Participant Information Sheet

Study Title:
Studying Pregnancy's VAscular and Retinal Changes

(SPARC)

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 and prevent complications related to high blood pressure during pregnancy, including pre-eclampsia and other issues that can lead to serious health risks for both the mother and baby. The aim is to identify early markers and risk factors for these conditions. The researchers hope to gain insight into the changes in the tiny blood vessels in the mother during 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.

Why have I been invited to take part?

We are seeking volunteers who are currently pregnant. You have been invited to participate because you meet the criteria for the study, we need women that have normal and high blood pressure during pregnancy.

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 we can arrange 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.

You can volunteer for one or two study assessments which will happen at the same time as your early and 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 minutes 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):** Performed 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 you 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.

- If you having blood taken as part of your routine NHS care we can take blood for our study at the same time.

These measurements will be taken one after the other.

Once all the measurements have been taken, there will be no further requirements or assessments. The measurements will be recorded on the case record form (CRF) only.

If there is any surplus blood, we would like permission to store anonymously in University of Dundee facilities 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 participants decide to withdraw from the study before any data is collected, their information will be deleted. However, if a participant initially agrees to take part but later decides to withdraw, we would request permission to retain and use their information. If permission is not granted, the participant's information and any stored blood will be removed from the study.

Once the results are accessible, 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 the participant's 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** . 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). 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 and TASC guidelines.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will request permission to keep information about you that we already have. Request to withdraw from the study should be made to Dr Colin Murdoch (c.z.murdoch@dundee.ac.uk)
- 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.
- **OPTION if data will be used for future research:** If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

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/
- 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
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 [Tayside REC] ((Dr F.V Nuritova), RGM, TASCgoverannce@dundee.ac.uk).
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**

PhD Medicine student
Medicine, University of Dundee
Ninewells Hospital and Medical School
Email: 2590444@dundee.ac.uk

- **Dr. Colin Murdoch**

Reader • Systems Medicine, University of Dundee
Ninewells Hospital and Medical School
Telephone: +441382383526
Email: czmurdoch@dundee.ac.uk

- **Dr. Sarah Martins Da Silva**

Clinical Reader • Diabetes Endocrinology and Reproductive Biology
Ninewells Hospital and Medical School
Telephone: +441382383201
Email: s.martinsdasilva@dundee.ac.uk

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