Health
Northern Sydney
Local Health District

Participant Information Sheet

BioHEART: Cardiology Biobanking for Biomarker Discovery

Coordinating Investigator: Professor Gemma Figtree

Name of main investigators: Professor Gemma Figtree

Contact details of main investigators:
Professor Gemma Figtree
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Biobank name and location:
BioHEART Biobank - Kolling Institute of Medical Research or NSW Health State Biobank

You have been given this information sheet because you have been asked to provide imaging data and/or a biological specimen such as blood and/or tissue to the BioHEART Biobank for the purposes of research.

BioHEART Introductory Video

What is a biobank?

A biobank is a stored collection of human biological samples (e.g. tissue, blood or bone) and/or their products (e.g. DNA), associated with personal information. Biobanks are an important resource for medical researchers to improve the understanding of diseases and to help find better ways to prevent or treat them. The samples and associated health information are stored securely and are used for medical and health-related research projects.

The BioHEART Biobank aims to improve the prevention, diagnosis and treatment of cardiovascular disease. By collecting samples and data from both healthy participants and cardiac patients, researchers can investigate why some people develop cardiovascular disease while others do not. This includes research on the cause, prevention, risks, diagnosis and treatment of cardiovascular disease, as well as genetics research and clinical trials.

Being a biobank participant

You are invited to participate in the biobank because you are either a patient at risk for cardiac disease, with known cardiac disease or a healthy volunteer. Your participation in the biobank is voluntary. If you choose to participate, you will be given the opportunity to discuss any questions with an approved individual responsible for obtaining biobank consent. If you are a patient, your scheduled medical procedure or investigation will happen as normal. Once your questions have been answered, if you agree to participate and have completed the consent form, the following biological samples will be biobanked:

> Most participants will contribute a small blood sample (approximately 50 mL). This will be collected through an existing cannula or venous access device where one is in place, otherwise it will be collected as a routine blood sample.

- If you have had an angiogram, a second blood sample may be collected six hours after the first.
- If you are having chemotherapy, a second blood sample may be collected prior to the next round of chemotherapy.
- If you are having surgery, a small sample of tissue and/or fluid will be collected during your scheduled medical procedure.
- If you are having a cardiac MRI, biological samples may not be collected. Note that the information pertaining to biological samples in this information sheet is not applicable to your participation in this biobank subgroup, but that the information pertaining to the storage and use of clinical/imaging data does apply.

How will my privacy be protected?

Identifying personal information will be removed from your samples and replaced with a unique number for research purposes before going into the biobank.

A separate list of identifying personal information will be stored by the biobank so that only the senior researchers can identify you. Your sample and information will be stored indefinitely in this way.

There may be rare instances where genetic information obtained from donated tissue may lead to the identification of participants, even without having the participant's name or other personal information included in the study data. This is because genetic information is unique to the participant. For example, if genetic information derived from your donated samples was matched to previously stored genetic information and your identifying data. However, the biobank requires this genetic information to be kept strictly confidential and there are legal requirements for researchers to maintain your privacy.

During the research process, data (including genomic data) will be shared with other researchers in the study. Your privacy and the confidentiality of biological samples are very important to us, and we will make every effort to protect them. When research samples are shared, they will only be identified by the unique number assigned to your samples. This coding will stop any linking of the samples with your identity. Additionally, biological samples are only available to researchers under terms and conditions in line with the informed consent document and each request is reviewed in detail.

What does it mean to consent to biobanking?

Consenting to biobanking means you are also consenting for researchers to access and link information from your medical records. This health information may include details about your medical procedures, diagnosis history, pathology results, imaging results, hospital records and genetic or family history details. Your health information may be linked with other personal information (e.g. education, employment status, lifestyle factors). By consenting to link your biological sample with your health and personal information, you are providing a valuable resource for future health and medical research that will only occur after approval from a human research ethics committee. This information will be de-identified after collection and will only be associated with a unique study number.

If you decide to participate in biobanking, you are encouraged to tell your family of your decision and why you chose to support medical research in this way. While your sample may contribute to research that has a commercial benefit, for example the development of a new technology, you will not be entitled to receive a financial return.

Frequently asked questions

1. Who is responsible for my samples?

The BioHEART Biobank will be the custodian of your samples, and will keep them in a location approved by the NSLHD HREC, such as the Kolling Institute of Medical Research or the NSW Health State Biobank. These facilities will be responsible for securely storing the samples, and for the release of samples to authorised researchers.

2. What will happen to my samples?

Your tissue sample will be stored in a location approved by the NSLHD HREC, such as the Kolling Institute of Medical Research or in the NSW Health Statewide Biobank. Regardless of location, your sample will remain under the custodianship of the investigators and your information will only ever be disclosed for research purposes as outlined in this information sheet.

The samples will be used for research into the causes of cardiovascular disease. Initially, this will include the development of blood-based signatures for coronary artery disease (CAD), vascular disease in other blood vessels (e.g., carotid artery or the vessels of the legs), individuals who are either vulnerable or resilient to vascular disease, and the performance of risk scores in an Australian population. These signatures will provide insights into how cardiovascular disease develops and in whom.

