

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)

Children's Acute Surgical Abdomen Programme: CASAP v1.0

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) Does the study involve the use of any ionising radiation? Yes No
- b) Will you be taking new human tissue samples (or other human biological samples)? Yes No
- c) Will you be using existing human tissue samples (or other human biological samples)? 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?

- IRAS Form
 Confidentiality Advisory Group (CAG)
 Her Majesty's 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 research e.g. NHS Support costs) for this study provided by a NIHR Biomedical Research Centre, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC), NIHR Patient Safety Translational Research Centre or Medtech and In Vitro Diagnostic Cooperative 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 Research administering questionnaires/interviews for quantitative analysis or mixed methodology study

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 familiar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
 Children's Acute Surgical Abdomen Programme: CASAP v1.0

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

REC Name:
HSC REC B

REC Reference Number:
19/NI/0021

Submission date:
21/01/2019

PART A: Core study information
1. ADMINISTRATIVE DETAILS
A1. Full title of the research:

Children's Acute Surgical Abdomen Programme: CASAP

A3-1. Chief Investigator:

	Title Forename/Initials Surname
	Prof S. Ramani Moonesinghe
Post	Professor and Head of Centre for Perioperative Medicine, UCL; Honorary Consultant in Anaesthesia, UCLH; Director NIAA Health Services Research Centre
Qualifications	BSc. (Hons) MBBS FRCP FRCA FFICM MD(Res)
ORCID ID	0000 0002 6730 5824
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Work E-mail	ramani.moonesinghe@ucl.ac.uk
* Personal E-mail	ramani.moonesinghe@nhs.net

Work Telephone 07956620717
 * Personal Telephone/Mobile 07956620717
 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 Suzanne Emerton
 Address JRO UCL Gower Street
 London
 Post Code WC1E 6BT
 E-mail uclh.randd@nhs.net
 Telephone 02034472122
 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): 18/0342
 Sponsor's/protocol number:
 Protocol Version:
 Protocol Date:
 Funder's reference number (enter the reference number or state not applicable): WKR0-2017-0022
 Project website: <https://www.niaa-hsrc.org.uk/CASAP-Home#pt>

Additional reference number(s):

Ref.Number	Description	Reference Number
	UCL Data Protection Registration Number	Z6364106/2018/08/38

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.*

CASAP will review the type and quality of care provided to children undergoing emergency abdominal surgery in the United Kingdom. In doing so it will enable a comparison of the standard of care provided to be made against evidence-based recommendations and will identify variations in care between individual hospitals. Additional aims of this study include establishing the risk factors associated with postoperative complications in children having unplanned abdominal surgery.

We will collect data on all patients (aged 1 - 16 years) undergoing unplanned abdominal surgery in the UK during the study period. We will measure complications using an objective measurement system. We will also establish the longer term outcomes in these children by linking the data we collect with national databases held by the NHS Digital (Hospital Episode Statistics and the Office of National Statistics Mortality register). In carrying out this study we shall determine the acceptability to parents and children of having such data collected routinely with the aim to subsequently establish a longer-term national research programme aimed at improving the care in this patient group.

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.

This study will aim to recruit all children undergoing emergency abdominal surgery during the study period. Some of these children will be very unwell and this will therefore present a time of great stress for for them and their families.

Data collected will include some patient identifiable information (name, hospital number, date of birth, sex, postcode) which will be stored confidentially and pseudonymised on entering into a secured online database. This information will be used for data linkage with national registries, such as Hospital Episode Statistics (HES), providing us with information about hospital re-admission rates and long term mortality.

As well as inviting parents/legal guardians to provide informed consent, we will provide patient information leaflets and posters in patient areas, informing patients and parents of the study, the methods of analysis and data linkage to be used, as well as information detailing how to contact the study team to ask questions.

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.

To characterise the type and quality of care being delivered to children undergoing emergency abdominal surgery within hospitals in the United Kingdom.

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

Research Questions:

1. What is the level of compliance with national and international recommendations for processes relevant to the care of children undergoing emergency abdominal surgery in the U.K.? (processes being what actually happens to each individual patient)
2. What are the risk factors for adverse postoperative outcomes in paediatric patients undergoing emergency abdominal surgery?
3. Is it possible, practical and acceptable to patients and parents to collect this dataset in the emergency setting?

