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)
Epidemiology of Critical Care provision after Surgery (EpiCCS)

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.

4a. Will you be seeking data from Hospital Episode Statistics (HES) or the Secondary Uses Service (SUS)?

◉ Yes ○ No

4b. Will you only be seeking non-identifiable HES/SUS data?

○ Yes ◉ No

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

Please describe briefly the involvement of the student(s):
Dr Danny Wong will analyse data for inclusion in an MD(Res) (medical doctorate in research) degree

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

◉ Yes ○ No

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

○ Yes ◉ No

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

(●) Yes ( ) No

NOTICE OF SUBSTANTIAL AMENDMENT

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

Details of Chief Investigator:

	Title	Forename/Initials	Surname
	Dr	S R	Moonesinghe
Work Address	Anaesthetics Department, Podium 3, Maple Link Corridor		
	University College Hospital, 235 Euston Road		
	London		
PostCode	NW1 2BU		
Email	ramani.moonesinghe@nhs.net		
Telephone			
Fax			

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

Full title of study:	The Second UK Sprint National Anaesthesia Project: Epidemiology of Critical Care provision after Surgery
Lead sponsor:	University College London
Name of REC:	SOUTH CENTRAL BERKSHIRE B
REC reference number:	16/SC/0349

Additional reference number(s):

Ref.Number Description	Reference Number

Name of lead R&D office:	University College London
Date study commenced:	Study commencing in March 2017
Protocol reference (if applicable), current version and date:	Ver. 1.5, 28/09/2016
Amendment number and date:	Ver. 1.6, 02/02/2017

Type of amendment

(a) Amendment to information previously given in IRAS

(●) Yes ( ) No

If yes, please refer to relevant sections of IRAS in the "summary of changes" below.

(b) Amendment to the protocol

(●) Yes ( ) No

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

Please see "Summary of changes" below.

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

(●) Yes ( ) No

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

Please see "Summary of changes" below.

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

( ) Yes (●) No

Summary of changes

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

This amendment makes changes to the IRAS form and study protocol in light of a completed pilot and feasibility study in two hospitals. The key changes are:

1. Removal of a sub-study (the Quality of Recovery sub-study) from the protocol.
2. Minor changes to the dataset/questionnaires to make them more concise and more straightforward to complete.

Details of the changes are more specifically addressed below:

Amendments to IRAS Sections:
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1. Section A5-1: Amended the Protocol Version number from 1.2 to 1.6. Amended the Protocol Date from 23/02/2016 to 02/02/2017.

2. Section A6-2: Removed the following text from the form,
"2. Quality-of-Recovery sub-study

In a sub-group of patients (all patients recruited on a single day during the study week), we will seek implied consent to collect their perceptions of their general health and quality of life on the day of surgery and 3 days after, in order to measure the quality of their recovery. The questionnaire we will use for this has been scientifically developed, validated and published."

3. Section A13: Removed the following text from the form,
"2. Quality of Recovery (QoR) sub-study

In a sub-group of patients who have surgery during a single 24-hour period during the study week, quality of recovery will also be recorded on day 3, both for inpatients and for those already discharged from hospital (through telephone interview). This will be measured using the validated Quality of Recovery (QoR)-15 measure."

4. Section A18: Removed the following item from the form, "Quality of Recovery questionnaire at baseline"

5. Section A27-1: Removed the following text from the form,
"Quality of Recovery sub-study

Patients undergoing surgery on a single day during the study week will be approached by local investigators on the day of surgery, who will provide a participant information sheet linked to the QoR questionnaires."

6. Section A29: Removed the following text from the form,
"Quality of Recovery (QoR) sub-study
Potential participants will be approached by local investigators in each study site on the day of surgery. By random allocation, hospitals will be asked to collect QoR sub-study data on patients undergoing surgery on either Monday, Tuesday, Friday, Saturday or Sundays."

7. Section A30-1: Removed the following text from the form,
"However, we will seek consent from patients participating in the Quality of Recovery sub-study. This will be implied consent through completion of the questionnaire and provision of contact details."

8. Section A40: Removed the following text from the form, "the QoR sub-study and".

9. Section A58: Removed the following text from the form, "Quality of Recovery -15 measured on day 7 postoperatively".

10. Amended the Chief Investigator's email address to: "ramani.moonesinghe@nhs.net" in Sections A2-1 and A3-1.

Amendments to the Study Protocol:
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1. Amended the protocol version number to 1.6, and protocol date to 02/02/2017

2. Removed "Deputy" from the job title of the Chief Investigator to change it to "Director, National Institute for Academic Anaesthesia's Health Services Research Centre".

3. Added the NIHR CPMS number to the protocol list of reference numbers on Page 3.

4. Added the following to the list of Key Study Milestones: "17 – 24 January 2017: pilot study in two hospitals"

5. Removed the Quality of Recovery Substudy from the Key Study Milestones.

6. Corrected the study dates in Key Study Milestones to:
"21 – 27 March 2017: Cohort recruitment week and study commencing
28 March – 3 April 2017: 7-day Post-Operative Morbidity Survey follow-up completion across all sites"

7. Removed references to Quality of Recovery (QoR) substudy from Section 1 (Summary), Section 5 (Study Schedule), Section 6 (Consent) and Section 8 (Recruitment).

8. Added the following line to Section 1 (Summary): "the number and reasons for any cancellations of surgery during the study"

9. Indicated that the QoR substudy has been removed from the study in the list of Appendices, by adding the text: " (This has now been removed from the study)", after the Reference to Appendix 2 and Appendix 6.

