



Health Research Authority

South West - Cornwall & Plymouth Research Ethics Committee

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Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

20 March 2019 Revised 24 May 2019

Professor Siobhan Quenby
Professor of Obstetrics
University Hospitals Coventry and Warwickshire NHS Trust
Clifford Bridge Road, Coventry
CV2 2DX

Dear Professor Quenby

Study title:	Induction of labour for predicted macrosomia
REC reference:	18/SW/0039
Amendment number:	AM05 28th February 2019
Amendment date:	28 February 2019
IRAS project ID:	229163

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

Amendment Summary

This amendment sought approval to modify the PIS about the chances for women predicted to have a large baby to actually deliver a baby over 90th centile.

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 on headed paper		11 March 2019
Notice of Substantial Amendment (non-CTIMP)	AM05 28th February 2019	28 February 2019
Participant information sheet (PIS)	6.0	28 February 2019

Membership of the Committee

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

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Statement of compliance

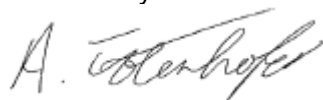
The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: <https://www.hra.nhs.uk/planning-and-improving-research/learning/>

18/SW/0039:	Please quote this number on all correspondence
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Yours sincerely



Signed on behalf of:

Dr Stephen Coles
Chair

E-mail: nrescommittee.southwest-cornwall-plymouth@nhs.net

Enclosures: *List of names and professions of members who took part in the review*

Copy to:



South West - Cornwall & Plymouth Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 21 March 2019

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mrs Isobel Brooks	Retired Social Care Manager	Yes	
Dr Stephen Coles	Consultant	Yes	

