We would like to invite you and your child to take part in our research study. Joining the study is entirely voluntary. Before you decide whether to join we would like you to understand why the research is being done and what it would involve for you and your child. One of our team will go through this information sheet with you, to help you decide whether or not you would like to take part and answer any questions you may have.

CASAP is a research study focused on the care delivered to children undergoing emergency surgery on their abdomen. We hope to include 5000 children who are cared for in NHS hospitals throughout the United Kingdom. It is an observational study – which means that participation will not have any impact on your child’s treatment. Please read on for further information.

What is the aim of this study?

This study is measuring how the care delivered to children undergoing emergency abdominal surgery in the United Kingdom compares to recommended national and international standards. In measuring this we aim to assess the quality of the care your child is receiving. Although it is unlikely, we know that after surgery patients sometimes encounter complications such as infections, which can be treated with antibiotics. We hope that by collecting information about the care children receive while in hospital, we will also be able to identify which factors may contribute to the development of complications.

What does taking part in this study involve?

Your child’s involvement in this study does not affect the medical care he or she will receive. The medical team looking after them will continue to treat them as they normally would.

This study is being organised by University College London (UCL). UCL will collect information about the care your child receives in hospital: for example, the time it takes from arriving in hospital to undergoing surgery, any treatments they may receive after their operation and the results of routine tests such as scans, blood tests and temperature measurements. No extra tests will take place.

This data we collect will include your child’s name, date of birth, NHS number, post code, gender and health information, which is regarded as a special category of information. We will use this information to match hospital data with information from other resources such as the national registries which record when patients are readmitted to hospital (NHS Digital in England, NHS Wales Informatic Services in Wales, and NHS National Services Scotland in Scotland). Linking the data we collect with these databases will enable us to develop a more complete picture of your child’s care.

The information collected will be entered into a secure database so that it can be stored safely in accordance with NHS recommendations and standards. Some of the information will be shared with a small group of NHS and University researchers to help us understand how to improve the care we provide to children having this kind of surgery in the future. Any data collected is only used for research after it has been made anonymous. The study will abide by strict information governance and confidentiality procedures.
[NHS site] has identified your child as being potentially eligible to participate in this study because they are having (or have had) an operation on their abdomen as an emergency. [NHS site] will use your child’s name, date of birth, NHS number, post code, gender, and contact details to make sure that relevant information about the study is recorded for his/her care, and to oversee the quality of the study. Individuals from UCL and regulatory organisations may look at your child’s medical and research records to check the accuracy of the research study. [NHS site] will pass these details to UCL along with the information collected from your child’s medical records. The only people in UCL who will have access to information that identifies you will be people who need to contact you to audit the data collection process. All the people who analyse the information will be doctors and professional scientists working for the NHS and UCL; they will not be able to identify you or your child and will not be able to find out your name, NHS number or contact details.

None of your or your child’s personal information will be made public.

What are the benefits of taking part in this study?

Whilst your participation in this study will not change the care you and your child receive during this stay we hope that the information we gain will improve the care delivered to children having emergency surgery in the future.

What are the disadvantages of taking part in this study?

We do not anticipate any disadvantages to taking part in this study. Your child will be looked after in the same way they would be normally.

How long will the study last?

Your child’s involvement in the study ends when they leave hospital. The data we collect and linked data from NHS databases will be kept securely for 10 years in order to track children’s long term recovery after surgery.

Can I withdraw my child from the study?

If you do not consent to your child being included in this study, their data will not be collected. If you do consent but later change your mind, you can notify a member of the study team (contact details below). We will then ensure that his or her details are not entered into the study; if they have already been entered but not yet analysed the data will be removed. If your child’s information has already been included in the analysis we will not then be able to remove it as at this point it will be fully anonymized.

A decision to not participate or to withdraw from the study will not change the care you or your child will receive whilst in hospital.

Is my child’s information safe?

