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)
Perioperative Quality Improvement Programme: Patient Study

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)*

[x] England
[x] 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?

IMPORTANT: If your project is taking place in the NHS and is led from England select 'IRAS Form'. If your project is led from Northern Ireland, Scotland or Wales select 'NHS/HSC Research and Development Offices' and/or relevant Research Ethics Committee applications, as appropriate.

☑ IRAS Form
☐ Confidentiality Advisory Group (CAG)
☐ National Offender Management Service (NOMS) (Prisons & Probation)

For NHS/HSC R&D Offices in Northern Ireland, Scotland and Wales the CI must create NHS/HSC Site Specific Information forms, for each site, in addition to the study wide forms, and transfer them to the PIs or local collaborators.

For participating NHS organisations in England different arrangements apply for the provision of site specific information. Refer to IRAS Help for more information.

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 Biomedical Research Unit, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC), NIHR Patient Safety Translational Research Centre or a Diagnostic Evidence Co-operative in all study sites?

Please see information button for further details.

○ Yes ◉ No

Please see information button for further details.

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

Please see information button for further details.

◉ Yes ○ No

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

If you select yes to this question, you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form (PAF) immediately after completing this project filter question and before submitting other applications. Failing to complete the PAF ahead of other applications e.g. HRA Approval, may mean that you will be unable to access NIHR CRN Support for your study.

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

○ Yes ◉ No

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

○ Yes ◉ No

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

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

○ Yes ◉ No

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

○ Yes ◉ No

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

○ Yes ◉ No

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

○ Yes ◉ No

Integrated Research Application System
Application Form for Research administering questionnaires/interviews for quantitative analysis or mixed methodology study

IRAS Form (project information)

Please refer to the E-Submission and Checklist tabs for instructions on submitting this application.

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting Help.

Please define any terms or acronyms that might not be familar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
Perioperative Quality Improvement Programme: Patient Study

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

REC Name:
South East Coast

REC Reference Number:
16/LO/1827

Submission date:
23/09/2016

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

Improving perioperative care through the use of quality data: Patient Study of the Perioperative Quality Improvement Programme

A3-1. Chief Investigator:

	Title Forename/Initials Surname
	Dr Suneetha Ramani Moonesinghe
Post	Director, UCL/UCLH Surgical Outcomes Research Centre; Consultant Anaesthetics & Intensive Care; Honorary Senior Lecturer, UCL
Qualifications	BSc (Hons) MRCP FRCA FFICM MD(Res)
Employer	University College London Hospitals NHS Trust
Work Address	Anaesthetics Department
	Podium 3, Maple Link corridor, University College Hospital
	235 Euston Road
Post Code	NW12BU
Work E-mail	ramani.moonesinghe@uclh.nhs.uk
* Personal E-mail	rmoonesinghe@gmail.com
Work Telephone	

* Personal Telephone/Mobile 07956620717
Fax

** This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.*
A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?
This contact will receive copies of all correspondence from REC and HRA/R&D reviewers that is sent to the CI.

	Title	Forename/Initials	Surname
	Ms	Suzanne	Emerton
Address	Joint Research Office,		
	1st floor Maple House, 149 Tottenham Court Road		
	London		
Post Code	W1T 7DB		
E-mail	randd@uclh.nhs.uk		
Telephone	02034472198		
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):	
Sponsor's/protocol number:	16/0577
Protocol Version:	1.4
Protocol Date:	21/09/2016
Funder's reference number:	
Project website:	www.niaa-hsrc.org.uk/PQIP

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.
PQIP Database (IRAS number 211179) - this application received a favourable REC opinion on 12th August 2016

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.*

This application is to gather and analyse patient data using the PQIP Database.

PQIP will measure complications after major planned surgery and seek to improve these outcomes through feedback of data to clinicians. A REC/CAG application for the PQIP Database has already received a favourable opinion. This analysis will answer important research questions about variation in quality of care in major surgery.

We expect that this substantial collaborative work will lead to valuable insights regarding the ways in which hospitals use data to drive improvements in 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.

This is an observational study and we do not see major ethical or other issues.

We will seek patient consent for participation. A Participant Information Sheet will be provided which will explain the reasons for data collection and give an overview of the data which will be collected and stored. Data will be stored in the PQIP Database which has already received a favourable REC/CAG opinion.

We anticipate a large number of hospitals participating, at least 70 in the first year, and we hope that this number will rise in years to come. This may pose some organisational challenges but both the Chief Investigator, and the organisation supporting this study (the National Institute for Academic Anaesthesia's Health Services Research Centre based at the Royal College of Anaesthetists) have experience in running major multi-centre studies involving up to 200 Trusts, therefore we are confident that we have the administrative and organizational capacity to manage the study.

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.*

What is the rate of postoperative complications after major inpatient surgery in the UK; how does it vary between hospitals and how is this information used to improve patient outcome?

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

RQ1. What is the failure to rescue rate in the NHS and how does it vary between hospitals?
RQ2. What is the relationship between short-term complications and longer-term Health Related Quality of Life (HRQOL), and can longer-term HRQOL be improved through reducing postoperative complications?
RQ3. Can the quality of care be improved through the feedback of data to clinicians and managers, leading to improvements in complications and failure to rescue?

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

There is currently no national or comprehensive database which records postoperative complications on patients in the UK outside a few specific surgical complications (e.g. return to operating room) or procedures (e.g. nephrectomy). This is an important omission as significant postoperative complications are up to 10 times more common than short-term mortality after surgery, and have been independently associated with reduced postoperative survival and quality of life. We currently have no way of measuring and therefore improving upon these important outcomes. We also know from the US, that there is wide variation in "failure to rescue" between different healthcare institutions - i.e. if a patient develops a postoperative complication, whether they die or not after this complication varies up to 15-fold between different healthcare providers. We do not have access to this type of information in the UK presently, and this study will provide these data.

PQIP will measure both objective outcomes (morbidity and mortality) and also outcome from the patient perspective after major surgery. The web-based data entry system will include the features which have been suggested by stakeholders to be important for facilitating the use of data for improvement, such as near-real time feedback, feedback provided in easily understandable and graphical formats, and explanations for statistical analyses and risk-adjustment techniques.

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.*

Data will be collected on a sample of patients undergoing major surgery (defined prospectively) in participating hospitals.

Sampling strategy:
All NHS hospitals in the UK will be invited to participate. So far we have interest from approximately 70 hospitals. Only patients undergoing surgery defined by our list of eligible procedures (see Appendix) will be eligible for inclusion. Each hospital will recruit a maximum 5 patients per week. The patients to be approached for consent will be based on a random sampling strategy which will involve an 8-day rolling sampling cycle (i.e. the first 5 patients starting from Monday morning in week one, followed by the first 5 patients starting from Tuesday in week two etc etc). If any of the first 5 patients approached refuse consent, then consecutive patients will be approached for consent until the target recruitment number has been achieved.

