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)
The structure of perioperative enhanced care within the UK

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

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

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

( ) Clinical investigation or other study of a medical device

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

( ) Basic science study involving procedures with human participants

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

( ) Study involving qualitative methods only

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

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

( ) Research tissue bank

( ) Research database

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

( ) Other study

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

a) 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)
☐ HM Prison and Probation Service (HMPPS)

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

◉ Yes ○ No

4b. Please confirm the reason(s) why the project does not require review by a REC within the UK Health Departments Research Ethics Service:

☐ Projects limited to the use of samples/data samples provided by a Research Tissue Bank (RTB) with generic ethical approval from a REC, in accordance with the conditions of approval.
☐ Projects limited to the use of data provided by a Research Database with generic ethical approval from a REC, in accordance with the conditions of approval.
☑ Research limited to use of previously collected, non-identifiable information
☐ Research limited to use of previously collected, non-identifiable tissue samples within terms of donor consent
☐ Research limited to use of acellular material
☐ Research limited to use of the premises or facilities of care organisations (no involvement of patients/service users as participants)
☐ Research limited to involvement of staff as participants (no involvement of patients/service users as participants)

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

◉ Yes ○ No

5a. Are all the research costs and infrastructure costs (funding for the support and facilities needed to carry out the research e.g. NHS support costs) for this study provided by a NIHR Biomedical Research Centre (BRC), NIHR Applied Research Collaboration (ARC), NIHR Patient Safety Translational Research Centre (PSTRC), or an NIHR Medtech and In Vitro Diagnostic Co-operative (MIC) in all study sites?

Please see information button for further details.

○ Yes ◉ No

Please see information button for further details.

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

Please see information button for further details.

○ Yes ◉ No

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

If you select yes to this question, information from your IRAS submission will automatically be shared with the NIHR CRN. ***Submission of a Portfolio Application Form (PAF) is no longer required.***

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

○ Yes ◉ No

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

○ Yes ◉ No

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

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

○ Yes ◉ No

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

○ Yes ◉ No

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

○ Yes ◉ No

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

○ Yes ◉ No

Integrated Research Application System
Application Form for 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 familar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
The structure of perioperative enhanced care within the UK

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

REC Name:

REC Reference Number: **Submission date:**

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

The structural and organisational impacts of perioperative enhanced care services in the UK: A Retrospective Evaluation of Post-operative Alternatives to Critical Care (REPACC)

A3-1. Chief Investigator:

	Title	Forename/Initials	Surname
	Dr	Christopher	Oddy
Post	Anaesthetics Trainee		
Qualifications	MBBS BSc (Hons)		
ORCID ID	0000 0002 2311 9261		
Employer	Kingston Hospital NHS Foundation Trust		
Work Address	Department of Anaesthesia Kingston Hospital Galsworthy Rd, Kingston upon Thames		
Post Code	KT2 7QB		
Work E-mail	chris.oddy@nhs.net		
* Personal E-mail	chris.oddy@nhs.net		
Work Telephone	07774364202		

* Personal Telephone/Mobile	07774364202
Fax	07774364202

** 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
Mr	Thomas	Lafferty

Address	Research and Innovation Department 5th Floor Surgical Centre, Kingston Hospital Galsworthy Rd, Kingston upon Thames
Post Code	KT2 7QB
E-mail	khft.researchgovernance@nhs.net
Telephone	02089342803
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):	N/A
Sponsor's/protocol number:	N/A
Protocol Version:	3.0
Protocol Date:	12/12/2023
Funder's reference number (enter the reference number or state not applicable):	N/A
Project website:	N/A

Additional reference number(s):

Ref.Number Description	Reference Number

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

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

○ Yes ◉ No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

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

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

Post-operative critical care services are under significant pressure due to long waiting lists and high occupancy rates. Due in part to this pressure, enhanced care units - wards with some, but not all, of the capabilities of intensive care - have been developed. These models of care were designed with the aim of taking pressure off critical care services, preventing cancellation of surgeries due critical care bed availability, and reducing costs.

As the vast majority of these enhanced care units have been established independently there is little known about the structure of these services within the UK. Furthermore, it is unclear whether these achieve the goal of improving organisational efficiency. We therefore intend to run a multicentre research project appraising the structure, and organisational impacts, of enhanced care services within the UK.

Our aims are:
1. To describe the current models of enhanced care operational within the UK.
2. To identify the structural and organisational factors associated with rate of on-the-day cancellation due to lack of an enhanced care bed space.
3. To evaluate the effect of different models of enhanced care on wider measures of organisational efficiency.

