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)
CRICKET - CRItiCal events in Kids undErgoing Tracheal intubation

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

( ) Ionising Radiation for combined review of clinical trial of an investigational medicinal product

( ) Ionising Radiation and Devices form for combined review of combined trial of an investigational medicinal product and an investigational medical device

( ) Clinical investigation or other study of a 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)*

[x] England
[x] Scotland
[x] Wales
[x] 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?

- [x] IRAS Form
- [ ] Confidentiality Advisory Group (CAG)
- [ ] HM Prison and Probation Service (HMPPS)

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 the research e.g. NHS support costs) for this study provided by a NIHR Biomedical Research Centre (BRC), NIHR Applied Research Collaboration (ARC), NIHR Patient Safety Translational Research Centre (PSTRC), or an NIHR Medtech and In Vitro Diagnostic Co-operative (MIC) 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 (CRN) provides researchers with the practical support they need to make clinical studies happen in the NHS in England 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, information from your IRAS submission will automatically be shared with the NIHR CRN. ***Submission of a Portfolio Application Form (PAF) is no longer required.***

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)
CRICKET - CRItiCal events in Kids undErgoing Tracheal intubation

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

REC Name:
PR Committee

REC Reference Number:
24/PR/0463

Submission date:
10/04/2024

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

CRICKET: Critical events in anaesthetised kids undergoing tracheal intubation – a prospective, multi-centre observational study

A3-1. Chief Investigator:

	Title	Forename/Initials	Surname
	Dr	Tom	Bennett
Post	Consultant Anaesthetist		
Qualifications	BM FRCA MRCPCH		
ORCID ID	0009 0007 6261 2271		
Employer	University Hospital Southampton		
Work Address	Tremona Road Southampton Hampshrie		
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Work E-mail	tom.bennett@uhs.nhs.uk		
* Personal E-mail	tbennett85@gmail.com		
Work Telephone	07590062152		

* Personal Telephone/Mobile 07590062152
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
Ms	Sharon	Davis-Dear

Address	R&D Department
	University Southampton NHT Foundation Trust (Mailpoint 138)
	Tremona Road
Post Code	SO16 6YD
E-mail	sharon.davies-dear@uhs.nhs.uk
Telephone	02381205044
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 CRI0441
Sponsor's/protocol number:	
Protocol Version:	V1.2
Protocol Date:	13/03/2024
Funder's reference number (enter the reference number or state not applicable):	not applicable
Project website:	https://cricketstudy.eu/

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.*

Critical Events in Kids Undergoing Tracheal Intubation (CRICKET) aims to quantify the rate of complications during airway management in paediatric anaesthesia. Around 30% of children undergoing anaesthesia in the UK will have a breathing tube placed in their trachea (tracheal intubation). This is a critical procedure and is a core skill of the anaesthetist who has undergone specific training in airway managemnet.

Data regarding the events of the intubation are routinely recorded on anaesthetic charts as well as complications arising from this. For the study, the clinical team will collate this observational data for all children between 0 and 16 years who are intubated by the anaesthetic team.

Data will be collected during a suitable 3 month data collection period for each participating centre until the end of December 2024. There will be no changes to routine care or any additional data collected other than that which should be recorded routinely in the patient notes. All hospitals in the UK who anaesthetise children are eligible to participate.

Significant complications of airway management such as death or disability as a result of hypoxia (lack of oxygen), are extremely rare. Previous studies have focused on major complications such as this. We aim to study a larger cohort of children and to record more detailed data on critical events associated with tracheal intubation in children. This may allow us to identify children at particularly high- risk for major complications which might consecutively help with the development of improved management strategies.

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, airway management and basic demographic data in children aged up to 16 years who are intubated by the anaesthesia team.

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, the patients will bear no additional risks.

All 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.

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.

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

- [x] 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 primary study outcome is the incidence of anaesthesia cases with critical events associated with endotracheal intubation requiring intervention in children aged 0 - 16 years.

