Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
PErioperAtive CHildhood obesitY (PEACHY)

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

( ) Clinical trial of an investigational medicinal product

( ) Clinical investigation or other study of a medical device

( ) Combined trial of an investigational medicinal product and an investigational medical device

( ) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice

( ) Basic science study involving procedures with human participants

( ) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology

( ) Study involving qualitative methods only

( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)

(●) Study limited to working with data (specific project only)

( ) Research tissue bank

( ) Research database

If your work does not fit any of these categories, select the option below:

( ) Other study

2a. Please answer the following question(s):

a) Will you be processing identifiable data at any stage of the research (including in the identification of participants)? (●) Yes ( ) No

3. In which countries of the UK will the research sites be located?*(Tick all that apply)*

☑ England
☑ Scotland
☑ Wales
☑ Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

- (●) England
- ( ) Scotland
- ( ) Wales
- ( ) Northern Ireland
- ( ) This study does not involve the NHS

4. Which applications do you require?

IMPORTANT: If your project is taking place in the NHS and is led from England select 'IRAS Form'. If your project is led from Northern Ireland, Scotland or Wales select 'NHS/HSC Research and Development Offices' and/or relevant Research Ethics Committee applications, as appropriate.

- [x] IRAS Form
- [ ] Confidentiality Advisory Group (CAG)
- [ ] Her Majesty's Prison and Probation Service (HMPPS)

For NHS/HSC R&D Offices in Northern Ireland, Scotland and Wales the CI must create NHS/HSC Site Specific Information forms, for each site, in addition to the study wide forms, and transfer them to the PIs or local collaborators.

For participating NHS organisations in England different arrangements apply for the provision of site specific information. Refer to IRAS Help for more information.

Most research projects require review by a REC within the UK Health Departments' Research Ethics Service. Is your study exempt from REC review?

( ) Yes (●) No

5. Will any research sites in this study be NHS organisations?

(●) Yes ( ) No

5a. Are all the research costs and infrastructure costs (funding for the support and facilities needed to carry out research e.g. NHS Support costs) for this study provided by a NIHR Biomedical Research Centre, NIHR Biomedical Research Unit, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC), NIHR Patient Safety Translational Research Centre or a Diagnostic Evidence Co-operative in all study sites?

Please see information button for further details.

( ) Yes (●) No

Please see information button for further details.

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) Support and inclusion in the NIHR Clinical Research Network Portfolio?

Please see information button for further details.

(●) Yes ( ) No

The NIHR Clinical Research Network provides researchers with the practical support they need to make clinical studies happen in the NHS e.g. by providing access to the people and facilities needed to carry out research "on the ground".

If you select yes to this question, you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form (PAF) immediately after completing this project filter question and before submitting other applications. Failing to complete the PAF ahead of other applications e.g. HRA Approval, may mean that you will be unable to access NIHR CRN Support for your study.

6. Do you plan to include any participants who are children?

(●) Yes ( ) No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

( ) Yes (●) No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

( ) Yes (●) No

9. Is the study or any part of it being undertaken as an educational project?

( ) Yes (●) No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

( ) Yes (●) No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

( ) Yes (●) No

Integrated Research Application System
Application Form for Study limited to working with data (specific project only)

IRAS Form (project information)

Please refer to the E-Submission and Checklist tabs for instructions on submitting this application.

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting Help.

Please define any terms or acronyms that might not be familar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
PErioperAtive CHildhood obesitY (PEACHY)

Please complete these details after you have booked the REC application for review.

REC Name:
West Midlands - Coventry & Warwickshire Research Ethics Committee

REC Reference Number:
18/WM/0394

Submission date:
29/11/2018

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

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

A3-1. Chief Investigator:

	Title	Forename/Initials	Surname
	Dr	Mark	Edwards
Post	Consultant in Anaesthesia and Perioperative Medicine		
Qualifications	BMedSci, BMBS, MRCP, FRCA, MD(Res)		
ORCID ID	0000 0002 5048 1784		
Employer	University Hospital Southampton NHS Foundation Trust		
Work Address	Southampton General Hospital Tremona Road Southampton		
Post Code	SO16 6YD		
Work E-mail	mark.edwards2@uhs.nhs.uk		
* Personal E-mail			

Work Telephone	02381208449
* Personal Telephone/Mobile	
Fax	

** This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.*
A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?
This contact will receive copies of all correspondence from REC and HRA/R&D reviewers that is sent to the CI.

Title	Forename/Initials	Surname
Mrs	Viki	Rumble

Address	R&D Department, SCBR, Mailpoint 138 University Hospital NHS Foundation Trust Tremona Road
Post Code	SO16 6YD
E-mail	viki.rumble@uhs.nhs.uk
Telephone	02381205663
Fax	

A5-1. Research reference numbers. *Please give any relevant references for your study:*

Applicant's/organisation's own reference number, e.g. R & D (if available):	RHM CRI0372
Sponsor's/protocol number:	
Protocol Version:	v1 final
Protocol Date:	07/10/2018
Funder's reference number (enter the reference number or state not applicable):	APAGBI PATRN PEACHY
Project website:	N/A

Additional reference number(s):

Ref.Number Description	Reference Number

Registration of research studies is encouraged wherever possible. You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you have registered your study please give details in the "Additional reference number(s)" section.

A5-2. Is this application linked to a previous study or another current application?

○ Yes ◉ No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

A6-1. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. Where the research is reviewed by a REC within the UK Health Departments' Research Ethics Service, this summary will be published on the Health Research Authority (HRA) website following the ethical review. Please refer to the question specific guidance for this question.*

The incidence of childhood obesity is at epidemic levels and increasing in the UK. Obese adults are considered a high-risk group of patients for general anaesthesia with published national guidelines on the best practice management.

