NHS
National Institute for Health Research

Patient and public involvement in health and social care research:

A handbook for researchers

Contents

Foreword

Welcome to the NIHR Research Design Service (RDS) patient and public involvement (PPI) Handbook. This handbook has been created for you and your research team to help you plan, manage and carry out your PPI activities. RDS aims to offer you the best possible research design advice and this includes guidance on PPI. We want this handbook to be your resource book and to help guide you through your work involving patients and the public in research.

Demonstrating PPI and the continued involvement of patients and members of the public is a very important part of developing a successful grant application and is often a marker of quality research. The National Institute for Health Research (NIHR) has stated in relation to funding that "Applications that are technically excellent but have little patient or public involvement may be asked to address this before an offer of funding is made". Since 2006, the main focus of the NIHR patient and public involvement activities has been to develop and support the involvement of members of the public in the commissioning processes of national research programmes. All NIHR programmes involve public contributors at each step of the research management process and there is an expectation that you will be equally committed to PPI in your research.

Involving patients and members of the public can seem a time consuming and daunting prospect for new and experienced researchers alike. This handbook will provide you with a firm foundation in PPI and give you insights into the contributions that patients and members of the public can make; the practical aspects of where to find people to involve, as well as considerations on costs. This handbook is based on the original version produced by RDS London and their former User Involvement lead Carol Porteous.

Best wishes
Research Design Service

01 Patient and public involvement in health and social care research: the basics

What do we mean by patient and public involvement in research?

Patient and public involvement (PPI) in research (also known as service user/lay involvement) refers to an active partnership between patients and/or members of the public and researchers. Involvement is distinct from participation in research: patients and the public you actively involve are contributing to the research process as advisers and possibly also as co-researchers.

Researchers and clinicians may not have first-hand experience of the illness, disease or health condition that they wish to research. PPI can therefore provide researchers with insights into what it is like to live with a particular disease, illness or health condition, and these insights can help to make health research more relevant to the needs of patients, carers and service users. You can actively involve patients and the public in all stages of the research process including:

- Prioritisation of studies
- design and management of studies
- data collection and analysis
- dissemination of findings.

The term PPI covers a wide variety of individual people as well as groups and organisations. The list below:

Who are patients and the public?

- People who use, or have used, health or social care services
- informal (unpaid) carers and family members
- parents
- members of the general public
- organisations who represent patients and users
- patient support groups
- charities that represent specific health conditions
- individuals with an interest in the topic being researched.

Why is patient and public involvement important?

The contributions of patients can be extremely valuable, providing alternative views from those of the research team or NHS staff. Patients are able to make judgements based on their understanding of their condition and may have different aspirations and thoughts about health outcomes that health care professionals and researchers may not have considered. Research funders, such as the NIHR, now require PPI as a condition of funding.

When should I involve patients and the public in the research development process?

Although PPI can be incorporated at different stages of the process it is generally best to develop links with potential patients and the public at the earliest stages of the project. The NIHR suggest five key stages in the research process where involvement could take place. These are:

- Design of the research
- development of the grant application (pre-protocol work)
- undertaking/management of the research
- analysis of data
- dissemination of research findings.

The research cycle on page 14 will provide more detail on the involvement activities at each stage of the research cycle. You do not need to undertake all the activities described to have suitable, relevant and good quality PPI within your project. You should try and undertake the activities of most relevance to your research project and to the patients and public that you actively involve. If you are in any doubt of where to involve patients and the public in your research project, then it is a good idea to ask them to advise you on areas they feel need their input.

02 Creating links with patients and the public

Before you begin your involvement activities you will first need to find patients and the public and make linkages with appropriate groups.

There are many methods by which you could locate patients and the public to ask if they would be interested in getting involved in your research, or you may already have links to suitable patients and or patients groups. The list below may help you identify the links that you already have:

- In clinic – do you treat any patients you think would want to get involved in your research? Why not ask them?

- Patient groups and charities – have you worked with patient groups or charities in this area previously? Either in research or on other projects? Get in touch again, and utilise the important contribution that organisations can bring.

- Individuals – do you know of people through your own networks that may be helpful or interested? Have you considered involving those that took part in your pilot?

- RDS – RDS may have individual or group contacts that we can put you in touch with.

- Clinical Research Networks – are there any networks in your research area that may be relevant and helpful.

- Comprehensive Biomedical Research Centres (cBRCs), Specialist Biomedical Research Centres (SBRC) Biomedical Research Units (BRU), Collaboration for Leadership in Applied Health Research and Care (CLAHRC) and Academic Health Science Networks (AHSN) – Are there cBRCs, BRUs, CLAHRCs or AHSNs locally or that are focused upon your research area? If so they may be able to help.

- People in Research – People in Research is a site hosted by INVOLVE where you can advertise your research opportunities www.peopleinresearch.org

You can also advertise for patients through websites, community boards and newspapers. On Page 22 you will find some useful information on how to put together advertisements and role descriptions.

You may find that you want to create a PPI research group for your research topic or team, this too can be a good way to get patients and the public involved and much of the information contained within this handbook will help you to do so. Setting up a patient group is useful if you, your research team, or your department have a particular focus on one research topic or theme. If you would like further specific information on setting up your own PPI group, please get in touch with your regional RDS PPI Lead.