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

Secondary study outcome parameters are the incidences of the individual critical events as listed below. Also, we will assess the number of events per case as a secondary outcome parameter.
The following critical events will be recorded:
- Death correlated to failed airway management
- Can't intubate, can't oxygenate (CICO) situation
- Negative pressure pulmonary oedema
- Pulmonary aspiration of gastric content
- Pneumothorax/pneumomediastinum (air around the lung or air around the heart)
- Stridor after extubation
- Acute airway bleeding/ epistaxis
- Obstruction of the tracheal tube requiring lavage (wash out) and/or tracheal tube exchange
- Bronchospasm
- Laryngospasm
- Accidental tracheal tube dislocation (after successful tracheal intubation)
- Unintended bronchial intubation (accompanied by desaturation and/or bradycardia)
- Oesophageal intubation not immediately recognized (accompanied by desaturation and/or bradycardia)
- Cardiac arrest leading to cardiopulmonary resuscitation
- Severe bradycardia
- Severe hypoxemia

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

Airway management is one of the most integral roles in paediatric anaesthesia. Current evidence suggests that the number of attempts at intubation correlates with an increase in critical events in children undergoing anaesthesia. A number of other factors may play a role in complications during airway management. These include patient factors such as obesity and surgical factors such as airway surgery.

There are also a variety of ways in which an airway can be managed during anaesthesia. The data we will collect will include detailed information about which equipment was used, the experience of the operator and which drugs were used to induce anaesthesia.

This study aims to study airway managment in children on a large scale, in detail. We hope to be able to draw conclusions, based on current practice, that will inform the decision making process around paediatric intubation relating (but not limited to) equipment, personelle and identification of cases where there is a higher risk of

complications. The data will be used to inform national and international guidelines regarding paediatric airway managment.

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.*

-Aims-
To identify the incidence of adverse events associated with tracheal intubation paediatric anaesthesia

-Sampling-
This observational cohort study will take place in NHS hospitals in the UK with consultant and junior anaesthetic doctors who anaesthetise children under 16 years of age.

To increase coverage of sites in the UK, the project will be advertised through trainee research networks including the Paediatric Anaesthetic Trainee Research Network (PATRN), 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 undergoing anaesthesia who are intubated during the study period in participating hospitals or selected theatres within the participating hospital. This study period will be three months of consecutive data collection or as long as the participating centre can feasibly achieve continuous data collection. The 3 month data collection period will be selected

-Sample size-
Previous paediatric anaesthetic audit and research projects have enrolled approximately 90 local sites. Around 35% of cases in the UK undergo tracheal intubation. If we enrol a similar number of sites this would give an estimated total of around 8000 children who are intubated during 3 months of data collection.

-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 tracheal intubation under general anaesthesia during the study period.

-Data Collection-
Patients aged between 0 and 16 years undergoing tracheal intubation will be included in the data collection. The study will not alter the management of the patient in any way. The clinicians will fill in a case report form which details the events around the time of intubation. At the end of the case, details regarding the removal of the breathing tube (extubation) are recorded. Once the patient is safely in the recovery area, the data collection is complete.

If a critical event occurs, the patient is followed up at 24 hours. If the event has resolved or they have been discharged, the data collection for this patient is complete. If there are ongoing complications, they are followed up until resolution of these or 30 days, whichever is sooner.

-Validation of tools-
Similar tools have been used in previous national studies and international research projects in paediatric anaesthesia.

-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 Unit of Biostatistics, Epidemiology and Public Health, Department of Cardiac-Thoracic-Vascular Sciences and Public Health, University of Padova, Italy. 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.

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

- ☐ Design of the research
- ☐ Management of the research
- ☐ Undertaking the research
- ☐ Analysis of results
- ☐ Dissemination of findings
- ☑ None of the above

Give details of involvement, or if none please justify the absence of involvement.
This is a observational study of complications of a procedure which is carried out by anaesthetists in theatres. It's purpose is to inform the practice of medical professionals who strive to improve care to service users and the public.

