

**Participant Information Sheet (PIS) for interviews
with pregnant women/people receiving the VIP intervention
Part 2**

Study title: Vaccination in pregnancy (VIP) study

Chief investigators: Professor Asma Khalil and Professor Caroline Free

We would like to invite you to participate in this research study. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Participants will be given a copy of this information sheet to keep.

What is the purpose of the study?

The aim of this study is to find out your views on vaccination in pregnancy and the way vaccines during pregnancy were (or weren't) offered to you. We will also ask about how this could be improved. We will ask you to watch a short video about vaccination in pregnancy and to provide feedback via a one-to-one interview.

We want to get the views of pregnant women/ people from a wide range of backgrounds. This could help us to improve the ways we explain about vaccinations in pregnancy and make it easier for pregnant women to get vaccinated.

Why have I been invited to take part?

You have been invited because you are a pregnant woman/ person receiving pregnancy care.

Do I have to take part?

No. It is up to you to decide whether to take part. We will describe the study and go through this information sheet. We will do this however you prefer including face to face, online, telephone, via WhatsApp or similar or text. If you do not want to take part, that is ok. If you wish to take part, we will give you this information sheet to keep. We will also ask you to sign a consent form. You are still free to withdraw at any time and without giving a reason. Whatever you decide, your medical care will not be affected in any way.

What will happen to me if I take part?

After you have had all your questions answered and have agreed to take part, we will ask you to sign the consent form. You can either sign the consent form in the normal way (by wet signature) or electronically. If you cannot sign the consent form for any reason, there is also an option to provide verbal consent only. We will audio-record the verbal consent.

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We will arrange an interview with a member of the research team. This can be conducted face to face in a private room at the clinic, or another safe, quiet public place, where you cannot be easily overheard, or at your home if possible. Another option is to have the interview over the phone, or via secure video conferencing (e.g. Zoom, Skype or WhatsApp video call), whichever you prefer.

With your agreement, the researcher will also check your medical records to see if you have received vaccines during pregnancy. In addition, we may call you to ask you about which vaccines you received during pregnancy.

What will happen during the interview?

With your permission, the interview will be audio-recorded. Everything you say will remain confidential as explained in detail below. We will also take notes at the same time. We will ask you what you think about being vaccinated in pregnancy. Then we will ask you to watch a short video and tell us what you think about it. The video is of mothers and health professionals talking about their experiences and opinions of vaccination in pregnancy.

Interviews will last about 20 to 40 minutes. They will be a relaxed and informal chat about you and your experiences of being offered vaccines in pregnancy. We will also ask if you have suggestions for improvements.

Will my partner, a family member or friend be able to join?

Interviews are usually conducted with the participant alone, but if you want to attend with another person, or if you need support for any reasons, you are free to bring another person. If so, please let us know beforehand, if possible.

There is no need to let us know beforehand if you wish to bring a young child with you. This is totally fine.

What if I need language support?

Please let us know if you need this information sheet to be translated into another language and/or if you need an interpreter for the interview and we can arrange this. If you think you do not need an interpreter but cannot speak and understand as well as an average native speaker, this is no problem. The researcher will make sure to speak slowly, repeat questions in different words and/or try to find other ways to communicate and make you feel comfortable.

Expenses and payments

We will give you £25 (as a gift voucher) for taking part in the interview, as a thank you for helping us. We will also pay your travel costs if needed (up to £20).

What are the possible benefits of taking part?

Participating in this study will not directly benefit you. However, it will help us find out more about people's experiences and opinions regarding vaccinations during pregnancy, possible reasons for low vaccination uptake, and how things could be improved in the future. It will also be an

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opportunity for you to talk about your experiences and views to an attentive listener.

What are the possible disadvantages and risks of taking part?

The main disadvantage of taking part is that it will take up some of your time.

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

You are free to withdraw from the study at any time without explanation. If you withdraw from the study, we will not collect any further information from you. If you withdraw within one month of taking part of the interview, we will withdraw all your data. However if you choose to withdraw after one month of taking part in the interview, we will keep and use any information you have already provided.

What if something goes wrong/ if there is a problem?

If you wish to complain or have any concerns about any aspect of the way you have been treated during this study, you may speak with the researchers/ local study team who will do their best to answer your questions or concerns.

Local Study Team coordination:

Name: Dr Sima Berendes

Job Role: Assistant Professor at London School of Hygiene & Tropical Medicine

Email: sima.berendes@lshtm.ac.uk / vip-study@lshtm.ac.uk

Phone: 07895 153469

St George's University Hospitals NHS Foundation Trust Sponsor Study Team:

Name: Professor Asma Khalil

Job Role: Chief Investigator of VIP Study

Email: Asma.Khalil@stgeorges.nhs.uk / akhalil@sgul.ac.uk

Phone: 020 8725 3664

London School of Hygiene & Tropical Medicine (LSHTM) Collaborating Study Team:

Name: Professor Caroline Free

Job Role: Co-Chief investigator of VIP study

Email: caroline.free@lshtm.ac.uk

Phone: 020 7958 8161

The normal National Health Service complaints mechanisms are also available to you: Patient Advice and Liaison Service (PALS)

St George's email: pals@stgeorges.nhs.uk

St George's PALS phone: 020 8725 2453

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St Thomas' email: pals@gstt.nhs.uk
St Thomas's PALS phone: [020 7188 8801](tel:02071888801)

Liverpool Women's email: PALS@lwh.nhs.uk
Liverpool Women's PALS phone: 0151 702 4353.

