The Royal Melbourne Hospital

Information/Consent Form for Adult Participant

Adult providing own consent

Title	Type1Screen: Diabetes autoantibody screening to identify individuals at risk for type 1 diabetes
Protocol Number and Version	Version 2, 17 June 2019
Project Sponsor	Melbourne Health
Coordinating Principal Investigator	Professor Peter Colman; A/Prof John Wentworth
Site Principal Investigators	A/Prof John Wentworth and Prof Peter Colman
Location	The Royal Melbourne Hospital
Version	17 June 2019

This Participant Information and Consent Form is 10 pages long. Please make sure you have all the pages.

1. Your consent

You are invited to take part in this research project, called *Type1Screen: Diabetes autoantibody screening to identify individuals at risk for type 1 diabetes*. This is because you have a relative with type 1 diabetes or you have previously had a blood test that suggests you are at increased risk of developing type 1 diabetes.

This Information/Consent Form tells you about the research project. It explains the tests and research involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to the tests and research that are described
- Consent to the use of your personal and health information as described.

You will be given a copy of this Information/Consent Form to keep.

2. Purpose and background

Type 1 (or juvenile) diabetes is an important health problem that affects many people and requires life-long insulin treatment to control blood sugar levels. We know that people with a close family member (blood relative) with type 1 diabetes have a 10 to 15 times greater risk of developing type 1 diabetes than those without. Close family members can include brothers, sisters, parents, children, cousins, aunts, uncles, and grandchildren.

Type 1 diabetes is now understood as a disease that starts many years before insulin injections are first needed to control blood sugar levels. This 'pre-clinical' phase of the disease can be detected by measuring proteins in the blood called antibodies. By identifying people at increased

risk of developing type 1 diabetes we can provide monitoring and support that aims to prevent serious illness if type 1 diabetes develops. People who test positive for antibodies may also wish to participate in other research studies that aim to delay or prevent the need for insulin treatment.

This research project aims to perform antibody testing to identify children and young adults who are at increased risk of developing type 1 diabetes. It has been initiated by the project doctors Peter Colman and John Wentworth and is being performed in collaboration with a network of diabetes researchers located in Australia and New Zealand. The project is supported by Melbourne Health and funded by Juvenile Diabetes Research Foundation (JDRF).

3. What is involved?

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

There are no costs associated with participating in this research project, nor will you be paid. You may be reimbursed for any reasonable travel, parking, meals and other expenses associated with the research project visits.

It is desirable that your local doctor be advised of your decision to participate in this research project. If you have a local doctor, we strongly recommend that you inform him or her of your participation in this research project.

Screening blood test for antibodies

We need you to sign the consent form and mail or email it back to us together with a completed questionnaire that seeks information concerning your contact details and some relevant health details about you and your family. This will take up to 30 minutes.

After receiving these forms, we will send you a blood test form for you to take to a local blood collection centre. The blood test visit may take up to 60 minutes if you arrive at the collection centre at a busy time you may have to wait at the collection centre for 45 minutes while the blood collector performs other duties. The blood test procedure will take no longer than 15 minutes. The blood collector will place a needle into a vein in your arm and remove 5ml (1 teaspoon) of blood. The blood sample will then be sent to Royal Melbourne Hospital to be tested for diabetes antibodies. We will communicate the result of the blood test to you by mail or email within 2 months of the sample being collected.

Procedures if the antibody result is negative

If the result of the antibody test is negative, the risk of type 1 diabetes is low and you will not need to repeat the blood test. A researcher will contact you by email or telephone every year to ask if you have developed any health problems since having the blood test. The researcher will also communicate information about any other relevant research opportunities when they contact you.