Ethics and consent

You do not need to obtain formal consent to involve patients and public in your research. For more information about this the National Research Ethics Service (NRES) and INVOLVE have written a statement to clarify the position of ethics and PPI. Their advice is as follows:

"The active involvement of patients or members of the public does not generally raise any ethical concerns *for the people who are actively involved,* even when those people are recruited for this role via the NHS. This is because they are not acting in the same way as research participants. They are acting as specialist advisers, providing valuable knowledge and expertise based on their experience of a health condition or public health concern.

Therefore ethical approval is **not needed for the active involvement element** of the research, (even when people are recruited via the NHS), where people are involved in **planning or advising** on research e.g. helping to develop a protocol, questionnaire or information sheet, member of advisory group, or co-applicant."

However, where people's involvement results in **direct contact with study participants,** the ethics committee will need to give specific consideration to the involvement as an element of the ethical consideration and approval. A REC will need to check that the person carrying out the research has adequate training, support and supervision appropriate to the circumstances in the usual way. Here there are two ethical issues to consider in addition to the usual concerns about the safety of researchers and the researcher / participant relationship:

• The well-being and safety of the *people who are actively involved as researchers.* They may find that talking to other people reminds them of their own negative experiences. This can cause distress, in which case the patient/member of the public who is carrying out the research may need additional counselling/ support. A REC will need to check this additional support is available

• the well-being and safety of the people *who are taking part in the research as study participants*. It is important to ensure that there are no additional risks to people taking part in a study. The REC will also need to consider any additional issues or sensitivities that may arise for those taking part in the research."

You can find the full NRES INVOLVE Statement here

03 Planning and preparing patient and public involvement

Before beginning to involve patients, carers and service users in research, many issues need to be carefully considered. The following is a list of questions and factors to consider, which should allow you to better prepare and plan for patient and public involvement in your research.

These are just suggestions and there are other factors that you may need to take into account and these will vary depending upon your research

Needs and expectations

- You should consider why you want people involved in your research– what do you think their perspective will bring, what can they add?

- Who will you involve and where will you find them? (See page 8) Remember it may take a long time to engage people and get them actively involved in your study. So you should start this process early

- What are your expectations of users?
  - What contribution will they be expected to make?
  - Are your demands on people's time reasonable?

- What skills would those you involve need to take part in this project?
  - Research skills?
  - Previous experience in research?
  - Will you need to include a glossary of terms to help them?
  - Will you provide or find appropriate training for them?
  - Maybe users do not need any skills for your project, just experience of a certain condition?

- Should you write a role description? This may be more suitable for more formal roles or may be something that the research team and patients, carers and service users agree on together.

Costs

- Will the project cover all reasonable costs?
  - The costs of a personal assistant for someone less able?
  - Or provide carer cover if the person you wish to involve is a carer?
  - Will the project cover childcare costs?
  - Will taxi costs be covered if the patient, carer or service user is less able?

- How will you pay expenses?

- Will your project pay an honorarium to those you involve?

In order to help you to ensure all potential costs for involvement are included within your research proposal, INVOLVE have created an on-line cost calculator: www.invo.org.uk/resource-centre/involvement-cost-calculator.

If you need money to pay for patient and public involvement in the design stage of your research, before you have funding, please check with your local RDS to see if they can help.

Organisation

- Travel arrangements – could these be made beforehand?
  Book trains, taxis etc in advance.

- Who will be the point of contact for service users? It is often better to have one point of contact that will work with patients, carers and service users to assist them, if and when they need it.

- How long will meetings take with users? Should you meet them beforehand and afterwards to ensure they feel comfortable. They may require more comfort breaks and the freedom to take medication during meetings.

- Do you need to have a physical meeting, could you discuss via email or telephone?