St George's University Hospitals NHS Foundation Trust sponsored research:

In the event that something goes wrong, and you are harmed during the research, and this is due to someone's negligence then you may have grounds for legal action for compensation against the sponsor (St Georges University Hospitals NHS Foundation Trust), but you may have to pay your legal costs. The normal NHS complaints mechanism will still be available to you.

Will my taking part in the study be kept confidential?

Yes, we will follow ethical and legal practice and all information about you will be handled in confidence. We will ensure that the minimum amount of data required to perform the study is collected.

Verbal consent provided without written consent will be audio recorded and transcribed.

The interview will be audio recorded and transcribed either by the research team or by a professional transcription service who are bound to confidentiality. Audio recordings will be stored securely at the London School of Hygiene and Tropical Medicine (LSHTM) for a limited time in case there are any queries needing checking. Only the VIP study researchers at LSHTM will have access. The recordings will be destroyed after transcription and within three months of completion of the study. All transcripts from these interviews will be stored with a unique study ID. We may use quotes or comments from your interview; however, this will be anonymised. You will not be identified in any report or publication.

Researchers at St George's University Hospitals NHS Foundation Trust and/or the London School of Hygiene and Tropical Medicine (LSHTM) University of London and/or the other study collaborators will process your personal data and are responsible for looking after your information and using it properly. Research data for this study will be held on secure password protected servers and/or database. This information will include your name and contact details. Your contact details will be held separately to your interview notes or transcripts and identifiable by participated identification number only.

The research is sponsored by St George's University Hospitals NHS Foundation Trust.

How will we use information about you?

We will need to use information from you and your medical notes for this research project.

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This information will include:

- Name
- Contact Details (i.e. email and/or telephone number etc.)
- Address and postcode
- Demographic Data (i.e. gender, ethnicity, educational background, religion etc.)
- Direct quotes from your interview (if applicable)
- Details from vaccination records (collected directly from medical notes or via a phone call to participant within 4 months after delivery)
- Responses from your interview
- Any requirements for the interview (i.e. interpreter etc.)
- Details about your pregnancy

People will use this information to do the research or to check your records to make sure that the research is being done properly. Relevant sections of participants' data collected during the study may be looked at by responsible researchers including individuals from London School of Hygiene and Tropical Medicine, University of London (LSHTM) and/or St George's University Hospitals NHS Foundation Trust (SGHT) and/or other study collaborators that are external to the sponsor and/or from regulatory authorities.

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.

International transfers

Your data will not be shared outside the UK.

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. We will keep your study data for a minimum period of time to write and publish the final report. The study data will then be fully anonymized and securely archived or destroyed.

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 keep information about you that we already have
- you have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- by asking one of the research team

- by sending an email to Chief Investigator Professor Asma Khalil (asma.khalil@stgeorges.nhs.uk / akhalil@sgul.ac.uk) and/or Data.Protection@stgeorges.nhs.uk (Data Protection Officer)
- by ringing us on 020 8725 3664 (fetal medicine unit)
- www.hra.nhs.uk/patientdataandresearch

What will happen to the results of the study?

The results will be published in a scientific journal so that other people know about it. If you would like a copy of the results once they are available, you may request a copy via email vip-study@lshtm.ac.uk. We will also include a link to the report on our study website: <http://www.lshtm.ac.uk/vip-study>. We may use quotes or comments from your interview; however, this will be anonymised. You will not be identified in any report or publication.

Who is organising and funding the research?

This study is being organised by St George's University Hospitals NHS Foundation Trust with some activities completed by researchers at the London School of Hygiene and Tropical Medicine (LSHTM) University of London and other study collaborators on behalf of the sponsor. This study is being funded by the National Institute for Health and Care Research (NIHR) with the funder reference number 'NIHR207562'. No participant data (identifiable or otherwise) will be shared with the funder.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee (REC), to protect your interests. This study has been reviewed and given favourable opinion by the London - Brighton & Sussex REC (ref. 24/PR/1590) and the London School of Hygiene & Tropical Medicine REC (ref. 31652).

Further Information and Contact Details:

Local Study Team coordination:

Name: Dr Sima Berendes

Job Role: Assistant Professor at London School of Hygiene & Tropical Medicine

Email: sima.berendes@lshtm.ac.uk / vip-study@lshtm.ac.uk

Phone: 07895 153469

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Name: Professor Asma Khalil

Job Role: Co-Chief Investigator of VIP Study

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London School of Hygiene & Tropical Medicine Collaborating Study Team:

Name: Professor Caroline Free

Job Role: Co-Chief investigator of VIP study

Email: caroline.free@lshtm.ac.uk

Phone: +44 (0) 20 7958 8161

Thank you for reading this information sheet and for considering taking part in this research.