NIHR | Oxford Biomedical Research Centre

MRC | Hubs for Trials Methodology Research

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Planning patient and public involvement (PPI) in surgical trials

This guidance is designed to help UK-based Chief Investigators (CIs) of surgical trials to **plan effective PPI** to enhance the recruitment and retention of trial participants.

It should be used as **early as possible** in the trial design process, ideally when the CI first has the idea or is formulating the research question. It could also be by other members of the trial team.

It focuses on the **design phase** of a trial lifecycle because it aims to optimise the recruitment and retention of trial participants. It does not replace more general PPI guidance which highlights the wider importance PPI at all stages of research, nor existing participant recruitment guidance.

The guidance centres around **3 key recommendations** for PPI in surgical trials (see diagram below). These recommendations are based on evidence generated through a four-stage research project (PIRRIST) and a systematic review of the impact of PPI on participant recruitment and retention. We have also gathered tips and resources from experienced PPI contributors, PPI coordinators and surgical trial staff.

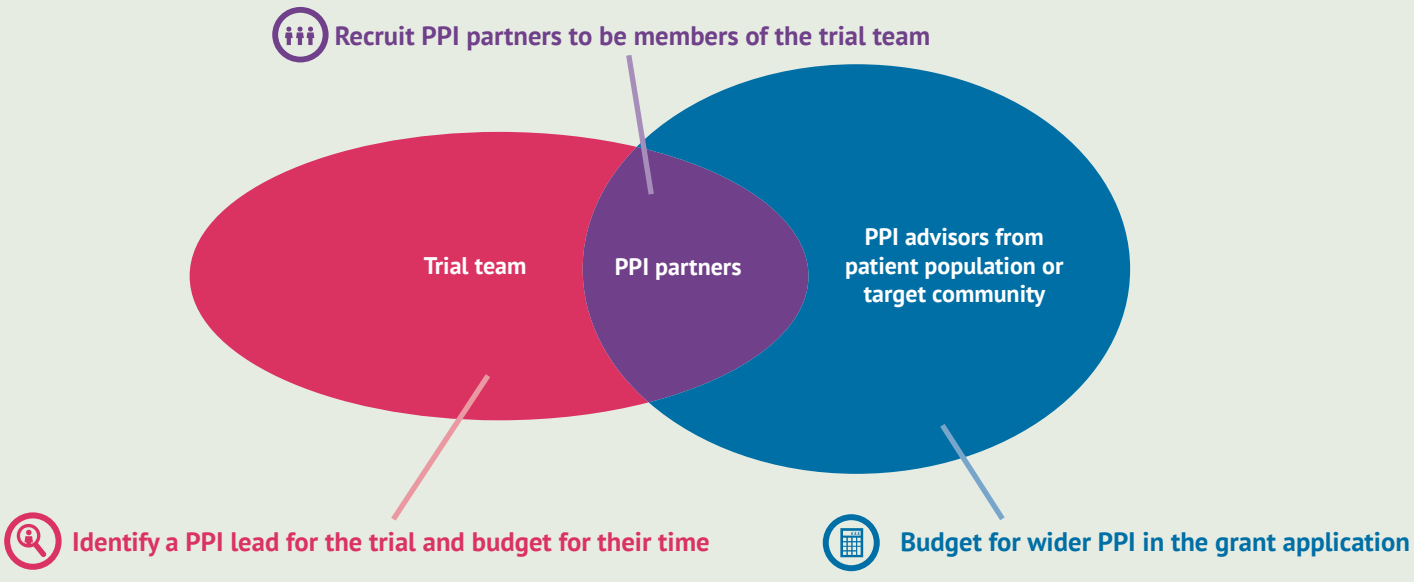
The guidance was developed with and for **UK-based surgical trials** (including trials of a surgical intervention and trials in a surgical context, where surgery is involved but is not one of the interventions under evaluation). It may be especially helpful for trials of surgical vs. non-surgical treatments, due to the likelihood that strong patient preferences may hinder recruitment. However, the guidance is also applicable to other types of UK-based clinical trials. PPI in international trials faces additional challenges beyond the scope of this guidance.

We recognise that each trial is unique and not all of our recommendations will be appropriate for every trial. This guidance is intended to be used flexibly with a 'pick and mix' approach.

The main guidance document is only 4 pages long, but with several appendices and underlined hyperlinks to additional resources.