Yes. Very strict rules and secure procedures are in place to ensure that your child’s information is kept safe. These systems and procedures comply with international standards and will be continuously monitored and adapted as necessary to maintain security over the lifetime of the project.
UCL is the sponsor for this study. We will be using information from your child’s medical records in order to undertake this study. UCL will act as the study data controller. This means that we are responsible for looking child’s information and using it properly. The legal basis for processing data related to health and care research is in the public interest. UCL’s data protection statement can be found here: https://www.ucl.ac.uk/joint-research-office/about/data-protection-statement. The Data Protection Officer can be contacted using this email address: data-protection@ucl.ac.uk.

Your rights to access, change or remove your child’s information are limited, as we need to manage the information in specific ways in order for the research to be reliable and accurate. If you withdraw your child from the study, we will keep the information we have obtained if it has already been submitted for analysis. To safeguard your child’s rights, we will anonymise any data we collect.

If you have any queries about the use of your child’s information please feel free to contact the study team – CASAP@rcoa.ac.uk. Alternatively, for more information about this study please visit the CASAP study website – https://www.niaa-hsrc.org.uk/CASAP-Home

What will happen to the results of the study?

The results from the study will be published in scientific journals, professional literature, social media, online on our study website and presented at conferences. They will also be made available to all hospitals throughout the UK who undertake children’s emergency surgery to enable them to improve the care they deliver. Some results may also be analysed as part of an academic project being undertaken at UCL but this will only be after the data has been anonymised. **Neither you nor your child will be identified in any publication.**

Who is organising the study?

The study is being organised by UCL and funded by the Association of Paediatric Anaesthetists of Great Britain & Ireland, the Royal College of Anaesthetists, and the UCL Surgical Outcomes Research Centre. Prof Ramani Moonesinghe is the Chief Investigator for CASAP.

If you have any questions about the study, including those relating to the use of personal data, please feel free to contact the study team via the study website or your local team using the contact details below.

What if there is a problem?

If you wish to complain, or have any concerns about any aspect of the way you or your child has been approached or treated by members of staff due to your participation in this study, National Health Service or UCL complaints mechanisms are available to you. Please ask a member of the research team if you would like more details information on this. Your hospital’s Patient Advisory Liaison Service (PALS), Community Health Council (CHC) in Wales or your local hospital’s complaints team may also be able to help.

In the unlikely event that your child is harmed by taking part in this study, compensation may be available. If you suspect that the harm is the result of the Sponsor’s (UCL) or hospital’s negligence then you may be able to claim compensation. After discussing with your research team, please make a claim in writing to Prof Ramani Moonesinghe who is the Chief Investigator for the research and is based at UCL. The Chief Investigator will then pass the claim to the Sponsor’s Insurers, via the Sponsor’s office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this.
You also have the right to lodge a complaint with the Information Commissioner’s Office (ICO), the supervisory authority in the UK responsible for the implementation and enforcement of data protection law, if you have concerns about the way your child’s personal data is being handled. You can contact the ICO via their website – [https://ico.org.uk/concerns/](https://ico.org.uk/concerns/) or by calling their helpline – 0303 123 1113.

**Useful Contact Details:**

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<th>Study Team</th>
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<tbody>
<tr>
<td>CASAP Website:</td>
<td><a href="https://www.niaa-hsrc.org.uk/CASAP-Home">https://www.niaa-hsrc.org.uk/CASAP-Home</a></td>
</tr>
<tr>
<td>CASAP Email:</td>
<td><a href="mailto:CASAP@rcoa.ac.uk">CASAP@rcoa.ac.uk</a></td>
</tr>
<tr>
<td>CASAP Address:</td>
<td>National Institute for Academic Anaesthesia’s Health Services Research Centre, Royal College of Anaesthetists, Churchill House, 35 Red Lion Square, London, WC1R 4SG</td>
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<th>Local Research Team</th>
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<td>Hospital Investigator:</td>
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<td>Research Nurse:</td>
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<td>Local PALS Office Contact Number:</td>
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