85 Park Road, Grafton
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The University of Auckland
Private Bag 92019
Auckland 1023

Participant Information Sheet

Study title:	*Understanding the Placenta*	
Locality:	**Auckland City Hospital**	Ethics committee ref.: NTX/12/06/057/AM012
Lead investigator:	**Prof. Larry Chamley**	Contact phone number: 09 9239501

You are invited to take part in a study on how the placenta functions in normal and abnormal pregnancies. Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care you receive. If you do choose to take part now, but change your mind later, you are free to pull out of the study.

This Participant Information Sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

The placenta (whenua) has significance in Māori culture, and you may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending your samples overseas and/or storing your tissue should be discussed with your family/whanau or kaumātua as appropriate. We also collaborate with Iwi United Engaged, a kaupapa Māori research and support organisation; if you would like to speak about your decision processes or concerns, we encourage you to speak with them at any time before, during, and after signing this PIS. There are a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult prior to participation in research where this occurs. However, it is acknowledged that individuals have the right to choose.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 5 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

WHAT IS THE PURPOSE OF THE STUDY?

The placenta is an important fetal organ that transfers nutrients and oxygen from the pregnant person's blood during pregnancy to help the baby grow, and produces hormones and other factors such as vesicles (small packages from the placental cells) that adapt the pregnant

person's body to sustain the pregnancy. The placenta contains unique cells that are found nowhere else in the body. We are investigating how placental cells grow and die (i.e. their life-cycle), and how they can interact with the mother during pregnancy. This will help us understand how diseases of pregnancy such as preeclampsia, small (growth restricted) babies and miscarriages are caused by abnormal behaviour and function of these cells. We also want to find out whether stem cells or other factors from the placenta could be used to help treat these pregnancy disorders, or other conditions. Finally, we are interested in how cells and blood vessels in the decidua (the layer of the uterus that the embryo implants in that is usually lost during your period) interact with the placenta to support pregnancy. To find out more about our research please visit https://profiles.auckland.ac.nz/j-james or https://profiles.auckland.ac.nz/l-chamley

This work has received ethical approval from the Northern X Ethics Committee (NTX/12/06/057/AM12).

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

Following the delivery of your baby the placenta would normally be disposed of by the hospital, sent for testing (if your pregnancy was complicated) or given to you. We would like to invite you to assist in our research by donating your placenta, or part of it. Participation in this study will not involve any additional clinic visits, or additional time on your behalf other than that required to read this information sheet and understand what is involved.

If you agree, following delivery we will take your placenta, or a part of it, to our laboratory at the Faculty of Medical and Health Sciences, University of Auckland. If your pregnancy was abnormal, and the clinical team wish to send it for pathological examination, our researchers may take only a portion of the placenta under clinical guidance so that this does not impact pathological assessment of the placenta. In order to link our findings to birth outcomes we may also collect some information on your pregnancy, such as fetal weight, fetal measurements, placental weight, Doppler ultrasound recordings of blood flow around your placenta, or your blood pressure. This data will be stored in secure databases, on password protected servers. All samples in the laboratory will be deidentified, and no identifiable information will be included in any form of communication of the findings.

In their laboratory, the researchers will study different factors that affect the way that specialised cells from the placenta grow, how they die, and how the placental cells and products made by the placenta interact with the mother's body. Understanding these processes will help us understand why some pregnancies are healthy while others are not. This research is ongoing, and we currently utilize approximately 1000 placentae per year to carry out this research.

In most cases your tissue will be used immediately and placed in short-term culture (up to six weeks). In other cases, cells will be maintained in longer-term cultures. In some cases your placental or decidual tissue, or cells from this tissue, will be stored in secure laboratories that do not have public access for the study duration. In some cases RNA or DNA will be extracted from cells and used to study gene expression and the factors that regulate this. To study the structure of the placenta, pieces of tissue may be imaged. The placenta produces many factors that interact with the mother's body such as, hormones and vesicles, and we may study the production and effects of those products. In some cases, we will administer these placental products to animals to see how they affect the health of the animals. Any remaining tissue fragments will be securely disposed of using approved laboratory protocols.

As term placentas are relatively large, we often do not use all of the tissue donated, but rather dissect portions of this tissue out to create tissue blocks or digest cells from. The remaining

unused placental tissue is securely disposed of using approved laboratory protocols. As the portions of tissue we dissect often do not remain intact during the procedures we use to study it, once we have used a part of your placental tissue for our experiments it will not be possible to return that portion of tissue to you. However, if you wish to have any remaining placental tissue (that not dissected out for use in experiments) returned to you rather than being sent for disposal please indicate this on the consent form below.

