



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 April 2020

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: AM07
Amendment date: 18 February 2020
IRAS project ID: 229163

The above amendment was reviewed 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.

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
GP/consultant information sheets or letters [Obstetrician Information Sheet: Making Decisions About How to Deliver Big Babies]	1.0	04 February 2020
GP/consultant information sheets or letters [Obstetrician	1.0	04 February 2020

Confirmation Form: Making Decisions About How to Deliver Big Babies]		
Interview schedules or topic guides for participants [Patient Topic Guide - Making Decisions about how to Deliver Big Babies]	1.0	04 February 2020
Non-validated questionnaire [Big Baby Six month telephone follow-up]	1.0	28 January 2019
Non-validated questionnaire [Big Baby Two month telephone follow-up]	1.0	28 January 2019
Notice of Substantial Amendment (non-CTIMP)	AM07	18 February 2020
Other [Cover letter of submitted documents]		18 February 2020
Other [Obstetrician Interview Consent Form: Making Decisions About how to Deliver Big Babies]	1.0	31 January 2020
Other [Obstetrician Topic Guide - Making Decisions About how to Deliver Big Babies]	1.0	04 February 2020
Participant consent form [Patient Consent Form]	1.0	04 February 2020
Participant consent form [Patient consent form for details to pass to researcher]	1.0	04 February 2020
Participant information sheet (PIS) [Participant Information Sheet for the Big Baby Trial (tracked)]	7.0	10 February 2020
Participant information sheet (PIS) [Patient Information Sheet - Making Decisions About how to Deliver Big Babies]	1.0	04 February 2020
Participant information sheet (PIS) [Participant Information Sheet for the Big Baby Trial (clean)]	7.0	10 February 2020
Research protocol or project proposal [Big Baby Trial Protocol (tracked)]	7.0	10 February 2020
Research protocol or project proposal [Sub-study Protocol - Making Decisions about how to Deliver Big Babies]	1.0	04 February 2020
Research protocol or project proposal [Big Baby Trial Protocol (clean)]	7.0	10 February 2020

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.

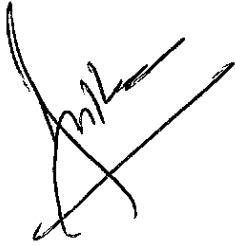
HRA Learning

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

Yours sincerely

A handwritten signature in black ink, appearing to be 'S. Coles', written over a large, light-colored 'X' mark.

pp Dr Stephen Coles
Chair

E-mail: cornwallandplymouth.rec@hra.nhs.uk

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 in correspondence

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Stephen Coles	Consultant	Yes	
Dr Kass Gibson	Lecturer	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Mr Rajat Khullar	