



## **Participant Information and Consent Form**

### **St Vincent's Hospital Melbourne**

**Full Project Title: ST VINCENT'S BIOBANK FACILITY**

**HREC Protocol Number:** HREC-A Protocol 135/13

**Version:** 6    **Dated:** 27 Jan 2021

**Principal Investigator:** Professor Tom Kay

#### **1. Introduction**

You are invited you to donate a sample to the St Vincent's BioBank Facility ('BioBank') on the St Vincent's Hospital campus. This is because your donation will make a valuable contribution to the BioBank repository. The BioBank will store thousands of samples from people affected by a range of diseases. The BioBank will make these samples available to approved research projects aimed at improving the treatment and prevention of diseases like diabetes, heart disease, infectious diseases, and cancer.

This Participant Information and Consent Form tells you about the BioBank and how it will help clinical research. It explains what is involved to help you decide if you want to take part.

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 your local health worker.

Participation in this research is voluntary. If you don't wish to take part, you don't have to.

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

- understand what you have read;
- consent to contribute one or more sample(s) to the BioBank and acknowledge that this/these sample(s) may be used in future research projects;
- consent to be involved in the procedures described;
- consent to the use of your personal and health information as described.

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

#### **2. What is the purpose of this research project?**

Poor access to human samples limits clinical research. The aim of our BioBank is to address this by providing a facility for processing, storing and distributing human samples that will be used to support future clinical research into a range of diseases. When a researcher requires human samples to study a particular disease, they can apply to the BioBank for appropriate samples if they have ethics approval for their study. The BioBank will operate at St Vincent's Hospital Melbourne and St Vincent's Private Hospital. Approximately 400 blood samples, and a smaller number of other samples such as urine and tissue, will be collected each year.

### **3. What does participation in this research project involve?**

If you agree to donate a blood sample for future research purposes, this may be collected from you at an SVHM Pathology Collection centre at the same time as a routine blood collection is made for tests requested by your doctor. Alternatively, a blood sample for future research purposes may be collected from you by a research nurse at a hospital clinic, outpatients or surgical unit. Approximately 25-50ml (about 2.5 to 3.5 tablespoons) of blood will be taken from a vein in your arm on these occasions to store in the BioBank for future research purposes. The procedure for taking blood for the BioBank is the same as having an ordinary blood test. Your doctor may ask you to contribute additional blood samples to the BioBank at follow-up visits. You can stop follow-up collections at any time by telling your clinician.

You may also agree to the Biobank obtaining other samples taken, such as urine, faecal and tissue samples. Tissue or surgical samples will only be collected as part of your clinical care. Clinical samples will be obtained from St Vincent's Pathology to ensure that diagnostic testing is not compromised. Your samples will be processed and stored in the National Serology Reference Laboratory (NRL) on the St Vincent's Hospital campus.

We also seek your permission to collect some of your health information from you, your doctor and/or medical record to retain in the BioBank database. This information will include your name, hospital UR number, date of birth, gender, ethnicity, race and disease diagnosis. This information will allow us to search for particular samples in the BioBank e.g. for samples from subjects of a certain age and diagnosis. The BioBank will safeguard your privacy and confidentiality by ensuring that your sample(s) and data are securely stored in an anonymous but re-identifiable (coded) form in the BioBank and only provided to scientists for research studies in this coded form. A small number of authorised BioBank staff will be able to re-identify your samples and data. This information will not be disclosed to researchers who are using your samples and data.

We seek your permission to hold your samples and information indefinitely for use in unspecified future research. Medical science is advancing very quickly, and so we are not in a position to be able to tell you exactly what form the future research might take, or the consequences of that research. Future research might involve determining important biomarkers that may predict the onset, prognosis or progression of disease, or determining the effects of different drugs on different people over time. Future research may also identify genetic predispositions to particular diseases, or may use cells from your sample(s) to establish cell lines. A cell line consists of cells cultured to grow for a very long time in the laboratory to create a large supply of material for research. You may opt out of studies that involve studying genetic material in your samples or developing cell lines from your samples if you wish. Your identity will not be revealed to the researcher who may use your sample(s) so you will not receive any results from this research or derive any personal benefit.