Data collection:
Each consenting patient will complete baseline questionnaires before their surgery, and again 1 day, 3 days, 6 months and 12 months after their surgery. Objective risk, process and outcome data will be collected on patients during their inpatient stay. Hospital data will be linked with Hospital Episode Statistics (HES) and Office of National Statistics (ONS) mortality data at patient identifiable level. This is necessary to track adverse outcomes which occur after discharge from hospital (e.g. readmission within 30 days of surgery - from HES data; longer term mortality - from ONS)

Dataset:
All data collected are evidence based and where appropriate, formally validated.
These include:
- Patient risk factors for the purposes of risk adjustment (the components of risk adjustment systems identified in a published systematic review as being accurate)
- Patient morbidity data - using the validated Post-Operative Morbidity Survey (POMS) on Day 7 post-op and the Clavien Dindo surgical complications grading system on discharge from hospital

- Patient reported outcome data - the EQ5D is a validated measure of health-related quality of life; the Quality of Recovery - 15 score is a validated measure of recovery from surgery; the Bauer patient satisfaction measure is a validated measure of postoperative discomfort and satisfaction with anaesthesia care; the WHO Disability Assessment Schedule 2.0 has been validated for use in patients undergoing major surgery.

Analysis plan:
Our primary outcome is POMS-defined morbidity on day 7. Our primary analysis will measure risk-adjusted variation between providers (comparing observed: expected ratios) in morbidity, mortality and failure to rescue rates, following standard methodology for ascertaining FTR rates described by Dimick. Secondary outcomes will include mortality at 90 days, disability-free survival at one year; patient reported outcome (change in health-related quality of life; time to full recovery. Analyses will include hierarchical regression modelling to determine the relationship between structure, process and outcome.

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
- [x] Management of the research
- [x] Undertaking the research
- [x] Analysis of results
- [x] Dissemination of findings
- [ ] None of the above

Give details of involvement, or if none please justify the absence of involvement.
We will address areas prioritised by 4 James Lind Alliance Priority Setting Partnerships (JLA-PSPs): anaesthesia/perioperative care, intensive care, dementia & pressure ulcers.

We received detailed structured feedback on our protocol from members of the PCPIE group at the National Institute for Academic Anaesthesia's Health Services Research Centre (NIAA-HSRC).

Our Clinical Reference Group has two lay members. Ms Elspeth Evans is a member of the RCoA lay committee and has provided feedback on this project proposal throughout development. Ms Siobhan Atherly volunteered to be a patient voice through the Royal College of Surgeons; she is currently in follow-up from surgery & is actively involved with her local Trust Board.

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:	No upper age limit

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

1. Adult patients aged 18 or older
2. Undergoing an elective major surgical procedure (see Appendix 5 for list of included procedures)
3. Has capacity to give consent to participate in this study

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

1. Aged less than 18years
2. Does not have capacity, or refuses, to give consent to participate in this study

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
Participant consent	1	0	10minutes	Conducted by Clinical Research Nurse in pre-operative assessment clinic or on morning of surgery
Patient-Reported Outcomes (PROMs) questionnaire	5	0	10	Pre-operative questions on morning of surgery; post-operative questions on days 1 and 3 after surgery as an inpatient, and then by telephone/email follow-up (dictated by patient preference) at 6 and 12 months after surgery.

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

12 months

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 main risk to patients will be the confidentiality of their identifiable information. The processes governing data security and governance have been already granted REC/CAG approval in the linked application ('PQIP Database' - IRAS reference 211179).

Patients will experience a minor burden completing a consent form and questionnaires.

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?

At an individual patient level, there is unlikely to be a specific benefit, apart from that of being a participant in a clinical study and therefore the potential for a greater degree of surveillance for postoperative problems (through involvement of researchers in monitoring postoperative outcomes while in hospital). However, over time we hope that patients recruited into the study later in its duration might benefit through improvement in quality of care conferred through their hospital's participation in PQIP.

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

None

RECRUITMENT AND INFORMED CONSENT

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

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

Clinicians in participating hospitals will identify patients for entry to the database. 5 patients per week undergoing any of a predefined list of eligible surgical procedures in each hospital will be recruited.

A random sampling technique for patient identification will be used, based on an 8-day rolling rota: e.g. the first 5 patients admitted on Monday for qualifying surgical procedures in week 1, followed by the first 5 patients on Tuesday in week 2, the first 5 patients on Wednesday in week 3, etc. The sampling strategy will be communicated by the central database team at the Royal College of Anaesthetists to local sites, and local principle investigators (PIs) will be responsible for ensuring that the patients recruited adhere to the strategy. Weekly updates will be sent out by email to local PIs reminding them of which patients are to be approached. If a patient refuses consent, the next sequential patient will be approached until 5 patients are recruited.

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

◉ Yes ○ No

Please give details below:
Patients will be identified, according to the sampling strategy described above, by clinicians in the course of routine healthcare provision or by local clinical research nurses.

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.*

Patients will be identified by clinicians in the course of routine healthcare provision or by local research nurses who will be bound by the principles of GCP

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

◉ Yes ○ No

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

◉ Yes ○ No

If Yes, please give details below.
Consent will be sought prospectively from all patients whose data are included in the database.

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

◉ Yes ○ No

If Yes, please give details of how and where publicity will be conducted, and enclose copy of all advertising material (with version numbers and dates).
Posters will be displayed in preoperative assessment clinics and surgical admission wards, giving patients brief details of the study (see appendix). If they attend preoperative assessment clinic, they will be offered a Patient Information Sheet (PIS, see appendix) at that time. Otherwise, they will be provided with a PIS on arrival in hospital for their surgery.

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

Patients will be approached by clinicians or by local research nurses either at preoperative clinic or on admission to hospital for their surgery.

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

◉ Yes ○ No

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

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.
Consent will be sought by clinicians or local research nurses. Potential participants will be provided with patient information sheets and consent forms for completion; these will provide contact details for further information including links to videos on the database website.

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

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

A30-2. Will you record informed consent (or advice from consultees) in writing?

(●) Yes ( ) No

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

This will be determined by local circumstances but will be a minimum of one hour. Posters will be displayed in preoperative assessment clinics and surgical admission wards, giving patients brief details of the study (see appendix). If they attend preoperative assessment clinic, they will be offered a Patient Information Sheet (PIS, see appendix) at that time. Otherwise, they will be provided with a PIS on arrival in hospital for their surgery. Consent will be taken prior to surgery and preoperative questionnaires completed at the time of consent. This methodology is similar to that used in the NHS Patient Reported Outcome Measures (PROMs) programme:

"....this [offering a patient a questionnaire for completion] should happen in the interval between the patient being passed fit for surgery and the treatment taking place, however, there is local discretion as to when precisely it is administered before the procedure. Completion of the pre-operative PROMs questionnaire is voluntary for the patient and their consent to participate must be granted for the data to be processed and used....."

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs?*(e.g. translation, use of interpreters)*

Language constraint will be an exclusion criterion.

A33-2. What arrangements will you make to comply with the principles of the Welsh Language Act in the provision of information to participants in Wales?

Information sheets, consent forms and questionnaires will be translated into Welsh.

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

( ) The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.

(●) The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.

( ) The participant would continue to be included in the study.

( ) Not applicable – informed consent will not be sought from any participants in this research.

( ) Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be assumed.

Further details:

This approach is reflected in the consent form.

If you plan to retain and make further use of identifiable data/tissue following loss of capacity, you should inform participants about this when seeking their consent initially.