To achieve these objectives we will disseminate a survey to all participating organisations to gain insight into their enhanced care services. At each centre we will also perform a retrospective audit to quantify the rates of on the day cancellation, alongside several other measures of organisational efficiency, amongst patients referred for post-operative enhanced and critical care.

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.

The protocol has been discussed with and approved by the research and innovation, and information governance, departments at Kingston Hospital. This study is purely observational, with no experimental drug or medical device being tested. There is no potential for clinical harm as a result of involvement in this study.

The primary risk posed to participants is that posed by data handling which may lead to linking of personally identifiable information. Information governance will be overseen by local governance teams at each site during set up. In addition, as this will be disseminated through regional trainee research networks (TRNs), specific instructions on how to handle data will be given to each region to provide further oversight. Finally, the study management group has assigned information governance champions who will work closely with the governance lead at Kingston Hospital to ensure that data handling procedures laid out in the protocol are followed.

All data will be handled in accordance with the Data Protection Act 2018. Data sourced from patient records at each site will be entered into the CRFs by a member of the direct care team. The proposed use of this data is to perform an evaluation of services and therefore is not considered sufficiently intrusive nor representative of sufficient risk to participants to justify seeking consent. Once participant identification is complete at each site, data will be collected for that cohort exclusively. No additional participants will be added to the cohort after this point.

The case report forms (CRFs) will be comprised of two Microsoft Excel workbooks and a survey designed in Microsoft Word. Individual patient data will be collated in the form of hospital numbers linked to generic demographic information (age, gender and ethnicity) at each site. Each subject's hospital identification numbers (IDs) will be used for identification by local investigators during the data collection process. Hospital IDs will be essential for collecting clinical data, however identifiable information linked to each number will only be accessible to members of the team directly responsible for their care. Hospital IDs will be automatically converted to study IDs by code written directly into the CRF, and only anonymised data will be shared with the SMG.

Completed CRFs will be submitted to the SMG and collated into a trial master file (TMF) for analysis. Data sharing with TRNs and the SMG will strictly exclude transfer of personally identifiable information including hospital IDs. Information linking study to hospital IDs will be retained by the direct care team should clarification or amendments be necessary.

All study documents at each site will be stored on encrypted, password-protected computer network or USB flash drives. Computer network drives (e.g. the “departmental X-drive”) are an extension of the medical record systems used locally and are widely used to store patient identifiable information. USBs, if used, will be provided by local information technology departments at each site. Several encrypted copies of the study documents will be created in order to provide a back-up in the eventuality of loss of this data. Data will only be made available to study investigators or to the sponsor for study monitoring.

Data, all of which will be anonymised prior to transfer between local investigators and the SMG, will only be transferred electronically between NHS.net e-mail accounts, all of which are password protected and require multi-factor authentication. Data will only be transferred directly between local teams of investigators and the SMG at Kingston Hospital with no intermediate. Regional and organisational leads will be responsible for the secure archiving and transfer of potentially identifiable information prior to submission to the SMG in accordance with NHS Information Governance standards. The CI will be responsible for the secure archiving and stewardship of study documentation after submission to the SMG. Archiving arrangements will include the secure storage of flash drives containing study documentation by local leads and the SMG. No external database or additional archiving systems will be utilised, as such, no funding will be sought for archiving purposes. Study documents will be kept for 10 years post-publication, after which they will be destroyed.

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.*

Our primary objective is to appraise and document the current models of enhanced care operational within the UK. We hope to gather information from all areas of the country to compare the current types of care that are delivered in these areas. Information concerning the criteria for referral, resources available, and organisational structures of these units will be gathered and compared.

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

We secondarily aim to examine the effects of these models of care on measures of organisational efficiency. In particular we are interested in whether these units prevent on the day cancellation in surgical patients who were referred to enhanced or critical care preoperatively. We are also interested in whether these same patients are admitted to different ward areas than planned in the post-operative period, whether they are admitted to critical care within 7 days of their procedure, and how long they stay in each level of care.

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

Delivery of post-operative critical care for high-risk surgical patients represents a significant challenge within the NHS due in part to high bed occupancy rates. Rates of on-the-day cancellation of elective procedures, and deferral of treatment until outside of the recommended 28-day window post-cancellation, due to absence of an appropriate post-operative destination are high, at a time when surgical waiting list pressures are at unprecedented levels.

The requirement for a post-operative critical care bed is independently predictive of on-the-day cancellation of elective surgery in the UK. In order to reduce unnecessary cancellation, and relieve pressure on critical care beds, new models of care such as enhanced care units have evolved.

