NIHR Cambridge Biomedical Research Centre

Patient and Public Involvement in research on the Cambridge Biomedical Campus

Key information to help you build PPI into your research

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Front cover image:
Researcher Peter Hartley holding a
focus group with CUH panel members

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Foreword

Hopefully, since you're picking up this toolkit, it means you have decided to involve patients and the public in your project and we're happy to help you in any way that we can. The NIHR Cambridge BRC Patient and Public Involvement (PPI) team have put together this series of fact sheets, with the help of some of our lay panel members, to provide you with some local guidance and to help get you started.

'Involvement' is a term that is often confused or conflated with other ways that the public are invited to interact with our research, such as 'engagement' or 'participation'. Although it is important not to get too caught up in semantics, these are equally important, but distinct ways of including the public in our research. What sets *involvement* apart from these activities is that involvement is really about *listening*. Listening to what patients and the public want from our research, and making appropriate changes and accommodations where we can. Asking patients and the public about their needs and priorities, helps to make research more relevant, more accessible and more likely to succeed in the real world.

We recognise that it can be a bit daunting to open up your research to an 'outsiders' view and that good PPI is a significant investment of time and resources – but I have yet to meet a researcher who was not pleasantly surprised and impressed by the insight of their public contributors and the useful suggestions they made.

Please get in touch if you would like to speak with us about your PPI needs or if you have comments about this Tool Kit.

Dr Amanda Stranks

Patient and Public Involvement and Engagement Lead, NIHR Cambridge BRC

The Cambridge University Hospitals (CUH) Patient and Public Involvement (PPI) Panel

Identifying, recruiting and retaining patient and public contributors can be a challenging step in good PPI. We are here to help – we can help you identify relevant stakeholders, suggest ways to recruit members of the communities that you identify, share involvement opportunities via our communications channels and review your proposed recruitment materials.

However, one of the most practical resources we can offer is the assistance of members of the public who have already expressed an interest in getting involved in research – the CUH PPI Panel.

About the Panel

The 'panel' currently consists of >80 members of the public, with and without health conditions, who are interested in getting involved in research projects. They cover a range of ages, ethnicities, occupations, experiences with illness and the NHS, and research experience. Some of them have been on the panel for >5 years (and, therefore have significant experience in PPI) and others are new joiners (and, therefore have excellent insight into what research looks like to those who have rarely or never encountered it before).

Many panel members also come from backgrounds such as law, marketing, education or business that can really add insightful value to your research; others have first- or second-hand experiences of health conditions or caring responsibilities. All are members of the public and can also give a 'public interest and understanding' viewpoint to your work. The panel is open to anyone to join, and members respond to projects that they find interesting.

Services offered

Document review

Members of the panel are happy to review your research related documents (eg. Funding proposals, lay summaries, PPI plans, consent forms, patient information leaflets, public engagement plans, recruitment strategies etc). This is all done remotely via email.

What happens?

After consultation, researchers email ppi@addenbrookes.nhs.uk with their documents and background information, which are forwarded on to the panel. Interested members have 2 weeks to respond with their comments, which we will then compile anonymously into a report for you.

How do I get the most out of this experience?

In addition to your 'core documents' (eg. The grant application/funding proposal/lay summary/consent form) please provide the panel with **background information that helps them understand the context** in which your (proposed) research takes place. This should be provided in a lay research brief, which could include (as appropriate):

- A brief outline of your own background and career stage
- A little bit about your funding or the funding program you are applying for
- Why and how you came to be working on this project
- A brief 'sales pitch' about why *your* work is important
- What the documents will be used for and who their audience will be

If a lay summary is already included in your documents, a short brief with the remaining information is appreciated. It is also useful to **think about what you would like to get from the experience**, and whether you have particular questions you would like the panel to answer. It also helps to be clear about anything that can't be changed in the documents.