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)*

- [x] Access to medical records by those outside the direct healthcare team
- [ ] Access to social care records by those outside the direct social care team
- [x] Electronic transfer by magnetic or optical media, email or computer networks
- [x] Sharing of personal data with other organisations
- [ ] Export of personal data outside the EEA
- [x] Use of personal addresses, postcodes, faxes, emails or telephone numbers
- [x] Publication of direct quotations from respondents
- [ ] Publication of data that might allow identification of individuals
- [ ] Use of audio/visual recording devices
- [x] Storage of personal data on any of the following:
  - [ ] Manual files (includes paper or film)
  - [x] NHS computers
  - [ ] Social Care Service computers
  - [ ] Home or other personal computers
  - [ ] University computers
  - [ ] Private company computers
  - [ ] Laptop computers

Further details:

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

Patient level data will be entered by local reporters directly onto electronic CRFs via the PQIP Database (IRAS form 211179 which already received a favourable REC opinion). The database will be hosted on a server managed by UK Fast on behalf of the Royal College of Anaesthetists (RCoA).

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.*

All study team members with access to confidential and/or identifiable data will be bound by the Data Protection Act, the NHS Information Governance framework and local information governance regulations. Staff within the NHS will follow the NHS Code of Confidentiality.

Among the patient identifiers, only sex will used for analysis. An anonymised dataset will be used by the central PQIP study team for analysis. In this dataset:
• the NHS number will be replaced by a unique study patient identifier
• Date of Birth will be converted to Age on date of surgery, and trimmed to month and year of birth
• Postcode will be converted to PCT, SHA of residence, and the Office for National Statistics Lower Super Output Area, which allows the allocation of the Index of Multiple Deprivation.

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.*

Access to personal data within PQIP are described in the PQIP research database application 211179 and associated

protocol. For completeness:
- Consent will be sought
- Data will be anonymised for linkage as detailed above
- Only members of the research team who have fulfilled GCP training will be able to access participant data

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 analysed at the following centres:

Royal College of Anaesthetists
University College London Hospitals NHS Foundation Trust
University College London Department of Applied Health Research

Analyses will be conducted by members of the study team:
Dr SR Moonesinghe (CI)
Research fellows appointed to work on the study - all clinical doctors who will have completed GCP training and who will be bound by NHS and DPA guidance on data confidentiality.
Study statistician.

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

	Title	Forename/Initials	Surname
	Mrs	Sharon	Drake
Post	Director of Clinical Quality and Research and Deputy Chief Executive, Royal College of		
Qualifications	BA (Hons) Classics and English, CTEFL, Postgraduate Diploma in Management Studies		
Work Address	Royal College of Anaesthetists		
	Churchill House		
	35 Red Lion Square, London		
Post Code	WC1R 4SG		
Work Email	sdrake@rcoa.ac.uk		
Work Telephone	02070921671		
Fax	02070921730		

A43. How long will personal data be stored or accessed after the study has ended?

- ○ Less than 3 months
- ○ 3 – 6 months
- ○ 6 – 12 months
- ○ 12 months – 3 years
- ◉ Over 3 years

If longer than 12 months, please justify:
The PQIP database will be tracking long-term survival (up to 20 years post-enrolment)

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

Years: 30
Months:

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

The data will be stored on servers hosted by UK Fast who have unassuming facilities, unmarked and inauspicious with 24/7/365 on site security. UKFast have to comply with ISO 27001 standards to retain certification. ISO 27001 specifically requires that the organisation examines its information security risks, taking account of the threats, vulnerabilities, and impacts.

INCENTIVES AND PAYMENTS

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

○ Yes ◉ No

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

○ Yes ◉ No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

○ Yes ◉ No

NOTIFICATION OF OTHER PROFESSIONALS

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

○ Yes ◉ No

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

PUBLICATION AND DISSEMINATION

A50. Will the research be registered on a public database?

◉ Yes ○ No

Please give details, or justify if not registering the research.
We will register the study on clinicaltrials.gov and publish our protocol after ethics approval received

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:*

- [x] Peer reviewed scientific journals
- [ ] Internal report
- [x] Conference presentation
- [x] Publication on website
- [x] Other publication
- [ ] Submission to regulatory authorities
- [x] Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
- [ ] No plans to report or disseminate the results
- [ ] Other (please specify)

A52. If you will be using identifiable personal data, how will you ensure that anonymity will be maintained when publishing the results?

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

A53. Will you inform participants of the results?

(•) Yes ( ) No

Please give details of how you will inform participants or justify if not doing so.
All participants will be given an information leaflet prior to consent. This will include details of the study website; all reports / results will be published on there and therefore participants will be able to access if they wish.

5. Scientific and Statistical Review

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

- [x] 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
- [ ] Review by educational supervisor
- [ ] Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:
The original protocol was peer reviewed on behalf of the Health Foundation who have provided grant funding. Since then we have refined the protocol and reviewed extensively over the past 8 months at monthly project team meetings and with input from a multi-disciplinary clinical reference group (listed at end of 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

☑ Review by a statistician within the Chief Investigator's institution

☑ Review by a statistician within the research team or multi−centre group

☐ Review by educational supervisor

☐ Other review by individual with relevant statistical expertise

☐ No review necessary as only frequencies and associations will be assessed – details of statistical input not required

In all cases please give details below of the individual responsible for reviewing the statistical aspects. If advice has been provided in confidence, give details of the department and institution concerned.

	Title	Forename/Initials	Surname
	Dr	Mizan	Khondoker
Department	Department of Applied Health Research		
Institution	University College London		
Work Address	1-19 Torrington Place, London		
Post Code	WC1E 7HB		
Telephone	02031083952		
Fax			
Mobile			
E-mail	m.khondoker@ucl.ac.uk		

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

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

Postoperative Morbidity (defined using the Post Operative Morbidity Survey or POMS) on day 7

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

Structural measures of engagement with PQIP:
Frequency of reports being presented at clinical and managerial meetings
Process measures of engagement with PQIP:
Case-ascertainment rates
Data completion
Process measures related to patient care:
Changes in compliance with process measures
Short-term patient outcome measures:
Clavien-Dindo classification of complications on discharge from hospital.
Resource utilisation:
Critical Care admission (planned)
Critical Care admission (unplanned)
Critical Care Length of Stay
Hospital length of stay
Hospital readmission within 30 days of index procedure
Longer-term patient outcome measures:
EQ5D (5L) at 6 months and one year post-surgery
World Health Organisation Disability Assessment Schedule 2.0 [26] at 6months and one year post-surgery

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:	70000
Total international sample size (including UK):	70000
Total in European Economic Area:	70000

Further details:
Based on the number of hospitals which have indicated they want to participate, and our target recruitment rate within these hospitals, we estimate that 70,000 patients will be recruited over 4 years, (median of 5 patients per week, 50 weeks per year, in 70 hospitals).

Our aim will be to expand the study to as many UK hospitals as want to participate - therefore the sample size may exceed our target; however, our end point will be dictated by the number of years of the study (as we wish to study how patient outcomes change over time to assess the impact of the data collection and feedback on outcome) - the planned study (recruitment) duration is 4 years.

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.*

The sample size calculation has been based on previous data from studies in the US

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 used to describe basic demographics of participants. Risk-adjustment will be based on backward stepwise logistic regression, including multiple patient-level and operation-level variables such as age, sex, operation type and known validated risk prediction scores and their constituent variables such as the Portsmouth Physiological and operative score for the enumeration of morbidity and mortality (P-POSSUM) and the Surgical Outcome Risk Tool (SORT). Risk-adjusted morbidity and mortality will be compared between hospitals using funnel plots. Variable life-adjusted displays will be used to feedback outcome data to clinicians in near-real time. Hierarchical regression modelling will be used to analyse the relative contributions of patient and hospital factors on patient outcomes.

6. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. *Please include all grant co−applicants, protocol co−authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

	Title	Forename/Initials	Surname
	Prof	Mike	Grocott
Post	Professor of Anaesthesia and Critical Care		
Qualifications	MD		
Employer	University of Southampton		
Work Address	Faculty of Medicine, University of Southampton		
	Building 85, Life Sciences Building		
	Highfield Campus, Southampton		
Post Code	SO171BJ		
Telephone	02381208449		
Fax			
Mobile			

Work Email	mike.grocott@soton.ac.uk

Title	Forename/Initials	Surname
Dr	Jonathon	Wilson

Post	Consultant Anaesthetist
Qualifications	FRCA
Employer	York Teaching Hospital Foundation Trust
Work Address	Anaesthetics Department, York Hospital Wigginton Road York
Post Code	YO318HE
Telephone	01904725398
Fax	
Mobile	
Work Email	jonathon.rjt.wilson@york.nhs.uk

Title	Forename/Initials	Surname
Dr	David	Gilhooly

Post	Research Associate
Qualifications	FFCAI
Employer	The London Clinic
Work Address	20 Devonshire Place London
Post Code	WCG6BW
Telephone	02079354444
Fax	
Mobile	
Work Email	d.gilhooly@excite.com

Title	Forename/Initials	Surname
Dr	Maria	Chazapis

Post	Research Associate
Qualifications	FRCA
Employer	University College London Hospitals NHS Foundation Trust
Work Address	Anaesthetics Department Podium 3, Maple Link corridor, University College Hospital 235 Euston Road
Post Code	NW12BU
Telephone	02034567890
Fax	
Mobile	
Work Email	m.chazapis@yahoo.com

Title	Forename/Initials	Surname
Dr	Duncan	Wagstaff

Post	Research Associate
Qualifications	FRCA
Employer	University College London

Work Address	Department of Applied Health Research 1-19 Torrington Place London
Post Code	WC1E 7HB
Telephone	
Fax	
Mobile	07812125650
Work Email	duncan_wagstaff@yahoo.co.uk

A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

Status:
- ○ NHS or HSC care organisation
- ◉ Academic
- ○ Pharmaceutical industry
- ○ Medical device industry
- ○ Local Authority
- ○ Other social care provider (including voluntary sector or private organisation)
- ○ Other

Commercial status: Non-Commercial

If Other, please specify:

Contact person

Name of organisation	University College London
Given name	Tabitha
Family name	Kavoi
Address	Joint Research Office, UCL, Gower St
Town/city	London
Post code	W1G8PH
Country	UNITED KINGDOM
Telephone	02034475274
Fax	
E-mail	

Is the sponsor based outside the UK?

○ Yes ◉ No

Under the Research Governance Framework for Health and Social Care, a sponsor outside the UK must appoint a legal representative established in the UK. Please consult the guidance notes.

A65. Has external funding for the research been secured?

- [x] Funding secured from one or more funders
- [ ] External funding application to one or more funders in progress
- [ ] No application for external funding will be made

What type of research project is this?

- ○ Standalone project
- ○ Project that is part of a programme grant
- ○ Project that is part of a Centre grant
- ○ Project that is part of a fellowship/ personal award/ research training award
- ○ Other

Other – please state:

Please give details of funding applications.

Organisation	The Health Foundation
Address	90 Long Acre London
Post Code	WC2E 9RA
Telephone	02072578000
Fax	
Mobile	
Email	daniela.d'alessio@health.org.uk

Funding Application Status: ◉ Secured ○ In progress

Amount: 374,709

Duration
Years: 3
Months:

If applicable, please specify the programme/ funding stream:

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

Organisation	Royal College of Anaesthetists
Address	Churchill House 35 Red Lion Square London
Post Code	WC1R 4SG
Telephone	02070921500
Fax	
Mobile	
Email	sdrake@rcoa.ac.uk

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

Amount: 71,892

Duration
Years:
Months:

If applicable, please specify the programme/ funding stream:

What is the funding stream/ programme for this research project?
Health Services Research Centre - statistician salary

Organisation	Royal College of Anaesthetists
Address	Churchill House
	35 Red Lion Square
	London
Post Code	WC1R 4SG
Telephone	02070921500
Fax	
Mobile	
Email	sdrake@rcoa.ac.uk

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

Amount: 260,000

Duration
Years: 5
Months:

If applicable, please specify the programme/ funding stream:

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

A66. Has responsibility for any specific research activities or procedures been delegated to a subcontractor (other than a co-sponsor listed in A64-1) ? *Please give details of subcontractors if applicable.*

( ) Yes (●) No

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

( ) Yes (●) No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68-1. Give details of the lead NHS R&D contact for this research:

Title	Forename/Initials	Surname
Ms	Suzanne	Emerton

Organisation	University College London Hospitals NHS Foundation Trust
Address	Joint Research Office, UCL
	Gower Street
	London
Post Code	WC1E6BT
Work Email	rand.d@uclh.nhs.uk
Telephone	02034475274
Fax	
Mobile	

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

A68-2. Select Local Clinical Research Network for NHS Organisation identified in A68-1:

North Thames

For more information, please refer to the question specific guidance.

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

Planned start date: 07/11/2016
Planned end date: 06/11/2020
Total duration:
Years: 4 Months: 0 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 70

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	65
☑ NHS organisations in Wales	2

☑ NHS organisations in Scotland	2
☑ HSC organisations in Northern Ireland	1
☐ 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:	70

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

○ Yes ◉ No

A74. What arrangements are in place for monitoring and auditing the conduct of the research?

The Chief Investigator will be responsible for the day to day monitoring and management of the study. The /UCL/ Joint Research Office, on behalf of UCL or as Sponsor, will monitor and conduct random audits on a selection of studies in its clinical research portfolio. Monitoring and auditing will be conducted in accordance with the Department of Health Research Governance Framework for Health & Social Care (April, 2005), and in accordance with the Sponsor's monitoring and audit policies and procedures.

The study project team are meeting monthly and reviews all aspects of the conduct of the research.

The study steering group meets quarterly and provides guidance on the study overall.
The study project team reports monthly to the Board of the National Institute for Academic Anaesthesia's Health.

Services Research Centre (NIAA-HSRC) based at the Royal College of Anaesthetists
All project team minutes are reviewed by the NIAA-HSRC monthly and the steering group quarterly.
The steering group minutes are reviewed by the NIAA-HSRC monthly.
An annual report will be provided to the R&D office at UCLH.

A76. Insurance/ indemnity to meet potential legal liabilities

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

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

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes.

Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

☐ NHS indemnity scheme will apply (NHS sponsors only)

☑ Other insurance or indemnity arrangements will apply (give details below)

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

Please enclose a copy of relevant documents.

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

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

☑ NHS indemnity scheme will apply (protocol authors with NHS contracts only)

☐ Other insurance or indemnity arrangements will apply (give details below)

The protocol author is an NHS employee (SR Moonesinghe)

Please enclose a copy of relevant documents.