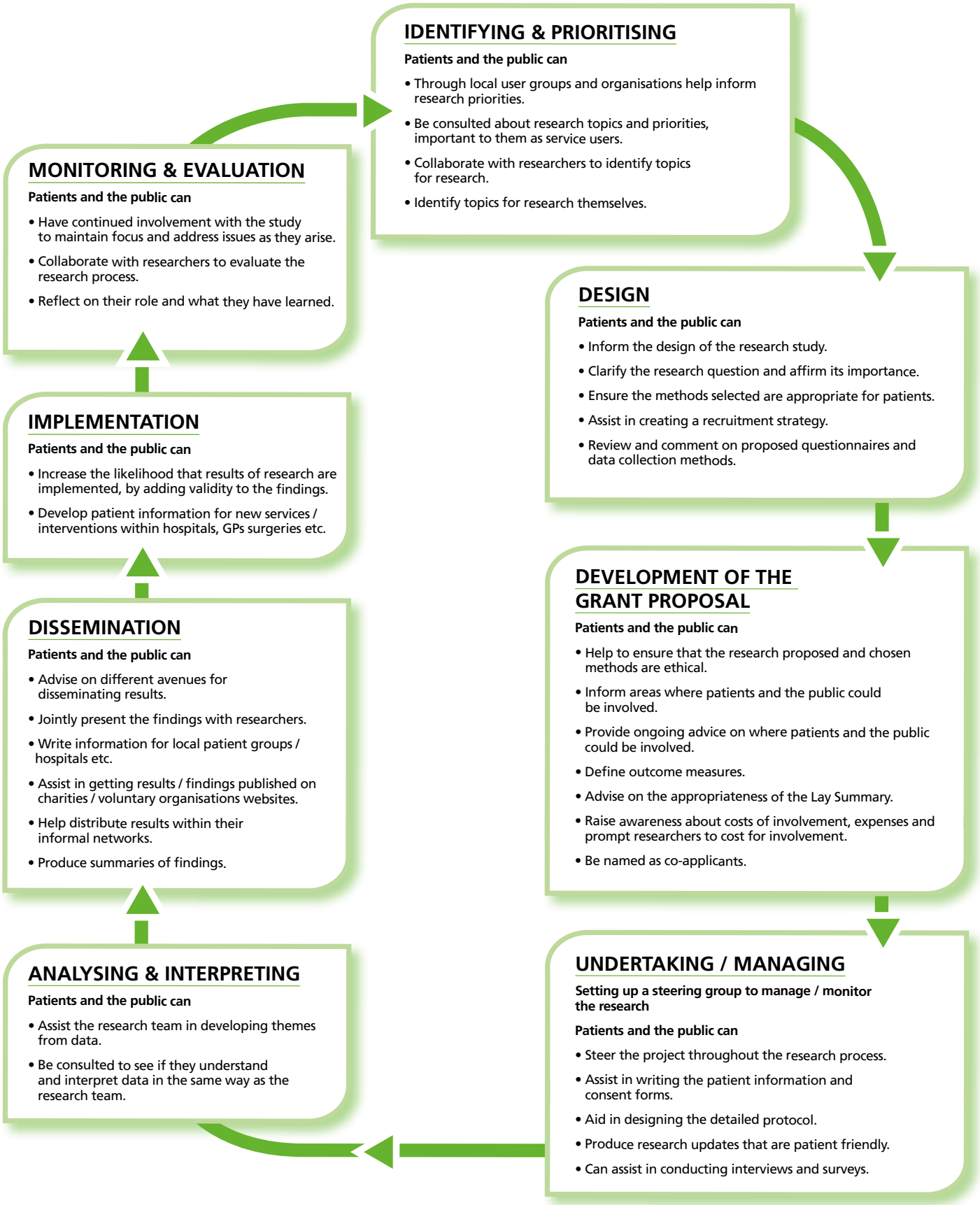
- Will you send printed or electronic reading materials well in advance of meetings in order for people to prepare?

- Where should meetings take place? Do you need wheelchair/disabled access?
  It may be that meetings could be more local to them, less formal or less intimidating
  - Community centres
  - Libraries
  - Coffee shops

- How will you distribute information to people?
  - Email, post or a telephone call?
  - Large print, braille or audio versions?

04 Patient and public involvement in the research cycle

How to incorporate patient and public involvement in the research process



NIHR's key areas of involvement

Design of the research/development of the grant application

Many of the PPI activities in both research design and grant application development can overlap as it is likely that some of these activities will be happening concurrently as the project develops and the funding deadline approaches.

At these stages you should already have a clear idea of who you are involving in your research, and quite possibly how. Remember those you involve may also suggest alternative ways of involving people, so there needs to be some flexibility. At this point, involvement may be informal and at a preliminary phase. At this point it is a good time to try and develop an understanding of the support needs of those you have involved. For example, do those you wish to involve need training in order to understand the basics of research, or the processes involved in applying for funding? Can you provide this level of support, or do you need to seek this from other sources? If so, then you will need to ensure that adequate time is given to researching potential training opportunities and establishing any associated costs.

As a first step you should consider discussing your research topic with those you have chosen to involve and use this as a starting point for other involvement activities.

At this stage in the development of your project, patients and the public may help to:

- Clarify the research questions and affirm their importance and help you focus the research questions to reflect the needs and priorities of patients and the public
- ensure the methods selected are appropriate from a patient perspective
- review the proposal and offer suggestions for changes
- review of data collection methods
- review and make suggestions on participant recruitment and consent strategies
- explore the burden being placed on participants. are there any barriers to participants taking part? This is when a lay perspective is most valuable in ensuring the study is feasible and practical. It answers the question "would a patient agree to take part in this study?"
- explore possible ethical issues from a patients perspective, are there any emotional, personal safety issues to participants? (from a ppi perspective)
- be named as a co-applicants
- plan subsequent PPI activities
- help write the plain English summary of the research.

Undertaking/management of the research

In the undertaking and managing of the research it is important not to forget about your patients and the public even though the study may be underway and you may have other priorities getting the study off the ground. There are many feasible and practical ways that they can be involved at this point.

Steering group

Some research teams invite patients and the public to join the steering group of their research. However you should carefully consider whether this is the most appropriate approach to take and whether you think this would be the best setting in which to involve patients in your research. Would you and your team be better setting up a separate lay advisory group just to focus on patient, carer, service user input to the research?