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

Deficiencies in the quality of emergency surgical care provided to children were highlighted in a NCEPOD report 2011 and more recent evidence suggest that whilst there has been a reduction in the number of some emergency procedures undertaken, this has been accompanied by an increase in the overall incidence of adverse outcomes. As a result, paediatric emergency general surgery has been identified by the Association of Paediatric Anaesthetists and the British Association of Paediatric Surgeons as a priority area for quality assurance and quality improvement, but until now there has been no consolidated national effort to measure or report processes or outcomes in this group. The paediatric surgical patient journey is sufficiently different from the adult patient's such that the direct mapping of adult quality assurance and improvement initiatives to children's perioperative care is likely to be of limited value. CASAP is a pilot study which aims to address this. It will evaluate the care and outcomes for children undergoing emergency abdominal surgery. We believe there are 27000 such procedures being performed a year in England alone. This study will measure baseline compliance against recommendations, and validate risk-adjustment and outcome measures to be used in a longer-term study which will target quality improvement in this high-risk group of patients.

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.

CASAP is a prospective observational cohort study of paediatric patients undergoing emergency abdominal surgery in participating hospitals to describe the case mix, morbidity and mortality.

Data will be collected on all patients meeting the inclusion criteria in all participating UK hospitals during the study period. We will aim to recruit 5000 patients.

Patients will first be identified by research nurses or by clinical nurses, emergency medicine doctors, critical care specialists, anaesthetists and/or surgeons involved in their care. These clinicians will complete the patient Case Report Forms (CRFs) for all patients who meet the inclusion criteria and who provide consent.

The dataset for the CRF has been determined via a systematic review of the peer-reviewed literature, grey literature and international recommendations by learned bodies for the care of children undergoing emergency abdominal surgery.

Patients will be followed up either at discharge or on Day 30 post-surgery, whichever occurs first. At this point, through reviewing the medical notes, a local investigator will determine whether any postoperative complications have occurred and subsequently grade the severity of any such complications using the Clavien Dindo classification system.

Inpatient stay will be censored at 30 days post-surgery. Therefore, the final entry in the CRF will be whichever of the following three options is the chronologically earliest date: date of discharge from hospital, date of death while in

hospital, or 30 days post-surgery if the patient remains in hospital on that date.

Prospectively collected patient data will be linked to NHS Digital's mortality data using the Bespoke Data Linkage service. We will specifically aim to establish mortality at 30 days, 90 days, and 1 year as well as longer term survival (up to 10 years). Follow up at 10 years will represent the last study activity for each individual participant.

A screening to recruitment log will be kept so that we can evaluate the feasibility and acceptability of a fully consenting model to parents and children.

Data Management:

At individual hospital level, patient identifiable data will be collected on paper CRFs and will be held in a secure location accessible only by the local PI and other named members of the study team in accordance with GCP guidelines and local information and research governance frameworks. Information from the paper CRF will be entered via a secure web-based portal onto the study database. Local investigators will have access to their own full datasets only. The database will be hosted securely on UCL servers.

The minimum amount of patient identifiable data will be extracted from the database by the central investigation team and sent in a secure way to NHS Digital to facilitate data linkage to centrally held mortality data. Mortality will be tracked for all patients with a final censure date of 10 years after participant recruitment.

Patient identifiable data will be used to ensure individual patient records within the CASAP system are managed correctly, keeping distinct treatment episodes linked to the correct patient and will enable data linkage with the NHS Digital mortality tracking system. Four patient identifiers will be used: patient name, date of birth, NHS number and postcode.

Data received from NHS Digital will be stored on the study database in a pseudonymised format. (Please see A39, the study protocol or Data Flow Diagram for more detailed information about the transfer of data to and from NHS Digital.)

The electronic patient datasets will be appropriately sent to Chief Investigator Prof Ramani Moonesinghe for statistical analysis. All participant datasets will be stored, processed and disposed of in accordance with all applicable legal and regulatory requirements, including the Data Protection Act 1998 and any amendments thereto.

An anonymised dataset will be used by the central CASAP study team, led by Prof Ramani Moonesinghe, for analysis. In this dataset the NHS number will be replaced by a unique study number, date of birth will be converted to 'Age at time of surgery' and postcode will be converted to PCT, SHA of residence and the Office for National Statistics Lower Super Output Area, which allows the allocation of the Index of Multiple Deprivation. Sex will be the only patient identifier used in the analysis.

Parents withhold to right to withdraw consent at any time. In this instance no further data will be collected. Any data which has already been collected and anonymised may still be used in the analysis.

Analysis plan:

Assessment of feasibility:

The main assessment of feasibility will be the screening to recruitment ratios at each site.

Statistical Analysis:

We will develop a full statistical analysis plan. We will provide descriptive epidemiology of this cohort, the compliance with processes of care, and outcomes. Hierarchical regression will be used to determine the relationship between structures, processes and outcomes. Our primary outcome is postoperative complications (measured according to the Clavien-Dindo scale) and secondary outcomes include length of stay and mortality. Patient level risk factors for adverse outcomes will also be determined to allow development and validation of the risk prediction models.

