Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
The 'Big Baby Trial'

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

( ) Clinical trial of an investigational medicinal product

( ) Clinical investigation or other study of a medical device

( ) Combined trial of an investigational medicinal product and an investigational medical device

(●) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice

( ) Basic science study involving procedures with human participants

( ) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology

( ) Study involving qualitative methods only

( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)

( ) Study limited to working with data (specific project only)

( ) Research tissue bank

( ) Research database

If your work does not fit any of these categories, select the option below:

( ) Other study

2a. Will the study involve the use of any medical device without a CE Mark, or a CE marked device which has been modified or will be used outside its intended purposes?

( ) Yes (●) No

2b. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation? ( ) Yes (●) No

b) Will you be taking new human tissue samples (or other human biological samples)? ( ) Yes (●) No

c) Will you be using existing human tissue samples (or other human biological samples)? ( ) Yes (●) No

3. In which countries of the UK will the research sites be located? *(Tick all that apply)*

- [x] England
- [x] Scotland
- [x] Wales
- [x] Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

- (•) England
- ( ) Scotland
- ( ) Wales
- ( ) Northern Ireland
- ( ) This study does not involve the NHS

4. Which applications do you require?

IMPORTANT: If your project is taking place in the NHS and is led from England select 'IRAS Form'. If your project is led from Northern Ireland, Scotland or Wales select 'NHS/HSC Research and Development Offices' and/or relevant Research Ethics Committee applications, as appropriate.

- [x] IRAS Form
- [ ] Confidentiality Advisory Group (CAG)
- [ ] Her Majesty's Prison and Probation Service (HMPPS)

For NHS/HSC R&D Offices in Northern Ireland, Scotland and Wales the CI must create NHS/HSC Site Specific Information forms, for each site, in addition to the study wide forms, and transfer them to the PIs or local collaborators.

For participating NHS organisations in England different arrangements apply for the provision of site specific information. Refer to IRAS Help for more information.

5. Will any research sites in this study be NHS organisations?

(•) Yes ( ) No

5a. Are all the research costs and infrastructure costs (funding for the support and facilities needed to carry out research e.g. NHS Support costs) for this study provided by a NIHR Biomedical Research Centre, NIHR Biomedical Research Unit, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC), NIHR Patient Safety Translational Research Centre or a Diagnostic Evidence Co-operative in all study sites?

Please see information button for further details.

( ) Yes (•) No

Please see information button for further details.

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) Support and inclusion in the NIHR Clinical Research Network Portfolio?

Please see information button for further details.

(•) Yes ( ) No

The NIHR Clinical Research Network provides researchers with the practical support they need to make clinical studies happen in the NHS e.g. by providing access to the people and facilities needed to carry out research "on the ground".

If you select yes to this question, you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form (PAF) immediately after completing this project filter question and before submitting other applications. Failing to complete the PAF ahead of other applications e.g. HRA Approval, may mean that you will be unable to access NIHR CRN Support for your study.

6. Do you plan to include any participants who are children?

◉ Yes ○ No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

○ Yes ◉ No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

○ Yes ◉ No

9. Is the study or any part of it being undertaken as an educational project?

○ Yes ◉ No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

○ Yes ◉ No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

○ Yes ◉ No

NOTICE OF SUBSTANTIAL AMENDMENT

Please use this form to notify the main REC of substantial amendments to all research other than clinical trials of investigational medicinal products (CTIMPs).
The form should be completed by the Chief Investigator using language comprehensible to a lay person.

Details of Chief Investigator:

	Title	Forename/Initials	Surname
	Professor	Siobhan	Quenby
Work Address	Clifford Bridge Road, Coventry		
PostCode	CV2 2DX		
Email	s.quenby@warwick.ac.uk		
Telephone	07873416716		
Fax			

For guidance on this section of the form refer to the guidance

Full title of study:	Induction of labour for predicted macrosomia
Lead sponsor:	University Hospitals Coventry and Warwickshire NHS Trust
Name of REC:	South West-Exeter Research Ethics Committee
REC reference number:	18/SW/0039

International Standard Randomised Controlled Trial Number (ISRCTN):	ISRCTN18229892
ClinicalTrials.gov Identifier (NCT number):	

Additional reference number(s):

Ref.Number Description	Reference Number

Name of lead R&D office:	University Hospitals Coventry & Warwickshire
Date study commenced:	1st January 2018
Protocol reference (if applicable), current version and date:	V2.0 12th April 2018
Amendment number and date:	AM02 18th September 2018

Type of amendment

(a) Amendment to information previously given in IRAS

(●) Yes ( ) No

If yes, please refer to relevant sections of IRAS in the "summary of changes" below.