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
- ☐ 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: 0	Days
Upper age limit: 16	Years

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

Any child under 16 planned for tracheal intubation as part of their general anaesthetic by the anaesthesia team.

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

Age over or equal to 16 years
Patient who is already intubated undergoing a procedure under general anaesthetic

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 (who may be independent of delivery of anaesthesia but part of the anaesthetic department of the hospital, and therefore members of the direct care team) and the clinicians in charge of the anaesthetic will identify all children planned for intubation 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.

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 children undergoing anaesthesia who have a critical event related to the placement of a tracheal tube. 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.

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 8000 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:

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. A data

transfer agreement details the storage and use of data once it is transferred to the central database.

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 Unit of Biostatistics, Epidemiology and Public Health of the University of Padua, Italy. All participating centres will be required to complete a data transfer agreement between their Trust and the University of Padua.

Data will be stored in accordance with EU Regulation 2016/679.

The central database contains no encrypted Data, so no data is traceable to the identification of the patient.

The data is to be used only for the academic purposes as described in Study protocol; (b) may not itself be commercialized and (c) shall not be transferred to or accessed by any third party, for any purposes whatsoever.

Data will be solely available to those individuals who require such access to the Data in order to conduct the Study.

Data is protected from unauthorized access.

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 (10years after completion of data collection).

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).

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 (10 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 the anaesthetist in charge of the case or members of the anaesthetic department in the hospital where the patient is being treated and as such form part of the clinical care team. Access to this information therefore forms part of their usual role within the hospitals anaesthetic 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 Prof Dario Gregori, Unit of Biostatistics, Epidemiology and Public Health of the University of Padua, Italy. All data will be subject to the data transfer agreement.

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

	Title	Forename/Initials	Surname
	Dr	Tom	Bennett
Post	Consultant Paediatric Anaesthetist		
Qualifications	BM FRCA MRCPCH		
Work Address	Shakleton Department of Anaesthesia Southampton General Hospital		
Post Code	SO166YD		
Work Email	tom.bennett@uhs.nhs.uk		
Work Telephone	07590062152		
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 allos any queries to be clarified and investigated from the raw data.

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

Years: 10
Months:

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 ended, data will be stored for 10 years on the REDCap system

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.
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, thus this is information they have access to as part of this role in the department.

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. How and when will you inform participants of the study results?

If there will be no arrangements in place to inform participants please justify this.
The results will be published in a peer-reviewed journal. Final decision on publishing the results will be kept by the steering committee of the study. This is an observational study with no change to clinical practice therefore has no impact on the individual patients care.

Authors of the publication will be team members of the steering committee who contributed to the design, conduct or analysis of the study and who approved of the final version of the manuscript. Local PIs agree not to individually publish or present the results they obtain from the participation in the multicentre study before the publication of the main result of the study. Local PIs may, however, upon written notice to Sponsor and Steering committee participate in a joint, multicentre publication of the study results with other third-party principal investigators and/or institutions, provided that the proposed publication is first reviewed by Sponsor and Steering committee.

5. Scientific and Statistical Review

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

- ☐ Independent external review
- ☐ Review within a company
- ☑ Review within a multi−centre research group
- ☐ 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:
A steering committee of international experts have reviewed and approved the most current study protocol.

Dr Tom Bennett is the UK representative on this committee.

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:*

- ☐ 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	Dario	Gregori
Department	Head of the Unit of Biostatistics,Epidemiology and Public Health, Padova University, Via C. Battisti 241, 35121 Padova		
Institution			
Work Address			
Post Code			
Telephone			
Fax			
Mobile			
E-mail			

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

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

The incidence of anaesthesia cases with critical events associated with endotracheal intubation

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

Secondary study outcome parameters are the incidences of the individual critical events associated with tracheal intubation and the number of critical events per case.

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: 8000

Total international sample size (including UK):

Total in European Economic Area:

Further details:
Previous multicentre studies in the UK have included around 100 centres and we anticipate a similar recruitment for this study. These studies have included between 5000 and 8000 cases during a 2 week data collection window. Given that around 30% of cases under go intubation and we intend to collect data for 3 months, the number of intubated patients will be around 8000.