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.

We have sought patient and public involvement from the NIAA Health Services Research Centre Patient, Carer & Public Involvement & Engagement group and the NIHR Young Persons Advisory Group (YPAG) in the West Midlands. They have kindly reviewed all our protocol and our participant information sheets. A member of the YPAG (Mohini Samani) has joined our steering group as our lay representative. PCPIE and the YPAG will also help with the dissemination of the results.

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: 1 Years

Upper age limit: 16 Years

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

Children between 12 months and 16 years of age undergoing unplanned (immediate or urgent, according to NCEPOD criteria) abdominal surgery – including laparotomy, laparoscopy or other surgical incisional approaches, undertaken by a surgeon in an operating theatre requiring the support of an anaesthetist.

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

Patients / parents who do not provide consent to participate in the study. Children <12 months old on day of surgery, elective procedures, organ transplants, insertion or removal of dialysis catheters, surgery relating to trauma, interventional radiology procedures and Caesarean sections.

RESEARCH PROCEDURES, RISKS AND BENEFITS

A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. These include seeking consent, interviews, non-clinical observations and use of questionnaires.

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
Seeking informed consent	1		15 min	To be completed by the local research team between the time that the decision to operate has been made and before discharge from hospital.
Patient Case Report Form - part 1	1		10 mins	To be completed either by the patient's anaesthetist at the time of surgery (if informed consent has been provided) or as soon as possible afterwards if consent not provided before surgery.
Patient Case Report Form - part 2	1		5 mins	To be completed by a member of the local research team by reviewing the notes at discharge or Day 30 if remains an inpatient post-surgery.

A21. How long do you expect each participant to be in the study in total?

Mortality will be tracked via NHS Digital for a maximum of 10 years after surgery.

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

This study involves the use of data so there are risks associated with breaches in confidence or failure to maintain data security. To minimise this risk patient identifiable information collected via paper-based case report forms (CRFs) will be securely and confidentially held (as would be expected of patients' medical notes) and with due attention to Good Clinical Practice (GCP), the Data Protection Act (DPA) 1998 and General Data Protection (GDPR) at each local study site.

Data will be transcribed by local investigators onto an electronic CRF held on a secure online database. This will include patient identifiable information to allow for data linkage to be performed via NHS Digital's Bespoke Data Linkage Service to obtain long term mortality data. Paper-based CRFs will be stored securely by local investigators for 5 years after the study recruitment window ends before being destroyed confidentially.

All investigators for each local study site will be expected to act in full compliance with GCP, GDPR, the DPA 1998 and

the Research Governance Framework for Health and Social Care (2005).

A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

Yes No

A24. What is the potential for benefit to research participants?

Participation in this study will not directly benefit the participants during their hospital stay. However, we hope that the information gained from conducting this study will improve the care delivered in hospitals in the future, thus potentially affording prospective benefits to the participants themselves, or their friends and family if they need to undergo emergency surgery.

A26. What are the potential risks for the researchers themselves? (if any)

None.

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).*

Potential participants will be all children (aged 1-16 years) undergoing emergency abdominal surgery (as detailed in the inclusion/exclusion criteria) in a participating hospital during the designated study period. They will first be identified by research nurses or by clinical nurses, emergency medicine doctors, critical care specialists, anaesthetists and/or surgeons involved in their care. Screening for patients who meet the inclusion criteria will be conducted on a daily basis through locally determined processes but which are likely to include screening of emergency operating theatre lists and ward occupancy lists.

Please Note: we aim to recruit every hospital in the UK which provides care to children undergoing emergency abdominal surgery, for this reason we have named only a sample of hospitals in in Part C: Overview of Research Sites. These named hospitals are the designated centres for our pilot run during which we will test the functionality of the CRFs and the secure online database before formal recruitment begins.

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:

Patients will be identified by clinicians in the course of routine healthcare provision or by local clinical research nurses who will review the operating theatre lists and/or ward occupancy lists to ensure all eligible patients have been approached. Where it is unclear on the operating list as to the exact nature of the procedure and thus whether a patient is eligible to be enrolled local investigators may refer to a patient's medical notes for further clarification.

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.*

Operating theatre lists, ward occupancy lists and on occasion (as detailed in question A27-2) a patient's medical records will be the sources used to identify potential participants.

Only staff who are employed by each participating NHS organisation will have access to operating theatre lists with patient identifiable data for that hospital. Local investigators will all be clinical staff employed by the NHS hospital in question and will be bound by the Data Protection Act, the NHS Information Governance Framework and local information governance regulations.

