1. **Project Title:**

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

26 June 2014, Version 4.1

2. **Invitation paragraph**

Thank you for your cooperation, we do appreciate you taking the time to help us at what is a difficult time for you. We would like to ask you to consider taking part in a research project which uses new methods of looking at a baby’s brain while still in the womb. The project involves magnetic resonance imaging (MRI), which is a type of scan already used in many hospitals for other reasons. Please read this information sheet carefully and if there is anything that is not clear or you need more information, please do not hesitate to ask us. Even if we cannot speak to you immediately, one of our team will get back to you.

3. **Why is the project happening?**

Ultrasound scanning is used throughout the country to check for possible problems during pregnancy. Although this technique is good, in fact no medical test is perfect and in some cases ultrasound does not provide all the information needed to make a full assessment of the unborn baby’s brain development. Newer MRI scanners like the ones we are using in this research project are able to scan much more quickly than we could ten years or so ago. This is very useful as a baby often moves during the scan and these faster scanners still allow us to take good, clear pictures of the baby’s brain and hence sometimes gather more information about any possible problems.

4. **What is the aim of the project?**

The aim of the project is to find out how and when MRI should be used to improve the information available to parents before birth about the health of their baby. In particular we are concentrating on situations where ultrasound scanning suggests there is a problem with the growth and development of their baby’s brain.
5. **Why have I been chosen?**
As you are aware there may have been a problem with your baby's brain shown on the ultrasound scan performed by your doctor. We believe that MRI scanning may be able to provide you with more information regarding this.

6. **Do I have to take part?**
No. Your participation in this study is voluntary. You may decline to participate. If you decide to participate, you will be given this information sheet to keep, and you will be asked to sign a written consent form. You can still withdraw at any time. You do not have to give a reason if you withdraw from the study prior to its completion. This will not affect your treatment.

7. **What will happen to me if I take part?**
If you decide to take part, we will first ask you some routine questions to make sure that MRI is a safe procedure for you. If you have a heart pacemaker, you have had previous brain or heart surgery, or you have suffered an injury to your eye (such as a metal splinter) you should inform us so we may check this before the MRI takes place. You will be seen by a member of staff in the MRI department before your scan and they will explain to you what will happen during the scan. You will also be able to ask questions before and after the scan takes place.

The MRI will either take place at the Academic Unit of Radiology in the Royal Hallamshire Hospital in Sheffield or it will be arranged by your doctor in the radiology department of your hospital. The MRI scan normally takes around 30 minutes in total, although this may be longer if you are carrying twins or if your baby is particularly active during the scan. You will be asked to lie very still. During the scan you will hear the loud noise made by the MRI scanner while it is working. You will receive earplugs or headphones before the scan starts to reduce this noise. Some people may feel enclosed inside the scanner, and possibly experience feelings of "claustrophobia", so you may wish to have another person present in the scanner room with you (for instance your partner, a close relative or friend). This is OK as long as they complete a visitor safety questionnaire so that we know they are safe to enter the scanner room.
Following your scan we will ask your doctor to let us know how useful the information from the MRI scan has been. We are also very interested in your views about the MRI scan, and we will ask you to fill out two questionnaires, both of them after you have seen your doctor and discussed the scan results, one of them a few months after the other. Once you have completed a questionnaire you can give it to a member of staff in clinic or return it to a member of the research team in a stamped addressed envelope which we will provide.

With your agreement (which is included on the consent form) we would like to be able to use some of the pictures, or “images”, from your scan for teaching purposes or where appropriate in other publications relevant to this research. None of your personal details would ever be printed on these images. We may also, with your agreement (which is included on the consent form), wish to gather some information about what happens later on in your pregnancy and around the time of delivery. Finally, in order to check how useful and accurate the information from your MRI scan has been we would like to see the results of any tests performed postnatally by your doctors up to 6 months term corrected after delivery. Sometimes this information can be collected entirely from your medical records, and those of your child, and we may not need to contact you directly. If this is not possible however, then either a member of the research team, your midwife or consultant obstetrician would contact you to help us check these details.

We may also wish (which is included on the consent form) to contact you regarding future studies into your child’s development. It is entirely your choice whether you agree to the use of images for teaching purposes, providing us with information after your child is born, or participation in any future studies as your child grows. It will not affect your care you receive if you decide not to take any of these options. Please note that the doctor who performed your ultrasound test will be informed of the results of the MRI study. They will in fact receive a full report which will be discussed with you when you next see them.
8. **What are the possible disadvantages and risks of taking part?**

There are no known problems regarding the use of MRI scanning in pregnant women. There are some possible disadvantages to having an MRI scan, as some people can find being in the scanner uncomfortable or unpleasant (please see paragraph 7 above "What will happen to me if I take part"). It is important to point out though that most people experience little or no problem at all when they are having their MRI scan.

