

South West - Exeter Research Ethics Committee

Whitefriars
Level 3
Block B
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.

15 May 2018

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

Dear Prof Quenby

Study title: Induction of labour for predicted macrosomia
REC reference: 18/SW/0039
Amendment number: AM01
Amendment date: 17 April 2018
IRAS project ID: 229163

The above amendment was reviewed at the meeting of the Sub-Committee held in May 2018 by the Sub-Committee in correspondence.

Summary of amendment

This study sought approval for the following:

1. Addition of non-validated questionnaires
2. Changes in the inclusion criteria and other substantial changes had been made to the protocol
3. Wording had been modified for clarification in the protocol and participant facing documents.

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>
Non-validated questionnaire [Baseline Questionnaire Big Baby CRF]	1.0	12 April 2018
Non-validated questionnaire [six month questionnaire A]	1.0	12 April 2018
Non-validated questionnaire [six month questionnaire B]	1.0	12 April 2018
Non-validated questionnaire [two month questionnaire A]	1.0	12 April 2018
Non-validated questionnaire [two month questionnaire B]	1.0	12 April 2018
Notice of Substantial Amendment (non-CTIMP)	AM01	17 April 2018
Other [Process evaluation - Interviews clinicians]	2.0	12 April 2018
Other [Process evaluation - RCT interviews]	2.0	12 April 2018
Participant consent form [Cohort]	2.0	12 April 2018
Participant consent form [RCT Consent Form Crystal Mark]	2.0	12 April 2018
Participant information sheet (PIS) [Interview Study - Main Trial]	2.0	12 April 2018
Participant information sheet (PIS) [Interview Study -Pilot]	2.0	12 April 2018
Participant information sheet (PIS) [PIS Site Investigator interviews]	2.0	12 April 2018
Participant information sheet (PIS)	2.0	12 April 2018
Research protocol or project proposal [Big Baby Protocol]	2.0	12 April 2018

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.

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

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

P.P. Denise Sheehan

Dr Denise Sheehan

Chair

E-mail: nrescommittee.southwest-exeter@nhs.net

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

Copy to: Mrs Ceri Jones, University Hospitals Coventry & Warwickshire

South West - Exeter Research Ethics Committee

Attendance at Sub-Committee of the REC meeting in May 2018

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mrs Joan Ramsay	Retired Associate Director of Nursing (Women and Children)	Yes	
Dr Denise Sheehan	Consultant Oncologist	Yes	