The proportion of children presenting for a procedure under general anaesthesia in the UK who are overweight or obese is currently unknown. Obese children are perceived to be at greater risk of complications from general anaesthesia. Previous non-UK studies suggest they take longer to recover from anaesthesia, require more medications to combat nausea and vomiting and are at greater risk of complications that may threaten their airway and breathing.

This study involves reviewing the anaesthetic care record and patient notes to collect information relating to general anaesthesia and basic demograhic data in children aged 2-16 years presenting for a procedure under general anaesthesia.

The aims of this study are to establish the prevalence of obesity in the paediatric surgical population (i.e. the proportion of children attending UK hospitals for procedures under general anaesthesia who are overweight or obese) and to ascertain whether obese children are at increased risk compared to their healthy weight counterparts.

This information will be used with the goal of reducing avoidable harm both at national and local level in the future. It will raise awareness of the prevalence of obesity in UK children having surgery, highlighting the additional risks involved for these children. Future harm reduction strategies may include pre-operative education of children and parents regarding childhood obesity, and increased input from clinicians in the pre-operative period in terms of optimisation of these children prior to surgery.

A6-2. Summary of main issues. *Please summarise the main ethical, legal, or management issues arising from your study and say how you have addressed them.*

Not all studies raise significant issues. Some studies may have straightforward ethical or other issues that can be identified and managed routinely. Others may present significant issues requiring further consideration by a REC, HRA, or other review body (as appropriate to the issue). Studies that present a minimal risk to participants may raise complex organisational or legal issues. You should try to consider all the types of issues that the different reviewers may need to consider.

We believe this is a simple and low risk study both ethically and legally. We plan to collect information relating to general anaesthesia and basic demographic data in children aged 2-16 years presenting for a procedure under general anaesthesia.

Local investigators will be part of the anaesthetic department in the hospital where the patient is being treated and therefore form part of the direct care team. As no burdensome additional tests, interventions or changes to care will be made (with the possible exception of height measurement), the patients will bear no additional risks. Height measurement is a non-invasive, low risk test and according to NICE guidelines this would be an appropriate time to measure and record this data. All other data being collected is already recorded as part of routine clinical care and will be pseudonymised. Additionally, no decisions affecting an individual patients care will be made based on the information collected by any member of the study team.

Local investigators will collect data from the anaesthesia care record and clinical notes. This information will be entered onto our database via a secure web-based programme (Project REDCap) from password protected NHS desktop computers. The data will be stored securely. No personal identifiable information will be stored outside the local hospital. The central research team will not have access to any directly identifiable personal data. All data will be disposed of securely.

The main issue with project management is achieving data recording consistency across the network. Guidance on measurement methods and definitions will be provided to all local sites. Additionally, all local lead investigators involved in the project will be required to complete the National Institute for Health Research's (NIHR) Good Clinical Practice e-learning, an online resource which aims to ensure that clinical research is conducted ethically and to high standards.

No member of the research team has a conflict of interest.

3. PURPOSE AND DESIGN OF THE RESEARCH

A7. Select the appropriate methodology description for this research. *Please tick all that apply*:

- ☐ Case series/ case note review
- ☐ Case control
- ☑ Cohort observation
- ☐ Controlled trial without randomisation
- ☐ Cross-sectional study
- ☐ Database analysis
- ☐ Epidemiology
- ☐ Feasibility/ pilot study
- ☐ Laboratory study
- ☐ Metanalysis
- ☐ Qualitative research
- ☐ Questionnaire, interview or observation study
- ☐ Randomised controlled trial
- ☐ Other (please specify)

A10. What is the principal research question/objective? *Please put this in language comprehensible to a lay person.*

The principal aim is to establish the prevalence of obesity in the paediatric surgical population (i.e. the proportion of children attending UK hospitals for procedures under general anaesthesia who are overweight or obese compared to the total number attending for procedures under general anaesthesia).

The findings of this study will allow participating hospitals to review the care they provide for obese children undergoing general anaesthesia, consider their current management strategies and compare themselves with other sites participating in this study.

A11. What are the secondary research questions/objectives if applicable? *Please put this in language comprehensible to a lay person.*

1. The proportion of defined adverse events occurring in obese children as compared to healthy weight children attending for a procedure under general anaesthesia.

2. The range of paracetamol dosing in mg/kg in obese children compared to the range of paracetamol dosing in mg/kg in healthy weight counterparts.

3. The proportion of obese children presenting for certain sub-types of surgery compared to their healthy weight counterparts (e.g. dental surgery, orthopaedic surgery).

4. The difference in the proportion of overweight and obesity in the perioperative setting compared to that from the UK National Child Measurement Programme (NCMP).

A12. What is the scientific justification for the research? *Please put this in language comprehensible to a lay person.*

Childhood obesity in the UK population is clearly reported by the UK Child Measurement Programme. However, the prevalence of obesity in the paediatric surgical population is currently unknown.

Obese adults are considered a high-risk group of patients for general anaesthesia as they are at greater risk of complications that may threaten their airway and breathing, with published national guidelines on the best practice management. Obese children are perceived to be at greater risk of complications with general anaesthesia and previous non-UK studies suggest they take longer to recover from anaesthesia, require more medications to combat

nausea and vomiting and are at greater risk of complications that may threaten their airway and breathing. However, it is currently unclear as to whether obese children represent a higher risk group in terms of adverse perioperative events in the UK. In addition, there is local audit evidence to suggest wide variation in certain drug dosing including paracetamol in overweight and obese children, which could be harmful.

By establishing the incidence of perioperative adverse events in obese children and investigating perioperative paracetamol dosing, this study will help to identify if obese children are at greater risk than non-obese children in the preoperative period. This information will be used with the goal of reducing avoidable harm both at national and local level in the future. It will raise awareness of the prevalence of obesity in UK children having surgery, highlighting the additional risks involved for these children. Future harm reduction strategies may include pre-operative education of children and parents regarding childhood obesity, and increased input from clinicians in the pre-operative period in terms of optimisation of these children prior to surgery.