Focus/discussion groups

Focus groups are ideal if you would like real-time discussion of your ideas or project, if you would like to get some consensus views, if you have a project that is difficult to describe on paper or when 'retrospective PPI' is required (eg. For a project already funded and underway that has met with public difficulties). Focus groups can also be very useful to follow up on issues raised during document review.

What happens?

After consultation, researchers arrange a suitable time and location (we have a meeting room that can be used when available) and send an invitation out to the panel, with a brief introduction/outline of the proposed research to be discussed. Attendees then participate in group discussion of the research idea/proposal/project, usually for around 90 min.

How do I get the most out of this experience?

There is no fixed format, but we suggest that researchers give a **short presentation about their background and research question** (see suggested points for lay research brief, above), and that they have **an outline of the topics** that they would like to discuss. It also helps to be clear about what can and can't be changed in the project. We can help to facilitate focus groups and to take notes on topics covered.

On-going involvement

If you have an opportunity for on-going involvement as part of your research project (eg. on a trial steering committee or patient advisory group), we can share this with our group.

What happens?

After consultation, we will share your role description with our panel and interested members will be encouraged to contact you directly.

How do I get the most out of this experience?

Have a clear outline of what you would like public involvement in your project to achieve, and what information and feedback about your project you would be willing to act upon. Ask your contributors what their expectations of involvement are, what training they need and how they would like to be supported. Outline your own expectations and reach a shared understanding of the relationship. Nominate a person within the research team who will act as point of contact.

Pre-document review advice

Before you create your research documents, consider these common pieces of feedback from our lay members:

1. What can be changed?

"They asked us what we thought of it and then told us nothing could be changed!"

The number one piece of feedback that we get from our panel members is frustration over being asked to comment on documents where nothing can be changed. If you are submitting protocols that have already been to ethical review, validated surveys or other documents that are 'fixed' for whatever reason, please be clear about this and explain what you would like people to comment on and how you will use any feedback that is given. If your documents can't be changed, but you would still like public feedback on your project, we would recommend using a focus group or workshop.

2. What will these documents be used for?

"Is this document for researchers or for patients?"

Give context; explain where each document is headed, who the intended audience is and how it will be used. This is especially important if you have submitted several documents with different intended audiences eg. A research proposal, trial protocol and lay summary together. Where appropriate, audience should also be clear within documents (eg. Patient information leaflets).

3. Is there avoidable jargon?

"Overwhelming use of jargon!"

Panel members understand well that medical research is a technical field, yet *unnecessarily* technical language frequently finds its way into lay summaries and patient documents. Describe medical terms in clear language and explain (not just expand) acronyms.

4. Is there unexplained medical and research terminology?

"Please explain [ambiguous generic medical/research word]"

A common example here is the 'burden' research might place on recipients – what exactly constitutes a burden and who decides this? In some ways, these kinds of words can be jargon in disguise, because they are similar to every day speech but different in the research context.

5. Are descriptions clear?

"There was no clear description… information was implied rather than stated."

The lay readers have no background context for your work except for what you've given them, nor do they have an in-depth understanding of research protocols or processes. Describe clearly what will happen to data that is collected, how it will be used and analysed, what is involved in the research plan. Also, use simple and explicit instructions where you are expecting the end user to do something (eg. Tick the box, sign the form, give/send it to etc).

6. Would a simple diagram help?

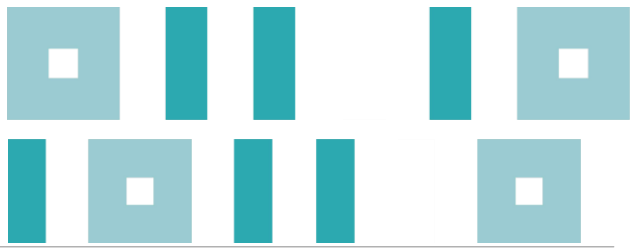
"A simple diagram would have helped!" "The photos helped remove uncertainty about what was meant."