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

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

☑ NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)

☐ Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

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 NHS sites, the host organisation is the Trust or Health Board. Where the research site is a primary care site, e.g. GP practice, please insert the host organisation (PCT or Health Board) in the Institution row and insert the research site (e.g. GP practice) in the Department row.*

Investigator identifier	Research site		Investigator Name	
IN1	(●) NHS site ( ) Non-NHS site Country: England		Forename Middle name Family name Email Qualification (MD...) Country	Adrienne Stewart adrienne.stewart@uclh.nhs.uk FRCA UNITED KINGDOM
	Organisation name	UNIVERSITY COLLEGE LONDON HOSPITALS NHS FOUNDATION TRUST		
	Address	250 EUSTON ROAD LONDON GREATER LONDON		
	Post Code	NW1 2PG		
IN2	(●) NHS site ( ) Non-NHS site Country: England		Forename Middle name Family name Email Qualification (MD...) Country	Mark Edwards m.edwards@soton.ac.uk FRCA UNITED KINGDOM
	Organisation name	SOUTHAMPTON UNIVERSITY HOSPITALS NHS TRUST		
	Address	MAILPOINT 18 SOUTHAMPTON GENERAL HOSPITAL TREMONA ROAD SOUTHAMPTON HAMPSHIRE		
	Post Code	SO16 6YD		

IN3

(●) NHS site
( ) Non-NHS site

Country: England

Organisation name	THE NEWCASTLE UPON TYNE HOSPITALS NHS FOUNDATION TRUST
Address	FREEMAN HOSPITAL FREEMAN ROAD HIGH HEATON NEWCASTLE-UPON-TYNE TYNE AND WEAR
Post Code	NE7 7DN

Forename	David
Middle name	
Family name	Saunders
Email	david.saunders@nuth.nhs.uk
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

IN4

(●) NHS site
( ) Non-NHS site

Country: England

Organisation name	ROYAL UNITED HOSPITAL BATH NHS TRUST
Address	COMBE PARK BATH AVON
Post Code	BA1 3NG

Forename	Tim
Middle name	
Family name	Cook
Email	timcook007@gmail.com
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

IN5

(●) NHS site
( ) Non-NHS site

Country: England

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

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

IN6

◉ NHS site
○ Non-NHS site

Country: England

Organisation name	CAMBRIDGE UNIVERSITY HOSPITALS NHS FOUNDATION TRUST
Address	ADDENBROOKES HOSPITAL HILLS ROAD CAMBRIDGE CAMBRIDGESHIRE
Post Code	CB2 0QQ

Forename	Vishal
Middle name	
Family name	Patil
Email	vishal.patil@addenbrookes.nhs.uk
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

IN7

◉ NHS site
○ Non-NHS site

Country: England

Organisation name	AINTREE UNIVERSITY HOSPITALS NHS FOUNDATION TRUST
Address	UNIVERSITY HOSPITAL AINTREE FAZAKERLEY HOSPITAL LOWER LANE LIVERPOOL MERSEYSIDE
Post Code	L9 7AL

Forename	Dermot
Middle name	
Family name	Moloney
Email	dmoloney586@googlemail.com
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

IN8

◉ NHS site
○ Non-NHS site

Country: England

Organisation name	ROYAL BOLTON HOSPITAL NHS FOUNDATION TRUST
Address	THE ROYAL BOLTON HOSPITAL MINERVA ROAD

Forename	Inese
Middle name	
Family name	Kutovaja
Email	Inese.kutovaja@boltonft.nhs.uk
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

	FARNWORTH BOLTON LANCASHIRE
Post Code	BL4 0JR

IN9

- (●) NHS site
- ( ) Non-NHS site

Country: England

Organisation name	BRADFORD TEACHING HOSPITALS NHS FOUNDATION TRUST
Address	BRADFORD ROYAL INFIRMARY DUCKWORTH LANE BRADFORD WEST YORKSHIRE
Post Code	BD9 6RJ

Forename	Andrew
Middle name	
Family name	Brennan
Email	Andrew.Brennan@bthft.nhs.uk
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

IN10

- (●) NHS site
- ( ) Non-NHS site

Country: England

Organisation name	BRIGHTON AND SUSSEX UNIVERSITY HOSPITALS NHS TRUST
Address	ROYAL SUSSEX COUNTY HOSPITAL EASTERN ROAD BRIGHTON EAST SUSSEX
Post Code	BN2 5BE

Forename	Mark
Middle name	
Family name	Paul
Email	Mark.Paul@bsuh.nhs.uk
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

IN11

- (●) NHS site
- ( ) Non-NHS site

Country: England

Organisation	MID ESSEX HOSPITAL

Forename	Alistair
Middle name	
Family name	Hughes
Email	alistairhughes@nhs.net
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

name	SERVICES NHS TRUST
Address	BROOMFIELD HOSPITAL COURT ROAD CHELMSFORD ESSEX
Post Code	CM1 7ET

IN12

(●) NHS site
( ) Non-NHS site

Country: England

Organisation name	BUCKINGHAMSHIRE HEALTHCARE NHS TRUST
Address	AMERSHAM HOSPITAL WHIELDEN STREET AMERSHAM BUCKINGHAMSHIRE
Post Code	HP7 0JD

Forename	Jeremy
Middle name	
Family name	Drake
Email	synapriori@doctors.org.uk
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

IN13

(●) NHS site
( ) Non-NHS site

Country: Scotland

Institution name	NHS Grampian
Department name	Aberdeen Royal Infirmary
Street address	2 Eday Rd
Town/city	Aberdeen
Post Code	AB15 6RE

Forename	Amr
Middle name	
Family name	Mahdy
Email	a.mahdy@nhs.net
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

IN14

(●) NHS site
( ) Non-NHS site

Country: England

Organisation name	CENTRAL MANCHESTER UNIVERSITY HOSPITALS NHS FOUNDATION TRUST
Address	TRUST HEADQUARTERS, COBBETT HOUSE

Forename	Swati
Middle name	
Family name	Karmarkar
Email	Swati.Karmarkar@cmft.nhs.uk
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

	MANCHESTER ROYAL INFIRMARY OXFORD ROAD MANCHESTER GREATER MANCHESTER
Post Code	M13 9WL

IN15

◉ NHS site
○ Non-NHS site

Country: England

Organisation name	IMPERIAL COLLEGE HEALTHCARE NHS TRUST
Address	ST. MARYS HOSPITAL PRAED STREET LONDON GREATER LONDON
Post Code	W2 1NY

Forename	Jim
Middle name	
Family name	Poncia
Email	James.Poncia@imperial.nhs.uk
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

IN16

◉ NHS site
○ Non-NHS site

Country: England

Organisation name	GLOUCESTERSHIRE HOSPITALS NHS FOUNDATION TRUST
Address	TRUST HQ 1 COLLEGE LAWN CHELTENHAM GLOUCESTERSHIRE
Post Code	GL53 7AG

Forename	David
Middle name	
Family name	Windsor
Email	David.Windsor@glos.nhs.uk
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

IN17

◉ NHS site
○ Non-NHS site

Country: England

Forename	Amir
Middle name	
Family name	Rafi
Email	amir.rafi@nhs.net
Qualification (MD...)	FRCA

			Country	UNITED KINGDOM
	Organisation name	COUNTY DURHAM AND DARLINGTON NHS FOUNDATION TRUST		
	Address	DARLINGTON MEMORIAL HOSPITAL HOLLYHURST ROAD DARLINGTON COUNTY DURHAM		
	Post Code	DL3 6HX		

