

**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.**

24 August 2020

Dear Research Team

**Study title:** Induction of labour for predicted macrosomia  
**REC reference:** 18/SW/0039  
**Amendment number:** SA08  
**Amendment date:** 31.07.2020  
**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 [229163 SA08 Amendment Tool	1.0	31 July 2020

Ooutput]		
Covering letter on headed paper [Big Baby Questionnaire B Cover Letter]	1.0	12 May 2020
Covering letter on headed paper [*Big Baby Remote Informed Consent Confirmation Cover Letter]	1.0	30 July 2020
Covering letter on headed paper [Big Baby Remote Informed Consent Cover letter]	1.0	24 July 2020
Covering letter on headed paper [Covering Letter]	1.0	31 July 2020
GP/consultant information sheets or letters [Big Baby GP notification letter]	2.0	06 May 2020
GP/consultant information sheets or letters [Big Baby GP notification letter – tracked]	2.0	06 May 2020
Other [Big Baby Remote Informed Consent email]	1.0	24 July 2020
Other [Big Baby Remote Informed Consent Confirmation email]	1.0	30 July 2020
Participant consent form [Big Baby RCT Verbal Consent Form]	1.0	17 July 2020
Participant consent form [Big Baby RCT Consent Form]	3.2	17 July 2020
Participant consent form [Big Baby Cohort Verbal Consent Form]	1.0	17 July 2020
Participant consent form [Big Baby Cohort Consent Form Scottish Sites]	3.2	17 July 2020
Participant consent form [*Big Baby Cohort Verbal Consent Form Scottish Sites]	1.0	17 July 2020
Participant consent form [Big Baby Cohort Consent Form]	3.2	17 July 2020
Participant consent form [Big Baby RCT Verbal Consent Form Scottish Sites]	1.0	17 July 2020
Participant consent form [Big Baby RCT Consent Form Scottish Sites]	3.2	17 July 2020
Participant consent form [Big Baby RCT Consent Form - tracked]	3.2	17 July 2020
Participant consent form [Big Baby RCT Consent Form Scottish Sites- tracked]	3.2	17 July 2020
Participant consent form [Big Baby Cohort Consent Form Scottish Sites - tracked]	3.2	17 July 2020
Participant consent form [Big Baby Cohort Consent Form - tracked]	3.2	17 July 2020
Participant information sheet (PIS) [Big Baby Participant Information Sheet]	7.1	17 July 2020
Participant information sheet (PIS) [Big Baby Participant Information Sheet - tracked]	7.1	17 July 2020
Research protocol or project proposal [Big Baby Protocol]	8.0	17 July 2020
Research protocol or project proposal [Big Baby Protocol-tracked]	8.0	17 July 2020

### 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



**Dr Stephen Coles**  
**Chair**

E-mail: [cornwallandplymouth.rec@hra.nhs.uk](mailto: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 August 2020**

**Committee Members:**

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Stephen Coles	Consultant	Yes	Chair
Professor Ann Demaine	Specialist Register for Diabetes and Endocrinology	Yes	