It is possible that the information from your MRI scan might be different from the information shown on your ultrasound scan. This can happen because no single medical test is perfect, and sometimes information provided by tests such as ultrasound and MRI may be incomplete or difficult to interpret. If this occurs your doctor will discuss this with you, and it will be up to you and your doctor to decide between you how best to use the information provided by each of your medical tests.

9. **What are the possible benefits of taking part?**

Researchers, doctors and other health care professionals who are involved in scanning babies before birth could benefit from this research by gaining a better understanding of how and when to perform MRI scans for pregnant women. In the future, other pregnant women who have been told their baby might have a problem could benefit from the results of this research. As a result of the MRI scan you might also gain some more information about your current pregnancy and your baby’s condition.

10. **What happens if the research study stops earlier than expected?**

If this is the case, the reason(s) will be explained to you by one or our research team.

11. **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 persons conducting the study, your referring consultant and any other individuals where you have given specific permission for us to do so (for instance your GP). All information will be kept in a locked room at the Academic Unit of Radiology in the University of Sheffield, within the hospital clinic or radiology department where your MRI scan takes place. Copies will also be stored in a locked room and on a secure electronic database at the University of Sheffield School for Health and Related Research (ScHARR). The questionnaires you complete after
your MRI scan will be stored by a member of the research team in a locked room within the University of Newcastle.

12. **Will I get travel expenses?**

We will be able to reimburse reasonable travel expenses if you are asked to travel to Sheffield for your MRI scan (and you would not normally have your scans or other hospital appointments there). Please ask the radiologist or another member of staff when you attend for your MRI scan, or contact the Academic Unit of Radiology in Sheffield for details (address and phone number are shown at the end of this information sheet).

13. **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 personal details will be identifiable.

14. **Who has reviewed the project?**

This study has been reviewed and commissioned by the National Institute for Health Research (NIHR) Health Technology Assessment Programme. This is a part of the National Health Service (NHS) involved in medical research. Ethical review is provided by means of the Integrated Research Application System (IRAS), and has been approved by a research ethics committee (South Yorkshire REC, reference: 11/YH/0006).

15. **What if something goes wrong?**

Since there are no known health risks specifically associated with this study, it is very unlikely that you will be harmed as a result of taking part. 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 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.

16. **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 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 2712587) 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 Service Team at the Royal Hallamshire Hospital at: Patient Partnership Department, B Floor, Royal Hallamshire Hospital, Glossop Road, Sheffield, South Yorkshire, S10 2JF, tel: 0114 2712400 or via e-mail: PST@sth.nhs.uk.

17. **Involvement of general practitioner (GP)**
Your GP will not be notified of your involvement in this study unless you specifically ask us to do so.

18. **Who is organising and funding the research?**
The funding of this research is obtained from the National Institute for Health Research (NIHR), which is a part of the NHS involved in medical research. The project is part of the NIHR Heath Technology Assessment (HTA) programme.

The sponsors of this study will pay the Academic Unit of Radiology for the cost of the MRI scan and also for your reasonable travel expenses to allow you to come for your MRI scan. The doctor conducting the research will not be paid specifically to perform the scan and therefore he/she has no conflict of interest in your care.

19. **Contact for further information**
If you would like further information about the study, please contact Professor Paul Griffiths at the Academic Unit of Radiology in Sheffield. Alternatively you can contact the person detailed below who is a member of our research team based at your local hospital or clinic.

**Paul D Griffiths**
Professor of Radiology  
Academic Unit of Radiology  
University of Sheffield  
C floor, Royal Hallamshire Hospital  
Sheffield S10 2JF  
Email: p.griffiths@sheffield.ac.uk  
Tel: 0114 2712587

**Dr Dilly OC Anumba**
Consultant in Obstetrics & Gynaecology and Senior Lecturer in Fetomaternal Medicine  
Academic Unit of Reproductive and Developmental Medicine  
The University of Sheffield  
4th Floor, Jessop Wing  
Tree Root Walk  
Sheffield S10 2SF  
Email: d.o.c.anumba@sheffield.ac.uk  
Tel: 0114 2261075