Newcastle 1000 Pilot Study

Participant Information and Consent Form: Genetic Material

Invitation

As part of the Newcastle 1000 Pilot Study we are requesting to use some of your biological samples to study genetic factors that may be related to health and development outcomes. This involves extracting genetic material (e.g. DNA, RNA and cell free DNA) from your blood and the umbilical cord blood sample you have previously given us permission to collect.

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

1. 'What is the purpose of this study?'

There are growing reasons to analyse genetic material. For example, new research is looking into identifying how a mother's and father's genetics can determine the growth of their baby before it is born. Genetic material such as DNA can also be analysed to identify genes that are associated with specific health outcomes such as high cholesterol or blood sugar. We are interested in how genetic material can be analysed to answer questions about growth and development during pregnancy and childhood and finding out which genes affect different health outcomes later in life.

2. 'Why have I been invited to participate in this study?'

This study is part of the Newcastle 1000 Pilot Study, which you are currently part of.

3. 'Are there any reasons why this study may not be suitable for me?"

Provided you have been consented into the Newcastle 1000 Pilot Study there is no reason you would be excluded from this component of the project.

4. 'What does this study involve?'

If you agree to participate in this study, you will be asked to sign the *Participant Consent Form: Genetic Material.* As part of your participation in the Newcastle 1000 Pilot Study we requested some biological samples, including blood. If you agree to this part of the study we would like your permission to extract genetic material from those sample for genetic analyses.

5. 'What if I don't want to take part in this study, or if I want to withdraw later?'

Participation in the genetic component of the Newcastle 1000 Pilot Study is completely voluntary. It is up to you whether or not you participate. If you decide not to agree to the genetic component of the study this will not affect your participation in the Newcastle 1000 Pilot Study, or the way you are treated in the study.

If you wish to withdraw from the genetic component of the study, or the Newcastle 1000 Pilot Study itself, you have the option of withdrawing all information relating to you and/or have any blood samples that have been taken destroyed. An exception to this is in the case of an adverse event, or a serious adverse event, where the information needs to be retained for regulatory reporting.

6. How Many Visits?

You will not need any additional visits, or to give any additional biological samples. We will use the samples that you have already given permission to collect as part of the Newcastle 1000 Study. This consent form is a separate consent for the extraction and analyses of genetic material from the samples collected.

7. 'How is this study being paid for?'

The study is supported through philanthropy (donations) and the Mothers and Babies Research Centre at Hunter Medical Research Centre.

8. 'Are there risks to me in taking part in this study?'

Generally genomic testing involves studying genes and their links to health, growth and development and disease. In our analyses, we are not undertaking an intentional search for known disease-causing genes, therefore the likelihood of an incidental finding is about 1 in 10,000. The type of genomic testing we will perform on your blood samples is not designed to directly provide information about your health, or risk of disease for you, your baby or your family.

On the extremely rare occasion that information is found that could impact on your health, or the health of your baby or other family members, we will seek the advice of a genetic counsellor. You will be notified by telephone and invited to attend a counselling session with the nominated genetic counsellor if the incidental finding is deemed life-changing or clinically significant. Although very unlikely, a genetic incidental finding could have implications for other family members.

9. 'Will the study cost me anything??'

Participation in this study will not cost you anything, nor will you be paid**.**

10. 'Will I benefit from the study?'

While we intend that this research study furthers medical knowledge and may be used as a foundation for future research projects, it will not be of direct benefit to you.

11. 'How will my privacy be protected?'

Only the researchers will know whether or not you are participating in this study. Any identifiable information that is collected about you in connection with this study will remain confidential and will be disclosed only with your permission, or except as required by law. The study results may be presented at a medical conference or in a scientific publication, but individual participants will not be identifiable in such presentations.

Your personal information will be accessed, used and stored in accordance with Commonwealth Privacy Laws and the NSW Health Records and Information Privacy Act 2002. All information will be de-identified and uploaded to a secure, password protected, University of Newcastle data repository (NOVA).

If you decide to withdraw from the study, you can request any data collected be withdrawn and destroyed. In some cases, your information may already be included in data analysis that has already been published in scientific publications or presented at a conference. In these cases, it may not be possible to withdraw your individual information from these presented data. Please be assured, any information used for publication or presentation will not be traceable back to your identity.

12. 'What happens with the genetic material?'

Samples collected from this study may be stored and used for future genomics studies by researchers in our department and/or national/international collaborators, including commercial partners. Any potential financial gains from commercial applications cannot be claimed by participants in the study. Any future proposed research study in which your blood sample is used will be reviewed by the Hunter New England Research Ethics Committee and The University of Newcastle Human Ethics Committee prior to commencement.

