

# PARTICIPANT INFORMATION SHEET

# Investigating the effects of air pollution in pregnancy

Before consenting to take part in this research, please read the following information.

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

We are conducting research to understand the effects of air pollution – or 'airborne material exposures' (AMEs) – during pregnancy. AMEs include pollution, dust, allergens, and household chemicals which we are all frequently exposed to both indoors and outdoors. We are interested in understanding how pregnant women might respond differently to these exposures throughout pregnancy, compared to non-pregnant women and men. We hope that any differences we discover could help us understand any downstream effects on the baby and later child health.

#### Who is carrying out the research?

The study is organised and carried out by a research team at Swansea University. The data is being collected by Dr Sophie Reed and Professor Cathy Thornton of Swansea University Medical School. *This research has been given a favourable ethical opinion by Swansea University Medical School Research Ethics committee, project reference 2022-0099.* 

## What happens if I agree to take part?

After you've read this participant information sheet and asked any questions you may have, we will record your consent to taking part in this study. Taking part in this study first involves answering a few questions about yourself (e.g., your age, ethnicity), your health (e.g., any chronic diseases, medications) and if applicable, your pregnancy (e.g., how many weeks pregnant you are). We kindly ask that you do not eat or drink 30 minutes before your appointment. We would then ask to collect some samples from you such as:

- Nasal epithelial lining fluid (NELF). This is the fluid inside of the nose. This will be collected using a small piece of specialist paper which is placed into the nose and held for 60 seconds. (This is a bit like taking a nasal swab for a lateral flow test for COVID-19).
- Nasal epithelium. These are the skin cells inside of the nose. This will be collected using a small swab which is used to sample the inside of the nose (This is a bit like taking a nasal swab for a lateral flow test for COVID-19).
- **Saliva.** You will be asked to rub a small swab around your gums for 60 seconds to collect saliva from your mouth.
- **Exhaled breath condensate.** You will be asked to breathe normally into a tube for 2 minutes which will collect air droplets.

- **Skin cells.** A small sticker similar to a plaster will be placed onto the skin on your inner forearm with a device and peeled off to remove some of the cells from your outermost layer of skin. This sticker process may be repeated in the same area up to 20 times.
- **Urine.** A urine sample will be collected into a small pot.
- A few drops of blood. A small needle called a lancet will be used to prick the end of one of your fingers. A few drops of your blood will be collected onto a piece of card.

You do not have to donate all 7 samples listed above if you do not wish to. You are welcome to choose how many, and which of these samples you donate. We will then ask you to fill in a short survey questionnaire afterwards to gain feedback on the comfort of the sample donation processes. Samples will be transferred to laboratories at Swansea University for analysis and storage. We will use these samples to measure protein and fat molecules. **We will not study your DNA**. At the end of the study, we will dispose of unused samples.

## Are there any risks associated with taking part?

The research has been approved by Swansea University Medical School Research Ethics Committee. There are no significant risks associated with participation. The finger prick can cause a bit of pain as it is done, with some discomfort persisting for a few hours afterwards and sometimes a bruise can develop at the site of the finger prick. The other sample donation processes are non-invasive and should cause no discomfort to you.

#### Are there any benefits associated with taking part?

There are no direct benefits associated with participation. A £10 Amazon voucher will be issued to you as a reimbursement for your travel to us to donate your samples. You will also be offered free car parking at Swansea University during your visit.

#### **Data Protection and Confidentiality**

Your data will be processed in accordance with the Data Protection Act 2018 and the General Data Protection Regulation 2016 (GDPR). All personal information collected will be kept strictly confidential. You will be assigned a unique study number that will be used to label your samples and link to the laboratory data gathered using your samples. The personal information provided by you will only be viewed by Dr Sophie Reed and Professor Cathy Thornton. As the principal investigator of this project, Professor Cathy Thornton will take responsibility for data destruction. All collected identifiable data will be destroyed on or before 31st October 2025 when it is no longer required for the researcher's endeavours.

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

An analysis of the information will form part of our report at the end of the study and may be presented to interested parties and published in scientific journals and related media. All information presented in any reports or publications will be anonymous and unidentifiable.

#### Is participation voluntary and what if I wish to later withdraw?

Your participation is entirely voluntary — you do not have to participate if you do not wish to. If you decide to participate, but later wish to withdraw from the study, then you are free to withdraw at any time, without giving a reason and without penalty. Upon withdrawal, all of your samples and data will

be destroyed. You may withdraw by contacting Dr Sophie Reed or Professor Cathy Thornton via the contact information at the end of this document.

# **Data Protection Privacy Notice**

The data controller for this project will be Swansea University. The University Data Protection Officer provides oversight of university activities involving the processing of personal data and can be contacted at the Vice Chancellor's Office.

Your personal data will be processed for the purposes outlined in this information sheet.

Standard ethical procedures will involve you providing your consent to participate in this study by completing the consent form that has been provided to you.

The legal basis that we will rely on to process your personal data will be processing is necessary for the performance of a task carried out in the public interest. This public interest justification is approved by Swansea University Medical School Research Ethics Committee.

The legal basis that we will rely on to process special categories of data will be processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes.

## How long will your information be held?

Any identifiable data held about you such as your name will be destroyed on or before 31<sup>st</sup> October 2025 when it is no longer required by the researcher. The laboratory data that we generate using your samples will be held for 10 years after the study has finished. This is to ensure all our findings from the study are published in scientific journals and comply with the regulations relating to this.

# What are your rights?

You have a right to access your personal information, to object to the processing of your personal information, to rectify, to erase, to restrict and to port your personal information. To safeguard your rights, we will use the minimum personally identifiable information possible. Please visit the University Data Protection webpages for further information in relation to your rights.

Any requests or objections should be made in writing to the University Data Protection Officer:

University Compliance Officer (FOI/DP) Vice-Chancellor's Office Swansea University Singleton Park Swansea SA2 8PP

Email: dataprotection@swansea.ac.uk

#### How to make a complaint

If you are unhappy with the way in which your personal data has been processed, you may in the first instance contact the University Data Protection Officer using the contact details above.

If you remain dissatisfied, then you have the right to apply directly to the Information Commissioner for a decision. The Information Commissioner can be contacted at:

Information Commissioner's Office Wycliffe House Water Lane Wilmslow Cheshire SK9 5AF www.ico.org.uk

# What if I have other questions?

If you have further questions about this study, please do not hesitate to contact us:

# immunuology-studies@swansea.ac.uk

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