The faculty of intensive care medicine has advocated for funding of these facilities, collating an evidence base comprised of a diverse sample of facilities whose introduction have led, in some small studies, to improvements in organisational efficiency and certain clinical outcomes. In 2015, approximately 55% of surveyed organisations in the UK had some form of intermediate enhanced care facility, such as PACU or OIR, for the care of high-risk post-operative patients. These were predominantly anaesthetist led, caring for a median of 4 patients, with just less than 30% of institutions having ring-fenced bedspaces for this purpose.

Whilst intuitively these models of care stand to improve organisational efficiency, there is speculation that reduced thresholds for admission to these intermediate units may serve to increase the likelihood of on-the-day cancellation if these services are over-burdened. The finding that institutions with an operational enhanced care unit demonstrate significantly higher rates of on-the-day cancellation adds weight to this concern.

Presently, there are no resources that describe the current status of enhanced care services operational within the UK. Furthermore, whilst these models of care are increasingly prevalent, there is a paucity of literature addressing the organisational impacts of their introduction, or indeed which models of care are most effective in reducing systemic pressure.

We therefore aim:
1. To describe the current models of enhanced care operational within the UK.
2. To identify the structural and organisational factors associated with rate of on-the-day cancellation due to lack of an enhanced care bed space.
3. To evaluate the effect of different models of enhanced care on wider measures of organisational efficiency.

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.*

We plan to run a multicentre research project with two main components:
1. A retrospective analysis of on-the-day cancellation rates, and several other measures of organisational efficiency, in patients referred to enhanced care facilities for post-operative care between 01/09/23 and 30/11/23.
2. A qualitative appraisal of the structure of enhanced care services at participating centres.

In practice, each site will be sent a survey that will describe the structure of enhanced care at their institution. Investigators will also collect data, from routine documentation covering a 3 month period, to quantify the total number of surgeries of different types (emergency, elective etc.) performed per day, the number of on-the-day surgical cancellations, and referrals & admissions to each level of care including enhanced care (PACU/OIR, level 1), high dependency care (HDU, level 2), and intensive care (ICU, level 3).

To further understand the patient journey within each institution, we will also follow up on what happens to each person who was referred to levels 1-3 care for post-operative management. Local investigators will collect information regarding their referral to enhanced care, their procedure, details of any cancellations that occur, and changes in planned post-operative destination. They will also collect basic demographic information (age, gender and ethnicity) and details of their past medical history. The cohort we follow up will be exclusively made up of adults undergoing elective surgery.

We will distribute our protocol via regional trainee research networks. This will mean regional leads will commission for volunteers to run the data collection process at each hospital. All volunteers will be clinicians that form part of the direct care team. Once data from each site is collected, the lead site will collate anonymised data for analysis. We expect data collection to be completed over a 9 month period during which time interim analyses may be performed to check if the data being collected is suitable to achieve our objectives. Final analysis and publication will likely take a further 3 months. A retrospective design was chosen to ensure we could pragmatically collect enough data for our results to be a true reflection of variation between sites. Our null hypothesis is that similar sized hospitals will perform similarly in the measures of organisational efficiency that we record. We aim to include at least 20 different hospitals of a variety of different sizes. These will follow up between 50-300 patients each.

We will analyse the data by comparing hospitals of similar size to each other on the parameters that we collect. For example, we will compare on-the-day cancellation rates in each participating centre after adjusting for how busy the hospital is, it's size, and the number of critical care beds available. We are interested to see if there are any differences in these measures of efficiency when different models of enhanced care employed, such as those that rely on on-the-day referral rather than admissions that are scheduled following surgical pre-assessment clinic.

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?

- [x] 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.
The study protocol has been discussed with ICUsteps, a patient led intensive care support charity, to ensure our objectives align with the priorities of service users. They have assisted with the creation of a plain English summary that is available on request.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

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

Select all that apply:

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

- [ ] Renal and Urogenital
- [ ] Reproductive Health and Childbirth
- [ ] Respiratory
- [ ] Skin
- [ ] Stroke

Gender:	Male and female participants
Lower age limit: 18	Years
Upper age limit:	Years

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

Inclusion criteria
Participants will be included if they meet the following criteria:
• Aged 18 years or older.
• Undergoing elective or expedited surgery (NCEPOD 3 and 4) between 01/09/23 and 30/11/23.
• Referred for a post-operative enhanced care bed.
• Decision made to refer for an enhanced care was made before the scheduled time of the procedure.

