

South West - Cornwall & Plymouth Research Ethics Committee

Ground Floor
Temple Quay House
2 The Square
Bristol
BS1 6PN

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 February 2022

Dear Siobhan Quenby

Study title: Induction of labour for predicted macrosomia
REC reference: 18/SW/0039
Amendment number: SA 10
Amendment date: 08 February 2022
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_SA10 Amendment Tool]	1	08 February 2022
Covering letter on headed paper [Covering Letter]	1.0	08 February 2022
GP/consultant information sheets or letters [Big Baby GP letter (tracked)]	3	24 January 2022
GP/consultant information sheets or letters [Big Baby GP letter]	3	24 January 2022

Participant information sheet (PIS) [Big Baby Tri-fold leaflet (tracked)]	3	24 January 2022
Participant information sheet (PIS) [Big Baby Tri-fold leaflet]	3	24 January 2022
Participant information sheet (PIS) [Big Baby Participant Information Sheet]	9	28 January 2022
Participant information sheet (PIS) [Big Baby Participant Information Sheet (tracked)]	9	28 January 2022
Research protocol or project proposal [Big Baby Protocol]	10	31 January 2022
Research protocol or project proposal [Big Baby Protocol (tracked)]	10	31 January 2022

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
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Yours sincerely



Vice Chair

Dr Kass Gibson

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 23 February 2022

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Kass Gibson	Lecturer	Yes	
Professor Stephen Lewis	Consultant Gastroenterologist	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Ms Zainab Tauqeer	REC Assistant