Procedures if the antibody result is positive

If the result of the antibody test is positive, the risk of type 1 diabetes is increased. In this event, a researcher will contact you by telephone or email to discuss the result and arrange for further blood tests (requiring up to 30ml or 1½ tablespoons of blood) at your local blood collection centre. This blood test visit will take up to 3 hours. For these tests, you will be asked to fast from midnight (with the exception of water) and arrive at the blood collection centre between 7am and 11am the following morning. Blood samples will be collected to measure blood glucose, glycated haemoglobin (a long-term measure of blood glucose) and C-peptide (a measure of pancreas function). You will then be asked to drink a sugary drink (up to 200ml containing up to 75 grams of glucose) and, after 2 hours, have another blood test to measure glucose and C-peptide. A sample will also be collected and sent to Royal Melbourne Hospital for antibody testing. Together, these

tests will enable the researchers confirm that you tested positive to antibodies and will help clarify your risk of developing type 1 diabetes. All test results will be sent to the Melbourne researchers who are coordinating the study. They will communicate these results to you by mail or email within two months of the blood samples being collected.

To meet our aim of supporting people who test positive for antibodies, researchers based in Melbourne will ask your permission for them to introduce you to researchers based at a local diabetes centre. If you agree for this to occur, researchers at the local diabetes center will contact you and may arrange to meet you at their centre to discuss the findings of the antibody tests and the results of the glycated haemoglobin, glucose and C-peptide tests. The local researchers will answer any questions you may have and help address any concerns that may arise. If you would not like to be introduced to your local diabetes team, researchers based in Melbourne would be happy to discuss the blood test results and resolve any questions or concerns that you may have.

Participants who test positive for antibodies will be offered annual retesting for antibodies and glycated haemoglobin as well as glucose and C-peptide before and 2 hours after the sugary drink. As before, these tests will require you to fast from midnight and will take up to 3 hours. The researchers will contact you every year to seek your permission to arrange these tests. The researchers will also ask you about any illnesses that you may have developed since your last blood test. The results of these annual blood tests will be used to monitor your antibody levels and help clarify your risk of type 1 diabetes. The results will be sent to the Melbourne researchers and, if applicable, the researchers based at your local diabetes centre. You will also receive results of the annual blood tests by mail or email within 2 months of the blood samples being collected.

The researchers may be running other studies to determine if experimental treatments can help people who test positive for antibodies by decreasing the need to use insulin treatment to control glucose levels. They will communicate information about any of relevant studies as it becomes available.

4 What do I have to do?

You will not need to change your lifestyle if you participate in this project. You must notify the study doctor if you feel unwell during this study so that he or she can determine if the illness is related to participating.

You must notify the study doctor of any medications that you need to take regularly at the time you enter the study, and any medications that you may need to take during the study period. This is because certain medications might make blood testing unsafe or may influence the test results.

5 Other relevant information about the research project

This project is anticipated to run for many years and will recruit about 1,000 Australians and New Zealanders aged between 2 and 30 years every year.

6 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to participate. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to agree to take part, you will be given this Information/Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with the Royal Melbourne Hospital.

7 What are the alternatives to participation?

You can decide not to participate in this research project. In this event, you will continue to receive your usual medical treatment.

8. Possible Benefits

We cannot guarantee or promise that you will receive any benefits from this research. However, possible benefits may include access to support services provided by the researchers outlined above, and to monitoring to assess the risk of type 1 diabetes.

9. Possible Risks

There are no major risks associated with giving blood. Only trained people will take blood from you. You could have discomfort and/or a bruise when you have blood drawn from your arm. When having blood drawn, once in a while, some people may faint. It is rare, but some people may get an infection, a small blood clot, swelling of the vein and surrounding tissue or bleeding where the needle enters the skin.

There is a very small risk that some of your information may not remain confidential. However, we have protections in place to prevent such breaches, which are detailed below in section 16.

This research is measuring antibodies that can predict getting diabetes and therefore knowing your results may mean you have to disclose this when questions are asked about your health by, for example, insurance companies and/or employers.