(b) Amendment to the protocol

(●) Yes ( ) No

If yes, please submit either the revised protocol with a new version number and date, highlighting changes in bold, or a document listing the changes and giving both the previous and revised text.

(c) Amendment to the information sheet(s) and consent form(s) for participants, or to any other supporting documentation for the study

(●) Yes ( ) No

If yes, please submit all revised documents with new version numbers and dates, highlighting new text in bold.

Is this a modified version of an amendment previously notified and not approved?

( ) Yes (●) No

Summary of changes

Briefly summarise the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study.
If this is a modified amendment, please explain how the modifications address the concerns raised previously by the ethics committee.
If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained.

Please find below a summary of changes categorised for your convenience.
Protocol
1. Protocol Table 1 – Study Team Contacts. The study team contact list has been updated to reflect the changing composition of the team.
The following people's details have been removed – Sukhdeep Dosanjh,
The following people's details have been added - Jaclyn Brown, Sally Buller, Ryan Griffin, Claire Kenna, Sara Wood
The following people's details have been amended – Joanne Fisher, Simon Gates, Kirsten Harris, Stavros Petrou, Martin Underwood
2. Protocol Table 2 – Trial Steering Committee. Ranjit Rana and Martin Underwood added to TSC
3. Protocol Table 4 – General trial Information – Trial co-ordinating centre and general enquiries contact details updated.
4. Protocol Risk Tables 5 and 6. The wording has been clarified in the risk tables to read that one in 10 babies, who experienced shoulder dystocia, may have stretching of the nerves of the neck
5. Protocol Risk Tables 5 and 6. The wording has been clarified in the risk tables to read that one in 10 babies, who experience shoulder dystocia, may fracture their collar bone.
6. Protocol Risk Tables 5 and 6. The wording has been clarified in the risk tables to read that four babies in 100, who experience shoulder dystocia, have a fracture to their arm.
7. Protocol Section 2.1. Figure 1 has the numbers for the estimated number of participants in the cohort study removed.
8. Protocol Section 2.1 and 2.8.2 and Amendment to information previously given in IRAS 'Epilepsy' removed from exclusion criterion caesarean section or induction indicated due to health conditions such as cardiac disease, epilepsy or hypertensive disorders, as epilepsy was thought to be a poor example of a health condition which would require induction.
9. Protocol section 2.9 and 2.9.2.3 Amendment to information previously given in IRAS. The wording has been amended to clarify which data is collected in the RCT and the cohort.
10. Protocol Section 2.9.2.1. Added 'hospital readmission within 30 days of postnatal inpatient discharge.' to Infant Outcomes to mirror the Maternal Outcomes section 2.9.2.2.

11. Protocol section 2.10.3, 5.2, 5.5, 7.6 (table 13) and Amendment to information previously given in IRAS The numbers for the estimated sample size for the cohort study has been removed or stated as anticipated numbers.
12. Protocol section 2.11 Internal pilot wording has been amended to clarify that sites will continue to open to recruitment during internal pilot and that it will occur when ten sites have been recruiting into the RCT for three months.
13. Protocol section 2.14. This section has been removed and added to section 3.1 participant recruitment.
14. Protocol section 3.1. Participant recruitment. Now the trial had opened to recruitment is has become clear that in order to recruit women into the trial each sites requires a number of different routes in order to identify potentially eligible women. The text has been amended to reflect this as well as add more clarity on the trial related recruitment process that must be consistent across all sites. We have also removed reference to the site manual as this document is no longer required.
15. Protocol Section 4. We have clarified that we will collect data on events that would be deemed to be SAEs in an interventional study as part of the outcomes from the cohort study.
16. Protocol section 5. A paragraph has been added to explain the process for dealing with depression identified in the Edinburgh post-natal depression scale in participant questionnaires.
17. Protocol section 7.7 The address of the coordination team has been amended

Participant Information Sheet
Throughout the participant information sheet, changes have been made to ensure that it is compliant to GDPR. These changes have been highlighted in yellow for ease of identification.
1. Page 1 section ‘What is this trial about? Information under the pictogram has been expanded to ‘1 in 150 big babies have a more difficult birth which may result in shoulder dystocia’.
2. Page 3 Section – ‘What if I do not want to join the trial?’ Wording amended to clarify how women who do not wish to be randomised can contribute to the trial in the cohort arm
3. Page 5 – ‘What are the possible disadvantages and risks of taking part?’ Pictogram
4. Risk Tables 1 and 2. The wording has been clarified in the risk tables to read that one in 10 babies, who experienced shoulder dystocia, may have stretching of the nerves of the neck.
5. Risk Tables 1 and 2. The wording has been clarified in the risk tables to read that ‘For babies who experience shoulder dystocia, one in 10 babies may have a fracture to their collar bone and four in 100 may have a fracture to their arm.
6. Page 7 – ‘What if I have a concern?’ Reference to PALS has been removed and replaced with ‘<<insert as appropriate>>’ as not all sites in the UK use PALS.
7. Page 9 – ‘How can I contact the hospital research team?’ ‘Trial team’ has been replaced with ‘Hospital research team’ and the corresponding contact details have been updated accordingly.
Interview Study (MAIN)
1. How can I contact the trial team? Contact details amended from Big baby Trial team details to the research midwife details.
2. What if I have a concern? Reference to PALS has been removed and replaced with ‘<<insert as appropriate>>’ as not all sites in the UK use PALS.