Patient / parent information leaflets and posters will be available in relevant patient areas (e.g. paediatric and surgical wards, Accident and Emergency Dept., theatre waiting room) in each participating hospital providing details about the study including that they will be approached to provide consent for their child to be included in the study. Details of how to find out further information and how to contact the study team should participants wish to withdraw will be clearly provided within these.

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

Yes No

A27-5. Has prior consent been obtained or will it be obtained for access to identifiable personal information?

Yes No

If Yes, please give details below.

Consent will be sought from parents.

Consent will be sought at some point between the decision to operate being made and the child being discharged from hospital (or death).

No data will be collected until written consent is provided by a parent.

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?

The parents of children on the planned or actual date of surgery will be approached to provide informed consent to participate. Patients will first be identified by research nurses or by clinical nurses, emergency medicine doctors, critical care specialists, anaesthetists and/or surgeons involved in their care.

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.

Consent will be sought by clinicians or local research nurses. Potential participants will be provided with patient information sheets and consent forms for completion; these will provide contact details for further information

including links to the study website.

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

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

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

Patients and parents will be given a minimum of one hour to consider the participant information leaflet before being approached for informed consent.

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)

Language constraint will be an exclusion criterion.

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?

All written information, including the questionnaires and patient information leaflets, will be made available in Welsh.

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? Tick one option only.

- The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.
- The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.
- The participant would continue to be included in the study.
- Not applicable – informed consent will not be sought from any participants in this research.
- Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be assumed.

Further details:

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:

Members of the research team at each hospital site will be required to access medical records to identify patient participants, obtain clinical information pertinent to the study dataset and to complete follow up.

Patient data will initially be collected on paper Case Report Forms (CRFs) at the time of the patients' surgery by the anaesthetist. This data will be pseudonymised and then transcribed into a secure online database via a web-based data collection platform (REDCap) where it will be accessible only by the patient's hospital primary investigator and those analysing the results under the direction of the study's chief investigator. The database will be hosted on secure servers at UCL. In a separate process a partial dataset will containing the patient identifiable data required for data linkage will be uploaded by local investigators onto UCL's Data Safe Haven using a secure file transfer portal. Local investigators' activity will be limited to uploading data only. They will not be able to access any of the data on the Safe Haven.

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

The completed paper Case Report Forms (CRFs) will be stored securely and confidentially at each site in line with local information governance guidelines. Each hospital will store study data in locked cabinets in locked rooms. These will not leave the local NHS organisation at any stage. Once data has been transcribed onto the secure online study database, all data stored electronically will be password protected.

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.

At individual hospital level, the completed CRFs will be held in a secure location accessible only by the local PI and other named members of the study team in accordance with GCP guidelines and local information and research governance frameworks. Information from the paper CRF will be entered via a secure web-based portal onto the study database. The uploading of data will occur in two steps. Firstly, a pseudonymised dataset with name, DoB, and date of surgery replaced by a unique CASAP Study ID, age and day of week on which surgery occurred will be uploaded onto the study database via UCL's Non-Data Safe Haven REDCAP web-based portal. This will be hosted on UCL servers. Local investigators will have access to enter and edit data from their own hospital. Secondly, a partial dataset containing the patient identifiers required for data linkage with NHS Digital will be uploaded by local investigators onto UCL's Data Safe Haven using a secure file transfer portal. Only the core CASAP study team will have access to this data.

For the purposes of data linkage with NHS Digital the minimum amount of patient identifiable data will be extracted from the database on the UCL Data Safe Haven by the central investigation team, onto a password protected Excel spreadsheet. This will be emailed securely NHS Digital, to facilitate linkage to centrally held mortality data. Mortality will be tracked for all patients with a final censure date of 10 years after participant recruitment. Please see the study Data

Flow Diagram for illustration. Four patient identifiers will be used to facilitate data linkage: patient name, date of birth, NHS number and postcode.

An anonymised dataset complete with the prospectively collected data and the NHS Digital data will be analysed by the core CASAP study team.

All study team members will be bound by the Data Protection Act, the NHS Information Governance Framework and local information governance regulations.

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 clinical teams and researchers will have access to participants' personal data during the study, limited to individuals with a formal governance role with the Trust (i.e. substantive or honorary contract).

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?

Data will be anonymised on entering into a secure online database. Anonymised data will be analysed at the Division of Surgery and Interventional Science, UCL.