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. The data from this study will contribute to a wider analysis with a target recruitment of 105000.

Based on our sample size calculation 105’000 patients. The sample size was determined based on
(i) assumptions from previous studies regarding the incidence of critical airway events (estimated incidence of critical events related to tracheal intubation 1%) and
(ii) the precision requirement that the relative error of the inferred incidence is within ±10% of the mean estimate. To be specific, the sample size was calculated with the aim that the inferred 95% confidence interval should lie between 0.9 – 1.1% with an estimated incidence of events of 1%.

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.

In terms of descriptive statistics, categorical data will be summarised with count and percentages. Continuous data will be summarized using median (interquartile range).

The incidence of critical events will be estimated and reported together with 95% Confidence Interval, Furthermore, critical events incidence will be provided for different age categories, operator's experience, operator's speciality, and centre volume (secondary and tertiary).

In terms of risk factor analysis, a univariable and multivariable mixed-effect logistic regression model will be computed based on possible predictors, which include e.g. age (< or equal to 12 months), weight (< or equal to 10 kg), number of attempts (>2), presence of co-morbidities (ASA score > or equal to 3), comorbidity related to airway management (e.g. relevant syndromes), expected difficult intubation, type of anaesthesia induction (IV or inhalational), no neuromuscular blocking agent given, airway surgery or ENT surgery and experience level of intubator. Goodness-of-fit, calibration, discriminatory capacity and predictive skill of the regression models will be assessed by means of Nagelkerke pseudo r-squared, calibration belts, Area Under the Receiver Operating Characteristics (AUROC) and Brier Score, respectively.

A p-value < 0.05 is considered statistically significant. All analyses will be performed with R

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
	Prof	Thomas	Riva
Post			
Qualifications	MD (Study Lead)		
Employer	Department of anaesthesiology and pain medicine		
Work Address	Inselspital Bern University Hopspital Friburgstrasse 8 Bern Switzerland		
Post Code	3010		
Telephone	+41 31 632 27 25.		
Fax			
Mobile			
Work Email	thomas.riva@insel.ch		

	Title	Forename/Initials	Surname
	Prof	Robert	Greif
Post			
Qualifications	MD (Chair of steering committee of international contributors, Dr Tom Bennett is the UK representative on this committee)		
Employer	Department of anaesthesiology and pain medicine		
Work Address	Inselspital Bern University Hopspital Friburgstrasse 8 Bern Switzerland		
Post Code	3010		
Telephone	+41316322725		

Fax	
Mobile	
Work Email	robert.greif@insel.ch

Title	Forename/Initials	Surname
Prof	Nicola	Disma

Post	
Qualifications	MD
Employer	G Gaslini Children's Hospital
Work Address	Via Gerolamo Gaslini Genova GE Italy
Post Code	16147
Telephone	
Fax	
Mobile	
Work Email	nicoladisma@gaslini.org

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 HOSPITAL SOUTHAMPTON NHS FOUNDATION TRUST
Given name	Sharon
Family name	Davis-Dear
Address	SOUTHAMPTON GENERAL HOSPITAL
Town/city	SOUTHAMPTON
Post code	SO16 6YD
Country	United Kingdom
Telephone	02381205044
Fax	
E-mail	sponsor@uhs.nhs.uk

Legal representative for clinical investigation of medical device (studies involving Northern Ireland only)
Clinical Investigations of Medical Devices that take place in Northern Ireland must have a legal representative of the sponsor that is based in Northern Ireland or the EU

Contact person

Name of organisation
Given name
Family name
Address
Town/city
Post code
Country
Telephone
Fax
E-mail

A65. Has external funding for the research been secured?

Please tick at least one check box.

