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?

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

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 Collaboration for Leadership in Health Research and Care (CLAHRC), NIHR Patient Safety Translational Research Centre or Medtech and In Vitro Diagnostic Cooperative 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:	01 January 2018
Protocol reference (if applicable), current version and date:	V6.0 16 May 2019
Amendment number and date:	AM07 18 February 2020

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.

Protocol:
Table 1: Update to contact details – Study Team Contacts
Table 4: Update to contact details – General Trial Information
Section 1.3: Correction of spelling error
Sections 1.7, 2.13, 2.14: Removal of the word 'fully' with respect to the amount of information that the woman receives about the trial. It was felt that the women will be informed to the best of our ability, but information is in constant review and we cannot guarantee that women will be fully informed at all times.
Section 1.7 - Table 6: Risk of induction table updated to include the possible risk of increased Special Educational Needs in babies that are induced before 40 weeks.
Section 2.9.2.3: Clarification that if two and six month questionnaires are not returned by post, then an attempt will be made to contact any woman who has not responded by telephone. The woman will then be asked if she is willing to complete a telephone questionnaire. This contains a reduced dataset of:
• Breastfeeding status at two and six months
• Health-related quality of life (EQ-5D-5L) at two and six months
• Maternal report of infant health at two and six months
• Maternal report of her own health at two and six months
Clarification that if the baby dies, there will be no attempt to collect follow-up questionnaire data. We have had one incidence of death and the Principal Investigator at site did not feel comfortable with contacting the woman for follow-up data. The Trial Monitoring Group agreed that this was probably a wise decision and suggested amending the protocol to reflect this
Section 2.14: Clarification that written informed consent must be obtained before a woman is recruited into the trial.
Section 4.2- Table 10: Addition of two further events that do not have to be reported as Serious Adverse Events - it was felt that these events were not clinically significant and would be captured elsewhere on the case Report Form:
• prophylactic antibiotics for the infant post-delivery if the mother had sepsis
• Hospitalisation/prolongation of hospitalisation for feeding support
Section 5.2 – Table 14: Table 14 updated to reflect that we will not be collecting follow-up questionnaires from the mother if the baby died.

Participant Information Sheet:
Wording ‘Usual care’ updated to ‘Standard care’ to be in line with protocol.
Risk of induction table updated to include the possible risk of increased Special Educational Needs in babies that are induced before 40 weeks.
Clarification on the ways in which the woman might be contacted by the Big Baby trial team; post, telephone, email or text.
Inclusion of further text to conform with GDPR

New Documents
Questionnaires:
Two Month Telephone Questionnaire (new)
Six Month Telephone Questionnaire (new)

Inclusion of protocol and associated documents for an Interview sub-study for the designated Big Baby Trial Clinical Research Fellow’s PhD:
Protocol - Making Decisions About how to Deliver Big Babies
Patient Topic Guide - Making Decisions about how to Deliver Big Babies
Patient Information Sheet - Making Decisions About how to Deliver Big Babies
Patient consent form for details to pass to researcher - Making Decisions about how to deliver Big Babies
Patient Consent Form - Making Decisions About how to Deliver Big Babies
Obstetrician Topic Guide - Making Decisions About how to Deliver Big Babies
Obstetrician Consent Form -Making Decisions About how to Deliver Big Babies
Obstetric Confirmation for Interview Study - Making Decisions about how to Deliver Big Babies
Obstetrician Information Sheet - Making Decisions about how to Deliver Big Babies

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*
Big Baby Protocol-tracked	7.0	10/02/2020
Big Baby Participant Information Sheet	7.0	10/02/2020
Big Baby two month telephone follow-up questionnaire	1.0	28/01/2019
Big Baby six month telephone follow-up questionnaire	1.0	28/01/2019
Sub-study Protocol - Making Decisions About he to Deliver Big babies	1.0	04/02/2020
Patient Topic Guide - Making Decisions about how to Deliver Big Babies	1.0	04/02/2020
Patient Information Sheet - Making Decisions About how to Deliver Big Babies	1.0	04/02/2020
Patient consent form for details to pass to researcher - Making Decisions about how to deliver Big Babies	1.0	04/02/2020
Patient Consent Form - Making Decisions About how to Deliver Big Babies	1.0	04/02/2020
Obstetrician Topic Guide - Making Decisions About how to Deliver Big Babies	1.0	04/02/2020
Obstetrician Consent Form -Making Decisions About how to Deliver Big Babies	1.0	31/01/2020
Obstetric Confirmation for Interview Study - Making Decisions about how to Deliver Big Babies	1.0	04/02/2020

Obstetrician Information Sheet - Making Decisions about how to Deliver Big Babies	1.0	04/02/2020
Notice of Substantial Amendment 07		
Cover letter		

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 19/02/2020 09:41.

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 19/02/2020 14:28.

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