

## Participant Information Sheet

# **Study Title: Tracking Retinal and Cardiovascular Effects in pregnancies with gestational hypertension (TRACE): Assessments after pregnancy**

We would like to invite you to take part in our study, which is part of the PhD research degree of Sarah Alkhurainej in Medicine, under the supervision of Dr.'s Colin Murdoch and Sarah Martins Da Silva at the University of Dundee. Before you take part, we invite you to read and understand why our research is being done and what is involved. We will go through the information and can answer any questions you have. Please take the time to read through this information carefully. You can talk to other people about the study if you wish and we will do our best to answer your questions. We can also give you any additional information that you would like. You do not have to decide straight away.

### **What is the purpose of the research?**

The research is being conducted to better understand the long-term impact on the mother of high blood pressure during pregnancy, including pre-eclampsia. The researchers hope to gain insight into the changes in the tiny blood vessels in the mother after pregnancy. By using eye imaging, ultrasound and blood samples. This non-invasive method could provide valuable information for monitoring the mother's blood vessel health and potentially lead to new diagnostic tools. The study aims to explore how tiny blood vessel changes relate to cardiovascular issues in the long term, providing important insights into the health of women after pregnancy. However, we also need women that had a normal blood pressure during pregnancy to see how their tiny blood vessels change.

### **Why have I been invited to take part?**

We are seeking volunteers who were pregnant 6 to 60 months ago. We need women that either had normal blood pressure or had high blood pressure during pregnancy. You have been invited to participate because you meet the criteria for the study.

### **Do I have to take part?**

No. It is up to you to choose, taking part in this study is entirely up to you. You can choose to take part or choose not to take part. If you choose to take part you can stop the study at any time. You do not have to give a reason for not taking part or for stopping. If you do not want to take part or want to stop the trial/study the medical care you get and your relationship with the medical or nursing staff looking after you will not be affected.

### **What will happen to me if I take part?**

It will be made sure that it is suitable for you to take part in this study.

If you are eligible, you will be invited to Ninewells. We will try to do this at the same time as your routine care (e.g. ultrasound scans) or a separate visit. We need to obtain consent from you prior to performing any study assessments. If you are happy to proceed, we will then start to conduct the study assessments.

Study assessments will be performed at the same time as your routine visits. Assessments will be at one or both the early and/or late scan. These assessments look at the blood vessels using non-invasive techniques. All of these assessments are completely non-invasive. Other measurements including height and weight measurement and blood pressure will also be taken. All the tests will take no more than 60 mins to complete.

**Retinal imaging:** Retinal imaging takes a digital photograph of the back of your eye. It shows the retina and blood vessels. This helps to look at the health of the tiny blood vessels. Your chin and forehead will be placed on a support to keep the head steady. You need to open your eyes and stare straight ahead at an object. Your eyes will be scanned, and the images will be uploaded to a computer. The test takes 5 minutes.

**Ultrasound:** The ultrasound is a painless and safe test that uses sound waves to make images of the region of interest.

1. **Eye Ultrasound (Ophthalmic ultrasound):** Done on the closed eye it looks at the blood vessel (ophthalmic artery) that goes to the eye. Reflections of the sound waves form a picture of the structure of the eye and blood moving in the blood vessel.
  - The test will be done while you lie back with your eyes closed. A gel is placed on the skin of the eyelids. A small device is placed gently against the front of your eye to do the test.
  - You will not feel any discomfort or pain, the ultrasound is conducted on the closed eye. You may need to look in different directions while your eye remains closed. The test takes less than 10 minutes.
- 2- **Neck Ultrasound (Carotid Ultrasound):** Ultrasound of the neck will measure blood flow through the carotid blood vessel, creating a picture of the blood flow using sound waves. The elasticity of the blood vessels will also be measured. A small pen-like device will be placed gently on the neck and at the same time a cuff is placed on the thigh (over your clothes).
  - During the test ultrasound gel is applied to the side of the neck to help the sound waves travel effectively.
  - These tests are painless and provide no risks for the participant's health. They will take less than 10mins.
- 3- **Blood sample:** The procedure involves cleaning the area, inserting the needle into the vein, collecting blood, labelling the tubes, and sending them to the laboratory for analysis. The test takes 5 minutes.

These measurements will be taken one after the other.

Once all the measurements have been taken, there will be no further requirements or assessments.

If there is any surplus blood, we would like permission to store anonymously in Tayside Biorepository for future studies or training. Note any future studies would require University of Dundee Ethical Approval before use.

If possible, we would like your permission to contact you about research in the future to assess the long-term impact of pregnancy on the mother's blood vessels.

### **Are there any risks in taking part?**

All blood vessels assessments are non-invasive. *There are no risks in taking part in the study, but:*

- Ultrasound: It may feel pressure — but no pain — during the ultrasound examinations.
- Retinal photograph will not cause any pain. A photograph is quickly taken when the eye is open. Similar to a visit to an optician.

Blood sampling is invasive however there is low risk.

- Blood sampling: You may feel a brief prick when the needle is inserted into your skin, but any discomfort should quickly subside.

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

There will be no direct benefits to you from your participation in the study. However, information from this study will be helpful for future pregnant women to help better identify women who are at risk of high blood pressure and early detection of complications later in life.

### **Who is funding the research?**

This study is being sponsored by the University of Dundee. Ms Sara Alkhurainej is studying for a PhD degree. The study is being organised by Dr. Colin Murdoch, Reader (Cardiovascular Research, School of Medicine) in partnership with Dr Sarah Martins Da Silva (Clinical Reader, School of Medicine). All data will be retained with the University of Dundee.