RECOMMENDATIONS FOR PPI IN UK SURGICAL TRIALS (IN A NUTSHELL)

TRIAL DESIGN & FUNDING PROPOSAL → TRIAL PROTOCOL & PATIENT-FACING MATERIALS



RECRUIT PPI PARTNERS TO BE MEMBERS OF THE TRIAL TEAM

- Aim to recruit at least **3 PPI partners** as integral members of the trial team.* They should also be co-applicants if appropriate.
- 1 or more PPI partners should have **personal experience (as a patient or carer)** of the health condition under study.
- Involve them all in decision making about the proposed trial design and in reviewing the funding proposal.

*INVOLVE recommend involving more than 1 person; we suggest at least 3 to account for absences due to ill health and external circumstances.

TIPS FOR RECRUITING PPI PARTNERS

If you are working to a very **short timeframe** for proposal submission, choose people with previous experience of research (ideally clinical trials) and/or training in research and the ability to collaborate effectively with researchers. These could include people you have already worked with. After the funding decision, or if you have time before submission, include a less experienced PPI partner for a fresh perspective.

Use a **written role description** to define what you need your PPI partners to do, how they will be supported, and the skills, experience and personal attributes required. This will help to ensure potential PPI partners and trial staff understand their roles and responsibilities. See INVOLVE's template role description and Bagley *et al.*'s template role descriptions for PPI members on Trial Management Groups and Trial Steering Committees.

Avoid recruiting current patients of a clinician on the trial team, as this relationship may hinder their ability to contribute usefully.

Consider whether to involve **lay members of the public** as well as patients or carers. See this paper regarding the various beneficial roles public members can have.

See INVOLVE's comprehensive guidance on involving public co-applicants in research.

More PPI recruitment tips and resources.

TIPS FOR PPI FUNDING

Pre-grant funding for PPI can be challenging. Check whether your research institution could contribute any funding, and try your regional NIHR Research Design Service (England only), which may offer up to £500 for this.

If possible, offer payment for PPI partners' time. At the very least, reimburse PPI partners' expenses, provide refreshments at meetings, and explain that their time on the project will be fully costed into the grant application.

DID YOU KNOW?

The earlier you involve PPI partners, the greater the potential benefit for recruitment and retention of trial participants.

When PPI included people with personal experience of the health condition under study, it was associated with increased participant recruitment to clinical trials in our published meta-analysis.

More tips for involving PPI partners

BUDGET FOR WIDER PPI IN THE GRANT APPLICATION

- Effective PPI should include more than your 3 PPI partners. Plan for wider PPI such as **focus groups,** a **patient advisory panel** and/or an existing **patient organisation**. This can be set up once you have funding for your trial.
- As far as possible, these additional **PPI advisors** should be patients and/or carers with personal experience of the health condition under study – ideally from the trial target population you hope to recruit. Try to include some people who have experienced the actual treatment under study too as they may have valuable insights.
- Plan to seek their advice on **trial design** details, participant **recruitment and retention strategies,** and the content and format of all **patient-facing materials.***
- Plan to ask PPI advisors specific questions in addition to seeking general feedback on draft plans and materials. See our list of suggested questions.
- Involve your **PPI partners** in planning this wider PPI. They may already have links with wider groups of patients and could also participate in, or help to facilitate, the PPI activities.

* information sheets, consent forms, recruitment adverts, recruitment scripts / verbal invitations, lay summaries and data collection tools.

TIPS FOR RECRUITING PPI ADVISORS (POST FUNDING)

Aim for a group of patients/carers which reflects the **diversity** of your target population.* Characteristics to consider include **demographics** (e.g. gender, age, ethnicity, education, socioeconomic status), **health experiences** (e.g. different treatments for the target health condition) and **geography** (e.g. all or several of your recruitment sites/regions).

Use **open adverts** in strategic healthcare or community locations and/or on social media, and search for relevant local or national **patient organisations.** Useful **online recruitment resources** include People In Research (UK wide) and SHARE (Scotland); see also Bagley et al.'s list of recommended resources. You could also recruit some patients via a clinician on the trial team, if the clinician and patients will not be attending the same project meetings.

*You are aiming for diversity, not representativeness (which would require consideration of the proportions of advisors within subgroups).

TIPS FOR PPI FUNDING

Include all PPI costs, from trial set-up through to dissemination of findings, in the grant. This should include payment for PPI partners' and advisors' time and expenses. Use the INVOLVE cost calculator to help you.

Check with your PPI partners that all possible PPI costs have been considered and included in the budget.

Remember to budget for PPI members of your Trial Steering Committee too (as for PPI partners, we recommend at least 3 and use of a written role description).

DID YOU KNOW?

The two-tier model of PPI described here (with PPI partners linked to a wider patient population) was found to be particularly effective in our study of UK surgical trials and a realist evaluation of PPI in health research.

