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

- [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?

- [x] IRAS Form
- [x] Confidentiality Advisory Group (CAG)
- [ ] Her Majesty's Prison and Probation Service (HMPPS)

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 Collaboration for Leadership in Health Research and Care (CLAHRC), NIHR Patient Safety Translational Research Centre or Medtech and In Vitro Diagnostic Cooperative 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
	Professor	Suneetha Ramani	Moonesinghe
Work Address	Centre for Perioperative Medicine, Department of Targeted Intervention, Division of Surgery and Interventional Science, University College London, Charles Bell House, 43-47 Foley Street, London		
PostCode	W1W 7TS		
Email	ramani.moonesinghe@nhs.net		
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:	16.09.2016
Protocol reference (if applicable), current version and date:	PQIP Patient Study Protocol v1.6 20102017
Amendment number and date:	5.0 03.01.19

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.

1. Minor changes to CI's titles and contact details (p1, 4)
2. Minor clarification to text regarding sampling strategy (p 8)

Minor change to communications plan regarding patient sampling (p 8)

(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 Study Participant Information Sheet v1.2 03.01.2019.docx
PQIP Patient Study Consent Form v1.3 03.01.2019.docx

PQIP Patient Study Questionnaires Booklet v0.9 03.01.2019.pptx
PQIP Patient Study Questionnaires Booklet v1.0 modified on 03.01.2019.pptx
6 month email invitation v1.0 03.01.2019.docx - new
6 month email reminder v1.0 03.01.2019.docx - new
1 year email invitation v1.0 03.01.2019.docx - new
1 year email reminder v1.0 03.01.2019.docx - new
PQIP Patient Study Protocol v1.8 21012019.docx

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.

The PQIP Patient Study has been running for 18 months. We wish to add two questions asked of patients. These are listed in PQIP Patient Study Questionnaires Booklet v0.9 03.01.2019.pptx on page 3, about smoking history/smoking cessation therapy and levels of activity before surgery.

Participant questionnaires are completed at 6 and 12 months after surgery. Response rates from participants have been relatively low. This has led to the introduction of email invitations to the questionnaires along with reminders. This will hopefully increase response rates.

The consent form has been modified to ascertain the participants preferred method of communication in the first instance. The Patient information sheet has been modified to inform participants that sites may email and/or call them to complete the questionnaires at 6 and 12 months following their operation. This will allow sites to contact patient that are struggling with the online completion of the questionnaires.

This will not add any additional costs to the sponsor / NHS.

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 Patient Study Participant Information Sheet v1.2 03.01.2019.docx	1.2	03/01/2019
PQIP Patient Study Consent Form v1.3 03.01.2019.docx	1.3	03/01/2019
PQIP Patient Study Questionnaires Booklet v0.9 modified on 03.01.2019.pptx	0.9	03/01/2019
6 month email invitation v1.0 03.01.2019.docx - new	1.0	03/01/2019
6 month email reminder v1.0 03.01.2019.docx - new	1.0	03/01/2019
1 year email invitation v1.0 03.01.2019.docx - new	1.0	03/01/2019
1 year email reminder v1.0 03.01.2019.docx - new	1.0	03/01/2019
PQIP Patient Study Protocol	1.8	21/01/2019

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 13/02/2019 13:31.

Job Title/Post:	Consultant
Organisation:	UCL
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 Mrs Suzanne Emerton on 13/02/2019 14:59.

Job Title/Post:	Sponsorship Officer
Organisation:	UCL
Email:	semerton@nhs.net