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

Exclusion criteria
Participants will be excluded if they meet the following criteria:
• Undergoing emergency surgery (NCEPOD 1 and 2, or Unclassified).
• Referred for an enhanced care bed intra-operatively or post-operatively.
• Undergoing obstetric, cardiothoracic or neurosurgery.
• Died intra-operatively.
• Receiving surgery for the purpose of organ donation.

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
N/A				

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

As all data collection is retrospective, participants will not be involved in the study. Participant data will be handled and stored in the manner specified in the relevant sections of this IRAS application.

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.

The protocol has been discussed with and approved by the research and innovation, and information governance, departments at Kingston Hospital. This study is purely observational, with no experimental drug or medical device being tested. There is no potential for clinical harm as a result of involvement in this study.

The primary risk posed to participants is that posed by data handling which may lead to linking of personally identifiable information. Information governance will be overseen by local governance teams at each site during set up. In addition, as this will be disseminated through regional trainee research networks (TRNs), specific instructions on how to handle data will be given to each region to provide further oversight. Finally, the study management group has assigned information governance champions who will work closely with the governance lead at Kingston Hospital to ensure that data handling procedures laid out in the protocol are followed.

All data will be handled in accordance with the Data Protection Act 2018. Data sourced from patient records at each site will be entered into the CRFs by a member of the direct care team. The proposed use of this data is to perform an evaluation of services and therefore is not considered sufficiently intrusive nor representative of sufficient risk to participants to justify seeking consent. Once participant identification is complete at each site, data will be collected for that cohort exclusively. No additional participants will be added to the cohort after this point.

The case report forms (CRFs) will be comprised of two Microsoft Excel workbooks and a survey designed in Microsoft Word. Individual patient data will be collated in the form of hospital numbers linked to generic demographic information at each site. Each subject's hospital identification numbers (IDs) will be used for identification by local investigators during the data collection process. Hospital IDs will be essential for collecting clinical data, however identifiable information linked to each number will only be accessible to members of the team directly responsible for their care. Hospital IDs will be automatically converted to study IDs by code written directly into the CRF, and only anonymised data will be shared with the SMG.

Completed CRFs will be submitted to the SMG and collated into a trial master file (TMF) for analysis. Data sharing with TRNs and the SMG will strictly exclude transfer of personally identifiable information including hospital IDs. Information linking study to hospital IDs will be retained by the direct care team should clarification or amendments be necessary.

All study documents at each site will be stored on encrypted, password-protected computer network or USB flash drives. Computer network drives (e.g. the "departmental X-drive") are an extension of the medical record systems used locally and are widely used to store patient identifiable information. USBs, if used, will be provided by local information technology departments at each site. Several encrypted copies of the study documents will be created in order to provide a back-up in the eventuality of loss of this data. Data will only be made available to study investigators or to the sponsor for study monitoring.

Data, all of which will be anonymised prior to transfer between local investigators and the SMG, will only be transferred electronically between NHS.net e-mail accounts, all of which are password protected and require multi-factor authentication. Data will only be transferred directly between local teams of investigators and the SMG at Kingston Hospital with no intermediate. Regional and organisational leads will be responsible for the secure archiving and transfer of potentially identifiable information prior to submission to the SMG in accordance with NHS Information Governance standards. The CI will be responsible for the secure archiving and stewardship of study documentation after submission to the SMG. Archiving arrangements will include the secure storage of flash drives containing study documentation by local leads and the SMG. No external database or additional archiving systems will be utilised, as such, no funding will be sought for archiving purposes. Study documents will be kept for 10 years post-publication, after which they will be destroyed.

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?

The results of these data may help to guide future healthcare policies surrounding the provision of post-operative enhanced care in the UK. From these data it may be possible to identify which models of care lead to the lowest rates of on-the-day cancellation. For example, we may discover that a certain ratio of referrals to the number of beds available is associated with a high rate of cancellation when adjusting for other factors. Our results may therefore be used to guide those developing these services to reduce the risk of this occurring.

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

There are no expected risks posed to researchers due to their involvement in this study.

RECRUITMENT AND INFORMED CONSENT

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

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

Local systems of referral to these units such as physical diaries, secure email inboxes, electronic health record data, and bespoke databases will be searched to identify the cohort of patients referred to each area. In addition, the hospital numbers of patients undergoing surgery, who had a procedure cancelled, or those that were admitted to levels 1-3 of care will be provided by the clinical informatics team at each site. This will be used to quantify the number of patients per day that experienced said outcome, as well as cross-reference with the referrals to each unit in order to identify those that were referred verbally. Members of the direct care team at each site will therefore use routine hospital documentation, linked to the hospital numbers provided, to identify participants that fit into each category.