If you choose to involve them in the steering group, ensure:

- They have received the relevant paperwork beforehand and have understood it
- you provide lay summaries/glossaries and omit jargon
- you meet with them before and after each meeting to ensure they are supported
- you make them feel part of the group, equal to other group members
- you explain things to them clearly (without being patronising)
- you create a meeting where they can ask questions and seek clarification.

Preparation of patient information sheets and consent forms

Before you submit your research proposal for ethical approval you will likely need to produce patient information sheets, adverts and consent forms (depending on your research design). This is often an extremely useful point at which to involve people. Those you involve can help you make this information relevant and accessible for those being recruited to the study, which may mean you are more likely to recruit patients to time and target (given that they may be able to understand and find the information sheets and adverts accessible).

Qualitative research

If you are undertaking qualitative research, there is a good possibility that patients and the public will be able to make useful contributions to the interview/focus group questions and schedule. Additionally you may wish to involve them in undertaking interviews if this is feasible and would add to the relevance of the research. It may be that you think those you intend to interview would be more likely to open up and discuss matters with someone who has similar experiences. If you would like to involve patients in interviewing in any way you must think about:

- Their training needs, will they need to be trained in interview skills and techniques, or qualitative research more generally?

- if they are interviewing patients they may need DBS checks or research passports. Be sure to discuss this with your local R&D team.

Recruitment

It is worthwhile discussing your study recruitment plans with those patients and the public you have involved. They will have different perspectives and may be able to raise any issues they see with your plans before they arise. They may also be able to suggest ways of avoiding any issues or changing elements in your recruitment to suit the needs of the participants. (However it is not the role of patients to 'solve' any recruitment issues you may have in your study).

Analysis of data

Do you want to include patients in your analysis plans? Researchers often find this a more difficult stage of the research cycle in which to include patients and the public. If you have involved patients and the public in undertaking research (and they have the necessary Disclosure and Barring Service (formally CRB) checks, research passport etc.) you can involve them in undertaking the analysis of the data too.

In addition patients and the public can:

- Develop themes from qualitative data and suggest gaps in the data which can help identify further research questions

- explore the data and provide their interpretation, from a patients' perspective which may be different to that of the research team.

Dissemination of research findings

Many researchers would like patients to be involved in the dissemination plans for their study. They can do this through a variety of ways:

Where to disseminate?

Patients and the public, at this stage can:

- Provide suggestions about different avenues for dissemination
- those you involve may have excellent links with local relevant groups and organisations that you could use to promote the findings of your research to
- help publicise your findings by getting them published on charity and voluntary sector websites.

Writing and presenting

Patients and the public can:

- Advise on and help develop reports on the research findings that are readily understood by the public
- participate in presenting the findings of the research and talk about their experience of being involved in the process
- write information for local patient groups, trusts etc.

One of the common complaints from members of the public is that they do not hear about research activities in general. Patients and public involved in your project could identify places to disseminate your results and help create a lay version or lay summary.

A recurrent theme emerging from feedback received from PPI representatives is that they hear nothing once the research is completed. To address this issue, ensure that those you have involved have been properly thanked and rewarded for their input. Remember you may want to involve them in the future in other studies, in other ways. PPI is about building and maintaining relationships with your research community.

For examples of Patient and Public Involvement in Research, please see INVOLVE's Senior Investigators and Public Involvement publication, which contains many examples: http://www.invo.org.uk/wp-content/uploads/2011/12/INVOLVESeniorInvestigatorsNov2009.pdf

At the end of the involvement on a particular research project, please do ensure to thank those you have involved and really express your gratitude for their involvement.

05 Template advert for patients and the public

1 – Title /Headline

Patient and public research **(detail what you will be calling people – lay adviser, panel member etc)** wanted

2 – Key questions to include in the body of the text

Do you have experience of (condition) as a patient or as a carer? Could add any role here such as patient, family member
Have you had experience of (what experience are you looking for)
Do you want to influence (write what influence if any patients and the public would have in this area)

3 – Background to the study

Describe some background to the study such as university, research group, funder, research team etc

When developing research it is important to understand patients and carers needs to ensure that the research is in the best interests of the patient. For this reason we want to invite people with experience of and/or affected by **(condition)** to act as advisers to our research.

4 - What would this mean for patients getting involved?

You would be working in partnership with other patients, carers and researchers to **write in what they would be involved in doing in your research or panel in (condition)** services.

You do not need any previous experience, just a willingness to attend meetings and to give your perspective as someone with experience of **(condition)**.

The position is voluntary but training and support will be provided, and all travel and out-of-pocket expenses will be reimbursed. **(detail here what expenses you will pay)**

You should live in **(detail any specific location, Trust or hospital)** or have used the healthcare services in this area.

If you are interested in finding out more please contact **name** on **number** or via email **give email** or **(consider adding an alternative contact)**

For further information - give details of your organisation or research group website.

06 Template role description

You will find below a role description that you may wish to create to help you get patients and the public involved in your research project. It may be something you and your team use to help you decide what qualities or skills you are looking for when getting patients involved in your project or it may be a role description you use to advertise for patients. This is a more formal approach to PPI but may be something you and your team consider. It is also worthwhile noting that this is more commonly used when creating a formalised lay panel or patient group.

