(Local Headed Paper if needed)

SNAP 3 Participant Information Sheet - Pilot

IRAS Project ID: **291236**

Title of Study: Smoking, Nicotine and Pregnancy (SNAP 3): a randomised controlled trial.

Name of Chief Investigator: <name>
Local Researcher(s): (hospital only) <name>

We would like to invite you to take part in our study. Before you decide, we would like you to understand why we are doing this research and what it would involve for you. Please read this information sheet carefully. One of our team will go through this with you and answer any questions you have. You may wish to talk to your family or friends about the study before you make the decision. Ask us, if there is anything that is not clear.

What is the purpose of the study?

We are looking to optimise the use of Nicotine Replacement Therapy (NRT) as a smoking cessation aid during pregnancy. NRT, such as nicotine patches, contains nicotine, but is free from harmful chemicals found in cigarettes. Using NRT is safer than smoking and it reduces the urge to smoke and can make it easier to stop smoking.

- Stopping smoking in pregnancy is one of the best things a woman can do for her baby's health.
- The NHS offers NRT for free to pregnant women to help them stop smoking.
- This study is testing whether some new ways of using NRT can help women to stop smoking and could improve women's and babies' health.

Why have I been invited?

We are inviting you to take part because you told us you are less than 25 weeks pregnant, are currently smoking and would like help to quit. We need 1430 women like you to join our study.

Do I have to take part?

It is your choice to join the study. One of our team will talk to you about this study and answer any questions you have. If you decide to take part, you will be asked to sign a consent form. Later, if you change your mind, you can stop the study at any time and without giving a reason. This would not affect the quality of medical care you receive or your legal rights. You will keep being given the help to stop smoking that other women in your area are given. If you lose capacity to give consent during the study, you will be withdrawn but any data and samples collected up to that point will be retained for analysis.

What will happen to me if I take part?

After you sign the consent form to say you agree to join the study, we will ask you some questions about you, your pregnancy and your smoking. A computer programme will then put you into one of two study groups. There is an equal chance of you being in either group.

Group one will receive standard care for smoking in pregnancy available in the local area. This will comprise advice and written materials about stopping smoking in pregnancy. Participants in group one will be put in touch with the NHS stop smoking care in their local area and offered NRT as part of this care.

Group two, in addition to standard care for smoking in pregnancy, will be given different instructions on how to use NRT. Participants in group two will receive additional advice on how to use NRT over the telephone, before they are referred to the NHS stop smoking care

Once you have been put into a group, we will send you more details, telling you exactly what will happen and when. You will choose how we contact you: by email, text message or post.

What to expect during the study (please see the Timeline below):

1. Spit (saliva) and breath samples:

We will ask participants to give up to four spit (saliva) and/or breath samples. Everyone will be asked to give samples at the start of the study. We may also ask participants in group two for samples at around day 7 and week 8-12. Some participants will be asked to provide samples at the end of the study, depending on smoking status. We will collect these samples either during your routine antenatal appointments, arrange to visit you at home, or we will give you the equipment and simple instructions to collect these at home to send to us.

2. Questionnaires:

We will ask you to complete two short questionnaires: one six weeks into the study and one at the end of the study. You will be asked to complete these either online, by post, or on the telephone with a researcher from the University of Nottingham. We will ask about smoking and NRT use. Each questionnaire will take around 10-15 minutes.

3. Smartphone application (NicUse app)

Between week six and the end of the study, some participants in group two will be asked to use a free phone app called 'NicUse' to track their smoking NRT and e-cigarette use. It will take less than 2 minutes to use the NicUse App, and we will never ask you to use it more than once a day.