At times, we may wish to send samples of placenta or trophoblasts to collaborators overseas in order to conduct expert analyses not possible in our laboratory, or help us better understand our results. In these cases the tissue would only be used for purposes aligned with our work to understand the placenta, and that is consistent with New Zealand ethical standards. It is your choice whether you are willing to allow your cells or fixed placental tissue to be sent overseas or not, and explicit consent for this is requested below. If you do not consent to this, tissues will be kept in New Zealand.

If you would like to have more details on what we will do with the placental tissue in the laboratory you can ask for more detailed written information.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

There will be no direct benefit to you of participating in this study. However, the knowledge that we gain from your tissue will help us develop ways to better understand why some pregnancies experience complications that can affect the pregnant person and baby. It is possible that you could regret donating your tissue at a later date after return of the tissue is no longer possible, so please consider carefully if you would like the remaining placental tissue to be returned to you.

WHO PAYS FOR THE STUDY?

Participation in this study will not incur any costs. No reimbursement will be provided for participation in this study.

WHAT IF SOMETHING GOES WRONG?

If you were injured in this study, you would be eligible **to apply** for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

WHAT ARE MY RIGHTS?

Your decision to take part in this study is your choice, and you may choose to withdraw from the study at any time prior to donating your tissue, without having to give a reason, and this will in no way affect your future care. If you decide not to participate your standard of care will not change.

To protect your privacy, following donation, tissue samples will be coded to de-identify your tissue in the laboratory. Information linking your clinical details (NHI number, placental and fetal weight,

Doppler ultrasound assessments) to these codes will be stored in a password protected database on a secure server at the University of Auckland, and will only be able to be accessed by the research team. Tissue will be stored securely within the researcher's laboratory at the Faculty of Medical and Health Sciences, University of Auckland.

You have a right to access information about the tissue you have donated as part of the study upon request. However, it is important to be aware that the aspects of the placental function we are measuring in this study provide information to help us understand our research only, and do not have any direct implications for your health.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

At the end of the study tissue will be securely destroyed. However, if you change your mind about participation at any time tissue will be destroyed as per your request.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Associate Prof. Jo James, University of Auckland
09 9232549 / j.james@auckland.ac.nz

or

Prof. Larry Chamley, University of Auckland
09 923 9501 l.chamley@auckland.ac.nz

or

Iwi United Engaged, Ltd
Misty Edmonds, RN 0274 890 804
Dr K L T (Kev) Roos 021 025 43909

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone:	0800 555 050
Fax:	0800 2 SUPPORT (0800 2787 7678)
Email:	advocacy@advocacy.org.nz

If you require Māori cultural support talk to your whānau in the first instance. Alternatively, you may contact the administrator for He Kamaka Waiora (Māori Health Team) by telephoning 09 486 8324 ext 42324. If you have any questions or complaints about the study you may contact the Auckland and Waitematā District Health Boards Maori Research Committee or Maori Research Advisor by phoning 09 4868920 ext 43204.

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone:	0800 4 ETHICS
Email:	hdecs@health.govt.nz

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UNIVERSITY OF AUCKLAND
Waipapa Taumata Rau
NEW ZEALAND

MEDICAL AND HEALTH SCIENCES

Consent Form

- I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.
- I have been given sufficient time to consider whether or not to participate in this study
- I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study.
- I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.
- I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study without this affecting my medical care.
- I consent to the research staff collecting and processing my information, including information about my health.
- I agree to an approved auditor appointed by the New Zealand Health and Disability Ethics Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.
- I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.
- I understand the compensation provisions in case of injury during the study.
- I know who to contact if I have any questions about the study in general.

Please tick to indicate your response to the following

I agree to my placental samples being sent overseas and I am aware that these samples will be disposed of using established guidelines for discarding biohazard waste.	Yes ☐	No ☐
I wish to have the remaining parts of my placenta returned to me after the researchers have taken the portions they wish to use for research (this would occur within days of the donation).	Yes ☐	No ☐
I wish to receive a summary of the results from the study. If yes, please provide a contact email address:_____	Yes ☐	No ☐

Declaration by participant:
I hereby consent to take part in this study.

Participant's name: _____

Signature: _____ Date: _____

Declaration by member of clinical staff or research team:
I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it. I believe that the participant understands the study and has given informed consent to participate.

Researcher's name: _____

Signature: _____ Date: _____