There is a tendency to over-rely on (lots of) descriptive text, when images/diagrams would be more accessible and equally appropriate. Diagrams and images are particularly helpful when the procedure/device/intervention is difficult to envision for people who have never seen it before. Similarly, flowcharts and diagrams are a good way to visualize complex protocols or research programmes.

7. Related, but different:

"We've seen this before" "…a re-hash of topics already studied by health research"

Our panel is frequently exposed to studies that appear to the lay-person as very similar, and this echoes a wider sentiment (and misconception) about research being unnecessarily repeated, time and money wasted, and results not acted upon. Sometimes this is as simple as two (or more!) researchers from the same research group approaching the panel with their (understandably) related projects. Researchers can help lay readers better appreciate the uniqueness and importance of their research by clearly indicating how, where and why the research is related to other similar projects, and highlighting what aspect of their work is unique and ground breaking. For example, explaining that it is approaching an existing problem in a novel way, or trying an existing protocol on a different population/disease etc. When in doubt, spell it out!



Ethical Considerations in PPI

One of the most common questions we are asked about PPI is whether activities such as focus groups, and posters to recruit public participants require approval from a research ethics board. The HRA and INVOLVE have released guidance confirming that you do **not** require ethical approval for PPI activities (emphasis in original text):

> *"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 2 in* ***planning or advising*** *on research e.g. helping to develop a protocol, questionnaire or information sheet, member of advisory group, or co-applicant."*

http://www.invo.org.uk/wp-content/uploads/2011/12/INVOLVENRESfinalStatement310309.pdf

However, there are a number of ethical considerations that you should be mindful of as you involve the public in your research.

- **Be clear about what involvement is** – make sure your contributor understands that they are assisting you with making your research better and providing feedback or contributing to the design and execution of a research project, and NOT participating in the research as a research participant.
- **Avoid involvement and participation crossover** – patient contributors should not generally be involved in a research project that they are also currently a participant in as it can become difficult for them to understand the difference between the roles, and can introduce issues with blinding, access to patient data etc. Former participants make great contributors to future projects however, as do carers. If a condition is particularly rare, dual involvement/participation roles may be appropriate with careful planning and discussion.

- **Equality of access** – good PPI aims to include the voices of a range of people that may be affected by your research, and this may include people who need special consideration when planning your PPI activity. Be mindful of the timing, location and required facilities of your contributors when planning your events
- **Financial constraints** – As when recruiting participants for research studies, payment rates need to strike the balance between maximising inclusion of as many voices as possible and creating coercive or selective incentives that encourage people to get involved for the wrong reasons
- **Researcher/clinician relationships** – existing relationships with patients can bring benefits to involvement as you have already established a rapport. However, such relationships can also blur the lines between treatment and research and make patient contributors more reluctant to give you candid feedback about your research. Be aware of such relationships and clearly separate research activities from clinical treatments (consider alternate locations, different attire etc). Ideally, also seek the views of other contributors who are independent of your clinical duties.
- **Raw emotions** – we involve patients and the public in research in order to learn from their lived experience of their health condition and their interaction with the research process. However, this naturally means asking and reminding people of potentially difficult experiences in their lives. For many such contributors, involvement can be a way of dealing with these experiences, to improve research and disease outcomes for future participants and patients, but it can bring to the surface emotions and frustrations related to things you have no control over. Be prepared to listen and to moderate/facilitate interactions between contributors and research staff if things get emotional or heated.
- **Research/medical words vs experience words** – be mindful of the words you use when interacting with contributors. Commonplace research words like foetus, cancer patient are babies, people with cancer etc to everyday people.

Aims and Expectations

Public involvement has the greatest impact when research teams have a good understanding of what they expect to gain from it. Everyone gets more out of the experience when expectations are made clear so that they can be adequately met by all parties. An awareness of what you hope they will achieve will help you determine who you need, what you want them to do and how long for.

Once this has been determined, it should be formalised for public contributors in a Letter of Engagement that outlines the expectations (terms) of involvement, the level of support provided and details (amount and when, how and to whom they will be paid) of payments offered so that the public can make an informed decision about whether they would like to participate.

Contributors in Receipt of Benefits

Payment (including non-cash payments such as gift vouchers) for involvement activities can be considered as income by the HMRC and can therefore affect benefit entitlements. Benefits that have weekly earnings limits are affected by 'permitted work' rules, and people who are in receipt of such benefits are required to obtain prior permission to start paid involvement[1]. Those in receipt of Universal Credit will need to notify the Jobcenter of any earnings before their next payment is due.

Legally, it is the responsibility of the individual to clarify the potential impact of involvement activities with their Benefits Advisor and make their own judgements about what level of payment they are prepared to receive and declare.

However, it is important that research teams are prepared to strongly encourage their contributors to obtain specialist information and equipped to signpost to appropriate resources, such as the Benefits Advice Service and the payments section of the INVOLVE website (http://www.invo.org.uk/resource-centre/benefits-advice-service/).

Importantly, public contributors have the option of refusing payment for their involvement activities, or requesting a lower amount, without it affecting their welfare benefits.

Payment Guidance for Public Contributors to Cambridge BRC Research

Patients and the public bring invaluable expertise and experience to the design and execution of the world-class research delivered on campus, and we believe that they should receive appropriate recognition for their contributions.

Payments and reimbursements are essential to ensuring that involvement in research activities is as equitable and accessible as possible. We encourage all researchers to ensure that financial concerns are not a barrier to public involvement in their work.

Definitions

Public contributors: patients, service users, carers and/or members of the public who are engaged by research teams for the purpose of shaping and improving their research project

Payment: The offer of money to recompense a public contributor for their time and expertise

Reimbursement: The offer of money to compensate for expenses incurred in the course of involvement activities (eg. Travel, food or accommodation costs)

Payment or Reimbursement? To pay or not to pay…

Reimbursement for expenses incurred in the course of involvement activities should *always* be offered to public contributors to ensure that financial constraints are not a barrier to involvement and to ensure that opportunities are accessible to as wide an audience as possible. Reimbursements do not affect benefit entitlements and should be offered whether or not further recompense is available.

The decision about whether to offer payment for public contributions is ultimately up to the Principal Investigator of the research project. What is appropriate will be different for each project, depending on what is required of the public contributors, the resources available and the individual circumstances of the contributors.

There is no 'one size fits all' rule, but offering payment may be more appropriate where involvement is on-going, comes with specific expectations, has a significant time burden, requires particular skills, experiences or expertise or where suitable contributors were selected via an application/acceptance model (akin to a job interview). Conversely, involvement opportunities that are flexible, require little time or preparation, do not require specific skill sets and are open to anyone may be suitable for voluntary contributors.

Aims and Expectations

Public involvement has the greatest impact when research teams have a good understanding of what they expect to gain from it. Everyone gets more out of the experience when expectations are made clear so that they can be adequately met by all parties. An awareness of what you hope they will achieve will help you determine who you need, what you want them to do and how long for.

Once this has been determined, it should be formalised for public contributors in a Letter of Engagement (appendix 1) that outlines the expectations (terms) of involvement, the level of support provided and details (amount and when, how and to whom they will be paid) of payments offered so that the public can make an informed decision about whether they would like to participate.

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Importantly, public contributors have the option of refusing payment for their involvement activities, or requesting a lower amount, without it affecting their welfare benefits.

Funding for Payments and Reimbursements

Funding for public involvement can (and should) be included as part of securing funding. Once public involvement opportunities and needs have been evaluated during the research design phase, expected costs for involvement should be included as part of the funding bid.

Claiming Expenses

The following expenses may be claimed with the prior agreement of the Principal Investigator:

- **Travel/parking**
- **Accommodation**
- **Food**
- **Stationary or equipment necessary to carry out involvement activity**
- **Facilitator fees (eg. Carer, translator)**
- **Conference or event booking fees**

It is expected that public contributors will use the most economical and practicable form of transport available, while meeting their individual needs. Travel by private car should be via the most direct route available, and is set at 45p/mile by CUH – this is a *minimum* amount and individual travel circumstances may warrant higher reimbursement (eg. travelling long distances). All travel claims should be supported by appropriate receipts.

Claims for reimbursement need to be made promptly following each involvement activity by submitting the appropriate expenses form to finance, which must be signed by both the claimant and the budget holder. Copies of all receipts should be attached.

Records of expense reimbursement are kept by the trust in cases of enquiries regarding benefits or tax. Similarly, Inland Revenue and/or the Benefits Agency may request details of payments made to individuals, and we can accept no responsibility if public contributors are penalised for failure to declare income.

Suggested Rates for Reimbursement

The Principal Investigator or nominee will have responsibility for the final approval, monitoring and timely processing of payments. The following table outlines suggested payment levels for common involvement activities (taken from 2018/2019 Agenda for Change). Where contributors are involved in part of a session, payment can be made pro rata.

[1] NIHR INVOLVE 'Updates on welfare benefits regulations', updated January 2018

Activity	Details	Suggested rate	Notes
Events, attendance and asked to give individual views only		Expenses and provision of refreshments	E.g. Using the CUH PPI panel for document review or single focus groups
Participation in working groups, focus groups, committees or recruitment panels	On-going commitment, > 1 meeting	£10/hour, plus refreshments and expenses	
Chairing groups or meetings		£15/hour, plus expenses	Training may also be necessary
Preparation time for meetings (eg. Preparing a discussion paper, preparing a presentation, reviewing policies and protocols)		£7.20/hr	Agree expected preparation time in advance
Giving a short (<30 min) presentation		£30 + expenses	
Giving a long (<60 min) presentation		£60 + expenses	Fee reflects included preparation time
Planning/preparing and co-facilitating half day event	For training staff/public	£15/hr + expenses	
Participation in large working committees at national level meetings		£16.50/hr + expenses	
Allowance Type	**Details**	**Amount**	
Overnight accommodation	To allow attendance at conference or meeting	£55	
Meal allowance	Per 24-hour period	£20	
Lunch allowance	When more than 5 hours from home	£5	
Evening meal allowance	When more than 10 hours away from base and return home after 7pm	£15	

Payment of young people (<18 years) involved in research

Participation in involvement activities for young people is allowed provided it does not significantly impact on their health, education or physical development and that consent has been obtained from parents/carers. It is the responsibility of the researchers to ensure that consent has been received for each young person involved.

Consent must also be obtained in order to be able to offer payments to young people. Involvement activities are not counted as 'employment' for people aged under 14 (since the young person is unlikely to be earning enough to pay tax), and thus researchers have some discretion over how cash payments are used.

However, young people who are no longer subject to compulsory schooling may be in receipt of benefits, which could be affected by payments. Such young people should be strongly encouraged to seek personalised benefits advice, and researchers should be prepared to assist with signposting them toward useful resources.

It is also possible that parent benefits could be influenced by a young person's involvement activities, and thus parents should be encouraged to seek advice.

Support and Advice

Research teams should support their public contributors to be properly involved in their research projects in order to reach the desired aims of the involvement activities. This includes provision of stationery and materials that are essential to a given activity as well as copies (either hard copies or electronic) of relevant documents.

Other areas of suggested support are the provision of appropriate training for public contributors (eg. Research methods, clinical trials) and assistance for completing forms and reimbursement claims.

We recommend that research groups have a named team member who public contributors can contact with queries, and that this person is equipped to sign-post to resources, organise appropriate training and assist with reimbursements and payments.

Question Checklist for Reimbursement Planning

* This checklist is intended to inform **planning** for public contributor payments, not as a prescriptive or exhaustive list of items to cover before you begin activities!

