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)*

☑ England
☑ Scotland

- [x] Wales
- [x] 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.

- [x] 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

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 Suneetha Ramani Moonesinghe
Work Address	Anaesthetics Department
	Podium 3, Maple Link corridor, University College Hospital
	235 Euston Road
PostCode	NW12BU
Email	ramani.moonesinghe@uclh.nhs.uk
Telephone	
Fax	

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

Full title of study:	Improving perioperative care through the use of quality data: Patient Study of the Perioperative Quality Improvement Programme
Lead sponsor:	University College London
Name of REC:	South East Coast
REC reference number:	16/LO/1827

Additional reference number(s):

Ref.Number Description	Reference Number

Name of lead R&D office:	University College London Hospitals NHS Foundation Trust
Date study commenced:	
Protocol reference (if applicable), current version and date:	
Amendment number and date:	3.0 28.03.17

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.

(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.

PQIP Patient participation invitation letter v3 24.04.2017
PQIP poster v1.1 24.03.2017

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

○ Yes ◉ No

Summary of changes

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

We have produced a patient participation letter (PQIP Patient participation invitation letter v3 24.04.2017), inviting patients to consider taking part in the study and referring to the Participant Information Sheet (PIS). This new invitation letter may be used at the discretion of the local participating sites, if they wish to send patients a PIS before they attend in person at the hospital. This will enable some sites to provide a longer duration of time for patients to consider the PIS before deciding whether or not to participate. All sites will continue to comply with the existing minimum requirement of 1 hour to consider the information before being approached for consent.

We have also produced a PQIP poster (PQIP poster v1.1 24.03.2017), explaining the study and its aims. This will be placed in areas where patient recruitment is taking place, for example surgical clinics and anaesthesia preassessment clinics

Any other relevant information

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

List of enclosed documents

Document	*Version*	*Date*
PQIP poster	v1.1 24.03.2017	28/03/2017
PQIP Patient participation information letter	v3 24.04.2017	24/04/2017

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 24/04/2017 07:15.

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 Miss Tabitha Kavoi on 28/04/2017 16:26.

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