

South West - Cornwall & Plymouth Research Ethics Committee

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Tel: 0207 104 8019

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.

18 May 2021

Dear Research Team

Study title: Induction of labour for predicted macrosomia
REC reference: 18/SW/0039
Amendment number: SA 09
Amendment date: 28.04.2021
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> |
|--|----------------|---------------|
| Completed Amendment Tool [Amendment Tool SA 09] | 1.0 | 28 April 2021 |
| Covering letter on headed paper [Covering Letter] | 1.0 | 28 April 2021 |
| Letters of invitation to participant [Big Baby 2UP invitation letter (Chief Investigator)] | 1.0 | 01 April 2021 |
| Letters of invitation to participant [Big Baby 2UP invitation letter (Erb's Palsy Group) 24 month follow-up] | 1.0 | 01 April 2021 |
| Letters of invitation to participant [Big Baby 24 Month Follow-up] | 1.0 | 01 April 2021 |

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|---|-----|-----------------|
| Invitation e-mail] | | |
| Non-validated questionnaire [Big Baby Combined Two and Six Month Follow-up Questionnaire A (Mother and Baby)] | 1.0 | 20 January 2021 |
| Non-validated questionnaire [Big Baby 24 Month Follow-up Questionnaire] | 1.0 | 16 April 2021 |
| Non-validated questionnaire [Big Baby Combined Two and Six Month Follow-up Questionnaire B (mother)] | 1.0 | 20 January 2021 |
| Non-validated questionnaire [Big Baby Combined Two and Six Month Telephone Follow-up Questionnaire A (Mother and Baby)] | 1.0 | 20 January 2021 |
| Participant information sheet (PIS) [Big Baby 2UP Participant Information Sheet] | 1.0 | 01 April 2021 |
| Participant information sheet (PIS) [Big Baby Participant Information Sheet] | 8.0 | 13 April 2021 |
| Participant information sheet (PIS) [Big baby Participant Information Sheet - Tracked] | 8.0 | 13 April 2021 |
| Research protocol or project proposal [Big Baby Protocol - Tracked] | 9.0 | 13 April 2021 |
| Research protocol or project proposal [Big Baby Protocol] | 9.0 | 13 April 2021 |

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.

Amendments related to COVID-19

We will update your research summary for the above study on the research summaries section of our website. During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you have not already done so, please register your study on a public registry as soon as possible and provide the HRA with the registration detail, which will be posted alongside other information relating to your project.

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/>

IRAS Project ID - 229163:

Please quote this number on all correspondence

Yours sincerely

A handwritten signature in black ink, appearing to be 'R. P. L.', written in a cursive style.

Chair

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

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

Copy to: Professor Siobhan Quenby, University Hospitals Coventry and Warwickshire NHS Trust

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Attendance at Sub-Committee of the REC meeting on 12 May 2021

Committee Members:

| <i>Name</i> | <i>Profession</i> | <i>Present</i> | <i>Notes</i> |
|---------------------------|--|----------------|--------------|
| Mrs Suzanne Lesley Blowey | Consultant Nurse Chronic Pain | Yes | |
| Professor Ann Demaine | Specialist Register for Diabetes and Endocrinology | Yes | |