Analyses will be conducted by members of the study team:

- Prof SR Moonesinghe
- Dr LA Sogbodjor
- Dr Peter Martin (UCL Statistician)
- Dr Cyrus Rayazi (Research Associate Division of Surgery and Interventional Science, UCL)

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

	Title Forename/Initials Surname
	Prof S.R. Moonesinghe
Post	Professor and Head of Centre for Perioperative Medicine, UCL; Honorary Consultant in Anaesthesia, UCLH; Director NIAA Health Services Research Centre
Qualifications	BSc. (Hons) MBBS FRCP FRCA FFICM MD(Res)
Work Address	Division of Surgery, University College London Charles Bell House 43-45 Foley Street, London
Post Code	W1W 7TS
Work Email	ramani.moonesinghe@ucl.ac.uk
Work Telephone	07956620717
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:

In the interests of data linkage to the determine longer-term mortality in this cohort of patients.

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

Years: 20

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.

All electronic data will continue to be securely stored in UCL servers hosted until 10 years after the last follow-up. (i.e. 20 years after study recruitment ends).

All paper CRFs will be held locally in secured cabinets within locked rooms in accordance with local and national data protection guidance and GCP. The paper CRFs will be destroyed securely by local PIs 5 years after the final patient has been recruited.

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**A49-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?**

Yes No

If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.

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.

We plan to register the study with www.clinicaltrials.gov a publically-accessible registry which accepts observational

research studies. (www.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?

We will not be publishing dis-aggregated patient level data.

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.

Information will be provided in the patient information sheet describing how they will be able to register with the study website so that they can be informed of the findings of the study when they are available.

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:

The study has been developed in conjunction with subject matter experts representing the Health Services Research Centre at the Royal College of Anaesthetists (research expertise), Association of Paediatric Anaesthetists of Great Britain and Ireland and the British Association of Paediatric Surgeons (clinical expertise).

We underwent peer review during a grant application process - the application was reviewed by three independent external assessors. As a result the full sum of £40,000 was awarded by the NIAA Small Research Grant Award scheme in June 2017.

We have also convened a Study Steering Committee comprising experts from multiple bodies as well as lay representation. This committee will have an independent chair and will meet every six months to discuss the ongoing planning and running of the study.

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
	Professor	Suneetha Ramani	Moonesinghe
Department	Professor and Head of Centre for Perioperative Medicine, UCL; Honorary Consultant in Anaesthesia, UCLH; Director NIAA Health Services Research Centre		
Institution	University College London		
Work Address	Division of Surgery, University College London Charles Bell House 43-45 Foley Street, London		
Post Code	W1W 7TS		
Telephone	07956620717		
Fax			
Mobile	07956620717		
E-mail	ramani.moonesinghe@ucl.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?

Postoperative morbidity measured using the Clavien-Dindo scale

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

- Length of hospital stay
- Mortality - inpatient, 30-day, 90-day, 1 year and through data linkage longer term survival up to 10 years.
- Compliance with processes of care

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: 5000
 Total international sample size (including UK): 5000
 Total in European Economic Area: 5000

Further details:

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.

As this is an observational study we are not including a formal sample size calculation.

However, we will aim to recruit 5000 patients to enable sufficiently large cohort to achieve our goals of being able to develop a risk adjustment model and validate the outcome measures. We have also considered likely recruitment rates when determining the duration of this pilot phase. A previous study (Reference: National Surgical Research Collaborative, 2013) recruited 703 patients undergoing emergency appendectomy over 2 months in 98 U.K. hospitals. Previous audits of emergency laparotomy in large children's hospitals have indicated that approximately one emergency laparotomy is undertaken per week. A previous study collected data from children of all ages undergoing anaesthesia in the UK and Europe. (Reference: Habre et al, 2017) 31,127 cases were recruited across Europe of which 5893 (18.9%) were emergency cases, and 1475 (4.73%) were emergency or urgent abdominal surgery. Extrapolating this incidence to UK data based on Hospital Episode Statistics, which shows that 565,373 children within our inclusion ages underwent surgery in the year 2015-16, we estimate that the annual number of emergency abdominal procedures which would fit our criteria in England alone would be 26,742. Therefore in 3 months in England alone we would hope to capture information on approximately 6500 children. Based on these data, we estimate that approximately 5000 children will be recruited to the study over a 3- month period from across the 4 devolved nations. Allowing for a slower start and gradual increase in recruitment rates, we will run the study until we reach this target of 5000, however long this may take. This is important to be able to estimate the feasibility of recruitment, avoidance of sampling bias and to be able to demonstrate sustainability of recruitment with a view to a longer-term programme.

References:

National Surgical Research Collaborative. Multicentre observational study of performance variation in provision and outcome of emergency appendicectomy. Br J Surg. 2013;100:1240-1252.