- ☐ 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:

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

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
	Ms	Catherine	Lee
Organisation	UNIVERSITY HOSPITAL SOUTHAMPTON NHS FOUNDATION TRUST		
Address	SOUTHAMPTON GENERAL HOSPITAL		
	TREMONA ROAD		
	SOUTHAMPTON		
Post Code	SO16 6YD		
Work Email	catherine.lee@uhs.nhs.uk		
Telephone	02381205044		
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: 01/06/2024
Planned end date: 31/12/2024
Total duration:
Years: 0 Months: 6 Days: 31

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 14

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	10
☑ NHS organisations in Wales	2
☑ NHS organisations in Scotland	2
☐ HSC organisations in Northern Ireland	
☐ 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:	14

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

◉ Yes ○ No

A73-2. If yes, will any of these organisations be NHS organisations?

○ Yes ◉ No

If yes, details should be given in Part C.

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 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.

- [x] 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.

- [x] 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.

- [x] 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.

Children aged 0 to 16. This is a study into the management of all children undergoing anaesthetisa

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

Controls are not required for this study which is observational

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 do not anticipate consent to be required

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.

No information regarding the study will be required as it does not change routine clinical care

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	Tom Bennett tom.bennett@uhs.nhs.uk
	Organisation name	UNIVERSITY HOSPITAL SOUTHAMPTON NHS FOUNDATION TRUST	Qualification (MD...)	BM MRCPCH FRCA
	Address	SOUTHAMPTON GENERAL HOSPITAL TREMONA ROAD SOUTHAMPTON	Country	United Kingdom
	Post Code	SO16 6YD		
	Country	ENGLAND		
IN2	◉ NHS/HSC Site ○ Non-NHS/HSC Site		Forename Middle name Family name Email	Hannah Lewis h.lewis4@nhs.net
	Organisation name	GUY'S AND ST THOMAS' NHS FOUNDATION TRUST	Qualification (MD...)	MBChB FRCA MSc
	Address	ST THOMAS' HOSPITAL WESTMINSTER BRIDGE ROAD LONDON	Country	United Kingdom
	Post Code	SE1 7EH		
	Country	ENGLAND		
IN3	◉ NHS/HSC Site ○ Non-NHS/HSC Site		Forename Middle name Family name Email	Xantha Holmwood xantha.holmwood@nhs.net
	Organisation name	SALISBURY NHS FOUNDATION TRUST	Qualification (MD...)	

Address	SALISBURY DISTRICT HOSPITAL ODSTOCK ROAD SALISBURY	Country	United Kingdom	
Post Code	SP2 8BJ			
Country	ENGLAND			

IN4

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Forename	Alun		
Middle name			
Family name	Thomas		
Email	Alun.w.thomas@wales.nhs.uk		
Organisation name	HYWEL DDA UNIVERSITY LHB	Qualification (MD...)	
Address	CORPORATE OFFICES, YSTWYTH BUILDING HAFAN DERWEN ST DAVIDS PARK, JOBSWELL ROAD CARMARTHEN DYFED	Country	
Post Code	SA31 3BB		
Country	WALES		

IN5

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Forename	James		
Middle name			
Family name	Gaynor		
Email	james.gaynor@nnuh.nhs.uk		
Organisation name	NORFOLK AND NORWICH UNIVERSITY HOSPITALS NHS FOUNDATION TRUST	Qualification (MD...)	
Address	COLNEY LANE COLNEY NORWICH	Country	
Post Code	NR4 7UY		
Country	ENGLAND		

IN6

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Forename	Karina
Middle name	Kinga

	Organisation name	LOTHIAN	Family name	Jabuowska
	Address	WAVERLEYGATE 2-4 WATERLOO PLACE EDINBURGH CITY OF EDINBURGH	Email	karina.jakubowska@nhslothian.scot.nhs.uk
			Qualification (MD...)	
			Country	
	Post Code	EH1 3EG		
	Country	SCOTLAND		

IN7

◉ NHS/HSC Site
○ Non-NHS/HSC Site

		Forename	James
		Middle name	
		Family name	Armstrong
		Email	James.Armstrong2@nuh.nhs.uk
Organisation name	NOTTINGHAM UNIVERSITY HOSPITALS NHS TRUST	Qualification (MD...)	
		Country	United Kingdom
Address	TRUST HEADQUARTERS QUEENS MEDICAL CENTRE DERBY ROAD NOTTINGHAM		
Post Code	NG7 2UH		
Country	ENGLAND		

