PATIENT INFORMATION SHEET

Snapshot Obstetric National Anaesthetic Research Project SONAR-1

IRAS reference number: 265964
Chief Investigator: Prof Ramani Moonesinghe
UK lead Investigator: James O'Carroll
Local Principal Investigator: [INSERT]

We are conducting a study in UK maternity units and would like to invite you to take part.

Before you decide whether or not to take part, we would like to explain why the study is being done and what it would involve for you. Please take time to read the following information carefully and talk to others about the study if you wish. Please ask us if there is anything that is not clear, or you would like more information.
We would like to assure you that your decision will not affect your care for you or your baby.

Thank you for taking the time to consider participation in SONAR1.

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What is the name of the study?

SONAR-1 (**S**napshot **O**bstetric **N**ational **A**naesthetic **R**esearch project)

Principal investigator:

{INSERT LOCAL PI}

What is the purpose of the study?

We want to find out about patients' experiences of caesarean section during and after delivery specifically their experience of anaesthesia and their recovery up to 6 (+/-3 days) weeks

Why have I been invited to take part in this study?

As a patient who had their baby a participating maternity unit, you may be eligible to take part in the study if you have a caesarean section. We are giving you this information sheet to tell you what the study involves and what will happen if you take part.

Do I have to take part?

No, taking part is entirely voluntary. It is your choice to take part or not. You are free to withdraw at any time without giving a reason. Your decision will not affect the care you receive.

What will I have to do?

1. After your caesarean section is finished, and when you are feeling able to do so, you will be visited by a member of the clinical or research team who will answer any questions and ask you to sign a consent form to confirm your participation. This might be in the recovery area, or when you've reached the post-natal ward, but not before you feel ready. A research team member that was also be part of the clinical team that provided your care will be available to answer questions.
2. We will then ask you to complete a questionnaire about your procedure, which will take about 10 minutes to complete with a member of the research team. This will happen about a day after your caesarean and will be before you go home.
3. We will then call you approximately 6 weeks (+/- 3 days) after your delivery to complete a second survey about how you have been feeling since leaving the hospital. This will take 10 – 15 minutes to complete. We will try to contact you a maximum of 3 times and will work with you on a best time to call.

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4. The study team would like to understand the experiences of those who have had pain during surgery. We plan to do this by interviews with patients. If you are happy for this optional part, we will contact you by email. Your contact details will not leave the hospital, and giving this information is entirely optional.

What are the possible disadvantages and risks of taking part?

We do not think there are any disadvantages or risks to taking part. The questionnaire has been designed by researchers working in collaboration with patients and has been used in other research studies with no reports of harm. There is a small possibility that answering the questionnaire may cause you to worry or feel anxious about your anaesthetic or your recovery. If you have any questions or concerns, there will be an opportunity to discuss these with a member of the research team.

Some of the questions asked at the 6-week telephone call will be about your current mood. In this call, we will be using questionnaires aiming to screen for anxiety, depression, and post-traumatic stress, If the questionnaires scores suggest that you might have such symptoms, then we will let you know at the time, and encourage you to visit your GP if you think that's right. We will also write to you and your GP, letting them know. The letter for you will include resources and groups available to you, that you may find beneficial.

What are the possible benefits of taking part?

This study may not benefit you directly. Our aim is to understand the experiences of delivery and recovery to try in improve it for those in the future. We will be asking you questions about your health and wellbeing which may highlight problems which we can inform you and your health care team about.

What will happen to the answers I provide in the questionnaires?

The local study team will transfer your answers from the paper questionnaire onto a secure database. All the paper questionnaires will be held in a secure location on the research site where only the research team have access to it, these will be destroyed after the study ends. (this is likely to be after 3 months, once all data is collected). The database will not have any of your personal details and is only accessible to the research team analysing the data. It will not be possible to identify you from the database.

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None of your personal details for example name, date of birth or identification numbers will be transferred out of your local hospital either electronically or on paper. The anonymised responses from hospitals across the UK will be analysed by a team of researchers based at University College London (UCL).

How will we use information about you?

The local study team will use only use the personal information collected to contact you at 6-weeks after your delivery, such as your phone number or email address. We will record the time of delivery, your hospital number, and name. This information will be collected using hospital records. This information will be in a secure location where only the research team members have access to it. Only the local research team will have access to your name and contact details.

People will use this information to do the research or to check your records to make sure that the research is being done properly. 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. We will keep all information about you safe and secure.

Once we have finished the study data collection, we will destroy all the questionnaires. We will keep some of the anonymised data on the database so we can check the results. The database will then be securely destroyed in 10 years' time.

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 may keep information we have already collected. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
If you wish, you can contact the UCL Data Protection team data-protection@ucl.ac.uk if you require more information.

What will happen to the results of the study?

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The data will be used as part of an academic degree thesis. We also intend to produce both oral and written reports of the study for academic publication. No references will be made that could link you personally to the study. A summary will be published as a press release to the funder and the sponsor for their websites, which is available for you, if you wish. You can also receive a copy of these results via email, if you choose to.

Who is funding and organising the study?

The study is being funded by the Obstetric Anaesthetists' Association and the National Institute for Health Research's Central London Patient Safety Research Collaboration. It is organised by the researchers that are named at the top of this leaflet.

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Who is the sponsor of the study?

The study is sponsored by University College London Hospitals

Who has reviewed the study?

All research in the NHS is checked by a Research Ethics Committee, an independent group whose job is to protect your safety, rights, wellbeing, and dignity.

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

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

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team

What do I do if there is a problem or I wish to make a complaint?

- If you wish to complain or you have any concerns about any aspect of the way you have been approached or treated due to your participation in the research, National Health Service or UCL complaints mechanisms are available to you. Please ask a member of the research team if you would like more information.
- If you want to complain about how researchers have handled your information, you should contact the local research team, or if you have further concerns, the research team in London. Details are in the final section of this information sheet.

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- Every hospital has a Patient Advice and Liaison service (PALS) who can be contacted and will provide information about the NHS complaints procedure, including how to get independent help if you want to make a complaint.
- If you suspect that the harm is the result of the Sponsor's (University College London Hospital) or the hospital's negligence, then you may be able to claim compensation. After discussing with the research team, please make the claim in writing to Prof. Ramani Moonesinghe. Prof Moonesinghe is the Chief Investigator for the research and based at University College London (UCL) and UCL Hospitals. She will then pass the claim to the Sponsor's Insurers, via the Sponsor's office.

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Further information and contact details:

Chief Investigator:
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UK Lead Investigator
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Email: james.ocarroll@nhs.net

You can also contact PALS for independent information regarding research at {your Institution}:
[INSERT LOCAL PALS INFORMATION]

PALS	Trust Complaints Department
[Location]	Trust complaints email
[Hospital	Trust complaints telephone [Address]
[Postal code]	
Email	
Telephone	

Deleted: Ground Floor
Atrium→→→→→uclh.complaints@nhs.net¶

Deleted: University College Hospital→→→→020 3447 7413¶
235 Euston Road¶
London NW1 2BU¶
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