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

(●) Yes ( ) No

Please give details below:
The direct care team will have access to the hospital records of each potential participant. This will only include information that would ordinarily be accessible to these members of staff.

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

All data will be handled in accordance with the Data Protection Act 2018. No personally identifiable information will be stored outside of the electronic health record systems that are already in use at each site. Hospital numbers will be retained by the direct care team and the protocol specifies that these should be stored on encrypted drives. Clinical governance teams at each site may also specify additional safety measures be obeyed to prevent data breach.

Only staff members with user access to health record systems may link these numbers to identifiable information. Before submission of data to the study management group hospital numbers will be converted to anonymous study IDs by the CRFs using code written directly into the files. Only anonymised data sheets will be submitted to the study management group. Detailed instructions on how to ensure the transfer process is performed correctly will be provided in our data collection guide. The direct care team will retain information linking study to hospital IDs should clarification or amendments be necessary. Data, all of which will be anonymised prior to transfer, will only be transferred electronically between NHS.net e-mail accounts, all of which are password protected and require multi-factor authentication. No potentially sensitive data will be shared with the study gmail account which will be used for organisational purposes only. This is clearly stated in our protocol, data collection guide and site briefing materials.

Information governance will be overseen by local governance teams at each site during set up. In addition, as this will be disseminated through regional trainee research networks, specific instructions on how to handle data will be given to each region to provide further oversight. Finally, the study management group has assigned information governance champions who will work closely with the governance lead at the lead site to ensure that data handling procedures laid out in the protocol are followed.

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

○ Yes ◉ No

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

○ Yes ◉ No

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

Participants will not be contacted during the conduct of this project.

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

○ Yes ◉ No

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

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

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

The proposed use of this data is to perform an evaluation of services and therefore is not considered sufficiently intrusive nor representative of sufficient risk to participants to justify seeking consent. At no stage will patient care be affected during the conduct of this study.

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

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:
Anonymised data will be shared between NHS mail accounts.

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

All study documents at each site will be stored on encrypted, password-protected computer network or USB flash drives. Computer network drives (e.g. the “departmental X-drive”) are an extension of the medical record systems used locally and are widely used to store patient identifiable information. USBs, if used, will be provided by local information technology departments at each site. Several encrypted copies of the study documents will be created in order to provide a back-up in the eventuality of loss of this data. Data will only be made available to study investigators or to the sponsor for study monitoring.

Data, all of which will be anonymised prior to transfer between local investigators and the SMG, will only be transferred electronically between NHS.net e-mail accounts, all of which are password protected and require multi-factor authentication. Data will only be transferred directly between local teams of investigators and the SMG at Kingston Hospital with no intermediate. Regional and organisational leads will be responsible for the secure archiving and transfer of potentially identifiable information prior to submission to the SMG in accordance with NHS Information Governance standards. The CI will be responsible for the secure archiving and stewardship of study documentation after submission to the SMG. Archiving arrangements will include the secure storage of flash drives containing study documentation by local leads and the SMG. No external database or additional archiving systems will be utilised, as such, no funding will be sought for archiving purposes. Study documents will be kept for 10 years post-publication, after which they will be destroyed.

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.*

Local investigators will hold data that links hospital numbers to basic demographic information (age, gender and ethnicity) . These data will only be possible to link to personal data with user access to hospital record systems. Data providing this linkage will be stored on encrypted, password-protected computer network or USB flash drives. Hospital numbers will be automatically converted to anonymised study IDs by the case report forms by code written directly into the files. Documentation providing the link between study and hospital IDs will not be shared outside of the direct care team.

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.*

Only members of the direct care team.

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?

Anonymised data will be collated and analysed in the UK only. This will be performed by the study management group, led by the chief investigator.

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

Title	Forename/Initials	Surname
Dr	Christopher	Oddy

Post	Anaesthetics Trainee
Qualifications	MBBS BSc (Hons)
Work Address	Department of Anaesthesia
	Kingston Hospital
	Kingston Hospital, Kingston upon Thames
Post Code	KT2 7QB
Work Email	chris.oddy@nhs.net
Work Telephone	07774364202
Fax	07774364202

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

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

Years: 10
Months: 0

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

Local investigators will be requested to delete data linking study and hospital IDs after publication of the findings of this project. Anonymised data will be retained for 10 years post-publication to permit scrutiny of our findings. These data will be stored on encrypted, password-protected computer network or USB flash drives and will only be accessible to members of the study management group unless further permissions are obtained to permit post-hoc analyses.

