

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.
- You choose whether or not to take part. If you have any questions please contact us.
- If you choose to take part, you may withdraw yourself and your information from the study without penalty at any time, and without giving a reason.
- We will treat your information as confidential and will not disclose it in an identifiable form outside the research team.

Summary

- The aim of this project is to develop a robust, evidence-based PPI 'intervention' to improve the success of surgical trials.
- We're inviting you to take part in the third stage of a four-stage project. This is a **survey** which asks about your views on some challenges to involving patients and the public in surgical trials.
- We're inviting you to take part because you've been a PPI contributor to at least one surgical trial in adult patients.
- The survey should take **15-20 minutes** to complete. You can do it **online** or on **paper**.
- We'll offer you a **£10 high street shopping voucher** to thank you for your time, and a copy of the study results.
- If you have read this information sheet and would like to take part, please **either** go to the following webpage to complete the survey online **or** contact us to receive a paper version.

<https://oxford.onlinesurveys.ac.uk/ppi-in-surgical-trials-survey-for-ppi-contributors-vers-2>



Contents

- 1 Background and aims of the project
- 2 Why have I been invited to take part?
- 3 Do I have to take part?
- 4 What will happen in this study?
- 5 What are the benefits of taking part?
- 6 Are there any potential risks?
- 7 What will happen to the data I provide?
- 8 What will happen to the results of this project?
- 9 Who has reviewed this project?
- 10 Who do I contact if I have a concern about the project?
- 11 What next?

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. Sometimes this means large amounts of public money unnecessarily wasted, and fewer or no benefits for patients.

Patient and public involvement (PPI) is when researchers consult or work alongside members of the public, patients, service users and/or carers in all or any part(s) of the research process. 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'**. (An intervention is something that aims to make a change and is tested through research.) This PPI intervention will aim to improve recruitment and/or retention in surgical trials. The development phase consists of four stages outlined on page 4. We're inviting you to take part in stage 3.

The project is a **collaboration** between patient and lay partners, researchers, trial administrators 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?

We're inviting you to take part in stage 3 of this project because **you have been involved in at least one adult surgical trial as a PPI contributor**.

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 staff and PPI coordinators to take part in a similar survey.

3 Do I have to take part?

It is entirely your choice whether or not to take part, and you can 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 future stages.

4 What will happen in this survey?

In order to develop an effective PPI intervention, we need to know which are the biggest challenges to recruiting and keeping participants in surgical trials, and the biggest challenges to doing successful PPI.

We are therefore inviting you to take part in a short online survey about **your experiences of PPI challenges** in adult surgical trials.

The survey should take **15-20 minutes** to complete. You can choose whether to do it online or on paper.

5 What are the benefits of taking part?

We hope you will enjoy contributing to developing an effective and practical PPI intervention, which aims to benefit surgical trials and patients 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**. We will also offer to 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 (contact details). 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 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. If you would like to opt out of this now, or view your data before it is archived, please contact us (page 1).

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 test the resulting PPI intervention in a number of different surgical trials, to see how well it works and what it's like for the PPI contributors and trial staff.

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 are happy to take part in the survey, please *either* go to the following webpage to complete the survey **online** or contact us (page 1) if you would prefer to complete a **paper version**.

<https://oxford.onlinesurveys.ac.uk/ppi-in-surgical-trials-survey-for-ppi-contributors-vers-2>

By completing the survey, you are giving your consent for the information to be used as described in this information sheet.

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 future stages of the project (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 – Dec 2015)

Aim:

Identify current PPI practices in UK surgical trials

Methods:

- (1) Online survey of active UK surgical trials
- (2) Analysis of existing National Research Ethics Service data



Stage 2
(Jan – Jul 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 staff, PPI contributors and PPI coordinators across the UK



Stage 3
(Jul – Nov 2017)

Aims:

Determine how the barriers to recruitment, retention and PPI identified from the literature and stage 2 are rated by stakeholders in terms of size/severity.

Method:

Two surveys:

- (a) Barriers to recruitment and retention (aimed at surgical trial staff and methodologists across the UK)
- (b) Barriers to successful PPI (aimed at surgical trial staff, PPI contributors and PPI coordinators across the UK)



Stage 4
(Jan – Feb 2018)

Aim:

Develop a suitable PPI intervention based on the findings of stages 1-3 and research literature.

Method:

Collaborative workshop with 20-40 key stakeholders (including surgical staff, PPI contributors, PPI coordinators, methodologists and others)