UNIVERSITY OF OXFORD

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 focus group

- 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 second stage of a four-stage project. This is a kind of group interview (called a '**focus group**') about your views and experiences of PPI.
- The focus group will be held in Oxford, Aberdeen, Bristol or Birmingham (whichever is most convenient for you). It will take about **90 minutes**, including a short break for refreshments.
- To thank you for your time, we will offer you a **£20** gift voucher (choice of two types). We will also cover reasonable travel expenses related to your participation, and will offer you a copy of the study results.
- If you have read this information sheet and would like to take part, please contact us (right) to register your interest.

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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, 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

Clinical trials, including surgical trials, often struggle to **recruit** patient participants and **keep** them in the trial (retention). These difficulties can mean a trial takes longer, costs more money, or even fails completely.

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 in designing and doing trials has the potential to enhance recruitment and retention, but the evidence for this is weak at best. We also don't know what kind of PPI is likely to lead to the biggest improvements in recruitment and retention.

We are going to investigate these issues by developing and testing a **PPI 'intervention'** aimed at improving recruitment and/or retention in surgical trials. The development phase consists of four stages outlined on page 4. You are being invited to take part in stage 2.

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 2 of this project because you are a PPI contributor in health research with relevant experience of surgical trials, clinical trials and/or surgery. 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. We are also asking surgical trial investigators, administrators and PPI co-ordinators to take part in separate focus groups.

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

In order to develop an effective and practical PPI intervention, we need to better understand what it is like to be involved in clinical trials (especially surgical trials), and what might help overcome any challenges.

We are therefore inviting you to take part in a group interview (called a '**focus group**') to explore these issues and what a useful PPI intervention might look like.

The focus group will take place in Oxford, Aberdeen, Bristol or Birmingham (whichever is most convenient for you), at a time that best suits most potential participants. We plan that 4-8 people will take part in the focus group, and it will last about **90 minutes**, including a short break for refreshments.

We will cover the cost of any reasonable travel expenses related to your participation, as well as offering a 'thank you' voucher (see section 5).

So that we know a bit about who has taken part in the focus groups, we will also ask you to provide your age, gender and ethnicity, although you can choose to withhold this information if you prefer.

Please note that if a focus group is not possible at your preferred location due to insufficient interest, you may be offered an individual face-to-face or telephone interview instead. If the focus group happens but you are unable to attend on the proposed date, you will be offered the opportunity to respond to the focus group questions in writing.

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 **£20** 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 within the focus group and will not be disclosed in an identifiable form outside the research team and transcriptionist (see section 7).

You may leave the focus group at any time without giving a reason. You will receive a list of the proposed focus group participants in advance, and can opt out at this stage if you wish. This means that other proposed participants will also see that you are considering taking part.

7 What will happen to the data I provide?

The focus group will be audio-recorded and then transcribed word-for-word into a Microsoft Word document.

How will the data be stored?

Both the audio file and transcription file will be stored securely at the University of Oxford and in accordance with the UK Data Protection Act. In the transcript document, your speech will be labelled with your participant ID number only. This will be stored separately from your personal identifying information (name and contact details) and any 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 any trial you might be involved in 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 focus group transcripts 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 the trial you are involved in. If you would like to opt out of this now, or view your transcript 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 include some anonymous quotes from focus groups. 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 (reference number MS-IDREC-C1-2015-163).

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 would like to take part in a focus group, please **contact us** (page 1) to let us know. We will then **ask you a few questions** about your experience of PPI, clinical trials and surgery to check you are eligible to take part, and to find out your preferred location and time for the focus group. Shortly afterwards, we will send you a proposed time, venue and list of potential participants for the focus group. If you then agree to take part, you will need to complete a consent form when you attend the focus group. A copy of the consent form can be viewed on the following webpage: http://www.situ.ox.ac.uk/documents/consent-form-stage-2-v3.1-final-2016-04-20-ppi-contributors-focus-group.pdf

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 for taking time to read this information.

PIRRIST Project Overview

Stage 1
(Sep – Dec 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
(Jan – Jun 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
(Mar – May 2017)

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
(Jun - Jul 2017)

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.