The Royal Melbourne Hospital

# Participant Information Sheet/Consent Form

*Adult providing own consent*

| | |
|---|---|
| **Title** | **TrialNet Pathway to Prevention Study- Screening** |
| **Protocol Number and Version** | TN-01 version dated 22 February 2019 |
| **Project Sponsor** | Type 1 Diabetes TrialNet |
| **Coordinating Principal Investigator** | Professor Peter Colman; Associate Professor John Wentworth |
| **Site Principal Investigators** | Professor Peter Colman; Associate Professor John Wentworth |
| **Location** | The Royal Melbourne Hospital |
| **Version** | 28 March 2019 |

This Participant Information and Consent Form is 9 pages long. Please make sure you have all the pages.

## 1. Your Consent

You are being asked to be in a research study called the TrialNet Pathway to Prevention Study. TrialNet is a research group dedicated to the study, prevention, and early treatment of type 1 diabetes. Type 1 diabetes is now understood as a disease that develops over time in stages. Stage 1 starts with the appearance of two or more autoantibodies. This is followed by Stage 2, which is the development of abnormal blood glucose levels. Stage 3 is the diagnosis of type 1 diabetes. This study will help us learn more about how type 1 diabetes occurs and provides monitoring to individuals at risk. In addition, the study will help us identify people who may be eligible for prevention trials.

The study is divided into two parts: Screening and Monitoring. This consent form is only for the Screening part of the study. During Screening, you will be tested for diabetes-related autoantibodies in the blood. Autoantibodies are proteins that are made by the body's immune system. If autoantibodies are present, it could mean that cells in the pancreas which produce insulin are damaged. Certain kinds of autoantibodies can be found in the blood years before type 1 diabetes occurs.

If the Screening blood tests show that you have autoantibodies, we will Invite you to participate in the Monitoring part of the study. We will then ask you to sign a separate consent form which explains more about this part of the study.

Feel free to ask questions about any information in the document. You may also wish to discuss the study with a relative or friend or your local health worker. Feel free to do this.

If you decide to join the study, you will be asked to sign this Consent Form. By signing the Consent Form, you indicate that you understand the information and that you give your consent to participate in the research study. You will be given a copy of the Participant Information and Consent Form to keep as a record.

## 2. Purpose and Background

Type 1 (or juvenile) diabetes is an important health problem that affects many people. We know that factors such as genes (DNA) play a major role in type 1 diabetes and 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.

Although we can now determine who is at increased risk, we need more understanding of how type 1 diabetes occurs and develops over time. Better understanding will help to develop a cure, better treatments or prevent health problems. This is why we are conducting this study. We need to study many people in different countries to gain such understanding. That is why interested doctors and scientists from around the world have joined together to create TrialNet. In Australia and New Zealand, we expect about 1200 people each year to enrol into the screening part of the Pathway to Prevention Study. The study is on-going.

## 3. Procedures

We will ask you to provide information about yourself and your family history of diabetes by completing a Family History questionnaire.

You will have a blood test to test for diabetes-related autoantibodies. The blood test can be done by placing a needle into a vein in your arm. We will take up to 1 tablespoon of blood at each screening visit.

You can also be screened by pricking your finger tip to collect about ½ teaspoon of blood (10 drops). If it is not possible to collect enough blood from your fingertip, you may need to repeat the test with a regular blood draw.

If you are positive for autoantibodies you will be contacted by a member of the TrialNet research team and may be invited to participate in the monitoring phase of the study..

If we do not find autoantibodies in your blood (you are negative), you will receive results by letter or secure electronic communication. Testing negative for autoantibodies does not mean you will never get diabetes, but the chances are much lower than if you tested positive. It is still possible that you could develop autoantibodies in the future. Whether you have autoantibodies or not, we may contact participants younger than 18 in the future to be rescreened or to ask about health.. We would like to know if you develop diabetes and we would also like to let you know about other research studies.

Blood samples for storage – This is **optional**

With your permission, we would also like to store any remaining blood samples. Your blood samples will be used to help us learn more about how the immune system might cause diabetes and about new ways of identifying people at risk for type 1 diabetes, as well as obtain ideas about new treatments in the future. These tests may include DNA (genetic) tests that will be used for research purposes only. Such genetic tests are not expected to identify gene mutations relevant to your health or to the health of others in your family. Results from testing of your stored samples, including genetic test results, will not be provided to you. In the highly unlikely event that researchers identify a genetic abnormality that is associated with a disease, this information will not be communicated to you.

Your blood samples will be stored indefinitely. They will be marked only with a code number allocated to you for the study. Your name or other identifying information will not be recorded. Only the study team at The Royal Melbourne Hoospital. will have access to the information linking you with your code number. When the TrialNet research program is no longer operating, the code number allocated to you for the study will be removed permanently ('de-identified') and it will not be possible for any researcher to learn if a blood sample belongs to you. As such, once the samples are placed in the repository after TrialNet is over it will not be possible to remove them.

