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)
FIRST-line support for Assistance in Breathing in Children (FIRST-ABC)

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
	Dr	Padmanabhan	Ramnarayan
Work Address	Children's Acute Transport Service		
	26-27 Boswell Street		
	London		
PostCode	WC1N 3JZ		
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Telephone	020 7430 5850		
Fax			

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

Full title of study:	FIRST-line support for Assistance in Breathing in Children (FIRST-ABC): A master protocol of two randomised trials to evaluate the non-inferiority of high flow nasal cannula (HFNC) versus continuous positive airway pressure (CPAP) for non-invasive respiratory support in paediatric critical care
Lead sponsor:	Great Ormond Street Hospital for Children NHS Foundation Trust
Name of REC:	East of England - Cambridge South Research Ethics Committee
REC reference number:	19/EE/0185

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

Additional reference number(s):

Ref.Number Description	Reference Number

Name of lead R&D office:	Great Ormond Street Hospital for Children NHS Foundation Trust
Date study commenced:	06/08/2019
Protocol reference (if applicable), current version and date:	v1.1, 24 June 2019

Amendment number and date: SA1, 31 January 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.

A6-2, A17-2, A13, A62, A75-2,

(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.

Tracked and clean versions of the updated Protocol have been submitted.

(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.

Additional age-appropriate versions of the Peds-QL questionnaire used in the six month follow-up have been submitted. An amended version of the Health Services Questionnaire has been submitted.

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.

This main purpose of this amendment is to 1) update the protocol. We have also taken the opportunity to add the additional age-appropriate Pediatric Quality of Life Inventory (Peds-QL) questionnaires and to update the Health Services Questionnaire that will be used as part of the six month follow-up (detailed in points 2) and 3) below).

1) We propose updating the protocol as follows:

a. FIRST-ABC is a master protocol comparing two modes of non-invasive respiratory support (High Flow Nasal Cannula (HFNC) versus Continuous Positive Airway Pressure (CPAP)). Therefore, patients in which a clinical decision is made to start a different form of non-invasive respiratory support are not eligible. This message is reinforced in study training materials however some sites have requested this be added as exclusion criteria for clarity amongst their teams. We have therefore added 'Clinician decision to start other form of non-invasive respiratory support (i.e. not HFNC or CPAP)' as an exclusion criterion.

b. In light of the higher than expected recruitment rate in the step-down RCT, no formal interim analysis will be performed. Safety data (counts and percentages of adverse events by arm, and a line listing of SAEs) will be available for scrutiny by the DMEC, by the end of the internal pilot stage. There are no changes to the planned interim analysis of the step-up RCT. This approach has been agreed with the DMEC.

c. We have also taken the opportunity to make minor administrative changes to the protocol and have updated and corrected the algorithms for HFNC and CPAP (unfortunately these algorithms are created in a software program that does not have a 'tracked changes' function).

2) We had added the further age-appropriate versions of the Peds-QL questionnaire which are used as part of the six-month follow-up.

3) We have reviewed the content of the health services questionnaire and improved the response options, reducing the burden of text on each of the pages.

Any other relevant information

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

None.

List of enclosed documents

Document	*Version*	*Date*
FIRST-ABC Master Protocol	1.2	23/01/2020
Peds-QL 2-4 years	1.0	16/12/2019
Peds-QL 5-7 years	1.0	16/12/2019
Peds-QL 8-12 years	1.0	16/12/2019
Peds-QL 13-18 years	1.0	16/12/2019
Health Services Questionnaire	2.0	21/01/2020

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 Dr Padmanabhan Ramnarayan on 03/02/2020 13:50.

Job Title/Post:	Consultant
Organisation:	Great Ormond Street Hospital
Email:	p.ramnarayan@gosh.nhs.uk

Declaration by the sponsor's representative

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

This section was signed electronically by Dr Vanshree Patel on 06/02/2020 16:46.

Job Title/Post:	Head of Governance, Clinical Trials and Contracts
Organisation:	Great Ormond Street Hospital for Children NHS Foundation Trust
Email:	Stephanie.DeSaMarquesBasset@gosh.nhs.uk