Government of South Australia
SA Health

THE UNIVERSITY of ADELAIDE

# PARTICIPANT INFORMATION SHEET

**PROJECT TITLE:** Carbon monoxide (CO) breath measurement in pregnancy

**ETHICS APPROVAL NUMBER:** 2021/HRE00038

**PRINCIPAL INVESTIGATOR:** Lisa Smithers

**LOCATION:** Northern Area Local Health Network (NALHN; Lyell McEwin and Modbury Hospital)

You are invited to take part in this research project, which is called 'Carbon monoxide (CO) breath measurement in pregnancy'. You have been invited to participate because you are pregnant, currently smoking cigarettes and accessing antenatal care with NALHN. Your contact details were obtained from staff at NALHN with your consent.

This Participant Information Sheet/Consent Form tells you about the research project. It explains what is involved and will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or a health worker.

Participation in this research is voluntary. If you don't wish to take part, you don't have to.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to be involved in the research described
- Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

**Why am I being invited to participate?**

We are testing the use of carbon monoxide (CO) monitors in pregnancy. Smoking tobacco increases the amount of CO in your blood. Through breath analysis, the CO monitor can calculate CO levels in your blood and CO levels in your baby's blood. As you are currently pregnant and a smoker, we are investigating if using the CO monitor during your antenatal care changes the way you think about smoking.

**What is the project about?**

In the northern suburbs of Adelaide, a high proportion of pregnant women who receive antenatal care at NALHN smoke cigarettes. Midwives and doctors ask women about smoking and routinely provide Quitline referrals, but not many women use this service. When we talked with women who smoked during pregnancy about what might help with quitting, they liked the idea of using CO monitoring antenatally. Therefore, we would like to test its use.

CO is a toxic gas released when tobacco burns. When you breathe in cigarette smoke, the CO binds with your red blood cells instead of oxygen. It also passes through the umbilical cord and does the same in your baby. When this happens, it can affect your health and your baby's health. The CO monitor measures the amount of CO in your breath, which is an indirect measure of the amount of CO in your bloodstream.

If you agree to participate in this study, you will be asked to breathe into a CO monitor at 2 points in your pregnancy. This involves taking a breath and holding it for 15 seconds, then blowing into a

mouthpiece attached to the CO monitor to empty your lungs. A new mouthpiece is used for each person on each occasion. The mouthpieces are hygienically wrapped and single-use only. Two readings are displayed on the monitor, one is the amount of CO in your breath and the other is a calculated measure of how much CO is passing into your baby's blood.

Once you have used the monitor, we would like to ask you some questions about the experience of using it and ask you to reflect on your smoking. With your consent, we will audio record the blowing into the monitor and answering questions. You will also be given a short questionnaire asking about how many times you have been pregnant and your current smoking status. Completing the questionnaire will take approximately five minutes.

We will contact you again in 4 weeks. We can arrange to meet you at NALHN at your next antenatal appointment, somewhere in the local community (community centre) or at your home. At this time we will ask you to use the CO monitor again and answer some questions. Again, with your consent we will audio record the blowing into the monitor and answering questions.

**How much time will my involvement in the project take?**
The initial interview at NALHN antenatal clinic will take no more than 30 minutes and we expect the follow up interview after 4 weeks will also take approximately 30 minutes. At the 4 week interview you will receive a $50 gift voucher for your time and participation. We can provide you with cab-charge vouchers to attend the 4 week follow up at a community location.

**Who is undertaking the project?**
This project is being undertaken by NALHN (Lyell McEwin and Modbury Hospital) in collaboration with the University of Adelaide, School of Public Health, Prof. Lisa Smithers, Prof. John Lynch, Prof. Gustaaf Dekker, Dr. Elizabeth Hoon, Dr. Angela Gialamas, Ms. Paula Medway, Ms. Julia Dalton, Ms. Cherise Fletcher and Ms. Kate Neadley.

The results of this research will be used by the researcher Cherise Fletcher to obtain a postgraduate doctoral degree and has been initiated by the researcher Lisa Smithers. Cherise Fletcher will be collecting and analysing the information provided from the people who participate in this research.

The project is being funded by The Channel 7 Children's Research Fund.

**What are the potential benefits of the research project?**
The benefit of being involved in this study is it may give you an opportunity to think differently about your smoking. You will also be helping others in the community by reflecting and sharing your views on using the CO monitor. This work will also help researchers and the health service understand whether to use the CO monitor in future research and health care.