If you would like to discuss what you should include in your role description further please do get in touch with your regional RDS PPI Lead, details of which can be found on page 40 of this handbook.

"Role description of user representative / lay panel member / patient panel member" (change to suit your project)

"Steering Group Name or Project Title"

For further details about this project – please contact (your details)

Role Description:

Role name e.g. User representative on Steering Group for X Research Project

Summary

Purpose of steering group/ main aims and objectives.

Background

Project name e.g. Dermatology Research Steering Group: This section should include (where relevant):

- A short history of the project or group, you may also want to include details about the university and/or department
- An overview of why you are inviting patients and the public to join the group
- A brief explanation of the main topics that will be discussed and decided upon at the meetings
- What will the outputs be? For example, for a project it could be research reports and lay summaries or for a steering group it could be decisions on what research is funded/approved
- Who makes up this group? List names, their role and where appropriate what organisations they represent
- You may need to add start and finish dates for a project.

Matters for consideration by user representatives:

Conflicts of interest: As a representative you will be required to disclose any involvement you may have with other organisations, government bodies or corporate/commercial interests which could result in a conflict of interest with the work of …you may need to give examples here. (this may not always be appropriate)

Confidentiality: As a representative of the [X Research Project at X University] you are asked not to share confidential information you may have received as a result of your position. This should be discussed with the project group and / or contact person.

Roles and responsibilities of user representative.

1. Duties e.g.

- To attend in person: include location, date, frequency of meetings.
- To be available: include other means such as telephone/e-mail etc.
- To represent: the patient/lay user views of the X Research Project at other meetings you are asked to attend.
- To contribute to: discussion within the project steering group.
- To contribute to: what activities will you involve people in?

2. Qualities

Users/lay persons/patients representatives should have experience and knowledge of X condition:

- As a patient
- as a family member or carer of a patient
- as a member of an organisation that represent patients'/the public's interests in issues relating to X condition.

Essential Criteria

- Understanding of the issues relating to having X condition.
- Be able to maintain confidentiality
  Have the time to attend meetings (either/preferably face-to-face or via telephone.)

Add or delete criteria as appropriate – for every project or panel there will be different criteria and needs.

Desirable Criteria

- Have access to a computer and e-mail.
- An understanding of the NHS.
- An understanding of research processes and procedures.

Add or delete criteria as appropriate – for every project or panel there will be different criteria and needs

3. Remuneration

User representation/lay panel members/patients on this project are paid/ unpaid [you decide]. However, travel expenses and out-of-pocket expenses will be reimbursed in accordance with [Trust Policy/INVOLVE] (a summary should be given to the user representative.) Refreshments will be provided where appropriate.
(You may also wish to provide other expenses such as accommodation at your own discretion, ideally all out of pocket expenses will be covered, particularly travel expenses)

You should decide which costs you will cover, in-line with your department/ Trust policy and what the needs of your patients are.

4. Support

User representatives/patients/lay persons are able to access support and advice from the (Group Chair, key contact person – who is this in your project?) and other members via email, telephone or in person.
(List contact names and numbers/ email addresses.)

You should also state something here about providing access to resources that the user may need, for example literature (e.g. glossaries of terminology etc) and that you will support their involvement by asking them for regular feedback on their experience and responding to their needs.

Are there local relevant training courses you will send them on or suggest they attend? Are there other courses you have access to which they could attend?

Further information

Provide them with research project website or university website.
Other topic relevant websites or organisation details.
A staff member's contact details.

Glossary

Add definition of words or acronyms that have been used in the document and information on where to find out more.

07 Glossary of common health and research terms for patients and the public

This common list of research terms and their definitions should be useful for you when working with patients and members of the public. It may help you to describe your study to them or it may be something you copy and give to those you involve as a reference.

Abstract: a summary of a research paper.

Action research: occurs when researchers design a field experiment, collect the data, and feed it back to the activists (i.e. participants) both as feedback and as a way of modelling the next stage of the experiment.

Adverse Event (AE): is an unintended response to an intervention, where there is at least a possibility of a causal relationship (i.e. a question of whether or not the intervention might have caused the event).

Arm: in a controlled trial relates to the group of participants allocated either to receive particular treatment/intervention (treatment arm) or to receive a placebo (control arm).

Baseline data: is data collected on patients at the start of a study.

Bias: describes anything that distorts or affects a study in a way that would alter the findings. It may relate to a number of different elements such as the researcher's opinion or how they chose the research participants.

Blinding: where the subjects of the research do not know whether they are receiving the treatment or the **placebo**. If the clinicians do not know either, then this is called **double blinding**.

Case control studies: Studies used to investigate causes of diseases, or to identify adverse or side effects of treatments. These studies identify people who had a particular outcome of interest (the cases) and a control group of patients without the outcome (the controls) and then looking back to see if they were exposed to something that the researchers are looking at as possible cause.

Case study: in depth analysis and systematic description of one patient or group of similar patients to promote a detailed understanding of their circumstances.