Interview Study (PILOT)
1. How can I contact the trial team? Contact details amended from Big baby Trial team details to the research midwife details.
2. What if I have a concern? Reference to PALS has been removed and replaced with ‘<<insert as appropriate>>’ as not all sites in the UK use PALS.

Site Investigator Information Sheet – Interview Study
1. What if I have a concern? Reference to PALS has been removed and replaced with ‘<<insert as appropriate>>’ as not all sites in the UK use PALS.

Interview with partner cover sheet. A space has been added for the site team to enter the version number and date of the Participant Information Sheet.

RCT Consent Form
1. Consent question 1 removed the version number and date of the Participant Information Sheet to allow the hospital trial team to enter it themselves.
2. Consent questions 9 and 10? Amended from ‘…is transferred to another hospital to receive treatment, …’ to ‘… treated at another hospital, …’ This is to cover the situation where a woman might be admitted to a hospital, other than the trial site, without being transferred from the trial site to the new hospital.

Cohort Consent Form
1. Consent question 1 removed the version number and date of the Participant Information Sheet to allow the hospital

trial team to enter it themselves.
2. Consent questions 9 and 10? Amended from '…is transferred to another hospital to receive treatment, …' to '… treated at another hospital, …' This is to cover the situation where a woman might be admitted to a hospital, other than the trial site, without being transferred from the trial site to the new hospital.

Site Investigator Team Interview Consent Form
1. Consent question 1 removed the version number and date of the Participant Information Sheet to allow the hospital trial team to enter it themselves.

Participant Interview Consent Form
1. Consent question 1 removed the version number and date of the Participant Information Sheet to allow the hospital trial team to enter it themselves.

Big Baby Poster
1. Contact Information Contact information amended to reflect the hospital trial team rather than the trial management team.

Any other relevant information

Applicants may indicate any specific issues relating to the amendment, on which the opinion of a reviewing body is sought.

List of enclosed documents

Document	*Version*	*Date*
Protocol-Tracked	3.0	22/08/2018
Protocol-Clean	3.0	22/08/2018
Participant Information Sheet-Tracked	3.0	22/08/2018
Pariticpant Information Sheet-Clean	3.0	22/08/2018
Consent Form RCT-Tracked	3.0	22/08/2018
Consent Form RCT-Clean	3.0	22/08/2018
Consent Form Cohort-Tracked	3.0	22/08/2018
Consent Form Cohort- Clean	3.0	22/08/2018
Site Investigator Interview Information Sheet-Tracked	3.0	22/08/2018
Site Investigator Interview Information Sheet-Clean	3.0	22/08/2018
Participant Interview Information Sheet- Pilot-Tracked	3.0	22/08/2018
Participant Interview Information Sheet- Pilot-Clean	3.0	22/08/2018
Participant Interview Information Sheet-Main-Tracked	3.0	22/08/2018
Participant Interview Information Sheet-Main-Clean	3.0	22/08/2018
Consent Form Participant Interviews-Tracked	2.0	22/08/2018
Consent Form Participant Interviews-Clean	2.0	22/08/2018
Consent Form Site Investigator Interviews-Tracked	2.0	22/08/2018
Consent Form Site Investigator Interviews-Clean	2.0	22/08/2018
Big Baby Poster-Tracked	2.0	22/08/2018
Big Baby Poster-Clean	2.0	22/08/2018

Big Baby Interview with Partner Cover Sheet-Tracked	2.0	22/08/2018
Big Baby Interview with Partner Cover Sheet-Clean	2.0	22/08/2018

Declaration by Chief Investigator

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

This section was signed electronically by Professor Siobhan Quenby on 24/09/2018 11:52.

Job Title/Post:	Prof of Obstetrics
Organisation:	University of Warwick
Email:	s.quenby@warwick.ac.uk

Declaration by the sponsor's representative

I confirm the sponsor's support for this substantial amendment.

This section was signed electronically by Ceri Jones on 24/09/2018 12:13.

Job Title/Post:	Head of R&D
Organisation:	UHCW NHS Trust
Email:	ceri.jones@uhcw.nhs.uk