A13. Please summarise your design and methodology. *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

Hypotheses:
1. Overweight and obese children are over-represented in children presenting for procedures under general anaesthesia.
2. Obese children are at higher risk of perioperative adverse events compared to their healthy-weight counterparts.
3. The range of paracetamol dosing in mg/kg in obese children will be greater than the range of paracetamol dosing in mg/kg in healthy weight counterparts as doses will be adjusted for lean or ideal body mass rather than total body mass.
4. Obese children are more likely to be over-represented in certain sub-sets of procedures compared to their healthy-weight counterparts for example dental surgery, orthopaedic surgery.

Sampling:
This observational cohort study will take place in NHS hospitals in the UK with trainee anaesthetists affiliated to the Paediatric Anaesthesia Trainee Research Network (PATRN). To increase coverage of sites in the UK, the project will be advertised through other trainee research networks including Research and Audit Federation of Trainees (RAFT) and through the Association of Paediatric Anaesthetists of Great Britain and Ireland (APAGBI) linkmen. Each hospital taking part will have a nominated lead investigator who will lead a team of local investigators collecting data. Data will be collected for all children aged greater than or equal to 2 years old and less than 16 year old and weighing >12kg presenting for a procedure under general anaesthesia during the defined study period. Local anaesthetic and sedation cases will not be included. This study period will be one week (7 consecutive days), confined to a four-week window.

Sample size:
Previous PATRN audit projects have enrolled approximately 90 local sites. If we enrol a similar number of sites this would give an estimated total of 7590 children attending for a procedure under general anaesthesia during a week period.

Identifying participants:
Patients will be identified by local trainee investigators (independent of delivery of anaesthesia but part of the anaesthetic department of the hospital) from operating department lists on the days of the study.

Likely response rates:
Data will be collected on all eligible patients who undergo a procedure under general anaesthesia during the study period.

Validation of tools:
Similar data collection tools has been used in previous PATRN audit projects and have yielded useful results.

Data handling:
Data will be collected from the paper or electronic anaesthetic record and clinical notes. Only routine clinical data will be included and where this is unavailable the domain will be left blank. Patient identifiable data including local hospital identification number and date of birth will be collected on the local case record form (CRF) to enable retrospective data collection. The completed CRF will be taken directly to a secure location accessible by the local investigator. The data will be entered electronically via a secure encrypted connection into an online portal managed by Aberdeen University. The software used for data capture will be REDCap (Research Electronic Data Capture – http://www.project-redcap.org). REDCap is a mature, secure web application for building and managing online surveys and databases. Each dataset entered will generate a unique identifier (ie the data will be pseudonymised); local investigators will be asked to keep a log of their unique identifiers linked to local hospital identification numbers. The

hospital number will remain within the respective trusts, meaning only the local NHS staff responsible for care have access to personal identifying information.

The study database will be closed for data entry a number of weeks after the study completion date. The anonymised responses from participating hospitals across the country will be analysed by a team of researchers.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A15. What is the sample group or cohort to be studied in this research?

Select all that apply:

- [ ] Blood
- [ ] Cancer
- [ ] Cardiovascular
- [ ] Congenital Disorders
- [ ] Dementias and Neurodegenerative Diseases
- [ ] Diabetes
- [ ] Ear
- [ ] Eye
- [x] Generic Health Relevance
- [ ] Infection
- [ ] Inflammatory and Immune System
- [ ] Injuries and Accidents
- [ ] Mental Health
- [ ] Metabolic and Endocrine
- [ ] Musculoskeletal
- [ ] Neurological
- [ ] Oral and Gastrointestinal
- [ ] Paediatrics
- [ ] Renal and Urogenital
- [ ] Reproductive Health and Childbirth
- [ ] Respiratory
- [ ] Skin
- [ ] Stroke

Gender:	Male and female participants
Lower age limit: 2	Years
Upper age limit: 16	Years

A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

• All children aged greater than or equal to 2 and less than 16 years presenting for a procedure under general anaesthesia.
• Elective cases, day case and emergency cases will all be included.

• MRI, radiology, oncology and dental cases will be included provided the patient receives a general anaesthetic.

A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).

• Procedures performed under sedation or local anaesthesia.
• Children aged less than 2 years since the 0-24 month age group has separate growth charts, which are not currently recommended for interpretation of BMI.
• Children weighing less than 12kg as these are not included on the growth charts for interpretation of BMI.
• Children requiring general anaesthesia purely for body system support in the intensive care setting.
• Children who are already anaesthetised in the intensive care setting being transferred for a scan or procedure without any intervention to their airway planned.
• Children 16 years or more may be counted as children in some hospitals but not for the purposes of this study.

RECRUITMENT AND INFORMED CONSENT

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used?*For example, identification may involve a disease register, computerised search of GP records, or review of medical records. Indicate whether this will be done by the direct healthcare team or by researchers acting under arrangements with the responsible care organisation(s).*

Local anaesthetic trainee investigators (independent of delivery of anaesthesia but part of the anaesthetic department of the hospital, and therefore members of the direct care team) will identify all children meeting the inclusion criteria from operating department lists during the study period. Additionally, emergency cases added may be identified by the anaesthetist at pre-operative assessment. Data will be collected on all eligible patients during the study period.

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

(●) Yes ( ) No

Please give details below:
The patients will be identified from operating theatre lists on the days on which the study takes place. There will be no need for access to medical records to assess suitability for inclusion as age and type of anaesthesia are routinely recorded on the operating lists. Operating theatre lists are only available to clinical staff within theatres in each NHS organisation. All local investigators will be NHS anaesthetic department staff.