Habre W, Disma N, Virag K, Becke K, Hansen TG, Jöhr M, Leva B, Morton NS, Vermeulen PM, Zielinska M, Boda K, Veyckemans F, APRICOT GOTESOACTN. Incidence of severe critical events in paediatric anaesthesia (APRICOT): a prospective multicentre observational study in 261 hospitals in Europe. Lancet Respir Med. 2017

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.

Descriptive Statistics:

We will describe the epidemiology of emergency abdominal surgery in children the UK - aiming to include all aspects of the patient pathway. Continuous data will be presented as mean and standard deviation (SD), or median and interquartile range when not normally distributed.

Subsequent analysis will include the use of Chi squared or Fisher's exact tests for categorical variables.

Our primary outcome will be postoperative complications measured using the Clavien-Dindo system. Secondary outcome measures will include: Length of hospital stay (postoperative and total) and mortality at various endpoints (inpatient, 30 days, 90 days and 1 year, plus longer term survival (up to 10 years).

Logistic regression will determine independent predictors for our primary and secondary outcomes, including both patient risk factors and structure / process level indicators with attention being paid to the hierarchical structure of the data (patients nested within hospitals).

Development of Risk Assessment tool:

We will use multivariable regression with bootstrapping to develop and internally validate a risk prediction model to predict short-term morbidity, classified according to the Clavien Dindo system. The purpose of this analysis is to develop models which can be used as a basis for risk adjustment in a longer-term study, and to remove unnecessarily measured variables.

Assessment of feasibility:

The main assessment of feasibility of a long term national quality improvement study will be screening to recruitment ratios. The second assessment will be quality of data linkage between our prospective dataset and nationally held registries of processes and outcomes.

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 L. Amaki Sogbodjor
Post	NIAA Health Services Research Centre Fellow in Paediatric Perioperative Medicine
Qualifications	BSc MBBS MA MRCP FRCA
Employer	National Institute of Academic Anaesthesia's Health Services Research Centre
Work Address	Royal College of Anaesthetists Churchill House 35 Red Lion Square, London
Post Code	WC1R 4SG
Telephone	
Fax	
Mobile	07930472625
Work Email	a.sogbodjor@ucl.ac.uk

	Title Forename/Initials Surname
	Dr Andrew Selman
Post	Anaesthetic Registrar
Qualifications	BSc.(Hons), MBBS, MRCPCH, FRCA
Employer	Great Ormond Street Hospital
Work Address	Great Ormond Street Hospital Great Ormond Street London
Post Code	WC1N 3JH
Telephone	
Fax	
Mobile	
Work Email	andrewselman@yahoo.co.uk

	Title Forename/Initials Surname
	Dr Suellen Walker

Post Reader & Honorary Consultant in Paediatric Anaesthesia and Pain Medicine, UCL Institute of Child Health and Great Ormond Street Hospital

Qualifications MBBS MMed MSc PhD FANZCA FFPMANZCA FPMRCA

Employer UCL Institute of Child Health and Great Ormond Street Hospital

Work Address Pain Research (Clinical Neurosciences)
Level 4, PUW South, UCL Institute of Child Health
30 Guildford Street, London

Post Code WC1N 1EH

Telephone 02075994105

Fax

Mobile

Work Email suellen.walker@ucl.ac.uk

Title Forename/Initials Surname
Professor Andrew Wolf

Post Consultant Anaesthetist

Qualifications MBBSChir FRCA MD

Employer University Hospitals Bristol NHS Foundation Trust

Work Address Department of Anaesthesia,
Bristol Royal Infirmary
Bristol

Post Code BS2 8BJ

Telephone 01179230000

Fax

Mobile

Work Email awolfbch@aol.com

Title Forename/Initials Surname
Dr Thomas Engelhardt

Post Consultant Anaesthetist

Qualifications MD PhD FRCA

Employer Royal Aberdeen Children's Hospital

Work Address Anaesthetic Department
Royal Aberdeen Children's Hospital
Westburn Road, Foresterhill, Aberdeen,

Post Code AB25 2ZG

Telephone 03454566000

Fax

Mobile

Work Email t.engelhardt@abdn.ac.uk

Title Forename/Initials Surname
Professor Mark Davenport

Post Professor of Paediatric Surgery and Consultant Surgeon

Qualifications MBChB, FRCS (Eng) 1985, FRCPS (Glas) 1984, FRCS (Paeds) 1994, ChM 1995