Causation: is when one factor necessarily alters the possibility of a second.

Clinical audit: a service or care which someone receives is evaluated against a set of standards/criteria by the people who provide the care, with the intention of improving the service.

Clinical effectiveness is a term used in health care to describe an intervention that does more good than harm.

Clinical trial: is a study in humans intended to discover or verify the effects of a medical product, to identify adverse reactions and to examine safety and efficacy.

Cochrane review: is a systematic summary of the evidence of the effects of healthcare interventions, e.g. looking at all the research relating to a specific topic and finding the common issues and differences.

Cohort studies (or follow up studies): Studies which begin with a group of people (the cohort) free from disease but who have been exposed to a potential cause of disease or outcome. The cohort is followed up to see the subsequent development of new cases of the outcome of interest. Cohort studies provide the best information about the causation of disease and the most direct measurement of the risk of developing disease. They can also be used to measure the outcome of treatments or exposure when, for ethical reasons, it is not possible to perform an RCT or to investigate the effects of a rare exposure.

Confidentiality agreement: is a legal agreement to protect confidential information revealed during discussions or negotiations with another party. It applies to both organisations and individuals and is likely to contain clauses covering protection of people against the copying or retention of confidential information, disclosing information that is not already in the public domain to a third party and remedy for a breach of the agreement.

Controls: is the comparison group in a **Random Controlled Trial**. They receive the usual treatment (or a **placebo**) while the experimental group receives the treatment being tested.

Content analysis: is a form of data analysis in which the data is searched for the meanings or themes held within it. The researcher develops brief descriptions of the themes or meanings, called codes. Similar codes may, at a later stage in the analysis, be grouped together to form categories.

Critical appraisal: the process of assessing and interpreting research evidence, by systematically considering the results of the research, and establishing how valid the evidence is and how relevant it is to your own work.

Data analysis: is a systematic process of working with the data to provide an understanding of the research participants' experiences. While there are several methods of qualitative analysis that can be used, the aim is always to provide an understanding through the interpretation of the data.

Direct observation: the process of watching participants directly in the natural setting. Observation can be participative (i.e. taking part in the activity or non -participative).

Dissemination: the communication of research findings to a wider audience through, for example, publication in medical journals, the media, and voluntary organisations' newsletters.

Efficacy: refers to whether the intervention worked or not.

Empirical evidence: relates to collection of data in the real world and based on observation rather than through assumption and abstract development of an argument using reasoning alone.

Epidemiology: the study or populations or communities rather than individuals.

Ethics: is the name given to the code of practice based on a set of decent, fair and moral principles and guidelines that researchers should abide by. Research that will seek to gain personal confidential information or to test a new intervention on people must get ethical approval from an **Research Ethics Committee (REC).**

Research Ethics Committee (REC:) groups of professionals and service users that review the ethical considerations of research studies.

Ethnography: is a qualitative research methodology that enables a detailed description of a culture or subculture to be generated. Data collection usually takes place through observation, interviews or the study of existing text. The importance of gathering data in context is stressed, as only in this way can an understanding of social processes and the behaviour that comes from them be developed.

Focus groups: are used to elicit the views of a group (usually around six to 10 individuals) that have common experiences or interests. They are brought together with the purpose of discussing a particular subject, under the guidance of a facilitator.

Grey literature: material that has not been published in easily accessible journals or databases. An example might be an unpublished thesis.

Grounded theory: is an approach to the collection and analysis of qualitative data. The overall aim of grounded theory is to generate a theory that is 'grounded in' or formed from the data. This contrasts with other approaches that stop at the point of describing the participants' experiences.

Hypothesis: an unproven theory tested through research – rather like a hunch.

Incidence: the number of new occurrences of something in a population over a period of time.

Inclusion criteria: describes the conditions or attributes of people that are eligible to take part in a trial.

Interviewing: is a data collection strategy. Participants are asked to talk about the area under consideration. Interviews can be:

- Focused interview: a loosely structured interview in which the interviewer guides the respondent through a set of questions using a topic guide
- unstructured: the researcher asks the respondent a general question regarding the area of interest and allows them to tell their own story

- **semi-structured:** the interviewer has a more focused agenda than in an unstructured approach. Questions are phrased to allow the participants to tell the story in their own way and an interview guide is used to ensure information is gathered on areas of interest to the researcher
- **structured interview:** an interview in which the questions are predetermined and asked to all subjects.

Mean: the average value. The mean age of a group of people would be calculated by adding up all the ages and dividing the result by the number of people in the group.

Median: the middle result or midpoint when all the data values are put in sequential order.

Meta-analysis: a statistical technique, which summarises the results of several studies into a single estimate. More importance is given to studies, which have been done with larger groups of people.

NIHR: The National Institute for Health Research is the NHS led organisation that governs and funds all NHS research.

Observation: is a strategy for data collection involving the watching of participants in a natural setting. Observation can be participative (the researcher takes part in the activity) or non-participative (the researcher watches from the outside).

Outcome: the result being looked for in a **trial** e.g. stopping smoking.

Placebo therapy: an inactive (dummy) treatment often given to controls in trials. The **placebo** is delivered in a form, which is apparently identical to the active treatment being tested in the trial, in order to eliminate psychological effects on the outcome.

Publication bias: results from the fact that studies with 'positive' results are more likely to be published.

Qualitative research: studies things in their natural setting and cannot always be expressed in numbers. Often the term "holistic" is used, meaning that the complexities of human behaviour are preserved in the study. An example would be a research study into how children develop with or without attending preschool.

Quantitative research: collects data that can be expressed in numbers. An example of a quantitative research study would be one that compares the use of an antibiotic or placebo for the treatment of acute cough. A hint for remembering – quantity is measured, counting numbers.

Randomised controlled trial (RCT): a research trial in which subjects are randomly assigned to two groups: one (the experimental group) receiving the intervention

that is being tested, and the other (the comparison group or controls) receiving no treatment or a conventional treatment. The two groups are then followed up to see if any differences between them result. This helps people assess the effectiveness of the intervention.

Research question: defines the reason for the research; It describes the area of the study and what the researchers want to learn about it.

Sampling: is the process of selecting participants to take part in the research on the basis that they can provide detailed information that is relevant to the enquiry.

- Purposive sampling is the selection of participants who have knowledge or experience of the area being investigated
- Theoretical sampling is a sampling strategy in which the selection of participants is guided by the ideas that are emerging from the data analysis.

Saturation: of data refers to the point at which no further themes are generated when data from more participants are included in the analysis. The sampling process can be considered to be complete at this point.

Significance: the difference seen between the control group and the treatment group will only be significant if it is unlikely to have occurred by chance. This is typically agreed to be the case if the likelihood of it having happened by chance is less than 5%.

Systematic review: a review, in which evidence on a topic has been systematically identified, appraised and summarised according to predetermined criteria. (Some people call this an 'overview').

Transferability: means that the research findings can be transferred from one context to similar situations or participants.

Trial: a study of the effects of an intervention.

Triangulation: is a process by which the area under investigation is investigated from different (two or more) perspectives. These can include two or more methods, sample groups or investigators. Triangulation can be used i) to ensure that the understanding of an area is as complete as possible by the use of data from one or more different sources or ii) to confirm interpretations through the comparison of different data sources.

Validity: refers to the soundness or rigour of a study. A study is valid if the way it is designed and carried out means that the results are unbiased that is, it gives you a 'true' estimate of clinical effectiveness of a treatment.

08 Costs and payment for patient and public involvement

Patient and public involvement is not free and when submitting a proposal for funding you should include costs for your PPI activities. Costs for PPI will include both payments to patients and the public for their time and effort and payment for involvement in activities. Funders will be looking to see that you have properly accounted for PPI activities. To help you to realise and calculate all potential costs for PPI involvement, INVOLVE have created an on-line cost calculator: http://www.invo.org.uk/resource-centre/involvement-cost-calculator

For more information about payment for patients and the public INVOLVE has two publications which are extremely useful:

1. **What you need to know about payment:** Guidance on covering expenses, payment for time, skills and expertise, and issues you need to be aware of when making payment. http://www.invo.org.uk/posttypepublication/payment-for-involvement/

2. Changes to welfare benefit regulations: How do they affect payment for involvement?: A guide for making payments to members of the public actively involved in NHS, public health and social care research who are in receipt of benefits - http://www.invo.org.uk/posttypepublication/changes-to-welfare-benefit-regulations-how-do-they-affect-payment-for-involvement/

Besides payment to patients and the public there are other costs associated with PPI. Typical costs and the considerations are outlined below:

Costs of patient and public involvement

This table is intended to get you thinking about what your costs for those you involve will be. If you are unsure where is best to meet or what transport costs to include, discuss this with those you are involving.

Cost	Considerations
Meeting room hire Rooms with wheelchair disabled access, disabled toilet access? Location if patients cannot walk far from transport or after being dropped off.	1. Can you use a free room within the university? 2. Would you be better using and paying for a community location e.g. a community centre or library? 3. How many times a year will you need this room for/need to pay for a room?
Refreshments Fruit instead of biscuits? De-caffeinated tea and coffee for pregnant women etc – think about your patients' needs and requirements.	1. How many patients are attending? 2. What catering should you order? 3. Roughly how much will this cost?
Photocopying Will patients need larger fonts, colour prints, Braille?	1. If you need larger font publications or information materials to print in colour what will these costs be?
Carer cover Professional carer or babysitter.	1. Are you inviting carers to get involved? Will you need to pay for professional carer cover? 2. Are you asking mothers or families to get involved? Will you need to provide a babysitter? 3. Will you need to pay for the costs of a personal assistant?
Transport What are the restrictions of tickets? Could you book the ticket in advance or buy an open ticket? Are they less able and need taxis provided or assistance at train stations?	1. Do you need to pay for long distance train or petrol costs, what will these costs be? 2. What will the costs for taxis be? 3 Do you need to account for any other travel costs?

09 Evaluating patient and public involvement

Evaluating PPI is increasingly viewed as an important activity for those undertaking PPI in research. There are many reasons why you and your research team may want to evaluate your PPI activities. By carrying out an evaluation of your involvement work you may be able to assess whether your original aims and objectives defined during the planning stages of the process were achieved. Evaluating your PPI activities may also prove to be important for those you have involved, as it can be encouraging for them to understand what impact their contribution has had on the research and on their own development.