The samples and genetic material remain your property, and as such if there is a clinical need for you to access any of the data or results from the genetic tests this can be requested through the Study Manager. When your child turns 18 years of age they will become the legal owners of their biological samples and will be re-consented into the study.

13. 'What happens with the results?'

Your participation in the study will benefit our understanding of what genetic factors influence pregnancy health and the growth and development of babies. Your personal information will be accessed, used and stored in accordance with Commonwealth Privacy Laws and the NSW Health Records and Information Privacy Act 2002.

We plan to publish the results of the study in peer reviewed journals. Results of the study will be presented to researchers and clinicians via presentations at national and international conferences, and publication in peer reviewed journal articles. Your privacy will be protected as the information will be de-identified (for more information on protecting your privacy see section 11).

14. 'What should I do if I want to discuss this study further before I decide?'

When you have read this information, one of the researchers will discuss it and any queries you may have with you. If you would like to know more at any stage, please do not hesitate to contact Professor Craig Pennell on the number listed below. If you want to discuss the study with family members or your baby's other parent, you are welcome to take the time to do so before you decide whether to participate in the study.

Professor Craig Pennell
Chair Obstetrics and Gynaecology
Head of Discipline Maternal and Fetal Medicine
University of Newcastle
Mothers and Babies Research Centre
Hunter Medical Research Institute
1 Kookaburra Circuit
New Lambton Heights, NSW, 2305
Tel: (02) 4042 0546

13. 'Who should I contact if I have concerns about the conduct of this study?'

This study has been approved by the Hunter New England Human Research Ethics Committee. If you have concerns or complaints about the conduct of this study you should contact:

Dr. Nicole Gerrand PhD
Ethics Manager
Research Office
Hunter New England Local Health District
Level 3 POD, HMRI, Lot 1 Kookaburra Circuit NEW LAMBTON HEIGHTS, NSW. 2305
Tel: (02) 4921 4950
Email: Nicole.Gerrand@health.nsw.gov.au

The Manager is the person nominated to receive complaints from research participants. You will need to quote reference number 2020/ETH02219

Thank you for taking the time to consider this study.
If you wish to take part in it, please sign the attached consent form.
This information sheet is for you to keep.

Newcastle 1000 Pilot Study

PARTICIPANT CONSENT FORM: GENETIC MATERIAL

I, ... (participant name), have read and understood the ***Participant Information and Consent Form: Genetic Material,*** a copy of which I have retained.

Adult Sample Statement : Maternal Paternal (please circle)	**Initial**
I agree that my genetic material can be used for epigenetic studies (which is studying how lifestyle factors affect DNA)	
I agree that my genetic material can be used for genetic analysis of risk factors associated with childhood and adult health, disease and development. I understand the genetic material will not be used to diagnose of any particular disease	
I agree that my genetic material can be stored for future research and analysis	
I understand that at any time the genetic material and data on the genetic material can be destroyed at my request	
I understand that my de-identified genetic material may be analysed outside of Australia as part of international collaborations with research bodies or commercial genetic laboratories studying the genetic/epigenetic basis of health and disease	
I understand that the biosamples and genetic material remain my property and if there is a clinical need to access results or data from them I am able to request this through the Study Manager	
I understand that any results of the analysis of my genetic material will not be made available or revealed to any person or organization except in circumstances where disclosure is required by law	
Child Sample Statements	**Initial**
I agree that genetic material may be extracted from biological samples (such as cord blood) pertaining to my child/ren who are part of the Newcastle 1000 Pilot Study and analysed for epigenetic studies	
I agree that the genetic material extracted from my child/ren who are part of the Newcastle 1000 Pilot Study can be used for genetic analysis of risk factors associated with childhood and adult health, disease and development	
I agree that my child's genetic material can be stored for future research and analysis, until such time as they are of legal age to provide their own consent	
I understand that, until such time as my child/ren are able to provide legal consent, I can request their samples and any data pertaining to the samples be destroyed at any time	
I understand that my child/ren's de-identified genetic material may be analysed outside Australia as part of international collaborations with research bodies or commercial genetic laboratories studying the genetic/epigenetic basis of health and disease	
I understand that until such as time as my child/ren are able to provide legal consent, their biosamples and genetic material remain my property and as such I can request access to them if there is a clinical need	

I understand that any results of the analysis of my child/ren genetic material will not be made available or revealed to any person or organization except in circumstances where disclosure is required by law	

I agree to participate in this study and understand that I can withdraw at any time without providing a reason.

I understand that my personal information will remain confidential to the researchers.

I have had the opportunity to have questions answered to my satisfaction.

I hereby agree to participate in this research study.

Signature of participant: .....

Date: .....

Declaration by person conducting the consent process

I, the undersigned, have fully explained this research to the patient named above.

Name: .....

Signature: .....

Date: .....