A27-3. Describe what measures will be taken to ensure there is no breach of any duty of confidentiality owed to patients, service users or any other person in the process of identifying potential participants.*Indicate what steps have been or will be taken to inform patients and service users of the potential use of their records for this purpose. Describe the arrangements to ensure that the wishes of patients and service users regarding access to their records are respected. Please consult the guidance notes on this topic.*

This is a non-consenting study, therefore no steps have been taken to inform patients about the use of their records.

Patients will be identified on the day of surgery from published theatre lists which contain limited personal identifiable information including age. These lists are routinely distributed to the clinical care team to enable them to complete their work using a variety of confidential methods including:

1. NHS trust e-mail accessed from secure password protected NHS desktop computers.
2. A specific theatre rostering programme, accessible via individual username/ password and only available on password protected NHS desktop computers.
3. Print outs displayed confidentially in staff only areas.

The individuals collecting data will be members of the anaesthetic department where the patients are treated, and therefore make up part of the clinical care team. Local investigators are required to complete Good Clinical Practice training to ensure the research is carried out following best practice.

A27-4. Will researchers or individuals other than the direct care team have access to identifiable personal information of any potential participants?

○ Yes ◉ No

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

○ Yes ◉ No

A29. How and by whom will potential participants first be approached?

We anticipate that patient consent will not be required for this study as the dataset will include information already recorded as part of routine clinical care, all data will be pseudonymised and no directly identifiable personal data will be stored outside of the individual hospital where the patient is treated. For this reason patients will not be approached in relation to the study.

A30-1. Will you obtain informed consent from or on behalf of research participants?

○ Yes ◉ No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

If you are not obtaining consent, please explain why not.

We anticipate that patient consent will not be required for this study as the dataset will include information already recorded as part of routine clinical care, all data will be pseudonymised and no directly identifiable personal data will be stored outside of the individual hospital where the patient is treated. Whilst height may not be routinely measured and recorded at all hospitals prior to a procedure under general anaesthesia, according to NICE guidelines this would be an appropriate time to measure and record this data. Hospitals will be asked to do so for the duration of the study period if they wish to participate.

In order for this study to make accurate, generalisable conclusions to provide future patient benefit the coverage of the study population at each local site and the number of sites participating needs to be maximised. By taking consent, we may be unable to gain full coverage of the study population and therefore be unable to accurately determine the proportion of obese children presenting for general anaesthesia. Directly identifiable personal data will not be stored outside of the hospital where each individual patient is treated. No additional tests or interventions are being made and no changes will be made to patient care, with the possible exception of height measurement. This is a non-invasive, low risk test and according to NICE guidelines, this would be an appropriate time to measure and record this data.

The clinicians collecting the data will be part of the anaesthetic department in the hospital where the patient is being treated and can therefore be considered part of the direct care team. Additionally, asking for consent would be impractical as we anticipate recruiting approximately 7500 patients; in taking consent we would limit the number of patients recruited, limiting the generalisability and usefulness of the findings. For these reasons we do not intend to take consent from patients.

Please enclose a copy of the information sheet(s) and consent form(s).

A30-2. Will you record informed consent (or advice from consultees) in writing?

○ Yes ◉ No

If No, how will it be recorded?

We anticipate that patient consent will not be required for this study.

A31. How long will you allow potential participants to decide whether or not to take part?

We anticipate that patient consent will not be required for this study.

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs?*(e.g. translation, use of interpreters)*

We anticipate that patient consent will not be required for this study.

A33-2. What arrangements will you make to comply with the principles of the Welsh Language Act in the provision of information to participants in Wales?

We anticipate that patient consent will not be required for this study.

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

Storage and use of personal data during the study

A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)?*(Tick as appropriate)*

- ☐ Access to medical records by those outside the direct healthcare team
- ☐ Access to social care records by those outside the direct social care team
- ☑ Electronic transfer by magnetic or optical media, email or computer networks
- ☐ Sharing of personal data with other organisations
- ☐ Export of personal data outside the EEA
- ☐ Use of personal addresses, postcodes, faxes, emails or telephone numbers
- ☐ Publication of direct quotations from respondents
- ☐ Publication of data that might allow identification of individuals
- ☐ Use of audio/visual recording devices
- ☑ Storage of personal data on any of the following:
  - ☑ Manual files (includes paper or film)
  - ☑ NHS computers
  - ☐ Social Care Service computers
  - ☐ Home or other personal computers
  - ☑ University computers
  - ☐ Private company computers
  - ☐ Laptop computers

Further details:
These may be used for the identification of potential participants (as some hospitals use NHS email accounts or password-protected programs to disseminate theatre operating lists).

NHS computers will be used for uploading the pseudonymised data and university computers and manual files may be used to store the pseudonymised data that has been uploaded.

A37. Please describe the physical security arrangements for storage of personal data during the study?

All information for this study will be held securely and treated as strictly confidential according to NHS policies.

Personal data entered onto paper case report forms (CRF) will be stored in a locally arranged secure location, typically a drawer or filing cabinet in a locked anaesthetic department office. Anaesthetic department offices are commonly located in the operating theatre complex, which is itself a secure environment. CRFs will be held locally until a specified time point (five years after the study ends) when they will be destroyed confidentially.

No directly identifiable personal data will be stored outside the local hospital either in paper or electronic format. Pseudonymised data will be collected in REDCap and stored on University of Aberdeen Server. The University's primary and secondary data centres are operated as co-hosted services under the North East Scotland Shared Services, with the Robert Gordon University (RGU), and North East Scotland College as partners. The University's primary data centre is on the Old Aberdeen campus and is operated by UoA. The secondary data centre is operated by the Robert Gordon University on the Garthdee campus.