The samples may also be used for future unspecified health and medical research after approval by a Human Research Ethics Committee, an independent committee that has ethical oversight of research involving humans. This committee will be required to meet Australian ethical standards. The results of the research may be published without your further consent; however, you will not be identified in any way.

3. What does data linkage mean?

Medical record or data linkage brings together information that relates to the same individual from different data sources. This helps researchers better understand people's health journey, which can improve treatment and health services delivery. For more information on how data linkage works see http://www.cherel.org.au/how-record-linkage-works.

4. What will happen to my data?

All personal data will be stored using strict privacy protocols and in accordance with NSW Government requirements. All studies using biospecimens and linked data must have ethical approval. Researchers are only provided information without identifying personal information (eg. your name and address). In the event of an incidental finding (see question 10), the biobank can de-code (ie. re-identify) the biospecimen if necessary so that you can be notified.

5. Will my samples and data only be used for Australian based research?

It is common in health and medical research for international and interstate-based researchers to collaborate. If you agree to participate, your samples and associated information may be sent interstate or overseas for collaborative research purposes. This will be done in such a way that you cannot be identified and only after a Human Research Ethics Committee (or an international equivalent that meets Australian ethical standards) has approved the research. Researchers will only have access to your samples, not your identifying personal information.

6. Are there any risks to my privacy by participating?

Your health information will be kept secure and confidential in accordance with legal requirements. Researchers are only provided information without identifying personal information (e.g. your name and address). Should any breach of privacy occur, the BioHEART Biobank will ensure the situation is dealt with in accordance with existing privacy laws and guidelines.

7. Can anyone other than BioHEART Biobank approved researchers access my health information?

In general, parties outside NSW Health cannot access your health information. However, there may be circumstances where a legal requirement to provide your health information outside NSW Health arises. While these situations are extremely rare, the BioHEART Biobank will be required to comply with its legal requirements and make your information available if ordered to by a court.

8. What if I change my mind and don't want to participate?

Participation in biobanking is entirely voluntary. Even after you have provided the BioHEART Biobank with your sample and health information, you are free to withdraw all, or part of, your consent at any time without having to give a reason by contacting the BioHEART Biobank or using the withdrawal of consent form attached to this document. Choosing not to participate, or withdrawing your consent to participate, will not affect your medical treatment in any way.

Should you choose to withdraw your consent entirely, the BioHEART Biobank will discard your stored tissue, blood samples and health information collected about you. However, if some or all of your tissue or blood samples have been provided to a research project, it will not be possible to retrieve these samples. Also, research that has been published cannot be deleted or discarded, but you will not be able to be identified in any way.

9. Will the BioHEART Biobank contact me after I have given my consent to participate?

If you consent to participate in the BioHEART study, a medical questionnaire may be completed with the researcher now that takes 5-10 minutes. The BioHEART study may also contact you to collect additional information at 30 days and then annually for the life of the study. This brief follow-up visit will occur by a method of your choosing, including telephone or email. The BioHEART Biobank will keep contact to a minimum, and you can request not to be contacted for further follow-up at any point in time.

There is also a small possibility that you may also be contacted by a clinician to notify you of any new incidental findings that arise.

10. What happens if serious health implications are discovered in my sample?

During research, information may be discovered that has serious and significant health implications for you (and possibly your genetic relatives). These are known as incidental findings. Only findings that are of a highly serious nature will be returned to you, such as the identification of a gene for sudden cardiac death. General health information, such as evidence of elevated risks for high cholesterol or diabetes, will not be returned. If you are not contacted to advise you of a finding, this does not mean that you do not have any health issues. It is important to continue any regular clinical check-ups, as researchers do not perform screening on your sample during their research.

The BioHEART study will utilise the Biobank samples to look for novel risk factors and biomarkers that identify cardiovascular disease. Part of this research will include genetic testing but based on previous studies that have determined genetic risk for cardiovascular disease, the likelihood of the BioHEART study identifying a factor with significant health implications for a participant is low.

In the unlikely event that information with potential health implications is discovered, the BioHEART Biobank will refer the matter to a clinical expert who will evaluate the result to determine whether it is a serious and significant finding and whether it should be returned to you for further action. This may involve further tests, genetic or otherwise, to ensure the validity of the finding.

You have the option to choose whether or not you would like to be informed of unexpected findings. In addition, you will have the opportunity to choose whether you would like an alternate person to be contacted and provided with the result, if you are deceased at the time a clinically significant result becomes available.

As the findings may impact on your genetic relatives, we encourage you to inform them of your participation in the biobank. After further testing, this information may become part of your health record as health information. You may be required by law to disclose this information to any future insurer. The results of a genetic test may affect your future income protection and insurance eligibility. If you are contacted about an incidental finding, you are encouraged to seek advice from your insurer. If you choose not to have these incidental findings returned to you, these results will not be available to you and your future requests for insurance will not be affected by participating in this research.

