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Doctor
Practice
Street
City
Postcode
Date

NAME ..... DATE RANDOMISED .....

DATE OF BIRTH ..... PLUTO NUMBER ☐☐☐☐

HOSPITAL NUMBER .....

Dear Dr *gp*

Your patient, named above, has agreed to take part in PLUTO, a randomised controlled trial and registry comparing intra-uterine vesico-amniotic shunting in the treatment of congenital bladder outflow obstruction. This is a UK multi-centre trial organised by the University of Birmingham Clinical Trials Unit and funded by the Wellbeing of Women charity and Health Technology Assessment Programme. PLUTO is a large, simple, "real-life" trial that aims to determine reliably whether vesico-amniotic shunt insertion is more, or less, effective than conservative management. The trial is designed to fit in with routine practice as far as possible and to impose minimal additional workload.

The above patient has consented to the PLUTO Trial and has been randomly allocated to:

Shunt insertion ☐

Conservative management ☐

The above patient has not been randomised but has agreed to be placed on the PLUTO Registry. The elective treatment is:

Shunt insertion ☐

Conservative Management ☐

The local co-ordinator for the trial is Dr *participant*, Department of Fetal Medicine, *hospital*. The trial has been approved by Nottingham Research Ethics Committee and *region* Local Research Ethics Committee.

If you require any further information about the Trial and Registry, it can be obtained from the PLUTO trial co-ordinator (see address below).

Please file this letter in the patient's notes. I would appreciate being notified if she is no longer one of your patients.

Yours sincerely

Local co-ordinator

PLUTO Trial Office, The University of Birmingham Clinical Trials Unit, FREEPOST RRKR-JUZR-HZHG,
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