

South West - Cornwall & Plymouth Research Ethics Committee

2 Redman Place
Stratford
London
E20 1JQ

05 June 2023

Dear Claire

Study title: Induction of labour for predicted macrosomia
REC reference: 18/SW/0039
Amendment number: SA 13
Amendment date: 09 May 2023
IRAS project ID: 229163

The above amendment was reviewed at the meeting of the Sub-Committee held on 31 May 2023 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 [Big baby Amendment Tool_SA 13]	1	09 May 2023
Covering letter on headed paper [Covering Letter]	1	16 May 2023
Research protocol or project proposal [Big Baby Tracked Protocol]	13	21 April 2023
Research protocol or project proposal [Big Baby Protocol]	13	21 April 2023

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



**pp Dr Stephen Coles
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

South West - Cornwall & Plymouth Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 31 May 2023

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Stephen Coles	Retired	Yes	
Mr Stephen Draper	Retired Head Teacher	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Sadi Cisse	Approvals Administrator