11. Where can I find more information?

If you would like more information about the BioHEART Biobank or your participation, please call (02) 9926 4915 or email: gemma.figtree@sydney.edu.au. Please also keep a copy of this information sheet for your records.

Additional information about the trial is also available by searching “BioHEART” on the Australia and New Zealand Clinical Trials Registry website – the trial ID is: ACTRN12618001322224.

12. Who should I contact if I have concerns or complaints about the study?

If you have any concerns or complaints about the conduct of the BioHEART Biobank, these should be directed to the Northern Sydney Local Health District Human Research Ethics Committee Ph: (02) 9926 4590 (Reference #2019/STE10028).

Subgroup – MI / CT / VASC / ONC / AS / Other:
ID #:
Recruitment date:

Health
Northern Sydney
Local Health District

Participant Consent Form

Tissue Bank and Genetic Study - Adult providing own consent

Royal North Shore Hospital

Title	Cardiology Biobanking for Biomarker Discovery
Short Title	**BioHEART**
Project Sponsors	Northern Sydney Local Health District, Sydney Local Health District, Western Sydney Local Health District
Coordinating Principal Investigator	Professor Gemma Figtree
Principal Investigator at Site	Professor Gemma Figtree
Location	Royal North Shore Hospital

Declaration by Participant

I consent to my health and personal information being collected and used in a de-identified manner for the purpose of such research. I also consent to my tissue (including blood and other tissue) removed during medical or surgical treatments or investigations to be stored by the biobank and used for any current project and/or future unspecified research projects. If having a cardiac MRI, I understand that biological samples may not be collected or stored.

In consenting to my tissue being stored by the biobank and used and disclosed for research purposes, I confirm that I agree to all of the following:

- I have read the Participant Information Sheet relating to participation in the biobank.
- I have been given the opportunity to discuss the information, ask questions and have any concerns addressed. I declare that I understand the information provided.
- I understand that participation in the biobank is entirely voluntary and I give my consent to donate blood or tissue and health information collected during my treatment, for use in health and medical research.
- I understand that I will be contacted for short follow up visits by a method of my choosing as outlined in the Participant Information Sheet.
- I understand that I can withdraw my consent at any time by contacting the biobank without any impact on any future treatment.
- I am aware that I may not be personally informed of the general research results of studies using my samples, but these may be published, taking care not to disclose the identities of those who have contributed samples.
- I permit the biobank to store samples collected from me for an indefinite period and the samples will be used in an anonymous form for Human Research Ethics Committee (HREC) approved future unspecified health and medical research.

- I permit the transfer and sharing of my tissue samples and de-identified health information to other researchers/biobanks both interstate and internationally for HREC approved health, medical, healthcare or health outcomes research. Including the sharing of data without identifying details (ie. name and address) to secure databases for the purposes of future research by approved investigators.
- I permit the linking of my health information (e.g. clinical records, diagnosis history, pathology results, hospital and emergency department records) and other relevant information (e.g. education, employment status, lifestyle factors) for use in health and medical research, subject to HREC approval. Researchers are only provided information without identifying details (e.g. name and address).
- I understand that there is a small chance I may be contacted in the future if an incidental finding is discovered that has serious and significant health implications for me (and possibly my genetic relatives)

Communication Preferences

I permit the study team to contact me for study communications and approved questionnaires through the following:

☐ **EMAIL:** _____

☐ **TELEPHONE:** _____

In respect to receiving a notice of study publications

I would like to receive updates from the study team on presentations and publications arising from the research project. I understand that I will not be able to be identified in any of the publication data.

a. I wish to be informed Yes ☐ No ☐

In respect to receiving a notice of future research opportunities

I would like to be contacted by the study team about future HREC-approved research projects for which I may qualify, which may or may not be related to this research project.

a. I wish to be informed Yes ☐ No ☐

In respect to receiving information in relation to Incidental Findings

If research reveals a clinical/relevant unexpected finding (“Incidental Findings”):

a. I wish to be informed Yes ☐ No ☐

Signature of participant	**Please PRINT name**	**Date**
_____		
Signature of investigator	**Please PRINT name**	**Date**
_____		

Health
Northern Sydney
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Withdrawal of Consent Form

Tissue Bank and Genetic Study

Royal North Shore Hospital

Title	Cardiology Biobanking for Biomarker Discovery
Short Title	**BioHEART**
Project Sponsors	Northern Sydney Local Health District, Sydney Local Health District, Western Sydney Local Health District
Coordinating Principal Investigator	Professor Gemma Figtree
Principal Investigator at Site	Professor Gemma Figtree
Location	Royal North Shore Hospital

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Royal North Shore Hospital.

Please check and initial relevant box

☐ I request no further follow up phone calls from the researcher, however my blood and /or tissue samples may remain in the Biobank.

☐ I request that all my blood and/or tissue sample collected and banked be deleted or destroyed if it is still identifiable.

Signature of Participant **Please PRINT name** **Date**

Mail this section to:
Prof Gemma Figtree, Department of Cardiology, E25 – Royal North Shore Hospital, St Leonards, 2065