Employer Kings College Hospital

Work Address Kings College Hospital
Denmark Hill
London

Post Code SE5 9RS

Telephone	02032993350
Fax	
Mobile	
Work Email	mark.davenport@nhs.net
	Title Forename/Initials Surname
	Ms Mohini Samani
Post	Lay representative
Qualifications	
Employer	NIHR Clinical Research Network: West Midlands Young Person's Steering Group
Work Address	Greyfriars Business Park , Frank Foley Way, Greyfriars, Stafford,
Post Code	ST16 2ST
Telephone	
Fax	
Mobile	
Work Email	mohini_samani@outlook.com
	Title Forename/Initials Surname
	Dr Cyrus Razavi
Post	NIAA Health Services Research Centre Fellow in Paediatric Perioperative Medicine
Qualifications	
Employer	National Institute of Academic Anaesthesia's Health Services Research Centre
Work Address	Royal College of Anaesthetists Churchill House 35 Red Lion Square, London
Post Code	WC1R 4SG
Telephone	
Fax	
Mobile	
Work Email	c.razavi@ucl.ac.uk

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 College London
 Given name Pushpsen
 Family name Joshi
 Address Joint Research Office, UCL, Gower Street
 Town/city London
 Post code WC1E 6BT
 Country UNITED KINGDOM
 Telephone 02034475199
 Fax 02073809937
 E-mail uclh.randd@nhs.net

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:

Please give details of funding applications.

Organisation Association of Paediatric Anaesthetists of Great Britain and Ireland
 Address 21 Portland Place,
 London
 Post Code W18 1PY
 Telephone 02076318887
 Fax
 Mobile
 Email treasurer@apagbi.org.uk

Funding Application Status: Secured In progress

Amount: 40,000

Duration

Years: 1

Months:

If applicable, please specify the programme/ funding stream:

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

National Institute of Academic Anaesthesia Small Grants Award

Organisation Health Services Research Centre, Royal College of Anaesthetists

Address Churchill House
35 Red Lion Square
London

Post Code WC1R 4SG

Telephone 02070921500

Fax

Mobile

Email hsrc@rcoa.ac.uk

Funding Application Status: Secured In progress

Amount: £144,000

Duration

Years: 6

Months:

If applicable, please specify the programme/ funding stream:

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

Royal College of Anaesthetists support for Chief Investigator

Organisation

Address

Post Code

Telephone

Fax

Mobile

Email

Funding Application Status: Secured In progress

Amount:

Duration

Years:

Months:

If applicable, please specify the programme/ funding stream:

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

--

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
		Rachel	Knight
Organisation	Feasibility Officer, University College London		
Address	JRO UCL		
	Gower Street		
	London		
Post Code	WC1E 6BT		
Work Email	uclh.randd@nhs.net		
Telephone	02034475199		
Fax	02073809937		
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:

North Thames

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: 01/02/2019

Planned end date: 01/08/2029

Total duration:

Years: 10 Months: 6 Days: 1

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 206

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:

- | | |
|---|-----|
| <input checked="" type="checkbox"/> NHS organisations in England | 176 |
| <input checked="" type="checkbox"/> NHS organisations in Wales | 8 |
| <input checked="" type="checkbox"/> NHS organisations in Scotland | 16 |
| <input checked="" type="checkbox"/> HSC organisations in Northern Ireland | 6 |
| <input type="checkbox"/> GP practices in England | |
| <input type="checkbox"/> GP practices in Wales | |
| <input type="checkbox"/> GP practices in Scotland | |
| <input type="checkbox"/> GP practices in Northern Ireland | |
| <input type="checkbox"/> Joint health and social care agencies (eg community mental health teams) | |
| <input type="checkbox"/> Local authorities | |
| <input type="checkbox"/> Phase 1 trial units | |
| <input type="checkbox"/> Prison establishments | |
| <input type="checkbox"/> Probation areas | |
| <input type="checkbox"/> Independent (private or voluntary sector) organisations | |
| <input type="checkbox"/> Educational establishments | |
| <input type="checkbox"/> Independent research units | |
| <input type="checkbox"/> Other (give details) | |

Total UK sites in study: 206

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?

The project team will be chaired by the Chief Investigator and will meet monthly to deliver the day-to-day organisation

of the study.

The Study Steering Group will meet biannually. It will be independently chaired by Prof Mark Peters (Professor of Paediatric Critical Care Medicine and Vice Chair of the Paediatric Intensive Care Society Study Group) and will provide guidance on the overall running of the study.

The Steering Group comprises representation from paediatrics, paediatric surgery and paediatric anaesthesia

The study team will also report to the R&D office at UCL.

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)

The management of the research will be covered by UCL insurance for negligent harm.

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)

UCL insurance provides cover for negligent harm arising from the design of the research.

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)

NHS Indemnity will apply for UK NHS hospitals.

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 over 1 - 16 years of age.

Children's emergency abdominal surgery has been highlighted as an area requiring quality assurance, improvement and research into ascertaining processes which may improve outcomes. This proposal is for a pilot research study to assess the feasibility of delivering a national quality improvement programme for this patient group.

