

**Partner Organisations:**

Health Research Authority, England

NHS Research Scotland

HSC Research &amp; 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**

<b>Full title of study:</b>	PERioperAtive CHildhood obesitY (PEACHY): A prospective observational cohort study investigating the proportion of overweight and obese children presenting for a procedure under general anaesthesia in the UK and the incidence of preoperative adverse outcomes in this patient group
<b>IRAS Project ID:</b>	248493
<b>Sponsor Amendment Notification number:</b>	5 Addition of new NHS sites Update study end date Minor correction of staff involved in the study
<b>Sponsor Amendment Notification date:</b>	10/09/2019
<b>Details of Chief Investigator:</b>	
Name [first name and surname]	Dr Mark Edwards
Address:	University Hospital Southampton NHS Foundation Trust Southampton General Hospital Tremona Road Southampton
Postcode:	SO16 6YD
Contact telephone number:	02381208449
Email address:	Mark.edwards2@uhs.nhs.uk
<b>Details of Lead Sponsor:</b>	

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Name:	Sharon Davies-Dear
Contact email address:	sponsor@uhs.nhs.uk
<b>Details of Lead Nation:</b>	
Name of lead nation <i>delete as appropriate</i>	England
If England led is the study going through CSP? <i>delete as appropriate</i>	No
<b>Name of lead R&amp;D office:</b>	University Hospital Southampton 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)	Version	R&D category of amendment (category A, B, C) For office use only
		Nation	Sites			
1	Addition of new NHS site: Basilston and Thurrock University Hospitals NHS Foundation Trust	England	– specific site named in description only			
2	Addition of new NHS site: East and North Hertfordshire NHS Trust	England	– specific site named in description only			
3	Update to A69-1 Planned end date updated from 06/10/19 to 27/10/19	England	All Sites			
		Northern Ireland	All Sites			
		Scotland	All Sites			
		Wales	All Sites			
4	Update to A38.  Minor correction – Paragraph 4 from “All staff involved in the study will be anaesthetic doctors” to “All staff involved in the study will be NHS Employees”	England	All Sites			
		Northern Ireland	All Sites			
		Scotland	All Sites			
		Wales	All Sites			
	Addition of new NHS site:	England	– specific site named in description only			
	Addition of new NHS site:	Scotland	– specific site named in description only			
	Addition of new NHS site:	Scotland	– specific site named in description only			
	Addition of new NHS site:	Scotland	– specific site named in description only			
		Scotland	– specific site named in description only			
		Scotland	– specific site named in description only			

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	Scotland – specific site named in description only				
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[Add further rows as required]



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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:

Mark Edwards.....

Date:

10<sup>th</sup> September 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:

Sharon Dawkes-Deer

Post:

Clinical Trials Project manager

Organisation:

University Hospital Southampton NHS  
Foundation Trust

Date:

11 September 2019

