Please report any **serious**, **unexpected** adverse events* believed to be due to the treatments given as part of the PLUTO trial by sending or faxing the following details to the PLUTO Trial Office (fax: 0121 415 9135) within 1 week of the event:

PLUTO Trial No: ☐☐☐☐ Mother's Date of Birth: .....

Mother's Hospital Number: .....

Responsible doctor: .....

Shunt inserted?: Yes ☐ No ☐ Date Shunt Inserted: .....

Date Event Started: ..... Date Event Ceased: .....

Event

- ☐ Miscarriage
- ☐ Premature rupture at membranes
- ☐ Preterm labour
- ☐ Maternal infection chorio-amniotitis or other inter-uterine infection
- ☐ Damage to maternal visera- vasculature, uterus or other abdominal organs
- ☐ Damage to fetal organs, such as bladder or bowel
- ☐ Migration of stent outside of the uterine cavity requiring a surgical procedure to remove it into bladder or abdomen resulting in re-stenting, recovery or delivery
- ☐ Adverse drug reactions to anaesthetic or antibiotic
- ☐ Other

Details of Adverse Event: .....

(please attach copies of .....

relevant reports) .....

.....

.....

Did the event require or prolong hospitalisation? Yes ☐ No ☐

If yes, how long? Which ward? .....

Do you consider the event to be treatment-related? Yes ☐ No ☐

If yes, why?

.....

Name of Person Reporting: (please print) _____

Telephone Number: ..... Today's Date: .....