Evaluating PPI can help to:

- Identify what works (or not), for whom and in what circumstances identify how the involvement impacted on the research process
- celebrate success – recognising the achievements of your research team and your patients and the public
- generate evidence and share learning of the value of PPI; could your PPI activities inspire others and help evidence the impact of PPI on the research process?
- improve the planning of future projects - evaluating what worked and what didn't will help you identify how to plan future projects.

There are many frameworks for evaluating PPI in research, none of which have been unanimously adopted by researchers, NIHR or INVOLVE. You could also undertake your feedback informally as feedback or in a final debriefing session with those you have involved, looking critically at what worked, what did not, etc.

Below are a list of commonly used publications around evaluating and reporting PPI:

Barber, R., Beresford, P., Boote,J., Cooper, C., & Faulkner, A. (2011). Evaluating the impact of service user involvement on research: a prospective study. *International Journal of Consumer Studies,* 35 (6), 609-615.

Boote, J., Baird, W., & Beecroft, C. (2010). Public involvement at the design stage of primary health research: a narrative review of case examples. *Health Policy*, 95(1), 10-23.

Boote, J., Baird, W., & Sutton, A. (2011). Public Involvement in the Design and Conduct of Clinical Trials: A Review. *The International Journal of Interdisciplinary Social Sciences,* 5(11), 91-111.

Brett, J., Staniszewska, S., Mockford, C., Herron-Marx, S., Hughes, J., Tysall, C., & Suleman, R. (2012). Mapping the impact of patient and public involvement on health and social care research: a systematic review. *Health Expectation*. doi: 10.1111/j.1369-7625.2012.00795.x

Brett, J., Staniszewska, S., Mockford C., Seers, K., Herron-Marx, S. & Bayliss, H. (2010). *The PIRICOM Study: A systematic review of the conceptualisation, measurement, impact and outcomes of patients and public involvement in health and social care research*. UK Clinical Research Collaboration.

INVOLVE. (2012). *Briefing notes for researchers: Involving the public in NHS, public health and social care research.* Eastleigh: INVOLVE Retrieved from http://www.invo.org.uk/wp-content/uploads/2012/04/INVOLVEBriefingNotesApr2012.pdf

Mockford, C., Staniszewska, S., Griffiths, F., & Herron-Marx, S. (2012). The impact of patient and public involvement on UK NHS health care: a systematic review. *International Journal for Quality in Health Care,* 24(1), 28-38.

Morrow , E., Ross, F., Grocott, P. & Bennett, J. (2010). A model and measure for quality service user involvement in health research. *International Journal of Consumer Studies,* 34(5), 532-539.

Nilsen, E., Myrhaug, H., Johansen, M., Oliver, S., & Oxman, A. (2006). Methods of consumer involvement in developing healthcare policy and research, clinical practice guidelines and patient information material. *Cochrane Database of Systematic Reviews*, 2006 (3), CD004563. doi:10.1002/14651858.CD004563

Popay, J., & Collins, M. (Eds.) (2014). PiiAF The Public Involvement Impact Assessment Framework Guidance. Retrieved from http://piiaf.org.uk/documents/piiaf-guidance-jan14.pdf

Staniszewska, S., Brett, J., Monkford, C., & Barber, R. (2011). The GRIPP Checklist: Strengthening the quality of patient and public involvement in research. *International Journal of Technology Assessment in Health Care*, 27(4), 391–399.

Wright , D., Foster, C., Amir, Z., Elliott, J., & Wilson, R. (2010). Critical appraisal guidelines for assessing the quality and impact of user involvement in research. *Health Expectations,*13(4), 359-68. doi: 10.1111/j.1369-7625.2010.00607.x

Finally, consider publishing an article about the PPI in your research. This can bring several benefits including an additional article about your research, add to the literature base on PPI which is a research topic in its own right, and allow other researchers and members of the public to learn from your experience. You could even write an article with a patient or member of the public that you involved as a lead or co-author.

With thanks to Macmillan Cancer and James Lind Alliance for use of their glossaries.

For further information on patient public involvement in health and social care research, INVOLVE have many resources available on their website from reports and studies to example of patient and public involvement www.invo.org.uk

For information on PPI organisations in your area, visit: http://www.invo.org.uk/find-out-more/invodirect/

You may wish to include patients and the public in helping you identify priorities for your topic area or research theme. It is also worthwhile speaking to patients and the public about topics they would like researched, or about what patient priorities are. Please see the James Lind Alliance website if you would like further information on setting priorities with patients and the public http://www.lindalliance.org/index.asp

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The RDS PPI Community

The NIHR Research Design Service provides design and methodological support to health and social care researchers across England to develop grant applications to the NIHR and other national peer-reviewed funding programmes. RDS advisers in bases across England offer a unique breadth of experience and a proven track record in improving research applications. Advice is confidential and free of charge.
For further information on the RDS and to contact your regional centre, please go to:
http://www.rds.nihr.ac.uk