SNAP 3 Participant Information Sheet Interview

IRAS Project ID: **291236**

Title of Study: Smoking, Nicotine and Pregnancy (SNAP 3): a randomised controlled trial. A qualitative sub-study to optimise recruitment.

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

We would like to invite you to take part in our study, which is linked to the SNAP 3 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. Talk to others about the study if you wish.

What is the purpose of the study?

In this interview study we would like to find out about the experiences of women, who were invited to take part in SNAP 3 Trial. We would like to find out what affected their decision, what was helpful and what we could do better in the future.

Why have I been invited?

We are inviting you to take part because you were recently asked to take part in the SNAP 3 Study. We would like to talk to you, whether you decided to take part in the study or not. We need 28 women like you to join our study – we would like to speak with 20 women who decided to take part in the study and another 8 women who decided not to take part.

Do I have to take part?

It is your choice to join the study or not. A researcher 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 or give consent over the telephone. Later, if you change your mind, you can stop the study at any time and without giving a reason. This would not affect the your medical care 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 If you lose capacity to give consent during the study, you will be withdrawn but any data and samples collected up to that point will be retained for analysis.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?

A researcher will contact you via email, text or telephone to arrange a time for the interview that works for you. The interview will be conducted over the telephone. At the start of the interview call, the researcher will explain the study, answer any questions you may have and go through the consent form. If you are happy to take part, you will be asked to give your consent to take part in the study. The researcher will then ask you some questions about how you felt about being asked to take part in the SNAP 3 Study and what affected your decision to take

part or not. If you decided to take part in the SNAP 3 Study, we would like to know how you found this, so that we can improve how we carry out research in the future.

Depending how much you have to tell us, the interview will last around 20 - 40 minutes, and, with your permission, will be audio recorded. The information you give will be kept confidential. Audio recordings will be securely sent to and transcribed by <Name of Transcription service>, who are a professional transcription service. An agreement is in place between the University of Nottingham and <Transcription service>, which means all data must be treated confidentially. Transcripts will be stored in a password protected area of the University of Nottingham IT network with only your study number used; personally identifying data, such as your name, will not be stored in the same place as interview transcripts.

The transcripts will be read by the research team, who will use these to help answer the study questions.

We may use quotes from the interviews when writing about the study, but all personal information, such as names, will be removed. You will not be recognised from any quotes.

You can change your mind and stop the interview at any time, but if this happens, we will still use the information you have provided until that point. You can also decide not to answer some of the questions.

We need to ensure that we interview a variety of women; therefore, it is not guaranteed that everyone who agrees to be interviewed will be contacted.

Expenses and payments

If you take part in the interview, we will send you a £20 shopping voucher to thank you for your time.

What are the possible disadvantages and risks of taking part?

There are no disadvantages or risks of taking part in this study, other than giving up your time. However, discussing smoking during pregnancy might be difficult for some women. If you are likely to be upset by this, please consider carefully if you wish to participate in the interview.

What are the possible benefits of taking part?

While speaking with us will not be of direct help to you, your participation may help us to improve the SNAP 3 Study and similar studies in the future.

What happens if new relevant information becomes available?

If new information 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 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 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 above) 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.

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.

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, should 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 do not want to carry on with the study?

Taking part in this study is voluntary and you can stop the study at any time, without giving any reason, and without your legal rights being affected. 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

If you withdraw we will no longer collect any information about you or from you but we will 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.

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.

If you want to hear about the results, we can send you an update about the study after it is finished. You will need to give us your permission to keep your contact details so that we can send these to you.

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: **<name and contact details>**

General Trial: Phone: <number>
Email: snap3study@nottingham.ac.uk

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