

Partner Organisations:

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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:	NSA1
Sponsor Amendment Notification date:	22 July 2019
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	Adding a new research site: Addenbrookes' Hospital (Cambridge University Hospitals NHS Foundation Trust) PI: Dr Nazima Pathan (np409@cam.ac.uk)	England	Addenbrookes' Hospital (Cambridge University Hospitals NHS Foundation Trust)			
2	Adding a new research site: Alder Hey Children's Hospital (Alder Hey Children's NHS Foundation Trust) PI: Dr Nayan Shetty (nayan.shetty@alderhey.nhs.uk)	England	Alder Hey Children's Hospital (Alder Hey Children's NHS Foundation Trust)			
3	Adding a new research site: Chelsea and Westminster Hospital (Chelsea and Westminster Hospital NHS Foundation Trust) PI: Dr Helen Raeside (helen.Raeside@chelwest.nhs.uk)	England	Chelsea and Westminster Hospital (Chelsea and Westminster Hospital NHS Foundation Trust)			
4	Adding a new research site: Great North Children's Hospital (Newcastle upon Tyne Hospitals NHS Foundation Trust) PI: Senior Sister Christine Mackerness	England	Great North Children's Hospital (Newcastle upon Tyne			

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	(Christine.mackerness@nuth.nhs.uk)		Hospitals NHS Foundation Trust)			
5	Adding a new research site: James Cook University Hospital (South Tees Hospitals NHS Foundation Trust) PI: Dr Arshid Murad (arshid.murad@nhs.net)	England	James Cook University Hospital (South Tees Hospitals NHS Foundation Trust)			
6	Adding a new research site: John Radcliffe Hospital (Oxford University Hospitals NHS Foundation Trust) PI: Dr Avishay Sarfatti (avishay.sarfatti@ouh.nhs.uk)	England	John Radcliffe Hospital (Oxford University Hospitals NHS Foundation Trust)			
7	Adding a new research site: King's College Hospital (King's College Hospital NHS Foundation Trust) PI: Dr Lynda Verhulst (lynda.verhulst@nhs.net)	England	King's College Hospital (King's College Hospital NHS Foundation Trust)			
8	Adding a new research site: Leicester Royal Infirmary and Glenfield Hospital (University Hospitals of Leicester NHS Trust) PI: Dr Bedangshu Saikia (bedangshu.saikia@uhl-tr.nhs.uk)	England	(University Hospitals of Leicester NHS Trust)			
9	Adding a new research site: Noah's Ark Children's Hospital for Wales (Cardiff and Vale University Health Board) PI: Dr Siva Oruganti (siva.oruganti@wales.nhs.uk)	Wales	Noah's Ark Children's Hospital for Wales (Cardiff and Vale University Health Board)			

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10	Adding a new research site: Queens Medical Centre (Nottingham University Hospitals NHS Trust) PI: Dr Catarina Silvestre (catarina.silvestre@nuh.nhs.uk)	England	Queens Medical Centre (Nottingham University Hospitals NHS Trust)			
11	Adding a new research site: Royal Alexandra Children's Hospital (Brighton and Sussex University Hospitals NHS Trust) PI: Dr Kamal Patel (k.patel17@nhs.net)	England	Royal Alexandra Children's Hospital (Brighton and Sussex University Hospitals NHS Trust)			
12	Adding a new site: Royal Brompton Hospital (Royal Brompton & Harefield NHS Foundation Trust) PI: Dr Angela Aramburo (a.aramburo@rbht.nhs.uk)	England	Royal Brompton Hospital (Royal Brompton & Harefield NHS Foundation Trust)			
13	Adding a new site: Royal Hospital for Sick Children Edinburgh (NHS Lothian) PI: Dr David Armstrong (david.armstrong@nhslothian.scot.nhs.uk)	Scotland	Royal Hospital for Sick Children Edinburgh (NHS Lothian)			
14	Adding a new site: Royal Manchester Children's Hospital (Manchester University NHS Foundation Trust) PI: Dr Graham Mason (graham.mason@mft.nhs.uk)	England	Royal Manchester Children's Hospital (Manchester University NHS)			

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			Foundation Trust)			
15	Adding a new site: Southampton Children's Hospital (University Hospital Southampton NHS Foundation Trust) PI: Dr V J Pappachan jvp@soton.ac.uk	England	Southampton Children's Hospital (University Hospital Southampton NHS Foundation Trust)			
16	Adding a new site: Hull Royal Infirmary (Hull University Teaching Hospitals NHS Trust) PI: Dr Hilary Klonin Hilary.Klonin@hey.nhs.uk	England	Hull Royal Infirmary (Hull University Teaching Hospitals NHS Trust)			

[Add further rows as required]

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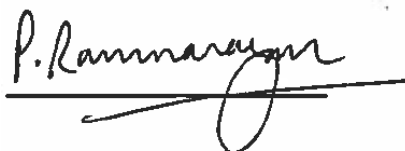
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3. Declaration(s)**Declaration by Chief Investigator**

- 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:

22 July 2019

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:*.....