

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:	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
IRAS Project ID:	248493
Sponsor Amendment Notification number:	1
Sponsor Amendment Notification date:	28/07/2019
Details of Chief Investigator:	
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
Details of Lead Sponsor:	

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Name:	Mrs Viki Rumble
Contact email address:	Viki.rumble@uhs.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>	No
Name of lead R&D office:	University Hospital Southampton NHS Foundation Trust

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2. Summary of amendment(s)

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If you need to notify a **Substantial Amendment** to your study then you **MUST** use the appropriate Substantial Amendment form in IRAS.

No.	Brief description of amendment <i>(please enter each separate amendment in a new row)</i>	Amendment applies to <i>(delete/ list as appropriate)</i>		List relevant supporting document(s), including version numbers <i>(please ensure all referenced supporting documents are submitted with this form)</i>		R&D category of amendment <i>(category A, B, C) For office use only</i>
		Nation	Sites	Document	Version	
1	Update to A69-1: Planned start date updated from Feb 2019 to 09/09/2019 Planned end date updated from Feb 2019 to 06/10/19	England	All sites or list affected sites			
		Northern Ireland	All sites or list affected sites			
		Scotland	All sites or list affected sites			
		Wales	All sites or list affected sites			

[Add further rows as required]

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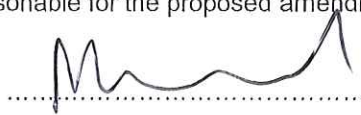
NISCHR Permissions Co-ordinating Unit, Wales

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 GAMMASS

Date:

29th 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:

Sharon Davies-Deas

Post:

Clinical Trials Project manager

Organisation:

University Hospital Southampton

OHS Foundation Trust

Date:

29 July 2019.