### **Will my taking part in this project be kept confidential?**

The University of Dundee will retain identifiable information about you as well as the data gathered about you for the project. This information will be accessible to specific members of the research team, and it might be shared with parties outside the research team when necessary to complete this study. Your private data gathered for this survey might be utilised in later, ethically permitted medical research. Before it is shared, any information that could be used to identify you will be deleted. Your personally identifiable information and coded study data will be safely kept at the University of Dundee on one or more password-protected databases. To handle your information and keep the database up to date,

specific members of the data management team will also have access to your personally identifiable information.

Following the conclusion of the study, your information will be stored safely for 15 years. It will be destroyed in fifteen years. We will ask you to sign a consent form allowing us to keep your contact information on file if you would like to be notified about future studies in which you might be interested in participating. Your personal information won't be shared or published. The study data will be completely anonymized and all personally identifiable information will be erased before sharing it with other academics in the UK, EU, or elsewhere.

### **What will happen to the information I provide?**

Your personally identifiable information and coded study data (*electronic and hard copies*) will be safely kept at the University of Dundee on one or more password-protected databases. To handle your information and keep the database up to date. Following the conclusion of the study, your information will be stored safely for 15 years. It will be destroyed in fifteen years. We will ask you to sign a consent form allowing us to keep your contact information on file if you would like to be notified about future studies in which you might be interested in participating. Your personal information won't be shared or published. The study data will be completely anonymized and all personally identifiable information will be erased before sharing it with other academics in the UK, EU, or elsewhere.

If you decide to withdraw from the study before any data is collected, your information will be deleted. However, if you are part way through the study and decide to withdraw later, we will ask your permission to retain the data collected from you and blood sample. If you do not want to grant this permission, your information and any stored blood will be removed from the study. Once the results have been analysed, they will be included in the PhD research project at the University of Dundee. Additionally, they might be submitted to medical journals for potential publication. Any participant-related information in the reported results will be completely anonymized, ensuring that you will not be identifiable in any reports or publications. You can request access to a copy of the published results from the researcher.

The University of Dundee Research Ethics Committee reviews all research proposals and will examine the proposal and note any objections.

Your GP will not be informed of the results from the study or participation unless you request. If the researchers discover abnormal findings (e.g. high blood pressure, structural or functional abnormality of the vasculature), they will discuss it in our medical team. It is likely that it would be referred to your GP only with the prior permission from the participant to do so. With permission a letter would be sent to the GP, outlining the abnormality.

### **Data Protection**

The personal data that will be collected and processed in this study are age and pregnancy week.

The University asserts that it is lawful for it to process your personal data in this project as the processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller.

The University of Dundee is the data controller for the personal data processed in this project.

The University respects your rights and preferences in relation to your data and if you wish to update, access, erase, or limit the use of your information, please let us know by emailing [czmurdoch@dundee.ac.uk](mailto:czmurdoch@dundee.ac.uk). Please note that some of your rights may be limited where personal data is processed for research, but we are happy to discuss that with you. If you wish to complain about the use of your information please contact the University's Data Protection Officer in the first instance (email: [dataprotection@dundee.ac.uk](mailto:dataprotection@dundee.ac.uk)). You may also wish to contact the Information Commissioner's Office (<https://ico.org.uk/>).

You can find more information about the ways that personal data is used at the University at: <https://www.dundee.ac.uk/information-governance/data-protection>.

### **How will we use information about you?**

We will need to use information from you and your medical records for this research project.

This information will include your initials, NHS number, name and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

Regulatory authorities or sponsor representatives may wish to audit the study. In doing so, may have access to participant information. Any audit will be carried out in accordance with University of Dundee SPONSOR guidelines.

### **What are your choices about how your information is used?**

- We ask that you contact us if you wish to stop being part of the study. You can do this at any time, without giving a reason, but we will keep the data that has already been analysed. Request to withdraw from the study should be made to Dr Colin Murdoch ([c.z.murdoch@dundee.ac.uk](mailto:c.z.murdoch@dundee.ac.uk)) or by mail (University of Dundee, CRC Level 7, Ninewells Hospital, James Arrott Drive, Dundee, DD19SY).
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

### **Where can you find out more about how your information is used?**

You can find out more about how we use your information at [www.hra.nhs.uk/information-about-patients/](http://www.hra.nhs.uk/information-about-patients/) by asking one of the research team.

### **What if something goes wrong?**

If you are concerned about your participation in the study you have the right to discuss your concern with a researcher involved in the study or a doctor involved in your care. If you have a complaint about your participation first of all please talk to the researcher. If you are not satisfied, you can make a formal complaint to a senior member of the research team or to the Complaints Officer for NHS Tayside.

Patient Experience Team

NHS Tayside

Ninewells Hospital

Dundee DD1 9SY

Freephone: 0800 027 5507

Email: [TAY.feedback@nhs.scot](mailto:TAY.feedback@nhs.scot)

If you think you have come to harm due to taking part in the study there are no automatic arrangements to get financial compensation.

### **Who has reviewed this study?**

This study has been reviewed and approved by

Research Ethics committee does not have any objections to this study going ahead.

Feel free to contact the study team if any further information is needed:

- **Sarah Alkhurainej**  
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Medicine, University of Dundee  
Ninewells Hospital and Medical School  
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- **Dr. Colin Murdoch**  
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- **Dr. Sarah Martins Da Silva**  
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Thank you for taking the time to read this information and considering taking part in this study.

If you would like more information, or want to ask questions about the study, please contact the study team using the contact details above.

You can contact us Monday-Friday between 09.00-17.00