a)

Participant study number (Screening no/randomisation no)

Dear Ms (Surname)

I am writing to thank you for your participation in the OPPTIMUM study and to share the findings with you.

As you may remember, the study was designed to find out whether giving Progesterone to women between 22-24 weeks and up to 34 weeks of gestation improves outcome in women at high risk of preterm delivery. The outcomes we were interested in were the number of weeks of pregnancy at delivery and the wellbeing of the baby from birth to the age of two. We spoke to 15,132 women and 6,408 women agreed to be tested and randomised 1,228 women into the study treatment of whom you were one. We are grateful for your participation.

Following analysis of the data, we found that progesterone had no significant effect on the timing of delivery or on the health of the child at birth; nor on the results of the "Bayley" developmental assessment that was done at around 2 years of age of the child. In this large study, vaginal progesterone did not reduce the risk of preterm birth or improve the risk of complex neonatal outcomes. There was no long term benefit or harm on outcomes in children at two years of age.

These findings are very useful. The study helps us to plan how best to care for pregnant women at high risk of preterm birth and we will be able to give future women at risk much more information about the effects of progesterone.

If you would like a full copy of the study report, or if you would like to know which treatment you were allocated, please contact the clinical trials team using the slip enclosed OR please call the Clinical Trials Office on 0131-242-2696. Alternatively you can email Opptimum.study@ed.ac.uk.

We are extremely grateful to you for participating in this important research. Please do not hesitate to contact me at Opptimum.study@ed.ac.uk, or your local study team, if you have any questions about the results of the study.

We hope to be able to keep in contact with you to invite you, or your baby, to participate in future research. If you do not wish to be contacted again, please let us know at Opptimum.study@ed.ac.uk or telephone 131-242-2696.

With best wishes

[redacted]

Professor Jane Norman, on behalf of the OPPTIMUM study team

The OPPTIMUM study was funded by the Efficacy and Mechanism Evaluation (EME) Programme, an MRC and NIHR partnership (Reference number: 84982 - 09/800/27). The EME Programme is funded by the MRC and NIHR, with contributions from the CSO in Scotland and NISCHR in Wales.

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Progesterone prophylaxis to prevent pre-term labour

REPLY SLIP

NAME: Name

STUDY NUMBER: (Screening no/randomisation no)

I WOULD LIKE TO KNOW MY TREATMENT ALLOCATION – YES / NO

I WOULD LIKE TO HAVE A COPY OF THE FULL STUDY RESULTS - YES/NO

I AM HAPPY FOR YOU TO CONTACT ME AGAIN - YES/ NO

MY CURRENT ADDRESS IS:

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……

MY CURRENT PHONE NUMBER IS:

Landline
……..

Mobile
……

MY CURRENT EMAIL ADDRESS IS:
……

b)

THE UNIVERSITY of EDINBURGH

MRC Centre for Reproductive Health

Opptimum
Progesterone prophylaxis to prevent pre-term labour

NHS
National Institute for Health Research

Participant study number:Screening/randomisation Dear Ms (Name)

I am writing to thank you for your valued participation in the OPPTIMUM study, to share the findings with you and to offer my sincere condolences on the loss of your baby.

As you may remember, the study was designed to find out whether giving Progesterone to women between 22-24 weeks and up to 34 weeks of gestation improves outcome in women at high risk of preterm delivery. The outcomes we were interested in were the number of weeks of pregnancy at delivery and the wellbeing of the baby from birth to the age of two. We spoke to 15,132 women and 6,408 women agreed to be tested. We randomised 1,228 women into the study treatment of whom you were one. We are grateful for your participation.

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With best wishes

[redacted]

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Progesterone prophylaxis to prevent pre-term labour

REPLY SLIP

NAME: (Name)

STUDY NUMBER: Screening/randomisation

I WOULD LIKE TO KNOW MY TREATMENT ALLOCATION – YES / NO

I WOULD LIKE TO HAVE A COPY OF THE FULL STUDY RESULTS - YES/NO

MY CURRENT ADDRESS IS:

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……

……

c)

THE UNIVERSITY of EDINBURGH

MRC Centre for Reproductive Health

Opptimum
Progesterone prophylaxis to prevent pre-term labour

NHS
National Institute for Health Research

Participant number:

Dear (Participant name),

Thank you for supporting the OPPTIMUM trial and for your enquiry about your treatment allocation.

You were allocated to treatment with PROGESTERONE/PLACEBO.

If you have any questions about the treatment you received, please contact your local study team (Site name and contact details) who will be happy to help you.

With best wishes

Prof Jane Norman on behalf of the OPPTIMUM study team

[redacted]

cc. Local investigator name and contact details

The OPPTIMUM study was funded by the (reference number 08/246/09). The views expressed in this letter are those of the authors and not necessarily those of the MRC, NHS, NIHR or the Department of Health.