

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 obesityY (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:	2 Addition of new NHS sites only
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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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)</i> <i>For office use only</i>
		Nation	Sites	Document	Version	
1	Addition of new NHS site: Medway NHS Foundation Trust	England	specific site named in description only			
2	Addition of new NHS site: Moorfields Eye Hospital NHS Foundation Trust	England	specific site named in description only			
3	Addition of new NHS site: St George's University Hospitals NHS Foundation Trust	England	specific site named in description only			
4	Addition of new NHS site: Sherwood Forest Hospitals NHS Foundation Trust	England	specific site named in description only			
5	Addition of new NHS site: Airedale NHS Foundation Trust	England	specific site named in description only			
6	Addition of new NHS site: Norfolk and Norwich University Hospitals NHS Foundation Trust	England	specific site named in description only			
7	Addition of new NHS site: County Durham and Darlington NHS Foundation Trust	England	specific site named in description only			
8	Addition of new NHS site: Great Ormond Street Hospital for Children NHS Foundation Trust	England	specific site named in description only			
9	Addition of new NHS site: Northern Devon Healthcare NHS Trust	England	specific site named in description only			
10	Addition of new NHS site: Sheffield Children's NHS Foundation Trust	England	specific site named in description only			
11	Addition of new NHS site: Nottingham University Hospitals NHS Trust	England	specific site named in description only			

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12	Addition of new NHS site: Hywel Dda University LHB	Wales – specific site named in description only			
13	Addition of new NHS site: South Tees Hospitals NHS Foundation Trust	England – specific site named in description only			
14	Addition of new NHS site: Wrightington, Wigan and Leigh NHS Foundation Trust	England – specific site named in description only			
15	Addition of new NHS site: Wye Valley NHS Trust	England – specific site named in description only			
16	Addition of new NHS site: Abertawe Bro Morgannwg University LTB	Wales – specific site named in description only			
17	Addition of new NHS site: Lewisham and Greenwich NHS Trust	England – specific site named in description only			
18	Addition of new NHS site: Royal Free London NHS Foundation Trust	England – specific site named in description only			
19	Addition of new NHS site: Imperial College Healthcare NHS Trust	England – specific site named in description only			
20	Addition of new NHS site: The Rotherham NHS Foundation Trust	England – specific site named in description only			
21	Addition of new NHS site: Wirral University Teaching Hospital NHS Foundation Trust	England – specific site named in description only			
22	Addition of new NHS site: East Lancashire Hospitals NHS Trust	England – specific site named in description only			
23	Addition of new NHS site: Torbay and South Devon NHS Foundation Trust	England – specific site named in description only			
24	Addition of new NHS site: University Hospitals Bristol NHS Foundation Trust	England – specific site named in description only			
25	Addition of new NHS site: Mid Essex Hospital Services NHS Trust	England – specific site named in description only			
26	Addition of new NHS site: Royal Cornwall Hospitals NHS Trust	England – specific site named in description only			
27	Addition of new NHS site: University Hospitals Coventry and Warwickshire NHS Trust	England – specific site named in description only			
28	Addition of new NHS site: Royal National Orthopaedic Hospital NHS Trust	England – specific site named in description only			

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29	Addition of new NHS site: Northampton General Hospital NHS Trust	England – specific site named in description only			
30	Addition of new NHS site: Alder Hey Children's NHS Foundation Trust	England – specific site named in description only			
31	Addition of new NHS site: Hull and East Yorkshire Hospitals NHS Trust	England – specific site named in description only			
32	Addition of new NHS site: Countess of Chester Hospital NHS Foundation Trust	England – specific site named in description only			
33	Addition of new NHS site: Manchester University NHS Foundation Trust	England – specific site named in description only			
34	Addition of new NHS site: University College London Hospitals NHS Foundation Trust	England – specific site named in description only			
35	Addition of new NHS site: University Hospitals Plymouth NHS Trust	England – specific site named in description only			
36	Addition of new NHS site: University Hospitals of Leicester NHS Trust	England – specific site named in description only			
37	Addition of new NHS site: Worcestershire Acute Hospitals NHS Trust	England – specific site named in description only			
38	Addition of new NHS site: Guy's and St Thomas' NHS Foundation Trust	England – specific site named in description only			
39	Addition of new NHS site: Royal United Hospitals Bath NHS Foundation Trust	England – specific site named in description only			
40	Addition of new NHS site: Royal Berkshire NHS Foundation Trust	England – specific site named in description only			
41	Addition of new NHS site: Tameside and Glossop Integrated Care NHS Foundation Trust	England – specific site named in description only			
42	Addition of new NHS site: Mid Yorkshire Hospitals NHS Trust	England – specific site named in description only			
43	Addition of new NHS site: Cardiff and Vale University LHB	Wales – specific site named in description only			
44	Addition of new NHS site: The Newcastle Upon Tyne Hospitals NHS Foundation Trust	England – specific site named in description only			

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45	Addition of new NHS site: Salisbury NHS Foundation Trust	England – specific site named in description only			
46	Addition of new NHS site: Oxford University Hospitals NHS Foundation Trust	England – specific site named in description only			
47	Addition of new NHS site: NHS Ayrshire and Arran	Scotland – specific site named in description only			
48	Addition of new NHS site: Kettering General Hospital NHS Foundation Trust	England – specific site named in description only			
49	Addition of new NHS site: Barking, Havering and Redbridge University Hospitals NHS Trust	England – specific site named in description only			
50	Addition of new NHS site: University Hospitals of Derby and Burton NHS Foundation Trust	England – specific site named in description only			
51	Addition of new NHS site: Gloucestershire Hospitals NHS Foundation Trust	England – specific site named in description only			

[Add further rows as required]

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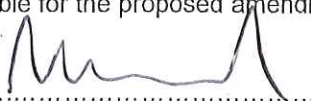
NISCHR Permissions Co-ordinating Unit, Wales

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 GOMERS

Date:

29 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-Dean

Post:

Clinical Trial Project Manager

Organisation:

University Hospital Southampton NHS

Foundation Trust.

Date:

29 July 2019.