

PROTOCOL NAME: A Peripheral Vascular Biobank

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STUDY CENTRE (SITE): THE TOWNSVILLE HOSPITAL

This **Participant Information Sheet** contains detailed information about the project. Its purpose is to explain to you as openly and clearly as possible all the procedures involved in this project before you decide whether or not to take part in it.

1. PROJECT PURPOSE & BACKGROUND HOW CAN BLOOD AND TISSUE SAMPLES

Our purpose is to **support approved research projects with** a repository (or pool) of **High quality:**

- Human blood,
- Tissue samples and
- Clinical information.

Such repositories are called Biobanks.

HELP RESEARCH?

Blood is made up of several parts including plasma and several types of cells. Separating blood into its component parts allows us to look at molecules called biomarkers. Biomarkers include DNA, lipids (fats) and proteins that can provide scientists with a greater understanding of how diseases develop and progress. Studying biomarkers can potentially help with earlier diagnosis and treatment of disease or provide new targets for treatment.

WHY TEST DNA?

Deoxyribonucleic Acid, commonly known as DNA is the chemical that genes are made of. It is a code that directs and controls how your body develops and functions.

The mix of genes you have can sometimes mean you are likely to have, or be more prone to develop, particular medical conditions. DNA testing can potentially give us information on what may happen to your general health, or perhaps the health of your family, now or in the future. The information gained from DNA testing may be used to assist in the management of a disease or for medical research.

WHY DO WE WANT TO STORE SAMPLES?

We do not yet know all of the genes and biomarkers associated with vascular disease but as advances in technology occur, the number of biomarkers scientists can study increases. Many biomarkers are stable when frozen, and can therefore be stored for a very long time and still be put to great use. The main advantage of a central 'Biobank' is the ability to test a large number of samples from different

people who have the same condition, which may in turn allow more rapid translation of research findings into clinical practice.

WHO IS PARTICIPATING?

The Biobank collects clinical information and, blood and tissue samples from people:

- with different types, and varying severities of vascular disease
- who have suffered a vascular related cardiovascular (CV) event such as a stroke or heart attack
- with no vascular disease and has not suffered a vascular related cardiovascular event.

At the time of reviewing and signing this consent form there is a possibility that we may not know which group you fall into. The inclusion of your samples in the biobank will not be affected by which group you do fall into. All patient groups are important and provide valuable information. We hope that comparing the results from these different groups will help us uncover biomarkers related to disease.

2. WHAT WILL I HAVE TO DO?

Participation in this project is voluntary, you are not required to take part if you would prefer not to.

2.1. FOR EVERYONE WHO CONSENTS TO THE BIOBANK

Participation, regardless of whether you have known peripheral vascular disease (or suffered a related CV event) or not will, involves:

1) A health interview; this interview will be conducted by either a doctor, hospital staff or research worker at your first visit after consenting to taking part in the biobank. In addition to basic information like age and gender and your past and current health issues, you **maybe** asked:

- about things such as your education level, employment status, ethnicity/race, living location, alcohol and tobacco use.
- to take part in questionnaires about your quality of life, dietary habits, general physical condition (including level of disability when relevant), financial cost you have experienced as a result of your condition, thinking ability and your presenting health problems.
- about any events like subsequent hospital admissions and the cause, for example, heart attack, operations, amputation, stroke, falls, and if there were complications from these events.

2) A blood donation; The blood collection process is exactly the same as having a blood test with your doctor; the blood is collected from a vein in your arm. There is a small risk of discomfort and bruising with this procedure. In the unlikely event that you suffer an injury as a result of participating in the Vascular Biobank, 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 at the public health service.

The Peripheral Vascular Biobank obtains samples from blood. Approximately 50ml (about three tablespoons) of blood from a vein is collected from each participant. We then spin the blood into its component parts (including plasma, white blood cells, DNA, serum and RNA) which we freeze and store at James Cook University.

3) Physical and vital status assessment; this may include blood pressure, height, weight, waist and hip measurements.

2.2. FOR PEOPLE WHO ARE ATTENDING VASCULAR APPOINTMENTS OR ARE ADMITTED TO HOSPITAL;

While waiting for your vascular appointment or while you are admitted to hospital you may be approached by a research worker, hospital staff and/or doctor to undertake the interview and physical and vital status assessment (as outlined in section 2.1.). If you are not available to participate in the interview and assessment at this time, information will be drawn from your hospital records if available or the research worker will contact you by telephone for more information.

Access to information in your health record held by Queensland Health; Information about you including medical imaging, pathology results, hospital admissions and medical procedures may be obtained from your health records held by Queensland Health; and other health care providers for the purposes of research. Information about your participation in this project may be recorded in your health records at the Townsville Hospital.

2.2.1. Will tissue samples be taken from me? As part of your routine medical care, if required your normal surgeon may send you to have an operation to remove diseased tissues. This tissue is usually discarded. We would like your permission for this extra tissue to be retained to help us learn more about the disease. Tissue samples are processed and either used immediately or stored for later use.

2.3. FOR PEOPLE WHO ARE NOT KNOWN TO HAVE VASCULAR DISEASE;

You will be asked to visit the research site where the interview and physical and vital status assessment will be conducted (as outlined in section 2.1.). At this visit the research worker will also perform an ankle brachial pressure index (ABPI) to assess how much blood flow is getting to your peripheries. You may also be asked to have an ultrasound of your aorta performed if required. If you have previously undergone medical imaging for unrelated medical purposes consent will be obtained from you to access these images.

2.3.1. What if I am found to have peripheral vascular disease? If the results of your assessment indicate possible peripheral vascular disease the principle investigator will notify you and your usual General Practitioner of the results. Your suitability to participate in the Peripheral Vascular Biobank will not alter, however your involvement may expand to include the aspects outlined in section 2.2. where applicable.

3. WILL MY DETAILS BE KEPT CONFIDENTIAL?

Yes; any information obtained in connection with the Vascular Biobank that can identify you will remain confidential and will only be used for the purpose of approved research projects. Identifying information about you will only be disclosed with your permission, except as required by law.

If you give us your permission by signing the Consent Form:

- The secure Vascular Biobank database will retain identifiable information about you, so that if needed we can contact you. However, this information will only be accessible by staff authorised by the Human Research Ethics Committee. Researchers using your samples will not have access to any information which identifies you.
- In any publication, only summary information will be published which will include no identifiable data. The group regularly conducts other vascular research projects such as clinical trials, where if suitable you may be interested in taking part and maybe invited to participate. You can indicate on the signed consent form (page 5/ or 6) if you **do not** wish to be contacted and invited to take part in any other research project run by the group.

In accordance with the *Freedom of Information Act 1982 (Vic)*, you have the right to access and to request correction of information held about you by the Biobank, and can do this by contacting the Biobank (see contact details in Section 5).

4. THINGS TO CONSIDER BEFORE BECOMING INVOLVED

- **Samples will be stored indefinitely** unless you or the Human Research Ethics Committee instructs the Vascular Biobank to destroy them.
- **You may not benefit directly from the outcome of this work.** It can take many years for this type of research to result in the discovery of an important gene or biomarker. It is also possible that your **sample may be tested in ways** that are **currently unknown**. Whilst the Vascular Biobank generally focuses on vascular disease, in the future samples may be used to study other associated diseases.
- Biomarker (including DNA) testing may result in **findings linked to conditions other than cardiovascular disease**. If our research uncovers any significant information specific to your health, our Human Research Ethics Committee may decide to authorise someone to contact you and offer you **access to this information**. You may decline the information. If you wish to be given this information a qualified person will explain it to you. If we need to contact you we will use the contact details (or any updated contact information) you provide us with.
- For some types of research it is helpful to have more than one sample from an individual. By looking at samples from different time points researchers can study the effect factors that change over time (for example with age or disease progression) have on the biomarker they are interested in. To assist researchers with this **we may invite some Vascular Biobank participants to donate an additional blood sample/s**. Donating a subsequent sample/s is entirely optional and you can say no to doing this.
- The Vascular Biobank may permit access to and use of the **samples and/or information by other research organisations** within Australia and/or overseas (**Other Researchers**). Samples will only be given to Other Researchers for projects that have been approved by a Human Research Ethics Committee.
- Since your sample/s is a donation there will be **no financial reward** to you for providing it. It is possible in the long term that research carried out on Biobank samples may lead to financial gain by James Cook University and/or Other Researchers utilising the samples.
- You may be approached for consent to access your Medicare data to determine other health cost associated with your condition. This consent will be obtained separate to this biobank.

5. WHO CAN I CONTACT?

For further information concerning this program, or questions about being a research participant in general contact the vascular research officer at the Townsville Hospital:

Office: ☎ 07 4433 1419

For any other concerns:

This project has been reviewed and approved by the Townsville Hospital and Health Service Human Research Ethics Committee. For concerns related to the conduct of this project, please contact an Ethics Officer:

The Townsville Hospital and Health Service, Human Research Ethics Committee:

☎ 07 4433 1440



PARTICIPATION IS VOLUNTARY

Participation in any research project is voluntary.

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

Before you make your decision, a member of the research team will be available so that you can ask any questions you have about the research project. You can ask for any information you want. Make your decision whether or not to sign the Consent Form only after you have had a chance to ask your questions and have received satisfactory answers. You may wish to discuss this project with friends or family members or your regular family doctor (GP). You are free to do so, and to show them this Information Sheet.

If you agree to participate and then **decide to withdraw** you need to notify the vascular research worker in writing (contact details above in Section 5). Once we receive your request your sample will be destroyed in an appropriate manner and all your details will be deleted from the Biobank's records. A letter of confirmation will be sent to you verifying that these procedures have been followed. Any de-identified information and samples already used in research projects cannot be withdrawn.

7. ETHICAL GUIDELINES

This project will be carried out according to the *National Statement on Ethical Conduct in Research Involving Humans 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 Human Research Ethics Committees of The Townsville Hospital and Health Service, Mater Health Services North Queensland (Mater Hospital, Pimlico) and James Cook University

REVOCAION of CONSENT FORM

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STUDY CENTRE (SITE): THE TOWNSVILLE HOSPITAL

I hereby wish to WITHDRAW my consent to participate in the research proposal named above and understand that such withdrawal WILL NOT jeopardise any treatment or my relationship with **THE TOWNSVILLE HOSPITAL**.

*Please select **one** of the following options:*

- I request that **all data and samples** collected from me **be destroyed and removed** from further analysis.
- I request that **all data and samples** previously collected from me **may continue to be analysed** as part of this research project.

Participants Name (Printed):			
Signature:		Date:	

PARTICIPANT CONSENT FORM

PROTOCOL NAME: A Peripheral Vascular Biobank (Participant)

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STUDY CENTRE (SITE): THE TOWNSVILLE HOSPITAL

Declaration by Participant: I have read, or have had read to me, in a language that I understand, this document and I understand the purposes, procedures and risks of this research project as described within it.

- I understand that the biobank collects information from both people with and without peripheral vascular disease and/or who have/have not experienced a vascular related CV event, and that I fall within one of these groups although at the time of consent which group may be unknown. I understand and consent to my information and samples to be used by the biobank regardless of which group I fall in to.
- I understand that I am consenting for my samples to be included in the Peripheral Vascular Biobank and that these samples will be stored indefinitely. I understand that the samples will be available for use by scientists researching vascular disease, but may be also used for research on other associated diseases in the future. I understand that researchers from other organisations may have access to my samples and that those studies will have been approved by a Human Research Ethics Committee.
- I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to James Cook University concerning my disease and treatment. I understand that such information will remain confidential and will only be shared outside this research team in the manner described.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I understand that I will be given a copy of this document to keep.

I **do not agree** to future contact regarding other research projects

Participants Name (Printed):			
Signature:		Date:	
Declaration by researcher*: I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation			
Researcher Name (Printed):			
Signature:		Date:	

* A senior member of the research team must provide the explanation and provision of information concerning the research project.
 Note: All parties signing the consent section must date their own signature.

PARTICIPANT INFORMATION AND CONSENT SHEET Post – Operative

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You are being given this form as you have recently had an operation to treat a vascular condition. As part of this operation your doctor has removed a diseased area of your tissue, which is required to confirm your diagnosis. There is usually surplus tissue not required for your clinical care which would normally be disposed of. We have temporarily stored this surplus tissue because we are interested in learning more about vascular disease. We would like your permission to store and study this surplus tissue to help us better understand vascular disease.

If you are happy for us to do this then please read the attached information sheet before signing the consent form below. **Participation in any research project is voluntary. 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 your clinicians or hospital.**

- I have read, or have had read to me, in a language that I understand, this document and I understand the purposes, procedures and risks of this research project as described within it.
- I understand that I am consenting for my samples to be included in the Peripheral Vascular Biobank and that these samples will be stored indefinitely. I understand that the samples will be available for use by scientists researching vascular disease, but may be also used for research on other associated diseases in the future. I understand that researchers from other organisations may have access to my samples and that those studies will have been approved by a Human Research Ethics Committee
- I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to James Cook University concerning my disease and treatment. I understand that such information will remain confidential and will only be shared outside this research team in the manner described.
- I have had the opportunity to ask questions and I am satisfied with the answers I have received.
- I understand that I will be given a copy of this document to keep.

Participant's name (printed)

Signature.....Date.....

I do not agree to future contact regarding other research projects

Declaration by researcher*: I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Researcher's name (printed)

Signature: _____ Date _____

* A senior member of the research team must provide the explanation and provision of information concerning the research project.

Note: All parties signing the consent section must date their own signature.

