

Partner Organisations:

Health Research Authority, England

NHS Research Scotland

HSC Research & Development, Public Health Agency, Northern Ireland

NIHR Clinical Research Network, England

NISCHR Permissions Co-ordinating Unit, Wales

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:	NSA5
Sponsor Amendment Notification date:	
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	Change of PI: St Mary's Hospital (Imperial College Healthcare NHS Trust) From: Dr David Inwald (david.inwald@nhs.net) To: Dr Rebecca Mitting (r.mitting@nhs.net)	England	St Mary's Hospital (Imperial College Healthcare NHS Trust)			
2	Change of PI: Birmingham Women and Children's Hospital (Birmingham Women's and Children's NHS Foundation Trust) From: Dr Kevin Morris (kevin.morris3@nhs.net) To: Dr Afeda Ali (afeda.mohamedali@nhs.net)	England	Birmingham Women and Children's Hospital (Birmingham Women's and Children's NHS Foundation Trust)			

[Add further rows as required]

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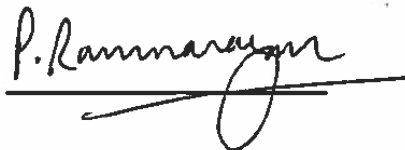
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3. Declaration(s)**Declaration by Chief Investigator**

- 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:

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:*.....