This research might also result in drugs or tests that are produced and marketed by private organisations for profit. St Vincent's may or may not profit from any of the revenue that such research would generate. Although knowledge acquired through medical research may lead to discoveries that are of commercial value to the researcher and their institution, there will be no financial benefit to yourself or your family. The BioBank is a non-profit service that advances clinical research endeavours and you will not be paid or reimbursed for your donation to the BioBank. The BioBank may charge researchers a fee to recover some of the costs of storing and administering its collection of tissue, but the samples you donate to the BioBank cannot be sold.

No research will take place using your samples and information unless that research is first reviewed and approved by a Human Research Ethics Committee, which will determine whether the benefits of the research outweigh the cost to you and your privacy.

#### **4. What are the possible benefits?**

Donating samples to the BioBank is unlikely to be of direct benefit to you or your family. You will not receive any results from the research conducted using your sample(s) or data. We plan to store your sample(s) for a very long time. Your sample(s) may not be used for many years until a new approach to study a particular disease is developed. Therefore, the benefit will not be to you but to future generations of patients.

#### **5. What are the possible risks?**

When blood is taken you may feel a slight pinch in your arm when the blood is drawn and you could develop a small bruise. After the procedure is over, there may be some soreness that could last 2-3 days. Fainting is also possible, although unlikely.

The collection of any other samples will be done as part of your clinical care, and will therefore not expose you to any risks, such as the use of anaesthetics, that you would not already be undertaking.

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

Participation in the BioBank is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at a later stage. If you wish to withdraw, you should contact your clinician or one of the investigators listed in section 12. If you withdraw, your stored samples in the BioBank will be destroyed and all of your personal information stored in the BioBank will be permanently deleted.

Your decision whether to take part or not, or to take part and then withdraw, will not affect your relationship with St Vincent's Hospital or any of the staff who work in the BioBank Facility or on the Hospital campus, including your treating doctor.

#### **7. How will I be informed of the final results of this research project?**

You will not receive specific research results. This is because research by its very nature, is experimental, can take many years and uses samples and data from a large number of people, so what a researcher discovers in this context may be of little value to you, your family or your future health.

#### **8. What will happen to information about me?**

Your information will be held in a dedicated BioBank database that will be password protected and only accessible to authorized BioBank staff including the laboratory technician, Biobank coordinator, Information Services Manager, and the Principal Investigator. These staff will keep this information secure and confidential in order to protect your privacy.

Your information and samples will be stored in a coded or re-identifiable format, meaning that personal information, such as your name and hospital medical record number are removed from your data and samples, and replaced with a unique code known only to authorized BioBank staff. If you do not already have a hospital medical record, one will be created for you, in keeping with the national ethical requirements.

If researchers have ethics approval for their study, we may release your data and samples to them but this will always be provided in a coded format to ensure that your identity is not disclosed. Providing researchers with coded data in this way means your privacy and confidentiality will be fully protected in any publications produced by these researchers.

Your privacy and confidentiality will be safeguarded if, in the future, your data in the BioBank is linked to your data in other health statistics databases such as the Australian Institute of Health and Welfare database. Linking these databases would allow more detailed medical information to be provided to authorised researchers in a re-identifiable (coded) form. This would help researchers identify what factors influence the progression of chronic disease.

We seek your permission to hold your information indefinitely, in case this is of benefit for future unspecified research. In accordance with regulatory guidelines, the information collected in the BioBank database will be kept for at least 7 years after the publication of data generated by researchers using BioBank samples. Samples that are not used by researchers will be destroyed if the samples are no longer useful. If you withdraw consent, your samples in the Biobank will be destroyed, and your personal information deleted. To ensure appropriate procedures are followed, the St Vincent's Hospital Human Research Ethics Committee monitors all research projects they approve. Destruction of any data and/or samples will be subject to any legal requirements or obligations on the part of St Vincent's Hospital Melbourne to retain this information.