Telephone Interview:

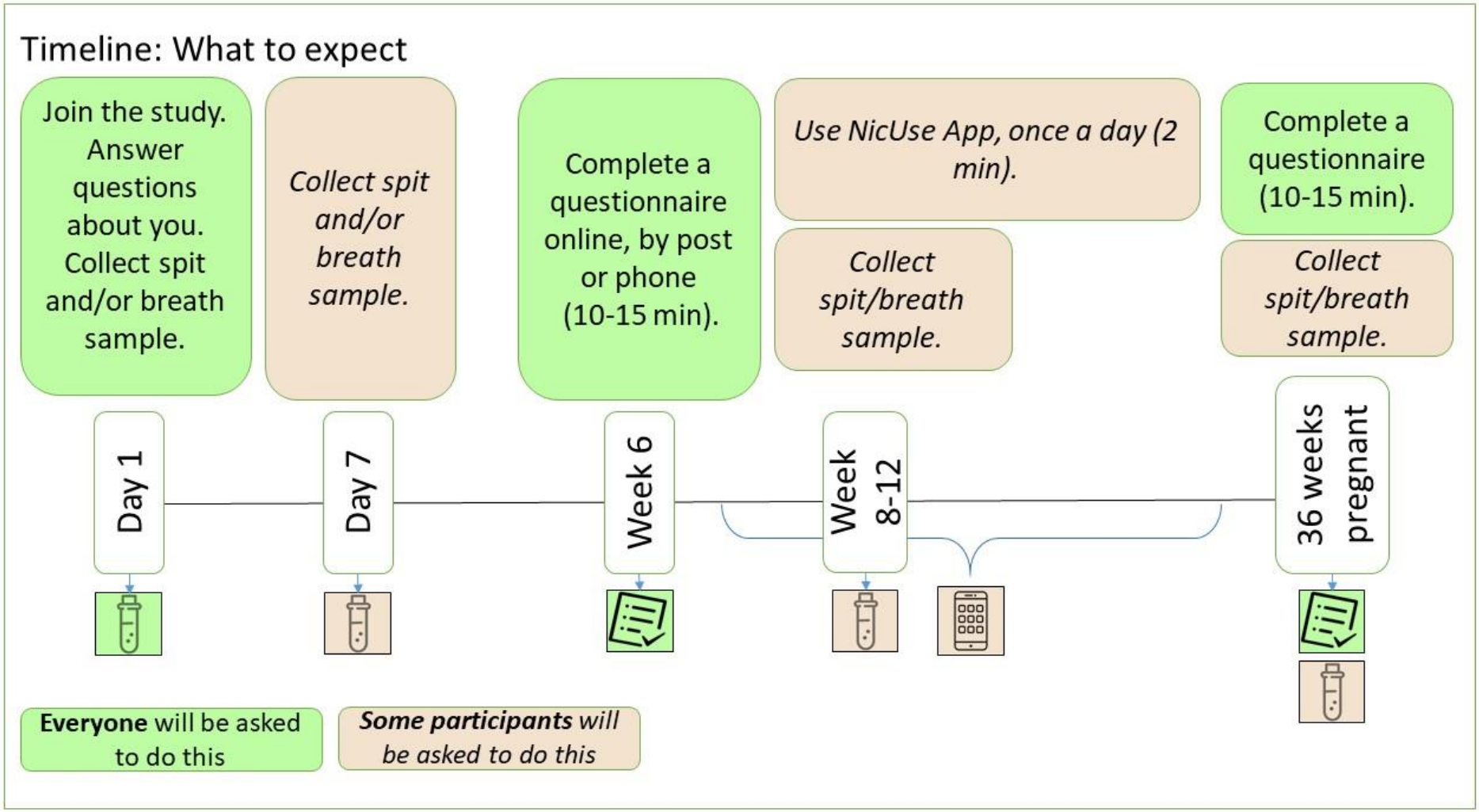
We will ask a proportion of women who agreed and who did not agree to take part in the study to tell us about their experiences with the study and the recruitment process, to see if we can improve it. Interviews would take place by telephone, at a time you choose. They would last no more than 40 minutes. The interviews will be audio recorded. We may use quotes when we are writing about the study, but any personal information, like names, will be removed. We aim to interview 28 women.