IN18

(●) NHS site
( ) Non-NHS site

Country: England

Forename	Susie		
Middle name			
Family name	Baker		
Email	Susie.baker@dchft.nhs.uk		
Qualification (MD...)	FRCA		
Country	UNITED KINGDOM		
Organisation name	DORSET COUNTY HOSPITAL NHS FOUNDATION TRUST		
Address	DORSET COUNTY HOSPITAL WILLIAMS AVENUE DORCHESTER DORSET		
Post Code	DT1 2JY		

IN19

(●) NHS site
( ) Non-NHS site

Country: England

Forename	Julian		
Middle name			
Family name	Sonksen		
Email	Julian.Sonksen@dgh.nhs.uk		
Qualification (MD...)	FRCA		
Country	UNITED KINGDOM		
Organisation name	THE DUDLEY GROUP OF HOSPITALS NHS FOUNDATION TRUST		
Address	C BLOCK RUSSELLS HALL HOSPITAL PENSNETT ROAD DUDLEY WEST MIDLANDS		
Post Code	DY1 2HQ		

IN20

(●) NHS site
( ) Non-NHS site

Forename	Srikanth
Middle name	

Country: England

Organisation name	EAST LANCASHIRE HOSPITALS NHS TRUST
Address	ROYAL BLACKBURN HOSPITAL HASLINGDEN ROAD BLACKBURN LANCASHIRE
Post Code	BB2 3HH

Family name	Chukkambotla
Email	Srikanth.Chukkambotla@elht.nhs.uk
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

IN21

(●) NHS site
( ) Non-NHS site

Country: England

Organisation name	EAST KENT HOSPITALS UNIVERSITY NHS FOUNDATION TRUST
Address	KENT & CANTERBURY HOSPITAL ETHELBERT ROAD CANTERBURY KENT
Post Code	CT1 3NG

Forename	Simon
Middle name	
Family name	Rang
Email	simon.rang@nhs.net
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

IN22

(●) NHS site
( ) Non-NHS site

Country: England

Organisation name	GREAT WESTERN HOSPITALS NHS FOUNDATION TRUST
Address	GREAT WESTERN HOSPITAL MARLBOROUGH ROAD SWINDON WILTSHIRE
Post Code	SN3 6BB

Forename	Zoe
Middle name	
Family name	Ridgway
Email	Zoe.Ridgway@gwh.nhs.uk
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

IN23

◉ NHS site
○ Non-NHS site

Country: England

Organisation name	HEART OF ENGLAND NHS FOUNDATION TRUST
Address	BIRMINGHAM HEARTLANDS HOSPITAL BORDESLEY GREEN EAST BIRMINGHAM WEST MIDLANDS
Post Code	B9 5ST

Forename	Fang
Middle name	
Family name	Gao Smith
Email	F.GaoSmith@bham.ac.uk
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

IN24

◉ NHS site
○ Non-NHS site

Country: England

Organisation name	HOMERTON UNIVERSITY HOSPITAL NHS FOUNDATION TRUST
Address	HOMERTON ROW LONDON GREATER LONDON
Post Code	E9 6SR

Forename	Tabitha
Middle name	
Family name	Tanqueray
Email	Tabitha.Tanqueray@homerton.nhs.uk
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

IN25

◉ NHS site
○ Non-NHS site

Country: England

Organisation name	KING'S COLLEGE HOSPITAL NHS FOUNDATION TRUST
Address	DENMARK HILL LONDON GREATER LONDON
Post Code	SE5 9RS

Forename	Tim
Middle name	
Family name	Hughes
Email	t.hughes1@nhs.net
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

IN26

◉ NHS site
○ Non-NHS site

Country: England

Organisation name	LANCASHIRE TEACHING HOSPITALS NHS FOUNDATION TRUST
Address	CHIEF EXECUTIVE'S OFFICE ROYAL PRESTON HOSPITAL SHAROE GREEN LANE, FULWOOD PRESTON LANCASHIRE
Post Code	PR2 9HT

Forename	Zara
Middle name	
Family name	Townley
Email	Zara.Townley@LTHTR.nhs.uk
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

IN27

◉ NHS site
○ Non-NHS site

Country: England

Organisation name	LEEDS TEACHING HOSPITALS NHS TRUST
Address	ST. JAMES'S UNIVERSITY HOSPITAL BECKETT STREET LEEDS WEST YORKSHIRE
Post Code	LS9 7TF

Forename	Simon
Middle name	
Family name	Howell
Email	s.howell@leeds.ac.uk
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

IN28

◉ NHS site
○ Non-NHS site

Country: England

Organisation name	NORTH WEST LONDON HOSPITALS NHS TRUST
Address	NORTHWICK PARK HOSPITAL WATFORD ROAD

Forename	Jamie
Middle name	
Family name	Gross
Email	j.gross@nhs.net
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

HARROW MIDDLESEX
Post Code HA1 3UJ

IN29

◉ NHS site
○ Non-NHS site

Country: England

Organisation name: MILTON KEYNES HOSPITAL NHS FOUNDATION TRUST
Address: STANDING WAY
EAGLESTONE
MILTON KEYNES
BUCKINGHAMSHIRE
Post Code: MK6 5LD

Forename: Graziana
Middle name:
Family name: Massolini
Email: Graziana.Massolini@mkhospital.nhs.uk
Qualification (MD...): FRCA
Country: UNITED KINGDOM

IN30

◉ NHS site
○ Non-NHS site

Country: England

Organisation name: TAUNTON AND SOMERSET NHS FOUNDATION TRUST
Address: MUSGROVE PARK HOSPITAL
TAUNTON SOMERSET
Post Code: TA1 5DA

Forename: Richard
Middle name:
Family name: Gibbs
Email: richardhgibbs@hotmail.com
Qualification (MD...): FRCA
Country: UNITED KINGDOM

IN31

◉ NHS site
○ Non-NHS site

Country: Scotland

Institution name: NHS Tayside
Department name: Ninewells Hospital
Street address:
Town/city: Dundee

Forename: Sharon
Middle name:
Family name: Hilton-Christie
Email: sharonchristie@nhs.net
Qualification (MD...): FRCA
Country: UNITED KINGDOM

Post Code DD1 9SY

IN32

◉ NHS site
○ Non-NHS site

Country: England

Organisation name	NORFOLK AND NORWICH UNIVERSITY HOSPITALS NHS FOUNDATION TRUST
Address	COLNEY LANE COLNEY NORWICH NORFOLK
Post Code	NR4 7UY

Forename	Caroline
Middle name	
Family name	Reavley
Email	caroline.reavley@btinternet.com
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

IN33

◉ NHS site
○ Non-NHS site

Country: England

Organisation name	NORTH BRISTOL NHS TRUST
Address	FRENCHAY HOSPITAL BECKSPOOL ROAD FRENCHAY BRISTOL AVON
Post Code	BS16 1JE

Forename	Sarah
Middle name	
Family name	Martindale
Email	Sarah.Martindale@nbt.nhs.uk
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

IN34

◉ NHS site
○ Non-NHS site

Country: England

Organisation name	NORTHERN DEVON HEALTHCARE NHS TRUST
Address	NORTH DEVON DISTRICT HOSPITAL RALEIGH PARK BARNSTAPLE DEVON
Post Code	EX31 4JB

Forename	Simon
Middle name	
Family name	Hebard
Email	simon.hebard@nhs.net
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

IN35

◉ NHS site
○ Non-NHS site

Country: England

Organisation name	PAPWORTH HOSPITAL NHS FOUNDATION TRUST
Address	PAPWORTH EVERARD CAMBRIDGE CAMBRIDGESHIRE
Post Code	CB23 3RE

