Patient Information Sheet – 13 April 2010, Version 2.0

Information Sheet for Research Participants

**Study title:**

Caesarean section scar in pregnancy, course and effects

Principal Investigators: Professor Tom Bourne PhD, FRCOG
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You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and members of hospital staff. Ask us if there is anything that is not clear or if you would like more information. Please take time to decide whether or not you wish to take part in the study.

If you do decide to take part, please let us know beforehand if you have been involved in any other study during the last year. If you decide not to take part or to withdraw at any other time without explanation, your future care will not be affected by your decision. Thank you for reading this.

**What is the purpose of the study?**

Delivery by caesarean section is becoming a common event. We would like to find out if previous delivery by caesarean section has any effect on future pregnancies or delivery. We plan to investigate this by carrying out ultrasound scans of the caesarean scar during the course of your current pregnancy.

**Why have I been chosen?**

You are currently pregnant and you have a previous history of having delivered by caesarean section.

**Do I have to take part?**

It is up to you to decide whether or not to take part. If you decide to take part you are still free to withdraw at any time and without giving a reason. This will not affect the standard of care you receive in the future.
What do I have to do?
You will be approached and informed about the study while attending the Early Pregnancy and Acute Gynaecology Unit (EPAGU) for early pregnancy scan, OR while attending your booking appointment in main ultrasound department. The research doctor will:

- Ask you about your previous delivery and any other surgery to your womb
- Explain the purpose of this study in further details and answer your questions

Taking part in this study will not affect the standard treatment that you receive. You can opt out of the study at any stage.

What will happen to me if I take part?
If you decide to take part in this study you will be asked to sign the necessary consent form, then you will have (3-4) ultrasound scans to your Caesarean scar as part of the routine scans that you will have during the course of your current pregnancy, as follows:

1. Early pregnancy scan (transvaginal) from 5-10 weeks gestation. This scan will be done if you are attending your routine EPAGU appointment.
2. First trimester scan (transvaginal and/or transabdominal) at around 11-13 weeks gestation. This will be done while having your routine booking scan.
3. Second trimester scan (transabdominal) at around 19-20 weeks gestation. This will be done while having your routine anomaly scan.
4. Third trimester scan (transabdominal) from 34 weeks gestation onwards. This will be done while attending antenatal clinic for routine check.

What are the possible disadvantages and risks of taking part?
There are no disadvantages or major risks associated with taking part. The ultrasound scan has no known adverse effects on the mother or the baby. Staff who are trained and experienced in the field will perform the ultrasound scanning.
**What are the possible benefits of taking part?**

Close monitoring of your caesarean scar might help us report potential difficulties that might occur during your labour or caesarean section, so that your obstetricians will pay extra attention when you give birth. However, as this is yet not evidence-based, there might not be immediate term benefits from this study.

**Will my taking part in this study be kept confidential?**

All information that is collected about you during the course of the research will be kept strictly confidential. Your name and address will be removed from the information when it is shown to other medical staff outside the study.

**Who is organising the research?**

This study is being organised by the staff of the department of Gynaecology at Imperial College NHS Trust and Imperial College London.

**Who has reviewed the study?**

The Research Ethics Committee of Hammersmith and Queen Charlotte’s Hospital has reviewed this study.

**What if something goes wrong?**

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone’s negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect, or about the way you have been treated during the course of this study then you should immediately inform Dr Ghaem-Maghami on 02083833267. The normal National Health Service complaint complaints mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial AHSC Joint Research Office.

**Contact for Further Information**

If you want more information, before or after you return your form, you can phone

Dr Sadaf Ghaem-Maghami on 020 8383 3267 or

Dr Osama Naji on 07852160560 or 02083831000 Bleep 9676 or

Professor Tom Bourne on womensultrasound@btinternet.com

The local Research Ethics Committee has approved the above statement.