PIRRIST Project

Developing a Patient and Public Involvement (PPI) intervention to enhance Recruitment and Retention In Surgical Trials

We invite you to take part in a survey

- Before you decide whether to take part, please read the following information carefully.
- It is entirely your choice whether or not to take part. If you have any questions please contact us.
- If you agree to take part, you may withdraw yourself and your information from the study without penalty at any time, and without giving a reason.
- Any information you provide will be treated as confidential and will not be disclosed in an identifiable form outside the research team.

Summary

- The aim of this project is to develop a robust, evidence-based PPI intervention aimed at improving recruitment and/or retention in surgical trials.
- You are being invited to take part in the first stage of a four-stage project. This is a **survey** about what sort of PPI (if any) you have been doing in your surgical trial.
- It doesn't matter whether you have done any PPI or not – all responses will be extremely helpful.
- The survey should only take about **10 minutes** to complete.
- To thank you for your time, we will offer you a **£10** gift voucher (choice of two types) and a copy of the study results.
- If you have read this information sheet and would like to take part, please go to the following webpage to start the survey: https://oxford.onlinesurveys.ac.uk/ppi-in-surgical-trials-version-1-final-21-august-2015

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How to contact us

If you have any questions about this project, please contact Joanna Crocker (Postdoctoral Research Fellow) at

Nuffield Department of Primary Care Health Sciences, University of Oxford, Gibson Building 1st Floor, Radcliffe Observatory Quarter, Woodstock Road, Oxford, OX2 6GG.

Email: **pirrist@phc.ox.ac.uk**

Tel: **01865 617837**

Or Mr Richard Bulbulia (Consultant Vascular Surgeon) at

Email: **richard.bulbulia@ctsu.ox.ac.uk**

Tel: **01865 743891**

1 Background and aims of the project

Slow **recruitment** and poor **retention** are common challenges to the successful delivery of clinical trials. **Patient and public involvement (PPI)** is research being carried out 'with' or 'by' patients and/or members of the public rather than 'to', 'about' or 'for' them. PPI could potentially enhance recruitment and retention in clinical trials; however, the evidence for this is weak at best, with few attempts to evaluate it experimentally.

The aim of this project is to develop a robust, evidence-based **PPI intervention** aimed at improving recruitment and/or retention in surgical trials, and ultimately to test its effectiveness. The intervention development phase consists of four stages outlined on page 4. You are being invited to take part in stage 1.

The project is a collaboration between researchers, trial administrators, patient and lay partners and PPI coordinators associated with the Universities of Oxford, Aberdeen and Liverpool. It is supported by the NIHR Oxford Biomedical Research Centre and the MRC Network of Hubs for Trials Methodology Research.

2 Why have I been invited to take part?

You have been invited to take part in stage 1 of this project because you are an investigator, a manager or coordinator of a surgical trial which is in set up, recruiting or in follow-up, according to the CRN portfolio database. (Alternatively, you may have been recommended by one of these people because of your knowledge of PPI within this trial.)

You are therefore an important stakeholder in this project and we would be very grateful for your help developing an intervention which is as effective and practical as possible.

3 Do I have to take part?

It is entirely your choice whether or not to take part, and we encourage you to contact us with any questions you may have (see section 11).

If you agree to take part, you may withdraw yourself and your data from the study without penalty at any time, and without giving a reason, by letting us know.

We will not tell anyone outside our research team of your decision to take part or not.

Each stage of the project is separate, so taking part in this stage does not mean you have to take part in any of the subsequent stages.

4 What will happen in this survey?

In order to develop a useful PPI intervention that enhances current PPI practice, we first need to determine what 'current PPI practice' looks like in UK surgical trials.

We are therefore inviting you to take part in a **short survey** to find out what sort of PPI (if any) you have been doing in your surgical trial. It doesn't matter whether you have done any PPI or not – your responses will be extremely helpful.

The survey should only take about **10 minutes** to complete online. You can request a paper version of the survey if you prefer.

5 What are the benefits of taking part?

We hope that you will enjoy contributing to developing an effective and practical PPI intervention, which may benefit surgical trials in the future. (If you would like to play a bigger role in this project, please contact us to discuss opportunities.)

To thank you for your time, we will offer you a **£10** high street shopping voucher or Blackwell's book voucher, as you prefer.