We will contact the hospital you are booked to deliver your baby in order to check how your pregnancy is progressing when you are around 34 weeks pregnant. We will ask the hospital again, at a later date, to find out details about the birth of your baby, for example the date you delivered your baby and your baby's birthweight and your smoking status.

Expenses and payments

To thank you for your time, we will give you:

- a £5 shopping voucher for completing each follow-up questionnaire (up to £10 in total).
- a £20 shopping voucher if you give a saliva and/or breath sample **at the end of the study** (not all women will be asked to do this).
- a £20 shopping voucher if you give a saliva and/or breath sample **midway through the study** (not all women will be asked to do this)
- a £20 shopping voucher if you take part in an interview


Timeline: What to expect
Join the study. Answer questions about you. Collect spit and/or breath sample.
Collect spit and/or breath sample.
Complete a questionnaire online, by post or phone (10-15 min).
Use NicUse App, once a day (2 min).
Collect spit/breath sample.
Complete a questionnaire (10-15 min).
Collect spit/breath sample.
Day 1
Day 7
Week 6
Week 8-12
36 weeks pregnant
Everyone will be asked to do this
Some participants will be asked to do this

What are the possible disadvantages and risks of taking part?

We do not expect there being any risks from taking part in this study. However, we know that taking part takes time and may be inconvenient. If you are likely to be upset by the information about the risks of smoking in pregnancy, then it is best not to take part. You will be expected to use NRT, which is recommended by NHS for stopping smoking in pregnancy. Although one group will be asked to use NRT differently to how it is currently prescribed in pregnancy, it is not expected that this will increase risk to your health. Using NRT is less harmful than smoking for you and your baby.

What are the possible benefits of taking part?

We cannot promise the study will help you, but running studies like this with women like you, helps us to develop new ways of supporting women to stop smoking during pregnancy. By taking part, you will be given up-to-date and correct information about stopping smoking; it is possible that this will give you a better chance of stopping smoking.

What happens if new relevant information becomes available?

If new information about the intervention becomes available or if there are any changes to the way the study is run, we will contact you to let you know about the changes. If you are happy with these changes, you will be asked to sign an updated consent form. If you decide not to carry on, you will still be entitled to receive the NHS stop smoking support available in your area.

What happens when the research study stops?

We will continue to collect information about your pregnancy until you have given birth. At this point, if you are still smoking and you would like to, you will be able to receive whatever NHS stop smoking support is available locally. We may pass your details to your local stop smoking services or contact your GP to discuss continuous provision of stop smoking support. If you want to hear about the results, we can send you an update about the study after it is finished. All you will need to do is to give us your permission to keep your contact details so that we can send these to you.

What if there is a problem?

If you are unhappy or worried about any part of this study, you should ask to speak to the study team who will do their best to answer your questions. The study teams' contact details are given at the end of this information sheet. If you are still unhappy with the information given or with the way your problem has been dealt with, you should contact <Local PALS details to be added>

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against the University of Nottingham but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Will my taking part in the study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, we will use information collected from you and your medical notes during the course of the research. All personal data will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database managed by the University of Nottingham. Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (named at the start of this document) is the Data Custodian (manages access to the data). This means we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your rights we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information and to read our privacy notice at:

https://www.nottingham.ac.uk/utilities/privacy.aspx.

The data collected for the study will be looked at and stored by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people from regulatory organisations to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty. Audio recordings will be anonymised and will be accessed by members of the research team and by transcription service staff. Only members of the research team will have access to any recordings where you could be identified.

If you consent, your contact information will be kept by the University of Nottingham for up to 3 years after the end of the study so that we are able to contact you about the findings of the study and possible follow-up studies. This information will be kept separately from the research data collected and only those who need to will have access to it. All other data (research data, including audio recordings) will be kept securely for 7 years. After this time your data will be disposed of securely. All precautions will be taken to maintain your confidentiality, and only members of the research team given permission by the data custodian will have access to your personal data.

