

South West - Cornwall & Plymouth Research Ethics Committee

Level 3
Block B
Whitefriars
Lewins Mead
Bristol
BS1 2NT

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.

25 June 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:	AM06
Amendment date:	28 May 2019
IRAS project ID:	229163

The above amendment was reviewed on 24 June 2019 by the Sub-Committee in correspondence.

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.

No ethical issues were raised

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Copies of advertisement materials for research participants [Big Baby Clinician Poster V1.0 15May19]	1.0	15 May 2019
Copies of advertisement materials for research participants [Big Baby Poster 1 V1.0 15May19]	1.0	15 May 2019
Covering letter on headed paper [Big Baby Questionnaire Cover Letter V1.0 13May2019]	1.0	13 May 2019
Covering letter on headed paper		29 May 2019
Non-validated questionnaire [Big Baby Follow-up Questionnaire messages V1.0 16 May 2019]	1.0	16 May 2019
Notice of Substantial Amendment (non-CTIMP)	AM06	28 May 2019
Participant information sheet (PIS) [Big Baby Tracked Trifold information leaflet V2.0 13May 2019]	2.0	13 May 2019
Research protocol or project proposal [Big Baby tracked Protocol V6.0 16May2019]	6.0	16 May 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,



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

South West - Cornwall & Plymouth Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 24 June 2019

Committee Members:

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

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Rebecca Morledge	Approvals Officer