Physical access to the data centres is restricted to essential IT operations personnel, and is only accessible by card controlled locks which log all accesses. Swipe cards to enter the datacentre are kept in a locked digital key safe which only approved personnel can access. All access to the datacentre requires authorisation through a Data Centre & Monitoring team member. All people entering the datacentre must also have completed a safety briefing if they have not done so previously. Access logs are reviewed regularly. RGU and UoA have similar data centre access protocols. RGU staff have no access to University of Aberdeen data hosted in their data centre.

A38. How will you ensure the confidentiality of personal data?*Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.*

Personal data entered onto the paper CRF at the local sites will be subject to the above physical security arrangements and the NHS code of confidentiality will be followed for local management of CRFs. Hospital number will be collected in order to allow retrospective data collection. The CRFs will be destroyed confidentially after a specified time point.

No directly identifiable personal data will leave the local site either in paper or electronic format. A unique identifiying number will be generated at upload for each case (i.e. the data will be pseudonymised). Date of birth will be inputed onto the REDCap system but this will be digitally stored as age to the nearest month. This is to enable BMI to be calculated and prevent any calculation errors of age by the local site. Gender is also required for BMI calculation.

Local investigators will keep a log of patients unique identifiers on the CRFs. This will enable data to be linked to each site to allow any missing data or possible transcribing errors to be identified and brought to the local investigators attention.

All staff involved in the study will be anaesthetic doctors, who are familiar with handling personal information confidentially and who will have completed Good Clinical Practice Training. All staff share the same duty of care to prevent unauthorised disclosure of personal information.

The pseudonymised electronic data held will be deleted confidentially after a specified time point (5 years after the end of the study).

A40. Who will have access to participants' personal data during the study? *Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.*

Local investigators will have access to participants' personal data during the study to enable identification of participants, data collection and uploading of pseudonymised data. The local investigators will be members of the anaesthetic department in the hospital where the patient is being treated and as such form part of the clinical care team.

Pseudonymised data will be accessed by the central analysis team and they will not have access to any directly identifiable personal data.

All staff involved in the study (clinical, academic) share the same duty of care to prevent unauthorised disclosure of personal information.

Storage and use of data after the end of the study

A41. Where will the data generated by the study be analysed and by whom?

The data will be analysed by a central analysis team headed by Prof Amanda Lee, University of Aberdeen. In addition the Chief Investigator and team of PATRN investigators will assist with analysis using password protected NHS desktop computers. Members of this team are anaesthetic trainees based at the sponsor site, University Hospital Southampton, and other NHS hospitals in the UK.

No data will be transported aoutside of the UK.

A42. Who will have control of and act as the custodian for the data generated by the study?

	Title	Forename/Initials	Surname
	Dr	Mark	Edwards
Post	Consultant in Anaesthesia and Perioperative Medicine		
Qualifications	BMedSci, BMBS, MRCP, FRCA, MD(Res)		
Work Address	University Hospital Southampton NHS Foundation Trust		
	Tremona Road		
	Southampton		
Post Code	SO16 6YD		
Work Email	mark.edwards2@uhs.nhs.uk		
Work Telephone			
Fax			

A43. How long will personal data be stored or accessed after the study has ended?

- ○ Less than 3 months
- ○ 3 – 6 months
- ○ 6 – 12 months
- ◉ 12 months – 3 years
- ○ Over 3 years

If longer than 12 months, please justify:
This period of local data retention would allow any data queries to be clarified and investigated from raw data during the writing up of this work for publication.

A44. For how long will you store research data generated by the study?

Years: 5
Months: 0

A45. Please give details of the long term arrangements for storage of research data after the study has ended.*Say where data will be stored, who will have access and the arrangements to ensure security.*

Once the study has finished, the data in the REDCAP system will be archived and access removed. It will be stored for 5 years and then deleted at the end of this period.

INCENTIVES AND PAYMENTS

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

○ Yes ◉ No

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

○ Yes ◉ No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

○ Yes ◉ No

NOTIFICATION OF OTHER PROFESSIONALS

PUBLICATION AND DISSEMINATION

A50. Will the research be registered on a public database?

◉ Yes ○ No

Please give details, or justify if not registering the research.
https://clinicaltrials.gov/

Registration of research studies is encouraged wherever possible.
You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you are aware of a suitable register or other method of publication, please give details. If not, you may indicate that no suitable register exists. Please ensure that you have entered registry reference number(s) in question A5-1.

A51. How do you intend to report and disseminate the results of the study? *Tick as appropriate:*

- ☑ Peer reviewed scientific journals
- ☑ Internal report
- ☑ Conference presentation
- ☑ Publication on website
- ☐ Other publication
- ☐ Submission to regulatory authorities
- ☐ Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
- ☐ No plans to report or disseminate the results
- ☐ Other (please specify)

A52. If you will be using identifiable personal data, how will you ensure that anonymity will be maintained when publishing the results?

Local investigators will have access to participants' personal data during the study to enable identification of participants, data collection and uploading of pseudonymised data. The local investigators will be members of the anaesthetic department in the hospital where the patient is being treated and as such form part of the clinical care team.

Pseudonymised data will be accessed by the central analysis team and they will not have access to any directly identifiable personal data, hence ensuring anonymity upon publication.

A53. Will you inform participants of the results?

(●) Yes ( ) No

Please give details of how you will inform participants or justify if not doing so.
A final study report will be published in lay language on the study website which may be accessed and disseminated to participants.

5. Scientific and Statistical Review

A54. How has the scientific quality of the research been assessed? *Tick as appropriate:*

- [x] Independent external review
- [ ] Review within a company
- [ ] Review within a multi−centre research group
- [x] Review within the Chief Investigator's institution or host organisation
- [ ] Review within the research team
- [ ] Review by educational supervisor
- [ ] Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:
Protocol reviewed by the Association of Paediatric Anaesthetists (APA) scientific committee and the Chief Investigator. The APA scientific committee comprises a number of paediatric anaesthetic consultants from several different NHS institutions with an interest in audit and research. Suggestions incorporated into the current version of the protocol.