10. What will happen to the test samples?

The blood samples will be used for the purposes described in Section 3 above. Blood that is sent to Melbourne for antibody testing will be discarded within 3 months of the antibody result being communicated to you unless the test is positive and you indicate that you would like the sample to be forwarded to another antibody testing laboratory to determine if you are eligible for another research project. The researchers will need to receive evidence that you have consented to join this other research project before your sample will be sent to that study's antibody testing laboratory.

Blood samples used to measure glycated haemoglobin, glucose and C-peptide will be sent to a local laboratory and destroyed after the results are determined. Typically, these samples are destroyed within 14 days of determining the test result.

11. What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the tests being studied. If this happens, the study doctor will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, the study doctor will arrange for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, your project doctor might consider it to be in your best interests to withdraw from the research project. If this happens, the doctor will explain the reasons and arrange for your regular health care to continue.

12. Can I have other treatments during this research project?

Whilst you are participating in this research project, you may not be able to take some or all of your usual medications or treatments. It is important to tell your study doctor and the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins

or herbal remedies, acupuncture or other alternative treatments. You should also tell your study doctor about any changes to these during your participation in the research project. Your study doctor will also inform you if any treatments or medications need to be stopped for the time you are involved in the research project.

13. What if I withdraw from this research project?

If you decide to withdraw from this research project, please notify a member of the research team before you withdraw. A member of the research team will inform you if there are any special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the sponsor up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

14. Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include lack of ongoing funding or a change in routine medical practice such that antibody testing is performed as part of routine clinical care.

15. What happens if the research project ends?

It this project ends, you will be notified by mail or email and, if relevant, given written recommendations about your ongoing medical needs to show to your usual doctor.

After the project ends, summaries of the overall findings can be obtained by contacting one of the researchers.

Part 2 How is the research project being conducted?

16 What will happen to information about me?

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential.

Your identifying details (e.g. name, date of birth) will be stored in a password-protected file on a computer server located at Royal Melbourne Hospital. Access to this information will be restricted to researchers based at Royal Melbourne Hospital and, with your permission, researchers based at your local diabetes centre.

You will be assigned a unique study number that will be linked to all of your other information, including questionnaire responses and blood test results. All researchers on this project will have access to this ‘de-identified’ dataset.

Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the research team accessing health records if they are relevant to your participation in this research project.

Your health records and any information obtained during the research project are subject to inspection for the purpose of verifying the procedures and the data. This review may be done by the relevant authorities and authorised representatives of the Sponsor, Melbourne Health, and the institution relevant to this Information Form, the Royal Melbourne Hospital or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant research personnel and regulatory authorities as noted above.

It is anticipated that the results of this research project will be published or presented in a variety of forums. In any publication or presentation, information will be provided in such a way that you cannot be identified.

Information about your participation in this research project may be recorded in your health records.

In accordance with relevant Australian privacy and other relevant laws, you have the right to request access to the information collected about you and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the research team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

Australasian Diabetes Data Network
The Australasian Diabetes Data Network (ADDN) captures health information about Australians and New Zealanders who have diabetes as they visit their diabetes clinic. ADDN aims to improve understanding of diabetes treatment and how diabetes affects the health of Australians and New Zealanders.

Many centres participating in this project are also linked to ADDN. Researchers at these sites may seek your consent to incorporate information collected in this study into ADDN. If you agree to join the ADDN Study, you will be asked to sign a separate consent form before any data is sent to the ADDN database. Any data from this project that is sent to ADDN will be de-identified (i.e. it will not be possible to identify which information in ADDN belongs to you). Further information about ADDN can be found at www.addn.org.au.

BioGrid Australia
In addition to being used in this research project your research information will also be used in the BioGrid project. BioGrid links participant information from multiple sources, allowing researchers to better understand how individuals' characteristics affect the way in which they respond to a disease and to its various potential treatments.