10. Corrected minor typographical errors and numbering changes for reference list and contents page following the removal of the QoR substudy.

Amendments to Study Protocol Appendix 1 - CRF main EPICCS:
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1. Added logos for the study sponsors, the Royal College of Anaesthetists and the Association of Anaesthetists of Great Britain and Ireland.

2. Amended the options for Question 2.4 to "Home" and "Inpatient".

3. Added the following follow-on Question to Question 2.4:

"2.4a. What level of support was the patient receiving on arrival to the operating theatre/anaesthetic room?
Level 0 ☐ Level 1 ☐ Level 2 ☐ Level 3 ☐"

4. Added the following option to Question 3.2: "None of the above".

5. Added the following option to Question 3.4: "Other treatment-dose anticoagulation? Y/N"

6. Amended the wording of Question 3.9 to: "Pre-anaesthetic induction systolic BP:"

7. Amended the wording of Question 3.10 to: "Pre-anaesthetic induction pulse rate:"

8. Added the following options for Question 3.19: "AF >90" and "Normal ECG".

9. Amended the wording of Question 3.20 to:

"Chest X-ray or scan done prior to surgery, and:
Normal appearances seen Y/N
Consolidation seen Y/N
Cardiomegaly seen Y/N
Other abnormality seen Y/N"

10. Added the following follow-on Question to Question 3.25:

"3.25a. If surgery previously cancelled/rescheduled, what was the reason?
No beds ☐ Clinical reasons ☐ Not known ☐
Other (please describe) ☐: _____"

11. Added the following option for Question 4.11: "N/A (patient not planned for critical care admission)"

12. Added the web address for the study data entry website: "https://snap2.snapresearch.org.uk/"

13. Added the web address for the study website: "http://www.niaa-hsrc.org.uk/SNAP-2"

Amendments to Study Protocol Appendix 2 - QoR CRF:
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1. Added a digital watermark to the document to indicate that it is no longer in use: "VOID: THIS IS NO LONGER IN USE"

Amendments to Study Protocol Appendix 3 - Occupancy CRF
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1 . Added logos for the study sponsors, the Royal College of Anaesthetists and the Association of Anaesthetists of Great Britain and Ireland.

Amendments to Study Protocol Appendix 4 - Clinician Perceptions CRF
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1. Added logos for the study sponsors, the Royal College of Anaesthetists and the Association of Anaesthetists of Great Britain and Ireland.

2. Added the following follow-on Question to Question 1.1:

"1.1a. If you are a surgeon or anaesthetist, which of the following best describes your primary workload (you may select more than one)?
☐Abdominal (including GI, HPB, endocrine)
☐Bariatric
☐Cardiothoracic
☐Endocrine
☐ENT, maxillo-facial, head and neck
☐Neurosurgery
☐Plastics, reconstructive and/or breast surgery
☐Trauma and orthopaedics
☐Vascular
☐Other (please state): _____"

3. Amended the wording for Question 2.1 to increase clarity:

"2.1. What is the minimum predicted risk of 30-day mortality you would you set as a minimum threshold for admitting patients to critical care immediately after surgery? (i.e. if the predicted risk was above this level you would seek a

planned critical care admission)"

4. Removed Question 2.8, and renumbered the subsequent questions to reflect the deletion.

5. Increased the box size for Question 2.9 to allow respondents to fill in the numbered options more easily.

Amendments to Study Protocol Appendix 5 - Patient Information Sheet
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1. Added logos for the study sponsors, the Royal College of Anaesthetists and the Association of Anaesthetists of Great Britain and Ireland.

Amendments to Study Protocol Appendix 6 - QoR Telephone Interview Script:
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1. Added a digital watermark to the document to indicate that it is no longer in use: "VOID: THIS IS NO LONGER IN USE"

Amendments to Study Protocol Appendix 5 - Patient Information Poster
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1. Added logos for the study sponsors, the Royal College of Anaesthetists and the Association of Anaesthetists of Great Britain and Ireland.

Any other relevant information

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

Following our study pilot we are electing to remove the Quality of Recovery substudy entirely from our study as it was apparent from the pilot study site investigators that delivering this substudy was very labour-intensive and likely to impact on the feasibility of delivering and data-quality of the rest of the study.

List of enclosed documents

Document	*Version*	*Date*
EPICCS Protocol v1.6 20170202.docx	1.6	02/02/2017
Appendix 1 - CRF main EPICCS v1.2 20170201.docx	1.2	01/02/2017
Appendix 2 - QoR CRF v1.0 20170201.docx	1.0	01/02/2017
Appendix 3 - OccupancyCRF v0.9 20170201.docx	0.9	01/02/2017
Appendix 4 - ClinicianPerceptionCRF v1.0 20170201.docx	1.0	01/02/2017
Appendix 5 - StudyPIS v0.7 20170201.docx	0.7	01/02/2017
Appendix 6 - QoR Telephone Interview Script v0.3 20170201.docx	0.3	01/02/2017
Appendix 7 - PatientPoster v1.1 20170201.docx	1.1	01/02/2017

Declaration by Chief Investigator

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

This section was signed electronically by Dr Suneetha Ramani Moonesinghe on 02/02/2017 16:26.

Job Title/Post:	Consultant
Organisation:	UCLH
Email:	ramani.moonesinghe@nhs.net

Declaration by the sponsor's representative

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

This section was signed electronically by Mr David Wilson on 03/02/2017 14:12.

Job Title/Post:	UCL Sponsor representative
Organisation:	UCL
Email:	Randd@uclh.nhs.uk