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.
The study protocol and all study materials will be publicly available on the study webpage (http://www.uk-plan.net/REPACC) published by the Pan-London Perioperative Audit and Research Network. The project is also registered with the research and development team at Kingston Hospital who maintain a database of ongoing projects.

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?

Personal data will be anonymised prior to transfer to the study management group by code written directly into the case report forms. All analyses will make use of exclusively anonymised data thus publication of the results of these analyses will maintain anonymity of all participants.

A53. How and when will you inform participants of the study results?

If there will be no arrangements in place to inform participants please justify this.
All published results will be distributed to local investigators to disseminate the findings in their region. ICUsteps, a patient advocacy charity that is working with the project team, will inform their members of the publication and publish the findings on their public platform. As participants will not be contacted in the conduct of this study no participants will be personally informed of the publication.

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
- [x] Review within a multi−centre research group
- [x] Review within the Chief Investigator's institution or host organisation
- [x] Review within the research team
- [x] Review by educational supervisor
- [x] 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:
This evaluation has been selected by the Pan-London Perioperative Audit and Research Network (PLAN) to be run as their yearly project in a competitive process requiring review by all committee members. Furthermore, the plan for this project was presented at a pan-London trainee conference where participants were invited to give feedback on the study methodology. Feedback from both stages of selection was integrated into the initial protocol.

A core committee was formed of members from the lead site and committee members from PLAN. In addition, the chief investigator's educational supervisor and two further research experienced consultants with history of delivering high quality national audit projects were brought on to the panel. Feedback from all members was sought and amendments made to the protocol.

Several other trainee research networks will support this project in their region and their comments have been integrated. Both the research and information governance teams at the lead site have also contributed to the final form of the protocol.

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

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

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

- [ ] Review by independent statistician commissioned by funder or sponsor
- [ ] Other review by independent statistician
- [ ] Review by company statistician
- [x] Review by a statistician within the Chief Investigator’s institution
- [x] Review by a statistician within the research team or multi−centre group
- [x] Review by educational supervisor
- [x] 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
	Dr	Christopher	Oddy
Department	Department of Anaesthesia		
Institution	Kingston Hospital NHS Foundation Trust		
Work Address	Department of Anaesthesia		
	Kingston Hospital		
	Kingston Hospital, Kingston upon Thames		
Post Code	KT2 7QB		
Telephone	07774364202		
Fax	07774364202		
Mobile	07774364202		
E-mail	chris.oddy@nhs.net		

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

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

On-the-day cancellation due to absence of a post-operative enhanced care bed.

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

- Referral to capacity ratio for enhanced care services.
- Rates of escalation of post-operative destination.
- Rates of de-escalation of post-operative destination.
- Rates of emergency admission to ICU/HDU within 7 days post-operatively.
- Average length of stay in each enhanced care facility.
- Average hospital length of stay.
- Cohort mortality.

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: 20

Total international sample size (including UK):

Total in European Economic Area:

Further details:
We aim to analyse at least 20 institutions which will each follow up between 50-300 participants. The current scale of this project is unknown as it will depend on identifying volunteers from each site to run the data collection process.

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.*

There is no comparative data with which to perform a power calculation. On this basis, 20 sites was deemed a pragmatic minimum number of data points for analysis when accounting for the number of variables (>15) we plan to enter into the analysis model to avoid overfitting and multicollinearity.

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 will be generated to describe organisational and outcome parameters. Interaction terms will be calculated by multivariable linear regression to assess associations between organisational factors, cancellation rates and other outcome measures. Continuous dependent variables will be standardised to the mean before model input. Size of hospital and geographical region will be considered as grouping variables in a mixed effects model with random intercepts. Publicly available data concerning site specific total cancellation rates, critical care bed availability, operating capacity, hospital episode statistics and local population variables will contribute to model adjustment. Assumption checking will be performed to assess for normality of input variables, multicollinearity, heteroscedasticity and overall model fit by visually assessing residual versus fitted values.

Modifier variables that have a high a-priori probability of explaining variance in our outcome measures include:
• Presence of an emergency department.
• Average number of procedures performed daily.
• Proportion of total procedures performed as NCEPOD 1 and 2 [11].
• Proportion of elective procedures performed as NCEPOD 3 and 4 [11].
• Proportion of elective procedures performed for cancer.
• General & acute bed occupancy.
• Critical care bed occupancy.
• Deprivation index of local population.
• Long term condition index of local population.

These variables will be assessed for univariate association with each of our outcome measures before entry into the model. Multicollinearity is likely to be high between several of these variables. Variables with a variance inflation factor of more than 10 will be dropped systematically.