IN8

◉ NHS/HSC Site
○ Non-NHS/HSC Site

		Forename	Amr
		Middle name	
		Family name	Abdelaal
		Email	amr.abdelaal@nhs.net
Organisation name	CAMBRIDGE UNIVERSITY HOSPITALS NHS FOUNDATION TRUST	Qualification (MD...)	
		Country	
Address	CAMBRIDGE BIOMEDICAL CAMPUS HILLS ROAD CAMBRIDGE		
Post Code	CB2 0QQ		
Country	ENGLAND		

IN10

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Organisation name	CARDIFF & VALE UNIVERSITY LHB
Address	WOODLAND HOUSE MAES-Y-COED ROAD CARDIFF
Post Code	CF14 4HH
Country	WALES

Forename	Mari
Middle name	
Family name	Roberts
Email	mari.roberts5@wales.nhs.uk
Qualification (MD...)	
Country	

IN9

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Organisation name	GRAMPIAN
Address	SUMMERFIELD HOUSE 2 EDAY ROAD ABERDEEN
Post Code	AB15 6RE
Country	SCOTLAND

Forename	Li Yen
Middle name	Jade
Family name	Liew
Email	liyen.liew@nhs.scot
Qualification (MD...)	
Country	

IN11

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Organisation name	YORK AND SCARBOROUGH TEACHING HOSPITALS NHS FOUNDATION TRUST
Address	YORK HOSPITAL WIGGINTON ROAD YORK
Post Code	YO31 8HE
Country	ENGLAND

Forename	Mark
Middle name	
Family name	Allford
Email	M.allford@nhs.net
Qualification (MD...)	
Country	

IN12

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

Organisation name	BEDFORDSHIRE HOSPITALS NHS FOUNDATION TRUST
Address	LEWSEY ROAD LUTON
Post Code	LU4 0DZ
Country	ENGLAND

Forename	Poojani
Middle name	
Family name	Arulrajah
Email	p.arulrajah@hotmail.co.uk
Qualification (MD...)	
Country	

IN13

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

Organisation name	UNIVERSITY HOSPITALS PLYMOUTH NHS TRUST
Address	DERRIFORD HOSPITAL DERRIFORD ROAD DERRIFORD PLYMOUTH
Post Code	PL6 8DH
Country	ENGLAND

Forename	Danielle
Middle name	
Family name	Franklin
Email	daniellefranklin@nhs.net
Qualification (MD...)	
Country	

IN14

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

Organisation name	ST GEORGE'S UNIVERSITY HOSPITALS NHS FOUNDATION TRUST
Address	ST GEORGE'S HOSPITAL BLACKSHAW ROAD TOOTING LONDON
Post Code	SW17 0QT
Country	ENGLAND

Forename	Joanne
Middle name	
Family name	Norman
Email	joanne.norman@stgeorges.nhs.uk
Qualification (MD...)	
Country	

IN16

(●) NHS/HSC Site

( ) Non-NHS/HSC Site

Forename	Ognyan
Middle name	
Family name	Ivanov
Email	ognyan.ivnov@qehkl.nhs.uk
Qualification (MD...)	
Country	

Organisation name	THE QUEEN ELIZABETH HOSPITAL, KING'S LYNN, NHS FOUNDATION TRUST
Address	QUEEN ELIZABETH HOSPITAL GAYTON ROAD KING'S LYNN
Post Code	PE30 4ET
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 2018.

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 2018.

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 Health Research Authority (HRA) together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after the issue of the ethics committee's final opinion or the withdrawal of the application.

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

HRA 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 Tom Bennett on 10/04/2024 08:25.

Job Title/Post:	Consultant Paediatric Anaesthetist
Organisation:	University Hospital Southampton
Email:	tom.bennett@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 Sharon Davies-Dear on 10/04/2024 09:54.

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