

**South West - Cornwall & Plymouth Research Ethics Committee**

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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.**

27 November 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:** AM03  
**Amendment date:** 01 November 2018  
**IRAS project ID:** 229163

The above amendment was reviewed at the meeting of the Sub-Committee held on 25 November 2018 by the Sub-Committee in correspondence.

### **Summary**

This amendment sought to correct information on risk of shoulder dystocia in women with big babies as it had been previously underestimated in the PIS. The rectification would provide an opportunity for women currently recruited to decide whether they wish to continue in the trial or not.

### **Discussion**

The Sub-Committee was advised that this NOSA covered the new information being given to new participants and the information given to those currently pregnant and re-consented as part of the Urgent Safety Measure.

Whilst The Chief Investigator and Sponsor requested the RECs opinion about the most ethical way of contacting the group of women who had already given birth and whose children had documented dystocia, it was made clear that this was not part of this amendment.

It was therefore agreed the discussion with the CI would be about this specific point and could be done at a different time, whether by teleconference with a few members or at full REC as an agenda item prior to the second NOSA being submitted. The REC would also seek paediatricians opinion on this if deemed necessary.

### **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>
Covering letter on headed paper		01 November 2018
Notice of Substantial Amendment (non-CTIMP)		01 November 2018
Participant information sheet (PIS)	4.0	30 October 2018
Research protocol or project proposal [Protocol]	4.0	30 October 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>
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Yours sincerely



**Mr Robert Wosley**  
**Alternate Vice Chair**

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

18/SW/0039/AM12

*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 - Cornwall & Plymouth Research Ethics Committee****Attendance at Sub-Committee of the REC meeting on 25 November 2018****Committee Members:**

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Professor Ann Demaine	Specialist Register for Diabetes and Endocrinology	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