Predictor variables of interest include the following:
• Availability of level 1 care.
• Presence of ring-fenced beds.
• Number of ring-fenced beds.
• Escalation capacity.
• Referral to capacity ratio.
• On-the-day vs pre-emptive referral.
• Score vs judgement-based referral.
• Patient to provider ratio.
• Patient to provider ratio at escalation capacity.
• Therapies supported in level 1 facility.

P-values generated by the model will be used to determine the significance of each variable in modifying each outcome. Statistical significance will be defined as $p<0.05$. Regression coefficients and odds ratios will be used to describe the relationships between predictor and outcome variables.

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	Henry	Lewith
Post	Consultant Anaesthetist		
Qualifications	MBBS		
Employer	Kingston Hospital NHS Foundation Trust		
Work Address	Department of Anaesthesia Kingston Hospital Galsworthy Rd, Kingston upon Thames		
Post Code	KT2 7QB		
Telephone			
Fax			
Mobile			

Work Email	henrylewith@nhs.net

Title	Forename/Initials	Surname
Dr	Paolo	Perella

Post	Consultant Anaesthetist
Qualifications	MBBS
Employer	Kingston Hospital NHS Foundation Trust
Work Address	Department of Anaesthesia Kingston Hospital Galsworthy Rd, Kingston upon Thames
Post Code	KT2 7QB
Telephone	
Fax	
Mobile	
Work Email	paolo.parella@nhs.net

Title	Forename/Initials	Surname
Dr	Danny	Wong

Post	Consultant Anaesthetist
Qualifications	MBBS PhD
Employer	Guy's and St Thomas' NHS Foundation Trust
Work Address	Department of Anaesthesia Guy's and St Thomas' NHS Foundation Trust Westminster Bridge Rd, London
Post Code	SE1 7EH
Telephone	
Fax	
Mobile	
Work Email	danny.wong@gstt.nhs.uk

Title	Forename/Initials	Surname
Dr	Mark	Burnett

Post	Anaesthetics Trainee
Qualifications	MBBS
Employer	Queen's Hospital Burton
Work Address	Department of Anaesthesia Queen's Hospital Burton Belvedere Road, Burton on Trent
Post Code	DE13 0RB
Telephone	
Fax	
Mobile	
Work Email	burnettmark01@gmail.com

Title	Forename/Initials	Surname
Dr	Sarah	Towey

Post	Anaesthetics Trainee
Qualifications	MBBS
Employer	Nottingham University Hospitals NHS Trust

Work Address	Department of Anaesthesia Queen's Medical Centre Derby Rd, Lenton, Nottingham
Post Code	NG7 2UH
Telephone	
Fax	
Mobile	
Work Email	sarahtowey.st@gmail.com

Title	Forename/Initials	Surname
Dr	Thomas	Davies

Post	Anaesthetics Registrar and NIHR Academic Clinical Fellow
Qualifications	MBBS
Employer	Queen Mary University of London
Work Address	Barts and the London School of Anaesthesia Charterhouse Square London
Post Code	EC1M 6BQ
Telephone	
Fax	
Mobile	
Work Email	thomas.davies6@nhs.net

Title	Forename/Initials	Surname
Dr	Adam	Green

Post	Anaesthetics Registrar
Qualifications	MBBS
Employer	St Georges Hospital NHS Foundation Trust
Work Address	Department of Anaesthesia St George’s Hospital Blackshaw Rd, London
Post Code	SW17 0QT
Telephone	
Fax	
Mobile	
Work Email	adam.green2@nhs.net

Title	Forename/Initials	Surname
Dr	Olivia	Bools

Post	FoundationTrainee
Qualifications	MBBS
Employer	Kingston Hospital NHS Foundation Trust
Work Address	Department of Anaesthesia Kingston Hospital Galsworthy Rd, Kingston upon Thames
Post Code	KT2 7QB
Telephone	
Fax	
Mobile	
Work Email	o.bools@nhs.net

	Title	Forename/Initials	Surname
	Dr	Joseph	Kennedy
Post	Acute Care Common Stem Trainee		
Qualifications	MBBS		
Employer	Kingston Hospital NHS Foundation Trust		
Work Address	Department of Emergency Medicine Kingston Hospital Galsworthy Rd, Kingston upon Thames		
Post Code	KT2 7QB		
Telephone			
Fax			
Mobile			
Work Email	joseph.kennedy3@nhs.net		

	Title	Forename/Initials	Surname
	Dr	Dominic	Lowcock
Post	Anaesthetics Trainee		
Qualifications	MBBS		
Employer	Kingston Hospital NHS Foundation Trust		
Work Address	Department of Anaesthesia Kingston Hospital Galsworthy Rd, Kingston upon Thames		
Post Code	KT2 7QB		
Telephone			
Fax			
Mobile			
Work Email	dominic.lowcock@nhs.net		