The samples will be stored under the supervision of the main TrialNet sponsor, the National Institutes of Diabetes & Digestive & Kidney Diseases (NIDDK) at the NIDDK repository (a storage centre for biological samples and data) located at ThermoFisher Biosciences, Germantown, MD, U.S.A.

While the TrialNet research program continues, your stored blood samples could be used by TrialNet researchers. Researchers not working within TrialNet could also use your blood samples but they must first get permission from TrialNet researchers and the NIDDK. When the TrialNet research program is complete, your blood samples will continue to be stored under the supervision of the NIDDK. Researchers will only be able to use your blood samples with the permission of the NIDDK.

As mentioned previously, even if you do not want to have your samples stored, you can still participate in the study. You will be asked to indicate on the Consent Form whether you are willing to have your blood and DNA samples stored indefinitely.

## 4. Collection of tissue samples for research purposes

By providing consent to take part in this study, you are agreeing to the collection, storage and use of tissue samples as outlined above. As outlined in the previous section, all of your blood samples will be marked only with a code number allocated to you for the study and your blood sample will be stored indefinitely only if you agree to this.

## 5. Possible Benefits

There are no direct benefits to you from this study. By you participating in this study, you may help doctors develop a cure, better treatment or prevention for type 1 diabetes and its complications.

## 6. 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 get your blood drawn from your arm or your fingertip. 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.

If the blood sample was collected from your fingertip, it is possible that you will be unable to collect enough blood or that the sample cannot be used for testing. In this case you will need to come to a study site for a regular blood test to obtain blood from your vein.

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 and these are discussed in the next section of this Participant Information.

This research is studying autoantibodies that can predict getting diabetes and therefore knowing your results may be relevant to questions asked about your health by, for example, insurance companies and/or employers.

## 7. Privacy, Confidentiality and Disclosure of Information

We will keep all of your medical information confidential to the extent the law allows. However, we cannot guarantee absolute confidentiality. Information about you will not be given to insurance companies, employers, or be used for any purposes other than those described in this agreement without your specific consent or as required by law. The results from this research may be published. These results could include laboratory tests. However, the results will be reported only for groups of people, not individuals and your identity will never be released,

The information collected (data) will be recorded on paper and in a computer database. Data will be stored in locked filing cabinets (for paper records) and on password-protected databases (for electronic records), accessible only to the study team. To protect your privacy, all data will be identified using a code number and will be stored without your name or other identifying information. As stated previously, only the study team at the Royal Melbourne Hospital will have access to the identifying information. After the study is completed, the data will be kept (archived) by the the Royal Melbourne Hospital study team for 15 years. The data will be archived either in the hospital or a hospital-approved site elsewhere. Once the archive period is complete, the data

will be destroyed following a procedure for disposal of confidential information.

Data will also be stored at the TrialNet Coordinating Center at the University of South Florida, USA. We will not provide them with your name or other identifying information and thus they will not be able to link any information to you. When the TrialNet research program is no longer operating, your data will be moved to a location under the supervision of the main TrialNet sponsor, the National Institutes of Diabetes & Digestive & Kidney Diseases (NIDDK). At this time, the code number allocated to you for the study will be removed permanently ('de-identified') and it will not be possible for any researcher to link the code with the data collected from you during the study.

In some cases, the following people may need to see your records to verify study information but they will not be told who you are: people from the organization coordinating this research (University of South Florida) or their representatives; and people from government agencies that assess research. Also, the the Royal Melbourne Hospital Ethics Committee may have access to your records to ensure that your rights are being properly protected.

In accordance with Australian and/or Victorian Privacy and other relevant laws, you have the right to access the information collected and stored by the researchers about you. You also have the right to request that any information with which you disagree be corrected. Please contact one of the researchers named in section 9 if you would like to access your information.

***AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION (PHI) FOR RESEARCH PURPOSES***

***What information may be used and given to others?***
*The study doctor will collect your personal and medical information such as:*

- *Past and present medical records with your permission*
- *Research records and results*
- *Your contact information*
- *Records about your study visits and contact with your study team*

***Who may use and give out information about you?***
*The study doctor and the study staff may use and share this information.*

***Who might get this information?***
*Your PHI may be used by and shared with the following groups of people during the conduct of this research:*

- *The medical staff that takes care of you and those who are part of this research study;*
- *TrialNet research sites and study teams involved in this research;*
- *Any laboratories, pharmacies, or others who are part of this research study;*
- *The sponsor(s) of this research;*
- *The data and safety monitoring board or others who monitor the data and safety of the study;*
- *The TrialNet Clinical Hub at the Benaroya Research Institute in Seattle, Washington;*
- *The TrialNet Coordinating Center at the University of South Florida*

***Your information may also be given to:***

- *The U.S. Food and Drug Administration (FDA),*
- *Department of Health and Human Services (DHHS) agencies,*
- *Governmental agencies to whom certain diseases (reportable diseases) must be reported*

***Why will this information be used and/or given to others?***

- *to do the research,*
- *to study the results, and*
- *to see if the research was done correctly*

*If the results of this study are made public, information that identifies you will not be used.*

***What if I decide not to give permission to use and give out my health information?***
*Then you will not be able to be in this research study.*

***May I review or copy my information?***
*Yes, but only after the research is over.*

***May I withdraw or revoke (cancel) my permission?***
*This authorization will not expire.*

*You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor [enter PI name here] at [enter address here]. If you withdraw your permission, you will not be able to stay in this study.*

*When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.*

***Is my health information protected after it has been given to others?***
*Once the information is shared with others, it may no longer be protected by the HIPAA Privacy Rule.*

BioGrid Australia

In addition to being used in this research project your research information may also be used in the BioGrid project. BioGrid links participant information from multiple sources, allowing researchers to better understand how individuals' genetic 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 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 Melbourne Health as part of the BioGrid project and which will assign a unique subject code by which your research information will be linked, de-identified and stored. Your de-identified research information will be made available for possible use in future research to specialist researchers, from Royal Melbourne Hospital 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 the Human Research Ethics Committee of Royal Melbourne Hospital. 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/or 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.

## 8. Results of Project

During the study, information will also be available through the TrialNet website (www.trialnet.org) At the end of the study, we will provide a summary of the results and information will also be available on the TrialNet website.

## 9. Further Information or Any Problems

If you require further information or if you have any problems concerning this study, you can contact the principal researcher or one of the research coordinators. The researchers responsible

for this study are Professor Peter Colman and Associate Professor John Wentworth (both contactable on Ph: 03 93427000).

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

**Complaints contact person**

| | |
|---|---|
| Position | Manager Human Research Ethics Committee |
| Telephone | 9342 8530 |
| Email | research@mh.org.au |

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

**Reviewing HREC approving this research and HREC Executive Officer details**

| | |
|---|---|
| Reviewing HREC name | Melbourne Health HREC |
| Telephone | 03 9342 8530 |
| Email | research@mh.org.au |

**Local HREC Office contact (Single Site - Research Governance Officer)**

| | | |
|---|---|---|
| Position | Director Of Research Governance Ethics | *[Position]* |
| Telephone | 9342 8530 | *[Phone numbe* |
| Email | research@mh.org.au | *[Email addres* |

## 10. Participation is Voluntary

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

Your decision 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 Royal Melbourne Hospital.

Before you make your decision, a member of the research team will be available to answer any questions you have about the research project. You can ask for any information you want. Sign the Consent Form only after you have had a chance to ask your questions and have received satisfactory answers.

If you decide to withdraw from this project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to inform you if there are any health risks or special requirements related to withdrawing.

## 11. Costs, compensation and treatment

There is no charge to you being in this study. You will also not receive any payment for being in this study. Information from this study may result in products being developed that have commercial value. If this happens, you will not receive any share of the profits. We will not give you any treatment as part of this study.

## 12. Ethical Guidelines

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

The ethical aspects of this research project have been approved by the Melbourne Health Human Research Ethics Committee.

## 13. Injury

If you suffer an injury as a result of participating in this research project, hospital care and treatment will be provided by the public health service at no extra cost to you if you elect to be treated as a public patient.

The Royal Melbourne Hospital

**PARTICIPANT CONSENT FORM**

| | |
|---|---|
| **Version:** | **Version date 28 March 2019** |
| **Site:** | **The Royal Melbourne Hospital** |
| **Full Project Title:** | **TrialNet Pathway to Prevention Study**<br>**Diabetes - Screening** |

I have read, or have had read to me in my first language, and I understand the Participant Information dated **28 March 2019**.

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

I will be given a copy of the Participant Information 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 study as outlined in Participant Information. I will indicate in the section below my decision on optional items relating to tissue sample collection and use.

The following checkbox gives you the choice of allowing us to put any remaining blood and DNA samples in the NIDDK repository when TrialNet is over. Even if you decide not to have your remaining blood and DNA samples stored when TrialNet is over, you can still participate in this study.
Are you willing to allow us to put any remaining blood and DNA samples in the NIDDK repository when TrialNet is over for indefinite storage for other research projects? (please initial yes or no)

_____YES _____NO

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**

**Full Project Title:** **TrialNet Pathway to Prevention Study**
**Diabetes - Screening**

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 Name (printed) …….

Signature …… Date ……