**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
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

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?
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
NOTICE OF SUBSTANTIAL AMENDMENT

Please use this form to notify the main REC of substantial amendments to all research other than clinical trials of investigational medicinal products (CTIMPs). The form should be completed by the Chief Investigator using language comprehensible to a lay person.

Details of Chief Investigator:

<table>
<thead>
<tr>
<th>Title</th>
<th>Forename/Initials</th>
<th>Surname</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prof</td>
<td>S. Ramani</td>
<td>Moonesinghe</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Work Address</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Division of Surgery, University College London</td>
<td>Charles Bell House 43-45 Foley Street, London W1W 7TS</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PostCode</th>
<th>Email</th>
<th>Telephone</th>
<th>Fax</th>
</tr>
</thead>
<tbody>
<tr>
<td>W1W 7TS</td>
<td><a href="mailto:ramani.moonesinghe@ucl.ac.uk">ramani.moonesinghe@ucl.ac.uk</a></td>
<td>07956620717</td>
<td></td>
</tr>
</tbody>
</table>

For guidance on this section of the form refer to the guidance

Full title of study: Children's Acute Surgical Abdomen Programme: CASAP

Lead sponsor: University College London

Name of REC: HSC REC B

REC reference number: 19/NI/0021

Additional reference number(s):

<table>
<thead>
<tr>
<th>Reference Number Description</th>
<th>Reference Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>UCL Data Protection Registration Number</td>
<td>Z6364106/2018/08/38</td>
</tr>
</tbody>
</table>

Name of lead R&D office: Feasibility Officer, University College London

Date study commenced: 01/02/2019

Protocol reference (if applicable), current version and date: CASAP Patient Study Protocol, Version 1.1, 21/05/2019

Amendment number and date: 1

Type of amendment

(a) Amendment to information previously given in IRAS

☐ Yes  ☐ No
If yes, please refer to relevant sections of IRAS in the "summary of changes" below.

(b) Amendment to the protocol

☐ Yes  ☐ No

If yes, please submit either the revised protocol with a new version number and date, highlighting changes in bold, or a document listing the changes and giving both the previous and revised text.

Eligibility Criteria: 7.2 Patient level (page 14)

(c) Amendment to the information sheet(s) and consent form(s) for participants, or to any other supporting documentation for the study

☐ Yes  ☐ No

If yes, please submit all revised documents with new version numbers and dates, highlighting new text in bold.

Is this a modified version of an amendment previously notified and not approved?

☐ Yes  ☐ No

Summary of changes

Briefly summarise the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study. If this is a modified amendment, please explain how the modifications address the concerns raised previously by the ethics committee. If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained.

We are seeking to clarify the inclusion and exclusion criteria by offering more information on which specific procedures are to be included in this study. Our original inclusion/exclusion criteria stated only that children undergoing unplanned abdominal surgery would be included. We would like to clarify that this refers to non-traumatic gastro-intestinal surgery, including appendicectomies, hepatobiliary (HPB) and splenic procedures, and also to add that urological and gynaecological procedures, as well as herniotomies not involving the intra-abdominal cavity will not be included.

Questions A17-1 and A17-2 on the IRAS form ask for the inclusion/exclusion criteria. These answers will now change from:

Original Inclusion Criteria

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.

Original Exclusion Criteria:

Patients / parents who do not provide consent. 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.

To:

Updated Inclusion Criteria:

Children between 12 months and 16 years of age undergoing unplanned abdominal surgery, where the preoperative diagnosis was considered to be related to a non-traumatic bowel (including appendix), hepatobiliary, and/or splenic pathology. Unplanned is defined as non-elective (i.e. the patient presented requiring emergency or urgent intervention, either as a primary presentation or as a complication of previous surgery). Surgery is defined as a procedure undertaken by a surgeon in an operating theatre requiring the support of an anaesthetist. Any surgical approach (e.g. open, laparoscopic, robotic assisted etc) is acceptable.
Updated Exclusion Criteria:

Patients / parents who do not provide consent. Children <12 months old on day of surgery, elective procedures, operations where the preoperative indication for surgery was considered to be traumatic, urological or gynaecological in origin, organ transplants, insertion/removal of dialysis catheters, interventional radiology procedures and Caesarean sections. Herniotomies are also excluded if the procedure does not involve access to the intra-abdominal cavity.

Any other relevant information

Applicants may indicate any specific issues relating to the amendment, on which the opinion of a reviewing body is sought.

List of enclosed documents

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>CASAP Patient Study Protocol</td>
<td>v1.2</td>
<td>11/09/2019</td>
</tr>
</tbody>
</table>

Declaration by Chief Investigator

1. I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.
2. I consider that it would be reasonable for the proposed amendment to be implemented.

This section was signed electronically by Dr Suneetha Ramani Moonesinghe on 13/09/2019 09:23.

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

Declaration by the sponsor's representative

I confirm the sponsor's support for this substantial amendment.

This section was signed electronically by Mr Pushpsen Joshi on 13/09/2019 11:51.

Job Title/Post: Research Management and Governance Manager
Organisation: UCL/UCLH JRO
Email: pushpsen.joshi1@nhs.net