from the study.	Yes ☐	No ☐

Declaration by participant:

I hereby 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: