Radar
Registry of
Advanced
Diabetic
Retinopathy

Participant Information Sheet

You have been provided with this information sheet as your specialist believes you may be a suitable candidate to participate in the

Registry of Advanced Diabetic Retinopathy

The Registry of Advanced Diabetic Retinopathy (RADAR) aims to collect DNA samples from patients who have undergone treatment for diabetic retinopathy, for research into the genetic causes of this sight-threatening disease. By better understanding why some people with diabetes develop these complications and others do not we may be able to predict who is at risk and develop appropriate therapies to prevent or delay these complications in future. The research is conducted by Associate Professor Jamie Craig and Dr Kathryn Burdon at Flinders Medical Centre in Adelaide, South Australia. Collaborators include Professor Mark Gillies at Sydney Eye Hospital in Sydney, New South Wales.

If you agree to participate in this research you will be asked to:

1. Provide a blood sample with a signed consent form allowing us to conduct genetic testing.

2. Complete a short interview of around 10 minutes, or complete a questionnaire to discuss your medical history.

3. Allow us to access clinical information related to your eye disease from your treating specialist, and medical records.

4. Consent to test results and other relevant clinical information being used by research studies which have been approved by an Institutional Ethics Committee. This currently includes the following:

    - Fight Retinal Blindness is a national Australian project based in Sydney focusing on studying treatments for retinal diseases including diabetic retinopathy.

Your blood sample will be taken at approved sites, and sent by mail to Flinders Medical Centre where the majority of this research is undertaken. If you have been referred to us by your treating specialist, you will be sent a sample collection kit. You will need to take the kit to your GP or pathology collection service to have a blood sample taken. You should then mail the kit back to us in the satchel provided.

We ask your permission to obtain information from your medical records in relation to your diagnosis and any existing test results. Your records will only be accessed by staff members of the hospital who would normally have access to the records. They will pass on to RADAR only the relevant information relating to your diabetic retinopathy. No information that could identify you will be passed on to anyone who is not a member of the research team. Only de-identified data (full names removed) will be sent to and used by other research studies after approval by an Ethics Committee.

We may also contact you in the future to ask if you would be willing to provide further information or additional blood samples for the research.

What is genetic research?

The cells of your body contain deoxyribonucleic acid, DNA for short. DNA is passed down from your parents. It carries the genes that determine physical features such as the colour of your hair and eyes. Differences in our genes help explain why we all look different. The DNA in most cells in your body is the same. The instructions for physical features are contained in your DNA. Other chemicals help to form physical features from these instructions. One of these chemicals is called ribonucleic acid, RNA for short. RNA acts as a messenger to tell your cells to produce certain features. Genes in your DNA get turned on and off like a light switch. When a gene is 'turned on' it makes RNA. When a gene is 'turned off,' it does not make RNA. The RNA is different in different cells in your body and under different conditions. The study of RNA allows scientists to focus on the genes in your DNA that are turned on (active). Differences in DNA and RNA may help to explain why some people develop certain conditions and others do not.

What will the sample be used for?

The sample will be enough both for the immediate study in relation to diabetic retinopathy, and for storage of a sample for future research. There are different parts to this testing, and you can agree to any or all of them, by ticking the boxes on the consent form before you sign it.

1. Testing DNA, RNA and blood proteins in relation to diabetic complications for immediate study:

In this part of the project, we may test DNA from your blood to look for specific genes that may be related to diabetic retinopathy. Testing of RNA and proteins in your blood helps to confirm whether these genes in your DNA have been 'switched on' during the time in which the diabetic complications are developing and progressing. If we have not been able to obtain particular information from your medical record, such as your HbA1c level, we may use some of your blood sample for this purpose in addition to the genetic tests.

2. Storage of DNA and general clinical information for future research:

You may agree to have us store the DNA from your blood to test for other genes that may be discovered in the future that might affect diabetic complications. Only research pertaining to diabetic complications or diabetes will be done. No other testing will be done on your sample. Some general clinical information (e.g. your age, sex, and severity of diabetic complications) will be stored with the sample. The sample will remain in storage for future research until it has been used up.

Confidentiality

These tests will be done at Flinders Medical Centre, Adelaide by staff of Flinders Medical Centre and Flinders University. At times it is necessary to send the samples to other research laboratories for specific tests. This includes the Garvan Institute of Medical Research in NSW. In this case, no identifying information is sent with the sample. The results of all tests will be analysed by the research team at Flinders University.

Your blood and DNA sample will be labelled only with a code number. Staff conducting the research will not be aware of your identity. It will be possible to refer back to the code key to identify your sample, but the information will be stored separately and only accessible by authorised personnel.

Genetic samples are never completely anonymous because they contain your unique DNA. However, without the code key, the sample can only be identified if there is another sample of your DNA to compare it with. General information about your age, sex and state of health will be

kept with the information about your sample. This information will not be specific enough to identify you.

The Registry will keep your signed consent forms for DNA testing separate from your medical record. Representatives of the research team, Flinders Medical Centre or health authorities, may at times access the records at your local research site to ensure that the research is being done correctly. Your results and samples will be kept securely at all times. Anyone who has access to your identified records is bound by law and by professional codes of conduct to keep your information confidential.

Results from this research will be published in various ways, including conference papers and journal articles, and may in future be used in the development of treatments for diabetic complications including new drugs. They will not be published in a form that could identify you.

