



Parent Information Sheet

Magnetic resonance imaging to enhance the diagnosis of fetal developmental brain abnormalities in utero. (MERIDIAN)

2-3 year follow-up study

Thank you for your interest in this research. We would like to invite you to take part in a follow up study to MERIDIAN, the study you agreed to be part of during your pregnancy a few years ago. This study aims to follow up children born during MERIDIAN when they are around 2-3 years old. Before you make any decisions about whether you wish to take part, please read this information sheet carefully and if there is anything that is not clear or you would like some more information, please do not hesitate to ask us.

Why is the project happening?

The follow up study is happening to find out more information about how suspected brain abnormalities, detected by antenatal Ultrasound scanning (USS) and Magnetic Resonance (MR) Imaging may affect the longer term development of the child. This extra information will help doctors and midwives understand the importance of such antenatal findings and provide pregnant women and their family with more information about any long term impacts on their child.

Why have I been chosen?

You have been asked about taking part because you previously participated in the MERIDIAN study and your child from that pregnancy is now aged 3 years or over. As part of the original consent process you agreed that you were happy to be contacted for future studies about your child's development. All parents who participated in MERIDIAN and have a child of this age are being contacted by the research team.

Do I have to take part?

No. It is completely up to you whether you and your child take part in the study or not. If you decide that you would like to take part then please keep this information sheet, and we will contact you to discuss the study further. If you agree to take part after you have had the opportunity to ask any



questions, then you will be asked to sign a written consent form like you did for the previous study. If you agree to take part and then change your mind you can withdraw from the study at any time without having to give a reason.

You can decide not to take part, and this will not affect any of the future care that you or your child will receive.

What will happen to me if I take part?

If you decide to take part a member of the research team will look through your child's medical notes to check for any additional information about your child's development. This will include us looking for the results of any development assessments or brain scans that were not collected during the original MERIDIAN study or have been done up until your child turned 3^{1/2} years old (term corrected). You will be asked to sign a consent form but you will not need to do anything further.

What are the possible disadvantages and risks of taking part?

There are no risks associated with taking part in this study. All assessment tools used are approved and completed by suitably trained health professionals.

What are the possible benefits of taking part?

Researchers, doctors and other health care professionals who are involved in performing antenatal USS could benefit from this research by gaining a better understanding of brain abnormalities detected antenatally and how they may affect a child's long term development. We think it is very unlikely we will detect any developmental problems you do not know about. However, if we do find anything of concern, we will help make appropriate arrangements. For example, with your permission we could contact your GP or any other doctor involved in your child's care. We will share the results of the questionnaires with you by writing to you afterwards, but we will not share them with anyone else without your permission.

The study will benefit pregnant women in the future who have been told that their baby might have a problem with their brain development. We hope this study will improve understanding for both parents and health professionals.



The data collected in this study will also allow the research team to update any changes in diagnoses made at birth, and therefore improve our knowledge of the accuracy of antenatal MRI scanning in detecting brain abnormalities.

Will my taking part in this project be kept confidential?

All data obtained in the study will be kept confidential. All information provided by you or recorded by the research team will be kept under code number and will only be linked together with your name where we need to contact you to make an appointment or request some further details from you. Data will be made available only to the research team, and with your permission, your child's GP and paediatrician (if your child has one).

All information will be kept in a locked room at the Clinical Trials Research Unit in the University of Sheffield and within the hospital clinic which you were approached by. Copies may also be stored in a locked room and on a secure electronic database at the Academic Unit of Radiology at the University of Sheffield.

The hospital staff may also post your consent form and other study documents to the University of Sheffield for monitoring purposes. This will be stored in a locked filing cabinet.

What will happen to the results of the research project?

Researchers may present the results of this project in research conferences, or they may publish in scientific or medical journals. None of your or your child's personal details will be identifiable. We will also use the information to design better information leaflets for parents. We will work with parents and support groups to do this.

What if something goes wrong?

We are not aware of any risks to your child as a result of taking part. In the event that something does go wrong and your child is harmed during the research, and this is due to someone's negligence, then you may have grounds for legal action for compensation against the University of Sheffield. You may however have to pay your own legal costs. The normal National Health Service complaints procedure will still be available to you.

What if I wish to make a complaint?

If you wish to raise a complaint about the way you have been dealt with, or about any harm you feel you or your child have suffered, you can contact Professor Paul Griffiths in the Academic Unit of



Radiology at the University of Sheffield via email (p.griffiths@sheffield.ac.uk), phone (0114 2159605) or send a letter to: Professor P D Griffiths, Academic Unit of Radiology, University of Sheffield, C floor Royal Hallamshire Hospital, S10 2JF.

Alternatively, you can contact the patient advisory and complaints service at your local hospital or NHS Trust.

Involvement of general practitioner (GP)

We will write to your GP and paediatric consultant (if your child has one) to let them know that you are taking part in this study. We will only share the results of the study if you would like us to, for example where there is a developmental issue that needs further follow up.

Safeguarding Children

All of our research staff with patient contact must follow standard NHS policies and guidance for child protection. We do not expect that any concerns will be raised as a result of this study but if a health care professional (midwife, nurse, doctor or therapist etc.) does have any concerns then they will have to follow standard procedure. This may mean them discussing any worries with their manager, your child's GP or paediatrician, if your child has one.

Who is organising and funding and reviewing the research?

This research is being carried out by the University of Sheffield and is funded by the National Institute for Health Research (NIHR) Health Technology Assessment programme (project number 09-06-01). This is a part of the NHS which is involved in medical research. The research has been approved by Yorkshire and The Humber – South Yorkshire ethics committee (REC reference 15-YH-0398).

Contact for further information

If you would like further information about the study, please contact:

Chief Investigator: Professor Paul Griffiths. Email (p.griffiths@sheffield.ac.uk), phone (0114 215 9605) or send a letter to: Professor P D Griffiths, Academic Unit of Radiology, University of Sheffield, C floor Royal Hallamshire Hospital, S10 2JF.

Thank you for taking the time to read this information sheet