

Partner Organisations:

Health Research Authority, England

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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

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
IRAS Project ID:	260536
Sponsor Amendment Notification number:	NSA4
Sponsor Amendment Notification date:	20 January 2020
Details of Chief Investigator:	
Name [first name and surname]	Dr Padmanabhan Ramnarayan
Address:	Great Ormond Street Hospital for Children NHS Foundation Trust 26-27 Boswell Street London
Postcode:	WC1N 3JZ
Contact telephone number:	020 7430 5850
Email address:	p.ramnarayan@gosh.nhs.uk
Details of Lead Sponsor:	

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Name:	Dr Jenny Rivers
Contact email address:	Research.Governance@gosh.nhs.uk
Details of Lead Nation:	
Name of lead nation <i>delete as appropriate</i>	England
If England led is the study going through CSP? <i>delete as appropriate</i>	Yes
Name of lead R&D office:	Great Ormond Street Hospital for Children NHS Foundation Trust

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2. Summary of amendment(s)

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No.	Brief description of amendment (please enter each separate amendment in a new row)	Amendment applies to (delete/ list as appropriate)		List relevant supporting document(s), including version numbers (please ensure all referenced supporting documents are submitted with this form)		R&D category of amendment (category A, B, C) For office use only
		Nation	Sites	Document	Version	
1	An administrative change has been made to point 1 of the FIRST-ABC Consent Forms. All of the parent/guardian consent forms have been updated to reflect the current approved version numbers and dates of the parent/guardian information sheets, which were updated as per non-substantial amendment 3.	England	Addenbrookes' Hospital, Cambridge (Cambridge University Hospitals NHS Foundation Trust)	Tracked and clean versions of:		
		Wales		Consent Form (Parent or Guardian)	v1.2, 17 January 2020	
		Scotland	Alder Hey Children's Hospital, Liverpool (Alder Hey Children's NHS Foundation Trust)	Postal Consent Form	v1.1, 17 January 2020	
			Birmingham Women and Children's Hospital (Birmingham Women's and Children's NHS Foundation Trust)	Bereaved Consent Form	v1.2, 17 January 2020	
			Bristol Royal Hospital for Children (University Hospitals Bristol NHS Foundation Trust)			
			Chelsea and Westminster Hospital (Chelsea and Westminster Hospital NHS Foundation Trust)			
			Evelina London Children's Hospital (Guy's and St Thomas' NHS Foundation Trust)			
			Great North Children's Hospital,			

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			<p>Newcastle (Newcastle upon Tyne Hospitals NHS Foundation Trust)</p> <p>Great Ormond Street Hospital, London (Great Ormond Street Hospital for Children NHS Foundation Trust)</p> <p>Hull Royal Infirmary (Hull University Teaching Hospitals NHS Trust)</p> <p>James Cook University Hospital, Middlesbrough (South Tees Hospitals NHS Foundation Trust)</p> <p>John Radcliffe Hospital, Oxford (Oxford University Hospitals NHS Foundation Trust)</p> <p>King's College Hospital, London (King's College Hospital NHS Foundation Trust)</p> <p>Leicester Royal Infirmary and Glenfield Hospital (University Hospitals of Leicester NHS Trust)</p> <p>Noah's Ark Children's Hospital for Wales, Cardiff (Cardiff and Vale University Health Board)</p> <p>Queens Medical Centre, Nottingham (Nottingham University Hospitals NHS Trust)</p> <p>Royal Alexandra Children's Hospital, Brighton (Brighton and</p>			
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			<p>Sussex University Hospitals NHS Trust)</p> <p>Royal Brompton Hospital, London (Royal Brompton & Harefield NHS Foundation Trust)</p> <p>Royal Hospital for Sick Children Edinburgh (NHS Lothian)</p> <p>Royal Manchester Children's Hospital (Manchester University NHS Foundation Trust)</p> <p>Southampton Children's Hospital (University Hospital Southampton NHS Foundation Trust)</p> <p>St George's Hospital, London (St George's University Hospitals NHS Foundation Trust)</p> <p>St Mary's Hospital, London (Imperial College Healthcare NHS Trust)</p> <p>The Royal London Hospital (Barts Health NHS Trust)</p> <p>Sheffield Children's Hospital (Sheffield Children's NHS Foundation Trust)</p>			
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[Add further rows as required]

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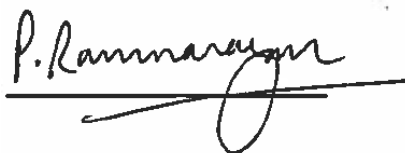
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3. Declaration(s)**Declaration by Chief Investigator**

- 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:*

Dr Padmanabhan Ramnarayan

Date:

20 January 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:*.....*Post:**Organisation:**Date:*.....