

**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.**

09 October 2018

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:** AM02  
**Amendment date:** 18 September 2018  
**IRAS project ID:** 229163

The above amendment was reviewed at the meeting of the Sub-Committee held on 30 September 2018 by the Sub-Committee in correspondence.

**Summary**

This amendment sought approval for the following:

1. Change the inclusion criteria
2. Provide further safety information to participants
3. Addition of Non-HRA-Standard GDPR wording
4. Other non-substantial wording had been added to some documents for clarification purposes.

**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>
Copies of advertisement materials for research participants [Poster ]	2.0	22 August 2018
Notice of Substantial Amendment (non-CTIMP)		18 September 2018
Participant consent form [ Cohort ]	3.0	22 August 2018
Participant consent form [Participant interviews ]	2.0	22 August 2018
Participant consent form [Site investigator team interviews ]	2.0	22 August 2018
Participant consent form [RCT Crystal Mark]	3.0	22 August 2018
Participant information sheet (PIS) [ Interview Study - Main Trial]	3.0	22 August 2018
Participant information sheet (PIS) [ Interview Study -Pilot- Partner ]	2.0	22 August 2018
Participant information sheet (PIS) [Interview Study -Pilot]	3.0	22 August 2018
Participant information sheet (PIS) [Site Investigator interviews ]	3.0	22 August 2018
Participant information sheet (PIS)	3.0	22 August 2018
Research protocol or project proposal [Protocol]	3.0	22 August 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/>

<b>18/SW/0039:</b>	<b>Please quote this number on all correspondence</b>
--------------------	---

Yours sincerely



**Ian Ainsworth-Smith**

**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 on 30 September 2018

#### Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Ian Ainsworth-Smith	Lay Plus	Yes	
Mr Robert Wosley	Deputy Service Line Cluster Manager	Yes	

#### Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Ms Lidia Gonzalez	REC Assistant