a)

Scotland A Research Ethics Committee

Secretariat
Deaconess House
[redacted]

NHS SCOTLAND

Professor J E Norman
Regius Professor of Obstetrics and Gynaecology
University of Glasgow
Section of Reproductive and Maternal Medicine
Queen Elizabeth Building
Glasgow Royal Infirmary
10 Alexandra Parade
Glasgow G31 2ER

Date: 19 February 2008
Your Ref.:
Our Ref.: 08/MRE00/6

Enquiries to: Walter Hunter
Extension: 89026
Direct Line:
Email: [redacted]

[redacted]

Dear Professor Norman

Study title: **Does progesterone prophylaxis to prevent preterm labour improve outcome? - A randomised double blind placebo controlled trial**

REC reference: **08/MRE00/6**

EudraCT number: **2007-007950-77**

Thank you for your letter of 1 February 2008, responding to the Committee's request for further information on the above research. The further information has been considered on behalf of the Committee by their Scientific Officer including the revised participant information sheet and consent form.

Ethical opinion

The Scientific Officer is satisfied that you have satisfactorily responded to the issue raised by the Committee.

Approved documents

The updated documents reviewed and approved are:

Document	Version	Date
Application Form Parts A and B		04 January 2008
Investigator CV		03 January 2008

Protocol	1	01 January 2008
Covering Letter		03 January 2008
Summary/Synopsis	1	01 January 2008
Letter from Sponsor		26 January 2007
GP/Consultant Information Sheets	1	01 January 2008
Participant Information Sheet: Fibronectin Testing	2.0	01 February 2008
Participant Information Sheet: Main	2.0	01 February 2008
Participant Consent Form: Fibronectin Testing	2	01 February 2008
Participant Consent Form: Main	2.	01 February 2008
Letter from Funding Body		10 December 2007

Research governance approval

The study should not commence at any NHS site until the local Principal Investigator has obtained final research governance approval from the R&D Department for the relevant NHS care organisation.

All researchers and research collaborators who will be participating in the research must obtain research governance approval from the relevant care organisation before commencing any research procedures. Where a substantive contract is not held with the care organisation, it may be necessary for an honorary contract to be issued before approval for the research can be given.

Statement of compliance

The Committee is recognised by the United Kingdom Ethics Committee Authority under the Medicines for Human Use (Clinical Trials) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.

The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

NHS
SCOTLAND

REC reference number: 08/MRE00/6-Please quote this number on all correspondence

Yours sincerely

[redacted]

WALTER HUNTER
Committee Co-ordinator
cc: Dr Fiona Graham *Clinical Trials Unit, MHRA*

[redacted]

b)

Scotland A Research Ethics Committee

Research Ethics Service
[redacted]

21 October 2013

Professor Jane Norman
[redacted]

Dear Prof Norman

Study title:	**Does progesterone prophylaxis to preventpreterm labour improve outcome? - a randomised double blind placebo controlled trial**
REC reference:	**08/MRE00/6**
EudraCT number:	**2007-007950-77**
Amendment number:	**No 21 (REC REF AM33)**
Amendment date:	**04 October 2013**

The above amendment was reviewed held in correspondence by the Sub-Committee.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Covering Letter		04 October 2013
European Commission Notification of Substantial Amendment Form		04 October 2013
Letter to woman from sites	V1	30 September 2013
Expenses Letter at 2 years	V1	26 September 2013
Protocol with and without tracked changes	V15	04 October 2013

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

This Committee is recognised by the United Kingdom Ethics Committee Authority under the Medicines for Human Use (Clinical Trials) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.

The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

08/MRE00/6:	***Please quote this number on all correspondence***

Yours sincerely

[redacted]

Dr Colin Selby
Committee Vice Chair

Copy to: *Lorraine Adamson*
Marise Bucukoglu, University of Edinburgh

Scotland A REC

Attendance at Sub-Committee
of the REC meeting

Name	Profession	Capacity
Dr Anthony Pottage	Retired Physician/Clinical Pharmacologist	Expert
Dr Colin Selby	Consultant Physician	Expert
Mrs Margaret Thomson	Retired	Lay Plus

Also in attendance:

Name	Position (or reason for attending)
Dr Alex Bailey	Scientific Officer
Mrs Dorothy Garrow	Sub-Committee Coordinator

c)

Safeguarding public health

MHRA

DR J NORMAN
[redacted]

18/03/2008

Dear DR J NORMAN

THE MEDICINES FOR HUMAN USE (CLINICAL TRIALS) REGULATIONS 2004 S.I. 2004/1031

Our Reference:	22931/0009/001-0001
Eudract Number:	2007-007950-77
Product:	UTROGESTAN CAPSULES 200MG
Protocol number:	OPPTIMUM

NOTICE OF ACCEPTANCE OF AMENDED REQUEST

I am writing to inform you that the Licensing Authority accepts your amended request for a clinical trial authorisation (CTA), received on 13/03/2008.

Authorisation of your clinical trial is subject to the following condition(s):
* The labelling will remain legible at the size intended for use.
If these conditions are met, the trial is authorised and you do not need to respond to this letter. If your trial does not meet these conditions, your trial does not have authorisation and therefore you can not proceed with the trial. You must inform the MHRA immediately if the trial does not meet the above conditions. All changes to the terms and conditions of this trial must be made as a request for a substantial amendment to this clinical trial authorisation.

The authorisation is effective from the date of this letter although your trial may be suspended or terminated at any time by the Licensing Authority in accordance with regulation 31. You must notify the Licensing Authority within 90 days of the trial ending.

Finally, you are reminded that a favourable opinion from the Ethics Committee is also required before this trial can proceed; changes made as part of your amended request may need to be notified to the Ethics Committee.

Yours sincerely,

Clinical Trials Unit
MHRA

[redacted]