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A56. How have the statistical aspects of the research been reviewed? *Tick as appropriate:*

- [x] Review by independent statistician commissioned by funder or sponsor
- [ ] Other review by independent statistician
- [ ] Review by company statistician
- [ ] Review by a statistician within the Chief Investigator’s institution
- [ ] Review by a statistician within the research team or multi−centre group
- [ ] Review by educational supervisor
- [ ] Other review by individual with relevant statistical expertise
- [ ] No review necessary as only frequencies and associations will be assessed – details of statistical input not required

In all cases please give details below of the individual responsible for reviewing the statistical aspects. If advice has been provided in confidence, give details of the department and institution concerned.

	Title	Forename/Initials	Surname
	Prof	Amanda	Lee
Department	Medical statistics Team, Institute of Applied Health Sciences		
Institution	University of Aberdeen		
Work Address	Medical Statistics Team, Institute of Applied Health Sciences		
	Room 1.006 Polwarth Building, Foresterhill		
	Aberdeen		
Post Code	AB25 2ZD		
Telephone	01224437111		
Fax			
Mobile			
E-mail	a.j.lee@abdn.ac.uk		

Please enclose a copy of any available comments or reports from a statistician.

A57. What is the primary outcome measure for the study?

The prevalence of obesity in the paediatric surgical population (i.e. the proportion of children attending UK hospitals for procedures under general anaesthesia who are overweight and obese).

A58. What are the secondary outcome measures?*(if any)*

1. The proportion of defined adverse events occurring in obese children as compared to healthy weight children attending for a procedure under general anaesthesia.

2. The range of paracetamol dosing in mg/kg in obese children compared to the range of paracetamol dosing in mg/kg in healthy weight counterparts.

3. The proportion of obese children presenting for certain sub-types of surgery compared to their healthy weight counterparts (e.g. dental surgery, orthopaedic surgery).

4. The difference in the proportion of overweight and obesity in the perioperative setting compared to that from the UK National Child Measurement Programme (NCMP).

A59. What is the sample size for the research? *How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.*

Total UK sample size:	7590
Total international sample size (including UK):	7590
Total in European Economic Area:	0

Further details:
Extracting data from PATRN's recent PAediatric unPlanned dAYcase Admissions (PAPAYA) study, it can be estimated that around 90 UK paediatric sites will participate in PEACHY. The mean number of day cases on a weekly basis was 83.5 across all sites that submitted data (range 3 – 230). Since day cases can be considered to account for up to 90-95% of all cases, we may expect a further 5-10% per week in addition. Across 90 sites this would mean we may expect to collect data from the region of 7590 patients. We would expect 20-25% of these patients not to have height and/or weight data and thus will be excluded from analysis.

A60. How was the sample size decided upon? *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

Our plan is to recruit as many centres as possible within the UK and for them to recruit all eligible patients in the study within the available time frame. We do not have a specific sample size and statistical models will be adapted to the event rate provided by the sample recruited.

A61. Will participants be allocated to groups at random?

○ Yes ◉ No

A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

For each variable, appropriate descriptive statistics will be calculated (percentage and n for categorical variables and mean, standard deviation or median interquartile range, plus minimum and maximum for continuous variables).

Using a STATA add-in zanthro, an individual child's BMI will be converted to a z score and centile using the UK90 reference curves. These will be used to define individuals as underweight, healthy, overweight or obese. It may be necessary to combine healthy weight and overweight children and compare with the obese.

The proportion and 95% confidence interval of overweight and obesity in UK children aged 2-16 years attending for surgery will be calculated.

A chi squared test will be used to compare the proportion of defined adverse events, comorbidities, perioperative adverse events and other complications occurring in obese children with that of healthy weight children attending for surgery.

The variation in paracetamol dosing in obese children in the UK perioperative setting will be tabulated and graphed by hospital.

The proportion of obese children presenting for certain types of surgery compared to their healthy weight counterparts will be compared using the chi squared test. A binary logistic regression model will be used to adjust for age and other potential confounders. A mixed effects logistic model will be considered to adjust for the clustering effect of individual patients within hospitals.

The difference in the proportion of overweight and obesity in the perioperative setting compared to that from the UK National Child Measurement Programme will be compared using the chi squared test.

6. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. *Please include all grant co−applicants, protocol co−authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

	Title	Forename/Initials	Surname
	Dr	Zoe	Burton
Post	Anaesthetics Registrar		
Qualifications	MBBCh FRCA BSc MSc DTM&H		
Employer	Portsmouth Hospitals NHS Trust		
Work Address	Queen Alexandra Hospital		
	Southwick Hill Road		
	Portsmouth		
Post Code	PO6 3LY		
Telephone			
Fax			
Mobile			
Work Email	drzoeburton@gmail.com		

	Title	Forename/Initials	Surname
	Dr	Rosie	Lewis

Post	Anaesthetics Registrar
Qualifications	BA BMBCh FRCA
Employer	Portsmouth Hospitals NHS Trust
Work Address	Queen Alexandra Hospital Southwick Hill Road Portsmouth
Post Code	PO6 3LY
Telephone	
Fax	
Mobile	07557957634
Work Email	rosie.anna.lewis@gmail.com

Title	Forename/Initials	Surname
Dr	Tom	Bennett

Post	Anaesthetics Registrar
Qualifications	BM MRCPCH
Employer	University Of Southampton NHS Foundation Trust
Work Address	Southampton General Hospital Tremona Road Southampton
Post Code	SO16 6YD
Telephone	
Fax	
Mobile	
Work Email	tbennett85@gmail.com

A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

Status:
- (●) NHS or HSC care organisation
- ( ) Academic
- ( ) Pharmaceutical industry
- ( ) Medical device industry
- ( ) Local Authority
- ( ) Other social care provider (including voluntary sector or private organisation)
- ( ) Other

Commercial status: Non-Commercial

If Other, please specify:

Contact person

Name of organisation University Hospitals NHS Foundation Trust
Given name Mikayala

Family name	King
Address	R&D Dept, SCBR, Mailpoint 138, Southampton General Hospital, Tremona Road
Town/city	Southampton
Post code	SO16 6YD
Country	UNITED KINGDOM
Telephone	02381205961
Fax	
E-mail	mikayala.king@uhs.nhs.uk

A65. Has external funding for the research been secured?