	Title	Forename/Initials	Surname
	Dr	Gareth	Davey
Post	Anaesthetics Trainee		
Qualifications	MBBS		
Employer	Kingston Hospital NHS Foundation Trust		
Work Address	Department of Anaesthesia Kingston Hospital Galsworthy Rd, Kingston upon Thames		
Post Code	KT2 7QB		
Telephone			
Fax			
Mobile			
Work Email	gareth.davey1@nhs.net		

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	Kingston Hospital NHS Foundation Trust
Given name	Thomas
Family name	Lafferty
Address	Research and Innovation Department
Town/city	5th Floor Surgical Centre, Kingston Hospital
Post code	KT2 7QB
Country	United Kingdom
Telephone	02089342803
Fax	
E-mail	khft.researchgovernance@nhs.net

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

Contact person

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

A65. Has external funding for the research been secured?

Please tick at least one check box.

- [ ] Funding secured from one or more funders
- [x] 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	The MPS Foundation
Address	Level 19, The Shard
	32 London Bridge Street
	London
Post Code	SE1 9SG
Telephone	+44(0)1132410259
Fax	
Mobile	
Email	info@thempsfoundation.org

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

Date Funding decision expected: 16/09/2024

Amount: 4000

Duration

Years: 0

Months: 6

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
	Mr	Thomas	Lafferty
Organisation	Kingston Hospital NHS Foundation Trust		
Address	Research and Innovation Department		
	5th Floor Surgical Centre, Kingston Hospital		
	Galsworthy Rd, Kingston upon Thames		
Post Code	KT2 7QB		
Work Email	khft.researchgovernance@nhs.net		
Telephone	02089342803		
Fax			
Mobile			

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

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

Planned start date: 25/03/2024
Planned end date: 24/09/2024
Total duration:
Years: 0 Months: 6 Days: 0

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

Does this trial involve countries outside the EU?
○ Yes ○ No

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

☑ NHS organisations in England	15
☑ NHS organisations in Wales	5

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

Total UK sites in study: 20

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?

Information governance will be overseen by local governance teams at each site during set up. In addition, as this will be disseminated through regional trainee research networks (TRNs), specific instructions on how to handle data will be given to each region to provide further oversight. Finally, the study management group has assigned information governance champions who will work closely with the governance lead at Kingston Hospital to ensure that data handling procedures laid out in the protocol are followed.

A76. Insurance/ indemnity to meet potential legal liabilities

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

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

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

- ☑ NHS indemnity scheme will apply (NHS sponsors only)
- ☐ Other insurance or indemnity arrangements will apply (give details below)

Please enclose a copy of relevant documents.

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

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

- [x] NHS indemnity scheme will apply (protocol authors with NHS contracts only)
- [ ] Other insurance or indemnity arrangements will apply (give details below)

Please enclose a copy of relevant documents.

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

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

- [x] NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)
- [ ] Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

Please enclose a copy of relevant documents.

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

○ Yes ◉ No ○ Not sure

PART C: Overview of research sites

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

Investigator identifier	Research site		Investigator Name	
IN1	(●) NHS/HSC Site ( ) Non-NHS/HSC Site		Forename Middle name Family name Email	Christopher John Oddy chris.oddy@nhs.net
	Organisation name	KINGSTON HOSPITAL NHS FOUNDATION TRUST	Qualification (MD...)	MBBS BSc (Hons)
	Address	GALSWORTHY ROAD KINGSTON UPON THAMES	Country	United Kingdom
	Post Code	KT2 7QB		
	Country	ENGLAND		

PART D: Declarations

D1. Declaration by Chief Investigator

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

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

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

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

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

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

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

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

9. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 2018.

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

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

11. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 2018.

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

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

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

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

- (●) Chief Investigator
- ( ) Sponsor
- ( ) Study co-ordinator
- ( ) Student
- ( ) Other – please give details
- ( ) None

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

Optional – please tick as appropriate:

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

This section was signed electronically by Dr Chris Oddy on 12/03/2024 13:19.

Job Title/Post:	Anaesthetics Trainee
Organisation:	Kingston Hospital NHS Foundation Trust
Email:	chris.oddy@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 Thomas Lafferty on 12/03/2024 13:50.

Job Title/Post:	Deputy CEO
Organisation:	Kingston Hospital NHS Foundation Trust
Email:	t.lafferty@nhs.net