More tips for planning wider PPI

IDENTIFY A PPI LEAD FOR THE TRIAL AND BUDGET FOR THEIR TIME

- This could be your local professional PPI coordinator (if you have one), a PPI partner, or another member of the trial team or unit.
- You may have access to a **professional PPI coordinator** via your research institution, NHS or NIHR organisation.
- The PPI lead will be responsible for **day-to-day management** of PPI in the trial, and will be the **primary contact** for PPI partners and advisors throughout the trial.

PPI LEAD'S KEY RESPONSIBILITIES COULD INCLUDE:

- Facilitate the involvement of PPI partners in the trial (e.g. ensure their contribution during meetings, provide one-to-one support before and after meetings, seek feedback in between meetings)
- Recruit PPI advisors / set up wider PPI (post funding)
- Invest time (outside of formal group meetings) in developing a good working relationship with PPI partners and advisors
- Regularly update PPI partners and advisors on trial progress
- Arrange prompt payments and reimbursements for PPI partners and advisors
- Monitor and evaluate PPI in the trial e.g. by regularly seeking feedback from PPI partners about their experiences and needs

TIPS FOR FUNDING A PPI LEAD

High quality, effective PPI often takes more time than anticipated, so if in doubt, **cost in more staff time**.

If the PPI lead is not a professional PPI coordinator, offer them **PPI training** (contact your local NIHR Research Design Service and check out the NIHR Learning for Involvement web resource).

Consider **sharing the role/budget** between a professional PPI coordinator and an existing member of your trial team.

DID YOU KNOW?

Insufficient staff time for PPI was the most commonly reported PPI issue in our survey of UK surgical trial staff.

Evidence shows that development of good working relationships with PPI members is an important driver of effective PPI.

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More tips for trial PPI lead

APPENDIX A

General guidance to help you plan PPI and participant recruitment

(i) General PPI guidance

We particularly recommend the following links:

- NIHR INVOLVE national advisory group for public involvement in research
- Cancer Research UK's patient involvement toolkit for researchers (applicable beyond cancer)
- Toolkit for PPI in clinical trials produced by the University of Liverpool
- Guide for successful patient involvement in EU-funded research
- Senior investigators championing PPI
- Patient and public contributors' views and experiences of PPI in health research – multimedia resource produced by the University of Oxford
- Researchers' views and experiences of PPI in health research – multimedia resource produced by the University of Oxford

(ii) General participant recruitment guidance

The following resources offer advice on planning participant recruitment to clinical trials:

- Tips to consider when optimising recruitment of patients to clinical trials, produced by the MRC Network of Hubs for Trials Methodology Research
- Evidence for effectiveness of recruitment interventions produced by Trial Forge
- Maximising the impact of qualitative research in feasibility studies for randomised controlled trials: guidance for researchers
- Planning for successful trial recruitment, produced by the Clinical Trials Transformation Initiative, United States

Return to PIRRIST main guidance

APPENDIX B

More tips to help you plan your PPI

(i) More tips for involving PPI partners

- Treat PPI partners the same way you would other team members. Include them in all team-wide communications and consider their availability when arranging meetings.
- Ideally PPI partners should attend face-to-face team meetings **in person** rather than by teleconference. They may need additional support to do so, e.g. overnight accommodation and subsistence. Treat them in the same way as you would any visiting collaborator, and invest time in getting to know them.
- If meetings are to be held by **teleconference**, ensure you provide support for PPI partners to contribute effectively e.g. one-to-one discussion with the trial PPI lead and Chief Investigator before and after the meeting. Aim to meet your PPI partners in person as soon as possible when they join the trial team.
- Share **Trial Management Group** (TMG) meeting agendas with your PPI partners and invite them to attend, or at least offer them the opportunity to attend if they wish.
- In team meetings with PPI partners present, include 'PPI' as a standalone item on the agenda. This can help to ensure PPI partners have a chance to contribute to the items discussed and/or raise issues the trial team may not have anticipated.
- Choose a skilled **chair** for meetings including PPI partners, ensuring they have ample opportunity to contribute to the meeting. TwoCan Associates for the UKCRC and NCRI have produced this useful guidance for chairing research group meetings which include PPI.
- Avoid abbreviations and jargon that may hinder PPI partners' ability to contribute. See the INVOLVE jargon buster of commonly used terms in health research.
- Regularly ask PPI partners about their **training needs/wishes** and accommodate them where possible. These may change as they become more familiar with the trial and involvement.
- Invite PPI partners to comment on the overall trial design and funding proposal. In addition, identify the elements which are **flexible/changeable**

and ask them specific questions about these. Try to manage expectations by being clear about which elements cannot be changed.

- Take a PPI partner to the **ethics committee meeting** to demonstrate the importance/ relevance of the application to patients. This could make the difference between approval and rejection.
- Build-in **additional time** for PPI activities during trial set-up. If PPI results in unanticipated delays, consider taking a PPI partner to meetings with the funder to request extensions.
- Consider involving a PPI partner in helping to **train recruiters** at your Site Initiation Visits.

Return to PIRRIST main guidance

(ii) More tips for planning wider PPI / involving PPI advisors

- Choose **timing** and **location** of PPI activities to best suit the group.
- Are there spaces/forums they already use (if an established group) or venues for hire in the community?
- Consider the age and availability of the target population – would daytime, evening or weekend activities suit them? School holidays?
- We recommend around **6-8 people** per focus group or advisory panel (in line with recommendations for focus groups in qualitative research). This permits a certain degree of diversity among group members, while enabling each member to contribute to discussions and keeping the group to a manageable size.
- Aim to recruit PPI advisors from a range of **different trial recruitment sites/regions**. You could consider an advisory panel with at least one representative from each site/region, or carry out focus groups at several different sites.
- Consider whether you need **continuity** (the same PPI advisors throughout the trial) or **fluidity** (a variety of PPI advisors across the lifetime of the trial) and what is realistic for your target population.
- Consider running an **induction day** to help advisory group members contribute effectively to the trial.
- A PPI **advisory panel** could allow various options for involvement including face-to-face meetings, phone or video conferencing and/or online discussion forums. Face-to-face meetings may result in richer discussion and provide an opportunity for PPI members to network with each other, but may not be appropriate or convenient for all patient populations due to travel requirements.

- For alternative, more innovative ways to involve PPI advisors, see this 'inventive involvement' resource produced by the University of Oxford.
- See our list of suggested questions to ask PPI partners and advisors about trial design, recruitment and retention strategies and patient-facing materials.
- It may not be possible to change the content of validated questionnaires, but PPI contributors can advise on the format, layout and introductory text.
- The Brain Trust has produced this useful guidance for writing a **lay summary**.
- Include information about the trial's PPI (as well as the trial team generally) in **participant information sheets**.
- Use any **professional skills** your PPI partners and advisors have e.g. poster/ flyer design, writing for a lay audience, etc.
- **Record/capture changes** to patient-facing materials following PPI review and share these with research colleagues. This may aid institutional learning such that the baseline quality of materials is improved over time.
- Consider involving **trial participants** as additional PPI once recruitment has kicked off. This could help you identify any issues with recruitment and retention early on, and improve participants' experience of taking part. Read more in this paper by the MRC Clinical Trials Unit at University College London.

Return to PIRRIST main guidance

(iii) More tips for trial PPI lead

- **Professional PPI coordinators** have valuable skills and expertise in facilitation, lay communication and local patient networks. If they are unable to take on full responsibility for coordinating the PPI throughout your trial, identify another member of the trial team who could take on this role, and cost in a small amount of the PPI coordinator's time for support and advice-giving.
- The PPI lead should ideally be someone with good communication, interpersonal and organisational skills.
- Consider asking your PPI lead to **chair** any meetings which involve PPI members, as this will help to ensure that the PPI members are able to contribute effectively. The chair may benefit from formal training, and TwoCan Associates for the UKCRC and NCRI have produced this useful guidance for chairing research group meetings which include PPI.

Return to PIRRIST main guidance

APPENDIX C

More tips for recruiting and retaining PPI partners

Recruiting PPI partners

- Recruitment of PPI partners may be more difficult than you expect. Some surgical patients may not want to revisit past experiences; others may not be well enough to contribute or may not wish to. **Start as early as possible** and **use a variety of strategies** e.g. advertising in community and healthcare settings and/or social media, tapping into existing patient organisations, contacting past or ongoing trial participants (if you have permission to do so), recruiting via public engagement events…
    - Does your trials unit or institution already have a database or pool of people who have expressed interest in being involved in research? If not, would it be possible to build one to facilitate recruitment to future trials?
    - Consider including an option for future contact about PPI opportunities on participant consent forms / reply slips in current trials.
- Use a **written role description** to define who you're looking for and to ensure potential PPI partners and trial staff understand the role and responsibilities.
    - See Bagley *et al.*'s **template role descriptions** for PPI members of Trial Management Groups and Trial Steering Committees.
    - Think about recruiting PPI partners with specific skills such as poster design, marketing, writing for a lay audience…
- Share your PPI plans and written role description(s) with the **whole trial team** to ensure everyone is aware of the purpose and role of PPI in the team.
- Aim for a **face-to-face meeting** with candidates (or at least a phone or video call) to discuss the opportunity, the candidate's motivation for being involved and their expectations.
- Make involvement as **easy** and **convenient** as possible e.g. choose time and location of meetings/activities to suit partners.
- Offer PPI partners **rewards and recognition** such as formal training, co-authorship or personal acknowledgement in trial publications, payment or vouchers, conference attendance, end of project party, trips around departments of interest, technological demonstrations (surgical robotics, MRI machines etc.)

- If any of your PPI partners receive **welfare benefits**, they should seek expert, personalised advice before accepting payment for involvement. See the latest INVOLVE guidance on the welfare benefits regulations that may affect people who are offered payment.

Return to PIRRIST main guidance

Retaining PPI partners

- **Update PPI partners regularly** throughout the trial (e.g. every 6–12 months) regarding trial progress and/or results.
- Show PPI partners **how they have made a difference** to the trial design and patient-facing information. See this evidence-based feedback resource for further guidance.
- Ensure **regular, one-to-one communication** between the PPI partners and PPI lead for the trial. This will help PPI partners to feel valued and will help establish and maintain a **good relationship** – found to be a key determinant of effective PPI in this realist evaluation
- Offer PPI partners **extra support** e.g. one-to-one meetings or telephone calls, especially before and after team meetings to help them prepare and debrief.
- Ask your PPI partners if there is any **training** they would find useful to understand the background to the project, the methods, treatments or technologies used, etc.
- Ensure that **payment for time** and **reimbursement of expenses** are processed as quickly as possible.
- Arrange **meetings** as far in advance as possible and try to avoid cancellations/rescheduling (which can undermine efforts to make PPI partners feel valued).
- If some of your PPI partners or TSC members are new to research involvement, consider a **mentoring or "buddying" scheme** where they are paired with more experienced PPI partners for extra support.

Return to PIRRIST main guidance

APPENDIX D

Suggested questions to ask PPI partners and advisors (pick those most relevant to your trial)

About proposed trial design(s):

- Would you be willing to take part in this trial? Why / why not?
- Would you be willing to receive either/any of the treatments offered in this trial? If not, why not?
- How would you feel about being randomly assigned to one or other of the treatments? (You may need to explain what randomisation means and why it is done – see the UKCRC's 'Understanding Clinical Trials' booklet page 17 for guidance).
- Would you prefer one treatment over another? If so, would this affect your decision to take part in the trial or not?
- Which of the following trial design options do you think would be most/least acceptable or appealing to patients, and why?
- If a surgical placebo may be used: Would you be willing to have [the placebo surgery]? If not, why not?
- How would you feel about not knowing (being blinded to) whether you had had [the treatment] or [the comparison]? How would you feel about the surgeon not knowing either?
- How long would you be prepared to wait before finding out whether you had had [the treatment] or [the comparison]?
- Would it make a difference to you if there was an option to convert from [the comparison] to [the treatment]?
- How long would you be prepared to wait before knowing the results of the trial / whether or not the treatment worked?
- What do you think about what participants would be asked to do before and after the treatment? Is there anything they might find difficult or off-putting? Is there any way we could make it easier, more comfortable or more enjoyable for participants?
- Are there any points in the participants' journey where they may be at greater risk of dropping out or disengaging? How could we reduce the risk of this happening?

About potential recruitment and retention strategies:

- Do you have any suggestions about where or how we could recruit participants?
- Who should approach or invite potential participants?
- Do you think the timing of approach is important? / When should potential participants be approached?
- What strategies or incentives could be used to encourage participants to stay in the trial?
- How could we encourage participants to complete and return their questionnaires after treatment?

About draft patient-facing materials:

- What do you think about this recruitment advert / invitation letter? Would it make you want to contact the research team? If not, why not? How could it be improved?
- How would you react if a [research nurse / doctor / other role] approached you and said this [recruitment script]? Would you want to find out more? If not, why not?
- What do you think of the participant information sheet and consent form? Are they clear and easy to understand? Is there any important information missing?
- See Bagley *et al.*'s guidance for PPI review of patient information and accompanying question bank.
- What do you think about this questionnaire / symptom diary? Is there any way we could improve the layout/format/content so that participants are more likely to complete it?
- What are your thoughts on this draft newsletter for participants? How could we improve it?

Return to PIRRIST main guidance

Please cite this guidance document as: PIRRIST Study Team (2019). "Planning patient and public involvement in surgical trials." Available from the University of Oxford: www.phc.ox.ac.uk/pirrist