Participant information sheet

Intelligent Fetal Imaging and Diagnosis study 3: further image data collection (iFIND3)

PART 1

We'd like to invite you to take part in our research study.
Joining the study is entirely up to you, before you decide we would like you to understand why the research is being done and what it would involve for you.
One of our team will go through this information sheet with you, to help you decide whether or not you would like to take part and answer any questions you may have. We suggest this should take about 5 minutes.
Please feel free to talk to others about the study if you wish.

The first part of the Participant Information Sheet tells you the purpose of the study and what will happen to you if you take part.

The second part will give you more detailed information about the conduct of the study. Please ask if anything is unclear.

What is the purpose of the study?

The purpose of this study is to collect images from ultrasound scans from pregnant participants, along with some other medical information.

The overall aim of the study is to use these images to develop special computer programmes (known as 'artificial intelligence') to help improve these scans in the future.

Why have I been invited?

You have been invited to take part in the study because you are pregnant and you are coming to this hospital to have ultrasound scans of your baby.
Patients from King's College Hospital only will be invited to take part. We expect approximately 10,000 patients will take part.

Do I have to take part?

It is up to you to decide. We will describe the study and go through this information sheet, which we will then give to you. You will be able to keep this information sheet and think about taking part. You are free to discuss the information with anyone you wish including your family and friends. If you agree, we will then ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive.

What will happen to me if I take part?

If you agree to take part you will be asked to read and sign a consent form. The person doing your scan will then record the entire video from your ultrasound scan onto a device attached to the ultrasound machine. This will happen in the background as the scan is performed, and will not affect the way the scan is performed, and will not make it shorter or longer in duration. The data collected may be used for future research studies, but you can opt-out of this if you wish.

What are the possible benefits of taking part?
We cannot promise the study will help you but the information we get from this study will help improve the future scans of unborn babies.

What are the possible disadvantages and risks of taking part?
Taking part will not affect the medical care you receive, or the way the scan is performed. Taking part will not involve any risks to the health of you or your baby. You will not receive any additional information about your pregnancy or you baby as a result of taking part in the study.

Who is organising and funding this study?
The doctor in charge of this study is Prof Reza Razavi. The study is funded by The Fetal Medicine Foundation and is being sponsored by King's College Hospital and King's College London.

How have patients and the public been involved in this study?
A group of people with experience of pregnancy, including healthy pregnancies and pregnancies affected by health problems have been involved in the development of this large research project. We have made sure that the objectives of this research align with their priorities, and have checked that they would be happy for their own data to be used in this way.

Who has reviewed this study?
All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by Dulwich_Research Ethics Committee. It has also been approved by the Health Research Authority and each local hospital will also give confirmation that the study can go ahead.

Expenses and Payments
There are no funds available for payments to those participating in this study.

This completes Part 1 of the Information Sheet.
If the Information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

PART 2
What will happen if I don't want to carry on with the study?
You are free to withdraw from the study at any time. If you would like to do so please speak to the study team.

Your decision to withdraw from the study will not affect the care you receive.

If you withdraw your consent information collected about you may be used if you are happy with this. You can withdraw consent for all information collected to be destroyed where this is possible.
What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to your doctor who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints procedure by contacting your local Patient Advice Liaison Service (PALS) office.

Details of your local office can be obtained by asking your study doctor, GP, telephoning your local hospital or looking on the NHS website. https://www.nhs.uk/nhs-services/hospitals/what-is-pals-patient-advice-and-liaison-service/

Every care will be taken in the course of this study. However in the unlikely event that you are injured by taking part, compensation may be available.

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 King's College Hospital NHS Trust but you may have to pay your legal costs.

Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff or about any side effects (adverse events) you may have experienced due to your participation in the study the normal NHS complaints mechanisms are available to you. Please ask your study doctor if you would like more information on this.

Will my taking part be kept confidential?

If you consent to take part in the research, any of the information collected about you may be inspected by the sponsor (including representatives of the sponsor). These inspections are solely for the purposes of the research and analysing the results. Your records may also be looked at by the regulatory authorities or ethics committees to check that the study is being carried out correctly.

The organisations listed above will keep information about you confidential and secure. Your name will not be used in any reports about the study and all data is stored in accordance with the principle of the Data Protection Act 2018. However, your hospital doctor may tell your GP about your participation if you agree to enter the study.

Involvement of the General Practitioner/Family Doctor (GP)

As there is no treatment given as part of this study and it does not change the care you receive, we will not need to inform your GP about your participation in the study.

What will happen to the results of the research study?

We intend to use the data collected in this study to develop computer programs that can help improve the scans in the future. We plan to publish our results in medical journals and at medical conferences. No personal or identifiable information will be published at any point. The ultrasound scans collected, and the information collected about you, may also be shared in de-identifiable form with commercial organisations, working with the study sponsors in order to support the development of products to improve healthcare.

How we will use your data

We will need to use information from your ultrasound scan and your medical records for this research project.

This information will include

- Scan images
- Medical information about your baby
- Your ethnicity
- Your age
- Your height and weight
- Your pregnancy gestation

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, 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.

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.

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

If you consent to take part we will use your data to deliver this project as described in the Patient Information Sheet. You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available entitled 'How we use your data' which you can request from the study team
- by asking one of the research team
- by contacting our DPO at [KCL: info-compliance@kcl.ac.uk or KCH: kch-tr.dpo@nhs.net]

KCL only: By visiting our webpage https://www.kcl.ac.uk/research/research-environment/rgei/research-ethics/use-of-personal-data-in-research

Thank you

Thank you for considering taking part and taking the time to read this information sheet.
If you decide to take part in the study, we will give you a copy of the information sheet and a signed consent form to keep.

Further information and contact details
https://www.ifindproject.com/

Local Contacts:

Your doctor ..... Tel: .....
Your nurse/study coordinator..... Tel: .....