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)
PRISM

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. Will the study involve the use of any medical device without a CE Mark, or a CE marked device which has been modified or will be used outside its intended purposes?

( ) Yes (●) No

2b. 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
- [ ] 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 review bodies are you applying to?

- [ ] HRA Approval
- [x] NHS/HSC Research and Development offices
- [ ] Social Care Research Ethics Committee
- [x] Research Ethics Committee
- [ ] Confidentiality Advisory Group (CAG)
- [ ] National Offender Management Service (NOMS) (Prisons & Probation)

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

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

(•) Yes ( ) No

5a. Are all the research costs and infrastructure costs for this study provided by an NIHR Biomedical Research Centre, NIHR Biomedical Research Unit, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC) or NIHR Research Centre for Patient Safety & Service Quality in all study sites?

( ) Yes (•) No

If yes and you have selected HRA Approval in question 4 above, your study will be processed through HRA Approval.

If yes, and you have not selected HRA Approval in question 4 above, NHS permission for your study will be processed through the NIHR Coordinated System for gaining NHS Permission (NIHR CSP).

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 (CRN) Portfolio? Please see information button for further details.

(•) Yes ( ) No

If yes, you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form immediately after completing this project filter and before submitting other applications. If you have selected HRA Approval in question 4 above your study will be processed through HRA Approval. If not, NHS permission for your study will be processed through the NIHR Coordinated System for gaining NHS Permission (NIHR CSP).

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	Rupert	Pearse
Work Address	Adult Critical Care Unit, Royal London Hospital London		
PostCode	E1 1BB		
Email	r.pearse@qmul.ac.uk		
Telephone	+442035940346		
Fax	+442035943140		

Full title of study:	Prevention of Respiratory Insufficiency after Surgical Management (PRISM) Trial: A pragmatic randomised controlled trial of continuous positive airway pressure (CPAP) to prevent respiratory complications and improve survival following major abdominal surgery
Lead sponsor:	Queen Mary University of London
Name of REC:	NRES Committee London - Central
REC reference number:	15/LO/1595
Name of lead R&D office:	Queen Mary University
Date study commenced:	3 December 2015
Protocol reference (if applicable), current version and date:	version 1.4 18 August 2015
Amendment number and date:	Amendment 1 dated 01 March 2016

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.

Project filter question 3 - In which countries of the UK will the research sites be located? ADD Northern Ireland.

(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.

Included is a new version of the protocol (version 1.5 01 March 2016) with changes in bold and a document listing each change with 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.

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 made a series of small changes to make the protocol consistent with the other trial documents and standard operating procedures. In addition, we have modified some sections to make them clearer, based on feedback from participating centres and external peer reviewers.

The main changes are:

1. Clarifying that the intended postoperative care destination should be declared before randomisation.

2. For patients in the intervention group, Continuous Positive Airways Pressure (CPAP) should be started within four hours after the end of surgery.

3. We have added guidance about when a clinician might increase the positive airway pressure above 5cm of water.

4. We have added a small number additional data points to be collected on the case report form.

5. Provided further detail regarding defining and reporting protocol deviations.

6. Added further detail about the self-assessment of investigator blinding, to make this section clearer.

7. Added detail to the research ethics section, to account for different procedures and regulations outside the UK.

8. Provided further detail regarding training of investigators, to take account of different procedures and regulations in countries outside the UK.

9. Provided further detail to the data monitoring and ethics committee (DMEC) section for consistency with the DMEC charter.

10. Updated funding details.

11. We have made a minor typographical change to the inclusion criteria listed in section 6.2, to include the word 'elective'. This was already included in the inclusion criteria listed in the summary in the previous protocol and in the other trial documents. The addition has been included for clarity and consistency, but it doesn't effect the conduct of the trial.

12. We have re-worded the section on safety reporting to make to make it clearer to investigators how to report an

adverse event. However, the trial procedures regarding adverse event reporting have not been changed. We have added an addition pre-defined adverse event 'aspiration of gastric contents'. This was previously covered under 'vomiting', but we wanted to be able to measure and report this particular adverse event separately.

13. We have added additional material to the definitions appendix based on feedback from investigators.

In addition, we have made a small number of minor typographical changes.

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*
PRISM trial protocol	1.5	01/03/2016
PRISM trial - summary of protocol changes	1.5	01/03/2016

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 Rupert Pearse on 07/03/2016 14:08.

Job Title/Post:

Organisation:

Email:

Declaration by the sponsor's representative

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

This section was signed electronically by Dr Sally Burtles on 07/03/2016 15:52.

Job Title/Post: Director of Research Services & Business Development

Organisation: Queen Mary University London

Email: sponsorsrep@bartshealth.nhs.uk