Please tick at least one check box.

- [x] Funding secured from one or more funders
- [ ] External funding application to one or more funders in progress
- [ ] No application for external funding will be made

What type of research project is this?

- (•) Standalone project
- ( ) Project that is part of a programme grant
- ( ) Project that is part of a Centre grant
- ( ) Project that is part of a fellowship/ personal award/ research training award
- ( ) Other

Other – please state:

Please give details of funding applications.

Organisation	Association of Paediatric Anaesthetists of Great Britain and Ireland (APAGBI)
Address	21 Portland Place Marylebone London
Post Code	W1B 1PY
Telephone	02076318887
Fax	
Mobile	
Email	Peter.Brooks@chelwest.nhs.uk

Funding Application Status: (•) Secured ( ) In progress

Amount: £11620

Duration
Years: 1
Months:

If applicable, please specify the programme/ funding stream:

What is the funding stream/ programme for this research project?

Dr Peter Brooks (email above) is a member of the scientific committee of the APAGBI

A66. Has responsibility for any specific research activities or procedures been delegated to a subcontractor (other than a co-sponsor listed in A64-1) ? *Please give details of subcontractors if applicable.*

(●) Yes ( ) No

Name: University of Aberdeen

Type of organisation:
( ) NHS (●) Academic ( ) Commercial ( ) Other

Please give further details of sub-contractor and main areas of delegated responsibility: REDCAP set-up and management and statistical analysis of pseudonymised data

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

( ) Yes (●) No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68-1. Give details of the lead NHS R&D contact for this research:

	Title	Forename/Initials	Surname
	Dr	Mikayala	King
Organisation	University Hospital Southampton NHS Foundation Trust		
Address	R&D Dept, SCBR, Mailpoint 138		
	University Hospital Southampton NHS Foundation Trust		
	Tremona Road, Southampton		
Post Code	SO16 6YD		
Work Email	mikayala.king@uhs.nhs.uk		
Telephone	02381205961		
Fax			
Mobile			

Details can be obtained from the NHS R&D Forum website: http://www.rdforum.nhs.uk

A68-2. Select Local Clinical Research Network for NHS Organisation identified in A68-1:

Wessex

For more information, please refer to the question specific guidance.

A69-1. How long do you expect the study to last in the UK?

Planned start date: 14/01/2019

Planned end date: 11/02/2019

Total duration:

Years: 0 Months: 0 Days: 29

A71-1. Is this study?

- ○ Single centre
- ◉ Multicentre

A71-2. Where will the research take place? *(Tick as appropriate)*

- ☑ England
- ☑ Scotland
- ☑ Wales
- ☑ Northern Ireland
- ☐ Other countries in European Economic Area

Total UK sites in study Approx 90

Does this trial involve countries outside the EU?

○ Yes ◉ No

A72. Which organisations in the UK will host the research?*Please indicate the type of organisation by ticking the box and give approximate numbers if known:*

☑ NHS organisations in England	76
☑ NHS organisations in Wales	4
☑ NHS organisations in Scotland	8
☑ HSC organisations in Northern Ireland	2
☐ GP practices in England	
☐ GP practices in Wales	
☐ GP practices in Scotland	
☐ GP practices in Northern Ireland	
☐ Joint health and social care agencies (eg community mental health teams)	
☐ Local authorities	
☐ Phase 1 trial units	
☐ Prison establishments	
☐ Probation areas	
☐ Independent (private or voluntary sector) organisations	
☐ Educational establishments	
☐ Independent research units	
☐ Other (give details)	

Total UK sites in study: 90

A73-1. Will potential participants be identified through any organisations other than the research sites listed above?

◯ Yes ◉ No

A74. What arrangements are in place for monitoring and auditing the conduct of the research?

At registration every local site will have to confirm local approval has been granted and local investigators have completed the National Institute for Health Research (NIHR) Good Clinical Practice e-learning, prior to being able to start. This aims to ensure that clinical research is conducted ethically and to high standards.

The main issue is achieving data recording consistency across the network. Guidance on measurement methods and definitions will be provided to all local sites and a central team will be available to answer any questions during the study period.

The data will be pseudonymised at upload. The central team will be auditing the data per local site for any inconsistencies with the ability to refer back to that local site as necessary and the database will have automatic checks for expected values on data input.

A76. Insurance/ indemnity to meet potential legal liabilities

***Note:* in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland**

A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? *Please tick box(es) as applicable.*

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

☑ NHS indemnity scheme will apply (NHS sponsors only)

☐ Other insurance or indemnity arrangements will apply (give details below)

Please enclose a copy of relevant documents.

A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? *Please tick box(es) as applicable.*

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

☑ NHS indemnity scheme will apply (protocol authors with NHS contracts only)

☐ Other insurance or indemnity arrangements will apply (give details below)

Please enclose a copy of relevant documents.

A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS

sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

☑ NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)

☐ Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

Please enclose a copy of relevant documents.

A78. Could the research lead to the development of a new product/process or the generation of intellectual property?

○ Yes ◉ No ○ Not sure

PART B: Section 7 - Children

1. Please specify the potential age range of children under 16 who will be included and give reasons for carrying out the research in this age group.