**9. Can I access research information kept about me?**

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access the information collected and stored in the BioBank about you. Please contact one of the investigators named at the end of this document if you would like to access your information. You will not be able to access this information if your sample has been destroyed because it was no longer useful for research purposes.

**10. Is this research project approved?**

The ethical aspects of the BioBank Facility have been approved by the Human Research Ethics Committee of St Vincent's Hospital Melbourne. Future unspecified research on samples in the BioBank will require approval by a Human Research Ethics Committee and the BioBank Management Committee before samples are released.

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.

**11. Consent (refer to next page)**

**12. Who can I contact?**

The person you may need to contact will depend on the nature of your query. Therefore, please note the following:

**For further information:**

If you want any further information concerning this project or if you have any problems which may be related to your involvement in the project (for example, feelings of distress), you can contact:

Katherine Woods (Biobank Coordinator) (03) 9418 1106  
Tom Kay (Principal Investigator) (03) 9288 2480

**For complaints:**

If you have any complaints about any aspect of the project or the way it is being conducted you may contact the Patient Liaison Officer at St Vincent's Hospital (Melbourne) on (03) 9231 1954. You will need to tell the Patient Liaison Officer the name of the person who is noted above as the Principal Investigator.

**Research Participants Rights:**

If you have any questions about your rights as a research participant, then you may contact the Executive Officer Research at St Vincent's Hospital (Melbourne) on (03) 9231 2394

## CONSENT FORM

**Title:** St Vincent's BioBank Facility  
**Protocol Number:** HREC-A 135/13  
**Principal Investigator:** Professor Tom Kay  
**Location:** St Vincent's Hospital Melbourne



**ST VINCENT'S  
HOSPITAL**  
MELBOURNE

A FACILITY OF ST VINCENT'S HEALTH AUSTRALIA

### Declaration by the participant:

- I have read, or someone has read it to me in a language that I understand, the Participant Information Sheet **version 6 dated 27/01/2021**
- I understand the purposes, procedures and risks of the research described in the project.
- I freely agree to donate my sample(s) to St Vincent's BioBank as described and understand that I am free to withdraw at any time during the study without affecting my future health care.
- I give permission for some of my personal and health information to be collected from my doctor and/or medical record and stored in the BioBank database. I understand that my identity will not be released to researchers using my samples.
- I give permission for my samples and health information to be used for future unspecified research by approved researchers. I understand that research may take many years and any information gained will not benefit me or my family personally or financially.
- I have had an opportunity to ask questions and am satisfied with the answers I received.
- I understand that I will be given a signed copy of this document to keep.

<b>Please read each of the following optional items carefully and tick either YES or NO:</b>	
1. I give permission for my information in the BioBank to be linked to other ethically-approved health databases to provide additional health information about me to researchers. I understand that my identity will not be disclosed to these researchers.	<input type="checkbox"/> YES <input type="checkbox"/> NO
2. I give permission for cells obtained from my samples to be used to establish cell lines (a cell line is comprised of cells that have been allowed to grow indefinitely)	<input type="checkbox"/> YES <input type="checkbox"/> NO
3. I give permission for my samples to be used in genetic research which may identify genes or diseases that can be passed on to my blood relatives.	<input type="checkbox"/> YES <input type="checkbox"/> NO
4. I give permission for samples collected for clinical purposes to be obtained and stored by the Biobank.	<input type="checkbox"/> YES <input type="checkbox"/> NO

Participant's Name (print):	Signature:	Date:
Witness Name (print):	Signature:	Date:

### Declaration by Researcher:

I have given a verbal explanation of the aims of the BioBank and its possible procedures and risks, and I believe that the participant has understood that explanation.

Name and Title  
(print):

Signature:

Date:

### If an Interpreter was used please fill in the following:

I have interpreted the Participant Information Sheet and Consent Form to the above in a language he/she may understand.

Language:

Relationship to participant:

Interpreter's Name (print):

Signature:

Date: