**PARTICIPANT INFORMATION SHEET/CONSENT FORM**

RESEARCH – PARTICIPANT INFORMATION CONSENT

 NORTHERN HEALTH

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| **Title** | **Northern Centre for Health Education and Research Reproductive Health Biobank** |
| **Short Title** | The NCHER Biobank |
| **HREC No.** | HREC/18/Austin/44 |
| **Protocol Number** | 1.0 |
| **Coordinating Principal Investigator/ Principal Investigator** | A/Prof Lisa Hui  |
| **Associate Investigator** | A/Prof Natalie Hannan |
| **Location**  | The Northern Hospital185 Cooper St Epping 3076 |

**Participant Involvement In Research Project:**

**Start Date:\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_**

**Part 1 What does my participation involve?**

1. **Introduction**

You are invited to contribute to the **Northern Centre for Health Education and Research (NCHER) Biobank**, which is managed by a team of Women’s Health researchers at the Department of Obstetrics and Gynaecology at the University of Melbourne. You have been approached because you are attending a Northern Health facility for your medical care.

Our biobank aims to collect samples from pregnant women that may be valuable for ongoing research in the University Department. This project has been approved by the Austin Human Research Ethics Committee.

This Participant Information and Consent Form explains this project and the procedures involved. Knowing what is involved will help you decide if you want to take part in this research.

Please read this information carefully. Ask questions about anything that you do not understand or that you want to know more about. Before deciding whether or not to take part, you may want to talk about it with a relative, friend or health worker. If you require an interpreter for your health care visits, we will arrange to have one available for you so that you can understand this project and decide if you wish to participate.

Participation in this research is voluntary. If you do not wish to take part, you do not have to. You will receive the best possible care whether you take part or not. If you would like to participate, you will be asked to sign the consent section of this document. By signing this form, you are telling us that you:

* understand what you have read;
* consent to take part in the research throughout your time as a patient of Northern Health;
* consent to participate in the research processes that are 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. You may ask questions at any time.

**2 What is the purpose of this research?**

The research has been initiated by the study doctor Assoc Prof Lisa Hui. Our women’s health research team at the University of Melbourne are investigating pregnancy conditions such as preeclampsia and fetal growth restriction. These conditions can be caused by abnormal placental growth in very early pregnancy and may lead to serious health problems for pregnant women and their babies. The purpose of our research is to make scientific discoveries about early placental development that can improve treatment for women with high risk pregnancies.

In order to make our research relevant to women, it is very important that we perform our research on human placentas rather than on animal or artificial placentas.

**3 What does a donation to the biobank involve?**

If you take part in this biobank project, we will ask you to donate up to three different samples. You have a choice of whether to donate all, some, or none of these samples.

1. The **blood sample** will be collected during your pregnancy when you have a blood test that your midwife or doctor has ordered as part of your routine care. Alternatively, we may collect this sample if you require an intravenous cannula during a hospital admission. We will collect up to 2 tablespoons of blood (around 30ml) at this collection. The amount of blood taken is small and will not affect your general health or recovery from childbirth.
2. The **placental tissue** will be obtained after your baby and the placenta (the ‘afterbirth’) have been born. Donating placental samples will not have any impact on how you give birth or inconvenience you, your midwife or doctor. These samples can be collected from the placenta in another room so that you and your family are not disturbed at this special time. If your placenta requires examination by a pathologist, we will ensure that our tissue collection does not compromise this testing.
3. The **umbilical cord blood** sample will be taken from the placental end of the umbilical cord AFTER the baby has been born and the cord has been cut and the placenta separated from the baby. This means that there will be no pain for your baby, or inconvenience to you or your maternity carers during the birth. Usually, the midwife will discard the placenta and cord after examining it after birth, so collecting the cord blood will not have any impact on your baby or yourself. If you need cord blood collected as part of your baby’s health care, or elect to have delayed cord clamping, this research sample will not be collected until after these procedures have been performed. We will aim to collect about 2 tablespoons of blood from the cord (30ml). We will only collect cord blood on a single occasion (immediately after birth).

We will also collect information on your **medical history** and medications from your hospital records. This will be stored under a biobank code number so that your privacy is maintained.

Participating in this study does not involve any changes to your usual health care. If you wish to involve your partner or other family member in this decision, we are very happy to include them in any discussion.

There are no costs associated with participating in this biobank project, nor will you be paid.

**4 What do I have to do?**

You do not need to make any changes to your behaviour or health care. You will be asked to sign a consent form for the collection of (i) your blood and/or (ii) placental tissue and/or (iii) cord blood during the biobank project. You can choose to donate any combination of these three samples if you take part in this study.

**5 How will my samples be used?**

We aim to use the samples in future studies on pregnancy complications, such as preeclampsia, growth restriction and gestational diabetes. The experiments will take place within the laboratories of the University of Melbourne Department of Obstetrics and Gynaecology, or their research collaborators. All future research on biobank samples, including that performed by external researchers, will be required to have prior approval from an approved Human Research Ethics Committee.

Your samples may undergo future research that studies the function of genes in health and disease. Such research will not have any implications for future health, either for you, for your children, or other family members. You and your child will not be identifiable from any genetic research published from the biobank samples.

Under special circumstances, we may also allow access to your de-identified samples and associated clinical data to collaborating research partners outside of the University of Melbourne Department of Obstetrics and Gynaecology. Your samples will NOT be sold to any commercial companies, or used for research that does not aim to improve health outcomes for women and babies. We will NOT be creating cell lines for commercial use.

**6 Do I have to donate to the biobank?**

All contributions to the biobank are 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 any stage.

You are free to consent to any type of sample (blood and/or placental tissue and/or cord blood). You will be asked to indicate on the consent form which samples you consent for donation.

If you do decide to take part, you will be given this Participant Information and 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 your hospital.

**7 What are the alternatives to participation?**

You do not have to take part in biobank to receive treatment at this hospital. Your decision will not have any impact on your clinical care.

**8 What are the possible benefits of taking part?**

There will be no clear benefit to you from your participation in this research. This research may benefit pregnant women and the babies in the future by developing new preventative treatments for pregnancy complications.

**9 What are the possible risks and disadvantages of taking part?**

You will not be asked to have any extra blood tests. The blood sample taken for this project will be taken with the same needle as your routine preoperative care. This may prolong the procedure by a few seconds.

Your blood and placental samples (tissue and/or cord blood) will not undergo any genetic or genomic testing that has potential for yielding information with health implications for you or your family.

The placental samples (tissue and/or cord blood) collected following the birth of your baby are those that are usually disposed of by the hospital as biological waste. The collection of these samples will not complicate your care or recovery in any way. We will NOT be testing the cord blood for any genetic conditions that might have long term implications for your child’s health. We will NOT be storing cord blood stem cells from your baby.

If you become upset or distressed as a result of your participation, the study doctor will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the biobank project team. This counselling will be provided free of charge.

**10 What will happen to my samples?**

We will store the samples securely at the University of Melbourne research laboratory at the Northern Centre for Health Education and Research at 185 Cooper St, Epping VIC.

These samples will be stored separately from clinical samples taken for your medical care. Samples and data will be coded with a biobank code to protect your privacy.

**11 Can I have other treatments and still contribute to the biobank?**

Yes, if you intend to participate in this research biobank, you should tell the research team about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other treatments.

**12 What if I withdraw from the biobank?**

If you decide to withdraw from the biobank, please notify a member of the research team. There are no special requirements linked to withdrawing. If you do withdraw your consent, we will destroy your samples in accordance with biosafety regulations and will not collect additional personal information from you. Health data collected for the research biobank will also be destroyed. We will only maintain the minimum personal information required to ensure that the conduct of the research complies with law.

**13 Could this biobank project be stopped unexpectedly?**

This biobank project may be stopped unexpectedly for a variety of reasons. These may include unexpected staffing or funding cuts.

**14 How long will my samples be stored for?**

The samples and associated clinical data may be stored indefinitely.

**15 What will happen to information about me?**

By signing the consent form you consent to the relevant research staff collecting and using personal health information about you. Any information obtained in connection with your biobank sample that can identify you will remain confidential. Your information will only be available to the members of the research team and will not be shared to other researchers. Data will be kept in password-locked files, and hard-copy documents will be kept in a locked cabinet in the NCHER. Your information will only be used for the purpose of ethically-approved research projects and it will only be disclosed with your permission, except as required by law.

Your health records and any information obtained during the research are subject to inspection for the purpose of verifying the procedures and the data. This review may be done by the relevant authorities, the institutions relevant to this Participant Information Sheet, Northern Health and University of Melbourne, 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 research arising from the biobank may be published and/or presented in a variety of forums. This may include storage of deidentified data in a public scientific repository for use by other researchers in accordance with international best practice in research. In any publication, presentation, or database submission, information will be provided in such a way that you cannot be identified, except with your permission.

Information about your participation in the biobank may be recorded in your health records. In accordance with relevant Australian and/or Victorianprivacy and other relevant laws, you have the right to request access to the information collected and stored by the research team about you. 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 future that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

**16 Complaints and compensation**

If you suffer any injuries or complications as a result of your sample donation, 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 any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

**17 Who is organising and funding the research?**

Associate Professor Lisa Hui MBBS PhD, and Associate Professor Natalie Hannan PhD are the lead investigators of this project. A/Prof Lisa Hui is an obstetrician and maternal fetal medicine specialist at the University of Melbourne and Northern Health. A/Prof Natalie Hannan is a senior scientist at the Translational Obstetrics Group at the University of Melbourne with laboratory expertise in placental research.

There is no commercial sponsorship involved in this project. No member of the research team will receive a personal financial benefit from your involvement in this biobank project (other than their ordinary wages). 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 or your family from these discoveries. Funding will be sought from government and philanthropic sources. Funding sources will have no role in the design, conduct, analysis or interpretation of the research findings.

**18 Who has reviewed the biobank 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 biobank project have been approved by the HREC of Austin Health. This project will be conducted 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**

The person you may need to contact will depend on the nature of your query.

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 (for example, any side effects), you can contact the principal researcher A/Prof Lisa Hui or any of the following people:

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| --- | --- |
| Name | Lisa Hui |
| Position | Principal investigator |
| Telephone | 03 8405 2313 |
| Email | lisa.hui@nh.org.au  |

|  |  |
| --- | --- |
| Name | Natalie Hannan |
| Position | Associate investigator |
| Telephone | 03 8458 4381 |
| Email | nhannan@unimelb.edu.au  |

***For complaints:***

If you wish to contact someone, independent of the study, about ethical issues or your rights or to make a complaint, you may contact:

**Local site office contact**

|  |  |
| --- | --- |
| Name | Jingfei Wu |
| Position | Research Governance Officer |
| Telephone | 8405 2918 |
| Email | ethics@nh.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 | Austin Health Human Research Ethics Committee |
| HREC Executive Officer | Ms Chelsea Webster |
| Telephone | 03 9496 4090 |
| Email | ethics@austin.org.au |

**CONSENT FORM (Biobank copy)**

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| **Coordinating Principal Investigator/ Principal Investigator** | A/Prof Lisa Hui  |
| **Associate Investigator** | A/Prof Natalie Hannan |
| **Location**  | The Northern Hospital185 Cooper St Epping 3076 |

**Declaration by Participant**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the biobank described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this biobank project as described and understand that I am free to withdraw at any time without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

**I consent to the donation of the following samples to the biobank (tick as appropriate).**

**1. Blood YES NO**

**2. Placental tissue YES NO**

**2. Cord blood YES NO**

Name of **participant** (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of **interpreter** if applicable (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_

Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the biobank project, its procedures and risks and I believe that the participant has understood that explanation.

Name of study **doctor/senior researcher**# (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# A senior member of the research team must provide the explanation of, and information concerning, the biobank project.

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

**CONSENT FORM (Participant copy)**

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Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the biobank project, its procedures and risks and I believe that the participant has understood that explanation.

Name of study **doctor/senior researcher**# (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# A senior member of the research team must provide the explanation of, and information concerning, the biobank project.

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

**Form for Withdrawal of Participation -** *Adult providing own consent*

|  |  |
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| **Associate Investigator** | A/Prof Natalie Hannan |
| **Location**  | The Northern Hospital185 Cooper St Epping 3076 |

**Declaration by Participant**

I wish to withdraw from participation in the above biobank project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Northern Health.

Name of **participant** (print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Reason for withdrawal (if provided)

**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the implications of withdrawal from the biobank project and I believe that the participant has understood that explanation.

Name of Study **Doctor/Senior researcher**† (print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the biobank project.

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