2-16 years. Children aged <2 years will be excluded as the 0-24 month age group has separate growth charts which are not currently recommended for interpretation of BMI.

This research is specifically looking at the proportion of overweight and obese children attending hospitals for procedures requiring general anaesthesia

2. Indicate whether any children under 16 will be recruited as controls and give further details.

All eligible children will be recruited in order to give an accurate proportion that are overweight and obese attending hospital for a procedure under general anaesthesia.

3-2. Please describe the arrangements for seeking informed consent from a person with parental responsibility and/or from children able to give consent for themselves.

We anticipate that patient consent will not be required for this study as the dataset will include information already recorded as part of routine clinical care, all data will be pseudonymised and no directly identifiable personal data will be stored outside of the individual hospital where the patient is treated.

4. If you intend to provide children under 16 with information about the research and seek their consent or agreement, please outline how this process will vary according to their age and level of understanding.

N/A

Copies of written information sheet(s) for parents and children, consent/assent form(s) and any other explanatory material should be enclosed with the application.

PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. *For further information please refer to guidance.*

Investigator identifier	Research site		Investigator Name	
IN1	◉ NHS/HSC Site ○ Non-NHS/HSC Site		Forename Middle name Family name Email Qualification (MD...) Country	Tom Bennett tbennett85@gmail.com BM MRCPCH FRCA (primary) UNITED KINGDOM
	Organisation name	UNIVERSITY HOSPITAL SOUTHAMPTON NHS FOUNDATION TRUST		
	Address	MAILPOINT 18 SOUTHAMPTON GENERAL HOSPITAL TREMONA ROAD SOUTHAMPTON HAMPSHIRE		
	Post Code	SO16 6YD		
	Country	ENGLAND		
IN2	◉ NHS/HSC Site ○ Non-NHS/HSC Site		Forename Middle name Family name Email Qualification (MD...) Country	Rosemary Anna Lewis rosie.anna.lewis@gmail.com BA BMBCh FRCA UNITED KINGDOM
	Organisation name	PORTSMOUTH HOSPITALS NHS TRUST		
	Address	DE LA COURT HOUSE QUEEN ALEXANDRA HOSPITAL SOUTHWICK HILL ROAD PORTSMOUTH HAMPSHIRE		
	Post Code	PO6 3LY		
	Country	ENGLAND		
IN3	◉ NHS/HSC Site ○ Non-NHS/HSC Site		Forename Middle name Family name Email	Deborshi Sinha deborshi@me.com

	Organisation name	BIRMINGHAM WOMEN'S AND CHILDREN'S NHS FOUNDATION TRUST	Qualification (MD...)	BA Hons (Oxon), MBBS, FRCA
	Address	STEELHOUSE LANE BIRMINGHAM WEST MIDLANDS	Country	UNITED KINGDOM
	Post Code	B4 6NH		
	Country	ENGLAND		

IN4

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

		Forename	Andrew
		Middle name	
		Family name	Selman
	Organisation name	EPSOM AND ST HELIER UNIVERSITY HOSPITALS NHS TRUST	Email andrewselman@yahoo.co.uk
	Address	ST HELIER HOSPITAL WRYTHE LANE CARSHALTON SURREY	Qualification (MD...)
	Post Code	SM5 1AA	Country UNITED KINGDOM
	Country	ENGLAND	

PART D: Declarations

D1. Declaration by Chief Investigator

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.

2. I undertake to fulfil the responsibilities of the chief investigator for this study as set out in the UK Policy Framework for Health and Social Care Research.

3. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.

4. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.

5. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.

6. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.

7. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.

8. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.

9. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 1998.

10. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:

    - Will be held by the REC (where applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
    - May be disclosed to the operational managers of review bodies, or the appointing authority for the REC (where applicable), in order to check that the application has been processed correctly or to investigate any complaint.
    - May be seen by auditors appointed to undertake accreditation of RECs (where applicable).
    - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
    - May be sent by email to REC members.

11. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 1998.

12. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

Contact point for publication*(Not applicable for R&D Forms)*

NRES would like to include a contact point with the published summary of the study for those wishing to seek further

information. We would be grateful if you would indicate one of the contact points below.

- ◯ Chief Investigator
- ◯ Sponsor
- ◯ Study co-ordinator
- ◯ Student
- ◯ Other – please give details
- ◯ None

Access to application for training purposes *(Not applicable for R&D Forms)*

Optional – please tick as appropriate:

☐ I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

This section was signed electronically by Dr Mark Edwards on 27/11/2018 09:24.

Job Title/Post:	Consultant Anaesthetist
Organisation:	University Hospital Southampton NHSFT
Email:	mark.edwards2@uhs.nhs.uk

D2. Declaration by the sponsor's representative

If there is more than one sponsor, this declaration should be signed on behalf of the co−sponsors by a representative of the lead sponsor named at A64-1.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.

2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.

3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.

4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.

5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.

6. The responsibilities of sponsors set out in the UK Policy Framework for Health and Social Care Research will be fulfilled in relation to this research.

   Please note: *The declarations below do not form part of the application for approval above. They will not be considered by the Research Ethics Committee.*

7. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

8. Specifically, for submissions to the Research Ethics Committees (RECs) I declare that any and all clinical trials approved by the HRA since 30th September 2013 (as defined on IRAS categories as clinical trials of medicines, devices, combination of medicines and devices or other clinical trials) have been registered on a publically accessible register in compliance with the HRA registration requirements for the UK, or that any deferral granted by the HRA still applies.

This section was signed electronically by Mrs Hope Howard on 27/11/2018 07:14.

Job Title/Post:	Divisional Research Manager
Organisation:	University Hospital Southampton NHS Foundation Trust
Email:	hope.howard@uhs.nhs.uk