Your personal contact details will be available to the University of Nottingham research team so they can contact you during the study and send the questionnaires. Your name and telephone number will be shared with Esendex, our text messaging provider and their sub processors. They will used these details to send you important text messages about the study whilst you are participating in the study. Esendex will hold your details for no longer than 2 years. After this time, they will delete your information. You can find their full information security statement here: https://www.esendex.co.uk/information-security-statement

No personal data will be stored on the NicUse app, which sends pseudo anonymised data to Amazon cloud. The researcher responsible for managing the NicUse app for this trial is based at the University of Nottingham. Application Programming Interface (API) will be used to transfer the data from NicUse to the University of Nottingham who are responsible for sending reminder texts, and a random security key will be required.

Participants, who have been asked to provide a breath sample at home, will be instructed to use a smartphone app with the carbon monoxide (CO) monitor, to send exhaled CO readings directly to the study team, with no third-party storage of participants' data.

In accordance with the University of Nottingham's, the Government's and our funders' policies we may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way is usually anonymised (so that you could not be identified) but if we need to share identifiable information, we will seek your consent for this and ensure it is secure. You will be made aware then if the data is to be shared with countries whose data protection laws differ to those of the UK and how we will protect your confidentiality.

Although what you say in the interview is confidential, if you disclose anything to us which we feel puts you or anyone else at any risk, we may feel it necessary to report this to the appropriate persons.

What will happen if I don't want to carry on with the study?

Your participation is voluntary. You are free to withdraw at any time, without giving a reason. If you withdraw, your legal rights will not be affected. If you withdraw, we will no longer collect any information about you or from you. We will, however, keep the information about you that we have already obtained as we are not allowed to tamper with study records and this information may have already been used in some analyses and may still be used in the final study analyses. To safeguard your rights, we will use the minimum personally-identifiable information possible.
If you want to withdraw from the study, you can do so at any time by calling us on <telephone number>, or by emailing snap3study@nottingham.ac.uk

Involvement of the General Practitioner/Family doctor (GP) and hospital

With your permission, we will tell your GP and the hospital where you are planning to deliver your baby that you are taking part in the study and what this involves.

We will ask your GP to let us know if there are any medical issues that mean you are unable to take part. For safety reasons, you will only be able to join the study if you also agree that we contact your GP. For participants recruited online, we will also ask their GP/hospital staff to confirm that they are a patient at that practice/hospital.

What will happen to any samples I give?

You may be asked to provide a spit (saliva) sample. Only the research team, relevant regulatory authorities and laboratory staff who test the saliva will have access to the results of samples analyses. Saliva samples will be tested for nicotine level. The samples will be labelled with a study number and your initials and date of birth so, only the research team will be able to link this sample to you. In accordance with the Human Tissue Act 2004, once the laboratory has analysed your saliva and we have checked this, the sample will be destroyed.

What will happen to the results of the research study?

The results of the study may be presented at conferences and published in scientific and medical journals. You will not be identifiable in any reports or presentations. Study findings may be used to help the NHS improve stop smoking support women receive when pregnant.

Who is organising and funding the research?

This research is being organised and coordinated by the University of Nottingham and funded by the National Institute for Health Research (NIHR), Health Technology Assessment (HTA) Programme (Project reference NIHR129210).

Who has reviewed the study?

To help protect your interests, all NHS research is looked at by an independent group of people, called a Research Ethics Committee. This study has been reviewed and given a favourable opinion by xxxxxxxxxxxxxxx Research Ethics Committee.

Further information and contact details

Chief investigator:	**<name and contact details>**
Trial Manager:	**<name and contact details>**
Researcher(s):	**<name and contact details>**
General Trial:	Phone: <number> Email: snap3study@nottingham.ac.uk

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