Unless the law requires it, your information will not be given to employers, insurance companies or other third parties.

What if I change my mind later?

If you change your mind at any time for any reason, you may withdraw from the Registry and ask for your samples to be destroyed, however the results of any tests done so far will remain in the study.

What are the benefits?

There is unlikely to be any benefit to you from taking part in this testing, but it may help other people with diabetes and its complications later on. The results of the research cannot be used directly to assist your medical treatment.

As genes associated with diabetic retinopathy become better understood, specific treatments may be developed that target these genetic pathways, and may be of benefit to patients with a mutation in those genes.

What are the risks?

The risks are the same as for any standard blood sampling. There may be some pain and bruising, and (very rarely) infection at the site of blood taking.

Taking part in DNA testing is not expected to affect your employment or health / life insurance because results will not be given to employers, insurance companies or any third party. Your results cannot be directly used to make a diagnosis about your health. However, if you ask for your test results from part 1, it is possible that you could later find out information about your health (or your relatives' health) that you (or they) did not want to know.

Compensation

If you suffer injury as a result of participation in this research project, compensation might be paid without litigation. However, such compensation is not automatic and you may have to take legal action to determine whether you should be paid.

What are the implications for me and my family?

Although this research is not intended to provide information about your individual health, it is possible that we might later find out information about risks of disease or other matters that might be relevant to you or members of your family. It is up to you whether you want to be contacted about this kind of information. Even if you do not wish to be notified, if information

arises that could be important for you or your family, we may be obligated to contact you to confirm whether you wish to know or not.

If the research reveals that a member of your family may be at risk of a serious illness for which treatment is available or likely to become available they can be contacted without your agreement, but only if an ethics committee has considered the evidence and approved the contact.

Other members of your family will only be contacted about the research project if you agree, and you will have the opportunity to contact them first. They will not be given results of your tests unless you authorise it.

There is no possibility that the research could give us unexpected information about your parentage or blood relationships to other family members.

How will my samples be stored?

All samples will be stored in a secure facility at Flinders Medical Centre. Only authorised people from the research team will be able to access them.

Will I get my DNA test results?

The tests will be performed in a research laboratory, and they are not designed to give information about a particular person's health. Also, research laboratories are not set up to provide health information or counselling. For these reasons, you will not be given your DNA results, unless you specifically request them, or unless information arises that is of relevance to you or your family. You may ask your trial doctor (in writing) for copies of your test results from part 1, and he or she will obtain them on your behalf. If you ask for your genetic results it is possible that they may be included in your medical file.

Will I be paid for taking part?

You will not be paid for taking part in the registry, even if the results of the study are profitable for the research team or their organisation/s. The results of the testing and any information that comes out of it are owned by the research team and their organisation/s.

For further information

If you would like more information about this study, now or later, you can contact the RADAR Co-ordinator Ms Bronwyn Usher on 08 8404 2035, or by email at Bronwyn.usher@health.sa.gov.au.

This study has been reviewed and approved by the Southern Adelaide Clinical Human Research Ethics Committee. Should you wish to discuss the study with someone not directly involved, in particular in relation to matters concerning policies, your rights as a participant, or should you wish to make a complaint, you may contact the Executive Officer on (08) 8204 6453 or email Health:SALHNofficeforresearch@sa.gov.au

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CONSENT TO PARTICIPATION IN RESEARCH

I,……give consent to my involvement in

(first or given names) *(last name)*

The Registry of Advanced DiAbetic Retinopathy (RADAR

I acknowledge the nature, purpose and contemplated effects of the research project, especially as far as they affect me, have been fully explained to my satisfaction by

..... and my consent is given voluntarily.

(first or given name) *(last name)*

I acknowledge that the details of the following have been explained to me, including indications of risks; any discomfort involved; anticipation of length of time; and the frequency with which they will be performed. I agree to the following procedures:

a) A blood sample for genetic testing be taken and the following tests done as agreed below.

☐ Part 1: Testing DNA, RNA and protein from my blood sample in relation to diabetic retinopathy. The blood sample may also be used to test long term glycaemic control (HbA1c) where necessary.

☐ Part 2: A stored blood sample may be used in future genetic research in relation to diabetic retinopathy.

☐ Part 3: I agree to be recontacted during routine clinic visits or via phone, email or mail if the collection of further information or samples is required.

☐ If the research discovers information relevant to me or my family, I agree to be notified.

b) A short interview or questionnaire.

c) Access to case notes and medical test results by the research team, and release of medical information from any treating doctor or medical record to the Registry of Advanced Diabetic Retinopathy.

d) De-identified test results and other relevant clinical information being used by research studies, which have been approved by an Institutional Ethics Committee:

- Fight Retinal Blindness

I have understood and am satisfied with the explanations that I have been given.

I have been provided with a written information sheet.

I understand that my involvement in this research project may not be of any direct benefit to me and that I may withdraw my consent at any stage before the completion of the research project without affecting my rights or the responsibilities of the researchers in any respect.

I declare that I am over the age of 18 years.

I acknowledge that I have been informed that should I receive an injury as a result of taking part in this study,

I may need to start legal action to determine whether I should be paid.

Signature of Research Participant: ..... Date: .....

I, ... have described to .....

the research project and nature and effects of procedure(s) involved. In my opinion he/she understands the explanation and has freely given his/her consent.

Signature: ..... Date: