

Roles and responsibilities for patient and public involvement in clinical trials



It is important to involve patients and the public at all stages in the research cycle

Involving patients and the public in research is key to ensuring all aspects of research are relevant and accessible to the community in which the research is directed. There are a variety of ways in which they can be involved:

IDENTIFYING AND PRIORITISING

- Determining research questions

COMMISSIONING

- As co-applicants on grant applications

DESIGNING AND MANAGING

- Advising on study designs
- As members on
 - » Protocol development groups
 - » Study Advisory Groups
 - » Trial Steering Committees
 - » Trial Management Groups
- Reviewing patient information documents

UNDERTAKING

- Running focus groups
- Gathering and reviewing evidence

DISSEMINATING

- Advising on and carrying out the dissemination of results

IMPLEMENTING

- Leading on the implementation of research findings

EVALUATING IMPACT

- Contributing to the evaluation of research and PPI

What happens when roles and responsibilities for patients and the public aren't clear?

Patients/the public may be uncertain of the aim of the activity or of what is required of them

Researchers may be unsure how best to employ the patients' / the public's knowledge and experience

Patients / the public may not be given the opportunity to contribute fully

Patients / the public may feel unfulfilled and frustrated

The patient / public–researcher collaboration may not achieve its potential

The project may not benefit from the full value of the patient / public involvement

How to ensure patients and the public are clear of their roles and responsibilities

BE CLEAR ABOUT

- 1 The role. What exactly are you asking patients / the public to do?
- 2 The duration and frequency of activities
- 3 What can change as a result of the PPI activity and what cannot?
- 4 Whether travel expenses will be reimbursed and / or whether a payment will be made*
- 5 How outputs from PPI activities will be fed back to patients/the public

COMMUNICATION IS KEY

Use different methods to communicate information about roles and responsibilities.



Telephone calls and face-to-face meetings may be useful initially.



Videos, podcasts and written descriptions of various PPI activities can be found online and sent to patient reps.



Role descriptions and terms of reference documents should be created for each PPI role.

INVOLVE templates for role description and terms of reference are very useful as a starting point. Each trial and each PPI activity within a trial will have individual requirements (invo.org.uk/resource-for-researchers-templates). Consider the following when creating communications:

TERMINOLOGY

Think carefully about the language used. Is it straightforward and easy to understand? Avoid jargon.

Be mindful of the term used to describe the people involved — patient representative / community representative / service user / public representative / carer? If in doubt, seek advice from a member of the community.

PRACTICALITIES

When planning activities, consider the needs of the group to be involved and aim to meet these as far as possible. If the group is disabled, is there disabled access to the venue? If the group are parents, is childcare provided or will there be reimbursement for childcare?

If the group are residents of an area, is it possible to hold meetings in their area rather than asking them to travel? If the group are working, hold meetings at suitable times in the evenings or at weekends.

Where funds allow provide a variety of good refreshments as a sign of appreciation for their time and contribution.

OPPORTUNITIES FOR CLARIFICATION

Ensure there are opportunities for people to clarify anything they are unsure of about the role. Encourage questions!

*See 'Rewards, Payment and Recognition for Patients/Members of the Public (PP) Involved in Research' NIHR Imperial BRC



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People-focused research in the NHS simply cannot be delivered without the involvement of patients and the public.

No matter how complicated the research or how brilliant the researcher, patients and the public always offer unique, valuable insight. Their advice when designing, implementing and evaluating research invariably makes studies more effective, more credible and often more cost effective too.

Professor Dame Sally C Davies, Chief Medical Officer