Your research information will be included in a computer system, controlled by the Royal Melbourne Hospital, comprising data from various studies conducted at this site. Your basic personal information will be communicated to a separate computer system, run by the Royal Melbourne Hospital as part of the BioGrid project and which will assign a unique subject code by which your research information will be linked, coded and stored. Your coded research information will be made available for possible use in future research to specialist researchers, from the Royal Melbourne Hopsital and other hospitals or research organisations participating in BioGrid. At this time we cannot say exactly what this future research will comprise, but all studies will require prior approval by a Human Research Ethics Committee. Data will be stored for an indefinite period of time and access will be restricted to authorised researchers, with all requests logged and audited.

Researchers using BioGrid data will only see coded information which does not identify you. Only the institution at which this study was conducted will have the key from which you can be identified. All users of BioGrid will be bound by an obligation of confidentiality, and information will only be used for the purpose of BioGrid.

If you require further information regarding BioGrid and the storage, use and disclosure of your personal and health information as part of that Project, please advise the Principal Researcher, who will provide you with further information. Also, the BioGrid web site (www.biogrid.org.au) has Frequently Asked Questions under Patient Information.

17 Complaints and compensation

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive medical treatment to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

18 Who is organising and funding the research?

This research project is being conducted by researchers in Australia and New Zealand who are interested in finding ways to prevent type 1 diabetes.

You will not benefit financially from your involvement in this research project even if, for example, your samples (or knowledge acquired from their analysis) prove to be of commercial value. In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to the study doctors or their institutions, there will be no financial benefit to you from these discoveries.

The research centre that you attend will receive a payment for undertaking this research project from JDRF. No member of the research team will receive a personal financial benefit from your involvement in this research project other than their ordinary wages.

19 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the Melbourne Health HREC.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

20 Further information and who to contact

If you require further information, the person you may need to contact will depend on the nature of your query.

General contact
If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project, please speak to the research nurse.
Name: Felicity Healy or Leanne Redl
Position: Research Coordinators
Telephone: 03 9342 7063
Email: felicity.healy@mh.org.au/leanne.redl@mh.org.au

Clinical contact
If you want any further information about any medical problems which may be related to your involvement in the project you can contact:
Name: Associate Professor John Wentworth
Position: Consultant Endocrinologist RMH
Telephone: 0422 992 891
Email: wentworth@wehi,edu.au

For medical enquiries outside business hours, please call 9342 7000 and ask to speak with the Endocrinologist on call

Complaints / Human Ethics contact
If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact the manager of the ethics committee responsible for approving this study:

Position: Manager, Melbourne Health Human Research Ethics
Telephone: 03 9342 8530
Email: research@mh.org.au

The Royal Melbourne Hospital

ADULT CONSENT FORM

Version: **Version date 17 June 2019**

Site: **The Royal Melbourne Hospital**

Full Project Title: **Type1Screen: Diabetes autoantibody screening to identify individuals at risk for type 1 diabetes**

I have read, or have had read to me in my first language, and I understand the Information Statement dated **17 June 2019**.

I freely agree to participate in this project according to the conditions in the Information Statement.

I will be given a copy of the Information Statement and Consent Form to keep.

The researcher has agreed not to reveal my identity and personal details if information about this project is published or presented in any public form.

I agree to the collection and use of the tissue samples collected for the project as outlined in Information Statement.

Participant's name (printed) ……

Signature …… Date ……

Name of Witness (printed)……..

Signature …… Date ……

Researcher's Name (printed) ……

Signature …… Date ……

Note: All parties signing the Consent Form must date their own signature.

The Royal Melbourne Hospital

REVOCATION OF CONSENT FORM FOR ADULT PARTICIPANT

Full Project Title: **Type1Screen: Diabetes autoantibody screening to identify individuals at risk for type 1 diabetes**

I hereby wish to WITHDRAW my consent to participate in the research proposal described above and understand that such withdrawal WILL NOT jeopardise my treatment by, or relationship with the Royal Melbourne Hospital.

Participant's Name (printed) ……..

Signature …… Date ……