**What are the potential disadvantages of the research project?**
Some women who have high CO readings may find the results confronting. Some women may also feel that the questions we ask are stressful or upsetting. If you do not wish to answer a question, you may decline to answer, or you may stop immediately. If you become upset or distressed as a result of participating in this research project, the research team will arrange referrals to help support you. Any counselling or support will be provided by qualified staff who are not members of the research team. This counselling will be provided free of charge.

**Can I withdraw from the project?**

Participation in this project is completely voluntary. If you do not wish to take part, you do not have to. If you agree to participate, you can withdraw from the study at any time. Either agreeing or disagreeing to participate in this study will not affect any future health treatment or care, or any relationships with professional staff at NALHN or community organisations. Also, you can choose not to answer a question from the interviews at any time. However, following participation in the interviews you will not be able to withdraw your contribution. Individual contributions will not be able to be identified.

Participation in this study does not impact on your basic legal right to seek compensation under Common Law.

If you decide to leave the research project, the researchers will not collect additional personal information from you, although personal information already collected will be retained and data collected up to the time you withdraw will form part of the research project results.

**What will happen to my information?**
By signing the consent form you consent to the research team collecting and using personal information about you for the research project. Audio recordings and data from interviews will be transcribed by a paid transcriber who has signed a confidentiality agreement. Any identifying information will be removed from the transcription. The transcription will be kept confidential and stored securely by the researchers on the University of Adelaide server for at least 7 years. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

The results of this study may be presented and published in academic journals and presented at conferences. You will not be identified in any publications. We may use quotes from the recordings but they will be anonymous with identifying information or events removed.

In accordance with relevant Australian and/or South Australian privacy and other relevant laws, you have the right to request access to the information about you that is collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please inform the research team member named at the end of this document if you would like to access your information.
At the end of the study we will send you a summary of the findings via email or mail.

**Who do I contact if I have questions about the project?**
If you are interested in participating, or have any questions or would like additional information, please contact clinical investigators: Cherise Fletcher, Phone 0466 458 274, Email: cherise.fletcher@adelaide.edu.au or Kate Neadley, Phone 0466 458 274, Email: kate.neadley@adelaide.edu.au
Alternatively, you can contact: Dr Elizabeth Hoon, Senior Research Fellow, University of Adelaide, School of Public Health, Phone (08) 8313 1567 Email: elizabeth.hoon@adelaide.edu.au

**What if I have a complaint or any concerns?**
The study has been approved by the Central Adelaide Local Health Network (CALHN) Human Research Ethics Committee (approval number 2021/HRE00038). This research will be conducted according to the NHMRC National Statement on Ethical Conduct in Human Research (2007). If you have questions or problems associated with the practical aspects of your participation in the project, or wish to raise a concern or complaint about the project, then you should consult the Principal Investigator. If you wish to speak with an independent person regarding concerns or a complaint, SA

Health's policy on research involving human participants, or your rights as a participant, please contact the CALHN Human Research Ethics Committee's Chair, Mr Ian Tindall on:

Phone: (08) 7117 2215 or (08) 7117 2229

Email: Health.CALHNResearchEthics@sa.gov.au

Any complaint or concern will be treated in confidence and fully investigated. You will be informed of the outcome.

Government of South Australia
SA Health

THE UNIVERSITY of ADELAIDE

# CONSENT FORM

**PROJECT TITLE:** Carbon monoxide (CO) breath measurement in pregnancy

**ETHICS APPROVAL NUMBER:** 2021/HRE00038

**PRINCIPAL INVESTIGATOR:** Lisa Smithers

**LOCATION:** Northern Area Local Health Network (NALHN; Lyell McEwin and Modbury Hospital)

**Declaration by Participant**

I have read the Participant Information Sheet

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future care.

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____

Signature _____ Date _____

**Declaration by Researcher†**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Researcher† (please print) _____

Signature _____ Date _____

† An appropriately qualified member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

Government of South Australia
SA Health

THE UNIVERSITY of ADELAIDE

# WITHDRAWAL OF PARTICIPATION

**PROJECT TITLE:** Carbon monoxide (CO) breath measurement in pregnancy

**ETHICS APPROVAL NUMBER:** 2021/HRE00038

**PRINCIPAL INVESTIGATOR:** Lisa Smithers

**LOCATION:** Northern Area Local Health Network (NALHN; Lyell McEwin and Modbury Hospital)

**Declaration by Participant**

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine care, or my relationships with the researchers or Lyell McEwin Hospital.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the researcher must provide a description of the circumstances below.

**Declaration by Researcher**[†]

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Researcher (please print) _____

Signature _____ Date _____

[†] An appropriately qualified member of the research team must provide information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.