Forename	Stephen
Middle name	
Family name	Webb
Email	stephen.webb@nhs.net
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

IN36

◉ NHS site
○ Non-NHS site

Country: England

Organisation name	PETERBOROUGH AND STAMFORD HOSPITALS NHS FOUNDATION TRUST
Address	EDITH CAVELL HOSPITAL BRETTON GATE BRETTON PETERBOROUGH CAMBRIDGESHIRE
Post Code	PE3 9GZ

Forename	Balraj
Middle name	
Family name	Appadu
Email	Balraj.Appadu@pbh-tr.nhs.uk
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

IN37

◉ NHS site
○ Non-NHS site

Country: England

Organisation name	PORTSMOUTH HOSPITALS NHS TRUST
Address	DE LA COURT HOUSE QUEEN ALEXANDRA HOSPITAL

Forename	Marie
Middle name	
Family name	Nixon
Email	marie@duboulay.net
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

	SOUTHWICK HILL ROAD PORTSMOUTH HAMPSHIRE
Post Code	PO6 3LY

IN38

◉ NHS site
○ Non-NHS site

Country: Scotland

Institution name	NHS Greater Glasgow and Clyde
Department name	Queen Elizabeth Hospital, Glasgow
Street address	1345 Govan Rd
Town/city	Glasgow
Post Code	G51 4TF

Forename	Brian
Middle name	
Family name	McCreath
Email	brianmccreath@nhs.net
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

IN39

◉ NHS site
○ Non-NHS site

Country: England

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

Forename	Emma
Middle name	
Family name	Gent
Email	emma_gent@doctors.org.uk
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

IN40

◉ NHS site
○ Non-NHS site

Country: England

Organisation name	GATESHEAD HEALTH NHS FOUNDATION TRUST
Address	QUEEN ELIZABETH HOSPITAL

Forename	Andy
Middle name	
Family name	Bracewell
Email	andrew.bracewell@ghnt.nhs.uk
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

	GATESHEAD TYNE AND WEAR
Post Code	NE9 6SX

IN41

- (●) NHS site
- ( ) Non-NHS site

Country: Scotland

Institution name	NHS Highland
Department name	Raigmore Hospital
Street address	Old Perth Rd
Town/city	Inverness
Post Code	IV2 3UJ

Forename	Dev
Middle name	
Family name	Srivastava
Email	dev.srivastava@nhs.net
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

IN42

- (●) NHS site
- ( ) Non-NHS site

Country: England

Organisation name	ROYAL BERKSHIRE NHS FOUNDATION TRUST
Address	ROYAL BERKSHIRE HOSPITAL LONDON ROAD READING BERKSHIRE
Post Code	RG1 5AN

Forename	Jennie
Middle name	
Family name	Rechner
Email	Jennie.Rechner@royalberkshire.nhs.uk
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

IN43

- (●) NHS site
- ( ) Non-NHS site

Country: England

Organisation name	THE ROYAL BOURNEMOUTH AND CHRISTCHURCH HOSPITALS NHS FOUNDATION TRUST
Address	ROYAL BOURNEMOUTH GENERAL HOSPITAL CASTLE LANE EAST

Forename	James
Middle name	
Family name	Craig
Email	James.Craig@rbch.nhs.uk
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

BOURNEMOUTH DORSET

Post Code BH7 7DW

IN44

◉ NHS site
○ Non-NHS site

Country: England

Organisation name: ROYAL DEVON AND EXETER NHS FOUNDATION TRUST

Address: ROYAL DEVON & EXETER HOSPITAL
BARRACK ROAD
EXETER DEVON

Post Code: EX2 5DW

Forename: Kath
Middle name:
Family name: Meikle
Email: katharine.meikle@nhs.net
Qualification (MD...): FRCA
Country: UNITED KINGDOM

IN45

◉ NHS site
○ Non-NHS site

Country: England

Organisation name: ROYAL FREE HAMPSTEAD NHS TRUST

Address: ROYAL FREE HOSPITAL
POND STREET
LONDON GREATER LONDON

Post Code: NW3 2QG

Forename: Dan
Middle name:
Family name: Martin
Email: daniel.martin@ucl.ac.uk
Qualification (MD...): FRCA
Country: UNITED KINGDOM

IN46

◉ NHS site
○ Non-NHS site

Country: England

Organisation name: BARTS AND THE LONDON NHS TRUST

Address: TRUST OFFICES, WHITECHAPEL

Forename: Matt
Middle name:
Family name: Wikner
Email: wiknermatt@yahoo.co.uk
Qualification (MD...): FRCA
Country: UNITED KINGDOM

	THE ROYAL LONDON HOSPITAL
	WHITECHAPEL LONDON GREATER LONDON
Post Code	E1 1BB

IN47

- (●) NHS site
- ( ) Non-NHS site

Country: England

Organisation name	THE ROYAL MARSDEN NHS FOUNDATION TRUST
Address	FULHAM ROAD
	LONDON GREATER LONDON
Post Code	SW3 6JJ

Forename	Susanna
Middle name	
Family name	Walker
Email	susannawalker@yahoo.co.uk
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

IN48

- (●) NHS site
- ( ) Non-NHS site

Country: England

Organisation name	SALFORD ROYAL NHS FOUNDATION TRUST
Address	SALFORD ROYAL
	STOTT LANE
	SALFORD GREATER MANCHESTER
Post Code	M6 8HD

Forename	Oliver
Middle name	
Family name	Pratt
Email	Oliver.Pratt@srft.nhs.uk
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

IN49

- (●) NHS site
- ( ) Non-NHS site

Country: England

Forename	Subash
Middle name	
Family name	Sivasubramaniam
Email	s.sivasubramaniam@nhs.net
Qualification (MD...)	FRCA

	Organisation name	SANDWELL AND WEST BIRMINGHAM HOSPITALS NHS TRUST	Country	UNITED KINGDOM
	Address	CITY HOSPITAL DUDLEY ROAD BIRMINGHAM WEST MIDLANDS		
	Post Code	B18 7QH		

IN50

◉ NHS site
○ Non-NHS site

Country: England

Organisation name	SHEFFIELD TEACHING HOSPITALS NHS FOUNDATION TRUST	Forename	Ian
Address	NORTHERN GENERAL HOSPITAL HERRIES ROAD SHEFFIELD SOUTH YORKSHIRE	Middle name	
Post Code	S5 7AU	Family name	Wrench
		Email	Ian.Wrench@sth.nhs.uk
		Qualification (MD...)	FRCA
		Country	UNITED KINGDOM

IN51

◉ NHS site
○ Non-NHS site

Country: England

Organisation name	SOUTH WARWICKSHIRE NHS FOUNDATION TRUST	Forename	Mohan
Address	WARWICK HOSPITAL LAKIN ROAD WARWICK WARWICKSHIRE	Middle name	
Post Code	CV34 5BW	Family name	Ranganathan
		Email	drmohan2k@hotmail.com
		Qualification (MD...)	FRCA
		Country	UNITED KINGDOM

IN52

◉ NHS site
○ Non-NHS site

Forename	Bobby
Middle name	
Family name	Krishnachetty

Country: England

Organisation name	SOUTHEND UNIVERSITY HOSPITAL NHS FOUNDATION TRUST
Address	PRITTLEWELL CHASE WESTCLIFF ON SEA ESSEX
Post Code	SS0 0RY

