

CONSENT FORM

TICK AS APPROPRIATE

I have read the information leaflet (version 4.0 01/05/08). I have discussed this trial with a Fetal Medicine Specialist and been able to ask questions.

I do not consent / my baby is not eligible for the PLUTO Trial (delete as appropriate). I consent for my pregnancy to be recorded in the PLUTO Registry (go to section B)

Section A: FOR TRIAL PARTICIPANTS

I consent to take part in the **PLUTO** Trial of vesico-amniotic shunting.

I understand that it will be randomly decided whether or not a shunt will be inserted into my baby's bladder and my specialist will not be able to decide which treatment I will have.

I understand that insertion of a shunt carries a small risks and that the benefits are currently unknown:

- Miscarriage/death of baby/preterm labour 5% Rupture of the membranes before labour 2%
 - Infection <1%
 - Damage to structures inside the mother or the baby but that this is rare <1%
 - Adverse drug reactions <1%
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I understand that occasionally the shunt may fail (block or move out of place: in small cohort studies the incidence is 20-25% but this is not known with certainty) and that it cannot be removed until after the baby is born.

I understand that I can withdraw from the trial at any time and that this will not affect the care that I receive.

I understand that my specialist will provide information about my progress and my baby's progress, in confidence, to the central organisers. I understand that the information held by the NHS and records maintained by the Office of National Statistics may be used to keep in touch with me and follow up my and my baby's health status.

Section B: FOR TRIAL AND REGISTRY PARTICIPANTS

I give consent to my GP being informed about my participation in this study.

I understand that the information will be used for medical research only and that I will not be identified in any way in the analysis and reporting of the results. I understand that sections of any of my or my baby's medical notes may be looked at by responsible individuals from the University of Birmingham or from regulatory authorities where it is relevant to my taking part in this research. I give permission for these individuals to have access to our records.

I understand that you will keep a frozen sample of my baby's urine, which may be used in future research.

Participants Name.....

Signature.....Date.....

Fetal Medicine Specialist Name.....

Signature.....Date.....