

**Partner Organisations:**

Health Research Authority, England  
 NHS Research Scotland  
 HSC Research & Development, Public Health Agency, Northern Ireland

NIHR Clinical Research Network, England  
 NISCHR Permissions Co-ordinating Unit, Wales

## Notification of Non-Substantial/Minor Amendments(s) for NHS Studies

This template **must only** be used to notify NHS/HSC R&D office(s) of amendments, which are **NOT** categorised as Substantial Amendments.

**If you need to notify a Substantial Amendment to your study then you MUST use the appropriate Substantial Amendment form in IRAS.**

### Instructions for using this template

- For guidance on amendments refer to <http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/>
- This template should be completed by the CI and optionally authorised by Sponsor, if required by sponsor guidelines.
- This form should be submitted according to the instructions provided for NHS/HSC R&D at <http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/which-review-bodies-need-to-approve-or-be-notified-of-which-types-of-amendments/> . If you do not submit your notification in accordance with these instructions then processing of your submission may be significantly delayed.

### 1. Study Information

<b>Full title of study:</b>	Induction of labour for predicted macrosomia 'The Big Baby Trial'
<b>IRAS Project ID:</b>	229163
<b>Sponsor Amendment Notification number:</b>	Non-Substantial Amendment 27
<b>Sponsor Amendment Notification date:</b>	30/03/2020
<b>Details of Chief Investigator:</b>	
Name [first name and surname]	Professor Siobhan Quenby
Address:	University Hospitals Coventry and Warwickshire NHS Trust, Clifford Bridge Road, Coventry.
Postcode:	CV2 2DX
Contact telephone number:	07873416716
Email address:	s.quenby@warwick.ac.uk
<b>Details of Lead Sponsor:</b>	
Name:	University Hospitals Coventry and Warwickshire
Contact email address:	R&DSponsorship@uhcw.nhs.uk
<b>Details of Lead Nation:</b>	
Name of lead nation <i>delete as appropriate</i>	England
If England led is the study going through CSP? <i>delete as appropriate</i>	N/A
<b>Name of lead R&amp;D office:</b>	University Hospitals Coventry and Warwickshire NHS Trust

**Partner Organisations:**  
 Health Research Authority, England  
 NHS Research Scotland  
 HSC Research & Development, Public Health Agency, Northern Ireland  
 NIHR Clinical Research Network, England  
 NISCHR Permissions Co-ordinating Unit, Wales

**2. Summary of amendments)**

This template must only be used to notify NHS/HSC R&D office(s) of amendments, which are NOT categorised as Substantial Amendments.  
 If you need to notify a Substantial Amendment to your study then you MUST use the appropriate Substantial Amendment form in IRAS.

No.	Brief description of amendment <i>(please enter each separate amendment in a new row)</i>	Amendment applies to <i>(delete/ list as appropriate)</i>		List relevant supporting document(s), <i>(please ensure all referenced supporting documents are submitted with this form)</i>	Version	R&D category of amendment <i>(category A, B, C) For office use only</i>
		Nation	Sites			
1	<p>Due to the Covid-19 epidemic, restrictions at Warwick Clinical Trials Unit mean that the staff are all working from home. As such staff are unable to send out paper questionnaires to participants in the Big Baby Trial at two- and six months post delivery as specified in the protocol.</p> <p>In order to continue collecting follow-up data, we are asking permission to contact the participants by telephone, in the first instance because of the covid outbreak; and will attempt to collect a reduced dataset by telephone, using a dedicated work mobile telephone.</p> <p>The reduced dataset Questionnaires were submitted as a substantial amendment on 27 February 2020 as part of Substantial Amendment 07.</p> <p>We may contact the women by text prior to ringing them up to warn them of a future phone call from a previously unknown number.</p> <p>If we are unable to contact them by telephone after 3 attempts, we will not telephone them again, but will send out a questionnaire by post once we return to the office, we will chase non-returned postal</p>	<p>England</p> <p>Scotland</p> <p>Wales</p>	<p>All sites or list affected sites</p> <p>All sites or list affected sites</p> <p>All sites or list affected sites</p>	N/A		

**Partner Organisations:**

Health Research Authority, England

NHS Research Scotland

HSC Research & Development, Public Health Agency, Northern Ireland

NIHR Clinical Research Network, England

NISCHR Permissions Co-ordinating Unit, Wales

questionnaires after 2 weeks and 4 weeks by sending reminder texts (text message is already approved by ethics). We realise that the data will be collected outside the preferred timeframe, but feel that we should make all reasonable effort to obtain these data.					
--	--	--	--	--	--

**Partner Organisations:**

Health Research Authority, England

NHS Research Scotland

HSC Research & Development, Public Health Agency, Northern Ireland

NIHR Clinical Research Network, England

NISCHR Permissions Co-ordinating Unit, Wales

**3. Declaration(s)**

**Declaration by Chief Investigator**

- I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.
- I consider that it would be reasonable for the proposed amendment(s) to be implemented.

Signature of Chief Investigator:



Print name: Siobhan Quenby

Date: 01 April 2020

**Optional Declaration by the Sponsor's Representative (as per Sponsor Guidelines)**

*The sponsor of an approved study is responsible for all amendments made during its conduct.*

*The person authorising the declaration should be authorised to do so. There is no requirement for a particular level of seniority; the sponsor's rules on delegated authority should be adhered to.*

- I confirm the sponsor's support for the amendment(s) in this notification.

Signature of sponsor's representative:



Print name: Becky Haley

Post: R&D Business Development Manager

Organisation: University Hospitals Coventry & Warwickshire

Date: 01/04/2020