- What form of public involvement is most suited to my research? Once off/on-going?
- Do I need patients with specific experience of this condition or will general experience of healthcare be enough?
- Do I want the same contributors each time?
- What expectations (time/expertise etc) do I have of them?
- What expenses will likely be incurred by them?
- What potential barriers to participation might they face?
- Am I aware of the resources available to public contributors in receipt of benefits and am I prepared to signpost them in the right direction?
- Have I prepared a 'role description' and/or 'letter of engagement' that can be given to potential participants specifying what involvement in my research would entail?
- Have I confirmed the correct procedure for reimbursement for my research team and can I find the forms etc that would be required for contributors to complete?
- Have I obtained consent for young person participation and reimbursement?

Recognition and Feedback

The simplest way to find out what form of feedback your contributors expect and prefer is to ask them! Providing regular, detailed feedback and updates on project outcomes and milestones are essential to appropriately recognising the impact public involvement has had on your research and acknowledging the efforts of your contributors.

1. Feedback about the impact the PPI contributions

Please inform your PPI members what input prompted changes and what those changes were. This may include alterations to documents, study design, recruitment strategy, ethics section or even your overall approach to your work. There may be reasons why certain comments cannot be incorporated – for example, if the comments were outside the scope of your work, infringe word limit, would cause ethical implications etc. Similarly, the views of your PPI members may be divergent or contradictory, such that it would not be possible to incorporate all (or any) of the opinions. A simple explanation of what was included and why is appreciated.

An explanation of PPI impact is required by many funding bodies (eg NIHR) as part of the application process. The impacts that you feed back to your contributors should provide you with the material that you need for this section of the application.

2. Outcomes and Updates

PPI contributors volunteer their services out of a genuine interest in research, the research process and a desire to improve outcomes. The vast majority of lay contributions happen at early stages of research, often prior to grant application or funding commencement (which is a good thing!). However, people are also very interested in the wider impact of their contributions and want to know what happens to the research after they see it – were the ethics approved? Grant funded? Study initiated? Recruitment finalised? Or, eventually… study concluded? Please update your PPI contributors even when the news isn't good. You'll help ensure that people continue to get involved with research.

3. Acknowledgement

When PPI has contributed to research that is subsequently presented or published, please acknowledge the PPI panel in the appropriate section.

PPI Activity and Impact Record Form

Project Title: _____

Principal Researcher/named PPI Lead:

Activity	*Date*	*People Involved*	*Responses*	*Feedback (outcomes)*	*Actions taken (impacts)*
Research Design Phase					
Lay Summary Distributed for Comment	*13/11/2019*	*CUH PPI panel*	*15 responses received*	*Layout was felt to be confusing and some aspects of the wording were felt to be insensitive.* *Excessive use of jargon* *Suggestion that a diagram may be beneficial*	*Adopted recommendations about wording and layout* *Improved lay understanding/removed jargon* *Produced diagrams of treatment flow*
Data Production Phase					
Post Project/Dissemination Phase					

In one year, CUH panel members provided researchers with over 500 responses

Over a course of a year, CUH panel members have spent over 400 hours in researchers' focus groups

CUH PUBLIC PANEL MEMBERS HAVE **WORKED ON**

Patient Information Sheets
diagrams **Questionnaires**
Plain English Summaries posters
Patient Diaries **websites**
Research Proposals
protocols Consent
telephone interview script
trialled apps Relatives Informati
Devices focus groups
Advisory Panels **Scenario Docs**
adverts **On-line**
Leaflets **newslet**
Patient Letters

SOME OF THE RESEARCH THEMES THE PANEL HAS BEEN **INVOLVED WITH**

Public Health metabolic conditions
Urology **medicine** **adherence**
transplants pregnancy **Diabetes**
Cardiovascular older people
esophageal conditions Research **Statistics**
Obesity **Cancer**
Neurosurgery **methodology**
Women and Children's Health
Dementia rare diseases **Care**
Mental Health blood pressure
Fragility Occupational **Health**
Intensive care autoimmunity
Arthritis commercial
Epidemiology ambulance service
data collection
Liver Disease **Pain**
blood and transplant