NHS
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.

15 January 2019

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:	**4**
Amendment date:	**17 December 2018**
IRAS project ID:	**229163**

The above amendment was reviewed at the meeting of the Sub-Committee held on 09 January 2019 by the Sub-Committee in correspondence.

Summary

This amendment sought approval for the changes as it follows:

A. The protocol:

1. Risk tables amended
2. Eligibility to be confirmed by a medically qualified doctor delegated to do so.
3. Trial database will now be developed by Warwick clinical trials unit.

4. When the obstetrician cannot provide written obstetric confirmation prior to randomisation has been explained.
5. Participants will be contacted to chase core missing data items.
6. Minor clarifications and typographical errors corrected.

B. The PIS has been amended to clarify and improve flow of information.

C. Update to the urgent safely measure notified to the REC as part of SA03: a copy of the shoulder dystocia risk letter has been submitted.

Discussion

Whilst reviewing this amendment the Sub-Committee found a couple of issues that needed clarification:

1. It was noted there was a letter to previous participants about miss-quoting of risk levels. It was agreed this letter could cause distress to potential participants. The Sub-Committee requested further clarification on how would this letter be used and how wold you avoid causing undue concerns.

   Researchers explained that the trial management committee considered this issue carefully and discussed this at length with obstetricians, legal and ethical experts and also patient representatives, weighing up our responsibility to inform women of this misinformation or whether this may cause unnecessary concern.

   With regard to women who had already delivered, the trial management felt they should be transparent and have a responsibility to inform them. They propose that women could be contacted by telephone and a letter sent if the patient accepts this. The PI at each site would be contacted and asked about contacting their patients and whether they would do this or whether they would be happy for the CI to contact them. Approach by telephone was the preferred option to mitigate distress so that this can be explained to women in a personal and sensitive manner.

   They carried on explaining that, if the women were distressed on the call, whether by the discussion of risk levels or for other post-natal issues then face-to-face appointments with appropriate professionals will be made.

   The letter was developed to use as appropriate by the site PI or CI or should women wish to have written information (with provision of the updated PIS) following the telephone conversation, or for those we are unable to contact by phone."

2. It was also noted the amendment sought to contact participants to chase missing data. It was agreed this should be added to the PIS and Consent Form more specific information on it e.g. '*once the study is complete we will review your data and if we find we are missing data we will contact you once/as many times it is needed, etc.'*

   Researchers submitted an updated PIS which included a statement informing women they will contact them should there be any important information missing from their questionnaire.

With regards to reflecting this in the consent form they felt that it had already been covered in the point:'I agree to the trial team holding contact details for me (address, email address, phone numbers) so the trial team can send me reminders and follow-up questionnaires, or contact me if they need me to explain anything in the follow-up questionnaires and to ask about my and my baby's health'.

The Sub-Committee was content with the responses

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:

Document	*Version*	*Date*
Covering letter on headed paper		19 December 2018
Notice of Substantial Amendment (non-CTIMP)	4	17 December 2018
Other [Big Baby - Shoulder Dystocia Risk Lette]	1	19 December 2018
Participant information sheet (PIS) [PIS]	5.1	09 January 2019
Research protocol or project proposal	5	19 December 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**

Yours sincerely

p.p.

Mr Robert Wosley
Chair
E-mail: nrescommittee.southwest-cornwall-plymouth@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 - Cornwall & Plymouth Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 9 January 2019

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Rachel Clarke	Clinical Psychologist	Yes	
Mr Robert Wosley	Deputy Service Line Cluster Manager	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Ms Lidia Gonzalez	REC Assistant