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

No, this is an observational study only and therefore controls will not be used.

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.

Parents or legal guardians will be consulted to provide informed consent.

Patients and parents will have access to our age appropriate patient information leaflets which have been reviewed by the NIHR Young Persons Advisory group (YPAG) in the West Midlands.

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.

Two different patient information sheets have been developed with information about the study: one for the child aged 10 - 15 years old and one for parents.

These information sheets have been reviewed by the NIHR - West Midlands' Young Person's Advisory Group (YPAG) who said they were "well written, of good length and easy to interpret".

These information sheets will include a link to the study website which in turn will have a dedicated section for patients and parents providing further information for participants.

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	<input checked="" type="radio"/> NHS/HSC Site <input type="radio"/> Non-NHS/HSC Site			
	Organisation name Address	UNIVERSITY COLLEGE LONDON HOSPITALS NHS FOUNDATION TRUST 250 EUSTON ROAD		
	Post Code Country	LONDON GREATER LONDON NW1 2PG ENGLAND		
		Forename Sarah Middle name Family name Barnett Email sarah.barnett2@nhs.net Qualification (MD...) MBBS BSc FRCA Country UNITED KINGDOM		
	IN2	<input checked="" type="radio"/> NHS/HSC Site <input type="radio"/> Non-NHS/HSC Site		
		Organisation name Address	Royal Aberdeen Children's Hospital Anaesthetic Department Westburn Road Aberdeen	
		Post Code Country	AB25 2ZG SCOTLAND	
			Forename Thomas Middle name Family name Engelherdt Email t.engelhardt@abdn.ac.uk Qualification (MD...) MD PhD FRCA Country UNITED KINGDOM	
		IN3	<input checked="" type="radio"/> NHS/HSC Site <input type="radio"/> Non-NHS/HSC Site	
			Organisation name Address	GREAT ORMOND STREET HOSPITAL FOR CHILDREN NHS FOUNDATION TRUST GREAT ORMOND STREET
Post Code Country			UNITED KINGDOM	
			Forename Suellen Middle name Family name Walker Email suellen.walker@ucl.ac.uk Qualification (MD...) MBBS MMed MSc PhD FANZCA FFPMANZCA FPMRCA Country UNITED KINGDOM	

IN4

LONDON GREATER LONDON
 Post Code WC1N 3JH
 Country ENGLAND

- NHS/HSC Site
- Non-NHS/HSC Site

Organisation name MANCHESTER UNIVERSITY NHS FOUNDATION TRUST
 Address COBBETT HOUSE
 OXFORD ROAD
 MANCHESTER GREATER MANCHESTER
 Post Code M13 9WL
 Country ENGLAND

Forename Russell
 Middle name
 Family name Perkins
 Email russell.perkins@cmft.nhs.uk
 Qualification (MD...) FRCA
 Country UNITED KINGDOM

IN5

- NHS/HSC Site
- Non-NHS/HSC Site

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

Forename Gary
 Middle name
 Family name Minto
 Email gary.minto@nhs.net
 Qualification (MD...) FRCA
 Country UNITED KINGDOM

IN6

- NHS/HSC Site
- Non-NHS/HSC Site

Organisation name TORBAY AND SOUTH DEVON NHS FOUNDATION TRUST
 Address HENGRIVE HOUSE
 TORBAY HOSPITAL
 NEWTON ROAD TORQUAY DEVON
 Post Code TQ2 7AA
 Country ENGLAND

Forename Michael
 Middle name
 Family name Swart
 Email michael.swart@nhs.net
 Qualification (MD...) MBBS FRCA EDICM FICM
 Country UNITED KINGDOM

IN7

- NHS/HSC Site
- Non-NHS/HSC Site

Organisation name KING'S COLLEGE HOSPITAL NHS FOUNDATION TRUST
 Address DENMARK HILL

 LONDON GREATER LONDON
 Post Code SE5 9RS
 Country ENGLAND

Forename Mark
 Middle name
 Family name Davenport
 Email mark.davenport@nhs.net
 Qualification (MD...) ChM FRCS (Paeds)
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IN8

- NHS/HSC Site
- Non-NHS/HSC Site

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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 Suneetha Ramani Moonesinghe on 24/05/2019 14:36.

Job Title/Post: Consultant
Organisation: UCL
Email: Ramani.moonesinghe@nhs.net

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 Mr Pushpsen Joshi on 24/05/2019 08:55.

Job Title/Post: Research Governance Manager
Organisation: Joint Research Office of UCL & UCLH
Email: pushpsen.joshi1@nhs.net