We will also send you a copy of the study results, which we hope you will find interesting.

6 Are there any potential risks?

We do not think there are any risks to you in taking part. Any information you provide will be treated as confidential and will not be disclosed in an identifiable form outside the research team. You may withdraw from the project at any time without giving a reason.

7 What will happen to the data I provide?

How will the data be stored?

All data we collect through this survey will be stored securely at the University of Oxford and in accordance with the UK Data Protection Act.

The research data collected will be labelled with your participant ID number only and will be stored separately from your personal identifying information (name and contact details) and trial identifying information. Only the research team will be able to access both of these datasets.

All of the identifying information will be securely destroyed within 10 years of publication of the results. You and your trial will not be identifiable in any publications or presentations.

Will the data be shared with anyone else?

The University of Oxford is committed to sharing its research for the benefit of society and the economy. We would like to archive anonymised research data from this survey at the University of Oxford, so that other professional researchers in the UK can access it free of charge on request.

All identifying data will be removed so that no one will be able to trace it back to you or your trial. If you would like to opt out of this now, or view your data before it is archived, please let us know.

8 What will happen to the results of this project?

We plan to publish the results of this study in an international, peer-reviewed, open-access academic journal article, a conference paper and an online lay summary. These will be promoted as widely as possible.

We also intend to apply for further funding to implement the resulting PPI intervention in a number of different surgical trials, and evaluate its effectiveness.

9 Who has reviewed this project?

This project has been reviewed by, and received ethics clearance through, the University of Oxford Central University Research Ethics Committee [ref number].

10 Who do I contact if I have a concern about the project?

If you have a concern about any aspect of this project, please speak to one of the lead researchers (Joanna Crocker or Richard Bulbulia - see contact details on page 1). They should acknowledge your concern within 10 working days and indicate how they intend to deal with it.

If you remain unhappy or wish to make a formal complaint, please contact the chair of the Medical Sciences Inter-Divisional Research Ethics Committee - Email: ethics@medsci.ox.ac.uk; Address: Research Services, University of Oxford, Wellington Square, Oxford OX1 2JD.

11 What next?

If you have read this information sheet and are happy to take part in the survey, please go to the following webpage to begin: https://oxford.onlinesurveys.ac.uk/ppi-in-surgical-trials-version-1-final-21-august-2015

By completing the survey, you are giving your consent for the information to be used as described in this information sheet. Please contact us (page 1) if you would prefer to complete a paper version of this survey.

If you would prefer **not** to take part and/or do **not** wish to receive further information about this project, please let us know so that we do not send you reminders or invitations to take part in later stages (see contact details on page 1).

If you are not sure and have questions, please contact us (page 1) and we will do our best to help.

Thank you taking the time to read this information.

PIRRIST Project Overview

Stage 1
(Sep – Oct 2015)

Aim:
Identify current PPI practices in UK surgical trials

Methods:
(1) Online survey of trial investigators and managers
(2) Analysis of existing National Research Ethics Service data

Stage 2
(Nov 2015 – May 2016)

Aims:
(1) Identify challenges & needs associated with PPI in surgical trials
(2) Identify possible components of a PPI intervention
(3) Identify perceived barriers to effective recruitment & retention *not* already identified from literature
(4) Explore stakeholders' views of PPI impact on recruitment & retention in surgical trials, including possible mechanisms of impact.

Method:
Focus groups with surgical trial investigators, administrators* , PPI contributors and PPI coordinators across the UK

Stage 3
(Jun - Sep 2016)

Aims:
(1) Determine how the possible components of an intervention identified in stage 2 are rated by stakeholders in terms of importance, feasibility and acceptability
(2) Determine how the barriers to recruitment & retention identified from the literature and stage 2 are rated by stakeholders in terms of size/importance.

Method:
Online survey of surgical trial investigators, administrators, PPI contributors and PPI coordinators across the UK

Stage 4
(Oct - Dec 2016)

Aim:
Determine the most suitable PPI intervention from several prototypes developed using the findings of stage 1-3.

Method:
Consensus workshop with 20-40 stakeholders (including surgical trial investigators, administrators, PPI contributors, PPI coordinators and others)

* Includes trial managers, trial co-ordinators, research nurses and research managers.