Email	Bobby.Krishnachetty@southend.nhs.uk
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

IN53

(●) NHS site
( ) Non-NHS site

Country: England

Organisation name	ST GEORGE'S HEALTHCARE NHS TRUST
Address	ST GEORGE'S HOSPITAL BLACKSHAW ROAD TOOTING LONDON GREATER LONDON
Post Code	SW17 0QT

Forename	Guy
Middle name	
Family name	Sanders
Email	guysanders@doctors.org.uk
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

IN54

(●) NHS site
( ) Non-NHS site

Country: England

Organisation name	CITY HOSPITALS SUNDERLAND NHS FOUNDATION TRUST
Address	SUNDERLAND ROYAL HOSPITAL KAYLL ROAD SUNDERLAND TYNE AND WEAR
Post Code	SR4 7TP

Forename	James
Middle name	
Family name	Tulloch
Email	james.tulloch@chsft.nhs.uk
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

IN55

(●) NHS site
( ) Non-NHS site

Country: England

Organisation name	SOUTH TEES HOSPITALS NHS FOUNDATION TRUST
Address	JAMES COOK UNIVERSITY HOSPITAL MARTON ROAD MIDDLESBROUGH CLEVELAND
Post Code	TS4 3BW

Forename	Dave
Middle name	
Family name	Murray
Email	dave.murray@stees.nhs.uk
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

IN56

(●) NHS site
( ) Non-NHS site

Country: England

Organisation name	SOUTH DEVON HEALTHCARE NHS FOUNDATION TRUST
Address	HENGRAVE HOUSE TORBAY HOSPITAL NEWTON ROAD TORQUAY DEVON
Post Code	TQ2 7AA

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

IN57

(●) NHS site
( ) Non-NHS site

Country: England

Organisation name	UNIVERSITY HOSPITALS COVENTRY AND WARWICKSHIRE NHS TRUST
Address	WALSGRAVE GENERAL HOSPITAL CLIFFORD BRIDGE ROAD

Forename	Mathew
Middle name	
Family name	Patteril
Email	Mathew.Patteril@uhcw.nhs.uk
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

	COVENTRY WEST MIDLANDS
Post Code	CV2 2DX

IN59

- (●) NHS site
- ( ) Non-NHS site

Country: England

Organisation name	UNIVERSITY HOSPITALS BRISTOL NHS FOUNDATION TRUST
Address	MARLBOROUGH STREET
	BRISTOL AVON
Post Code	BS1 3NU

Forename	Claire
Middle name	
Family name	Dowse
Email	Claire.Dowse@UHBristol.nhs.uk
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

IN60

- (●) NHS site
- ( ) Non-NHS site

Country: England

Organisation name	UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST
Address	GWENDOLEN HOUSE
	GWENDOLEN ROAD
	LEICESTER LEICESTERSHIRE
Post Code	LE5 4QF

Forename	Prea
Middle name	
Family name	Ramasamy
Email	prea.ramasamy@uhl-tr.nhs.uk
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

IN61

- (●) NHS site
- ( ) Non-NHS site

Country: Scotland

Institution name	NHS Lothian
Department name	Western General Hospital
Street address	Crewe Rd S

Forename	Matthew
Middle name	
Family name	Royds
Email	Matthew.Royds@nhslothian.scot.nhs.uk
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

Town/city	Edinburgh
Post Code	EH4 2XU

IN62

- (●) NHS site
- ( ) Non-NHS site

Country: England

Organisation name	THE WHITTINGTON HOSPITAL NHS TRUST
Address	THE WHITTINGTON HOSPITAL MAGDALA AVENUE LONDON GREATER LONDON
Post Code	N19 5NF

Forename	Jane
Middle name	
Family name	Silk
Email	jane.silk@nhs.net
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

IN63

- (●) NHS site
- ( ) Non-NHS site

Country: England

Organisation name	WIRRAL UNIVERSITY TEACHING HOSPITAL NHS FOUNDATION TRUST
Address	ARROWE PARK HOSPITAL ARROWE PARK ROAD UPTON WIRRAL MERSEYSIDE
Post Code	CH49 5PE

Forename	Kathryn
Middle name	
Family name	Brodbelt
Email	kathrynbrodbelt@nhs.net
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

IN64

- (●) NHS site
- ( ) Non-NHS site

Country: England

Organisation name	YEOVIL DISTRICT HOSPITAL NHS FOUNDATION TRUST
Address	YEOVIL DISTRICT HOSPITAL HIGHER KINGSTON YEOVIL SOMERSET

Forename	Agniezsa
Middle name	
Family name	Kubisz-Pudelko
Email	agnieszka.kubisz-pudelko@ydh.nhs.uk
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

Post Code BA21 4AT

IN65

◉ NHS site
○ Non-NHS site

Country: England

Organisation name	YORK TEACHING HOSPITAL NHS FOUNDATION TRUST
Address	YORK HOSPITAL WIGGINTON ROAD YORK NORTH YORKSHIRE
Post Code	YO31 8HE

Forename	Jonathan
Middle name	
Family name	Wilson
Email	Jonathan.RJT.Wilson@York.NHS.UK
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

IN66

◉ NHS site
○ Non-NHS site

Country: England

Organisation name	ROYAL SURREY COUNTY HOSPITAL NHS FOUNDATION TRUST
Address	EGERTON ROAD GUILDFORD SURREY
Post Code	GU2 7XX

Forename	Matt
Middle name	
Family name	Dickinson
Email	matthew.dickinson@gmail.com
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

IN67

◉ NHS site
○ Non-NHS site

Country: Wales

Institution name	Aneurin Bevan University Healthboard
Department name	Nevill Hall Hospital
Street address	Brecon Road
Town/city	Abergavenny
Post Code	NP7 7EG

Forename	Vincent
Middle name	
Family name	Hamlyn
Email	vincent.hamlyn@doctors.org.uk
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

IN68

(●) NHS site
( ) Non-NHS site

Country: Northern Ireland

Institution name	Belfast Health and Social Care Trust
Department name	Belfast City Hospital
Street address	Lisburn Road
Town/city	Belfast
Post Code	BT9 7AB

Forename	Clare
Middle name	
Family name	Kelly
Email	Clare.Kelly@belfasttrust.hscni.net
Qualification (MD...)	FRCA
Country	UNITED KINGDOM

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 abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.
3. 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.
4. 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.
5. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.
6. 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.
7. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.
8. 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 1998.
9. 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.
10. 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 1998.
11. 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 below. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

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

NRES would like to include a contact point with the published summary of the study for those wishing to seek further information. We would be grateful if you would indicate one of the contact points below.

◯ Chief Investigator

- ◯ Sponsor
- ◯ Study co-ordinator
- ◯ Student
- ◯ Other – please give details
- ◯ None

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

Optional – please tick as appropriate:

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

This section was signed electronically by Dr Suneetha Ramani Moonesinghe on 23/09/2016 15:56.

Job Title/Post:	Consultant Anaesthetist
Organisation:	UCLH
Email:	rmoonesinghe@gmail.com

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 duties of sponsors set out in the Research Governance Framework for Health and Social Care will be undertaken 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 Miss Tabitha Kavoi on 23/09/2016 16:54.

Job Title/Post:	Research Management and Governance Manager
Organisation:	University College London
Email:	randd@uclh.nhs.uk