

# Patient and Public Involvement in Research

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## Birmingham Health Partners

Delivered by

**UNIVERSITY OF  
BIRMINGHAM**

**NHS**  
University Hospitals  
Birmingham  
NHS Foundation Trust

**NHS**  
Birmingham Women's  
and Children's  
NHS Foundation Trust

# Patients at the Heart

- Formation of the NIHR (2006)
- Government White Paper on Health (2010) *Equity and Excellence*
- Patients at the heart of decision making in the NHS
- NHS constitution principle 4 “The patient will be at the heart of everything the NHS does”



**No decision about  
me without me**

# NIHR says...



“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 researchers, patients and the public always offer unique, invaluable insight.”

*Prof Dame Sally C Davies, Chief Medical Officer and Chief Scientific Adviser, Dept of Health*

# INVOLVE



*National Institute for  
Health Research*

**Briefing notes  
for researchers:**  
public involvement in  
NHS, public health and  
social care research

A pink starburst graphic with a dark red outline, containing the text 'READ THIS' in white.

**READ  
THIS**

<http://www.invo.org.uk/resource-centre/resource-for-researchers/>



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# INVOLVE defines 3 separate activities

## INVOLVEMENT

As co-applicant on research project

Identify research priorities

On advisory or steering groups

Commenting on PI leaflets

Carrying out research

## PARTICIPATION

Giving an extra biopsy sample

Completing a questionnaire

Taking trial drugs

## ENGAGEMENT

Science festivals, open days

Public lectures

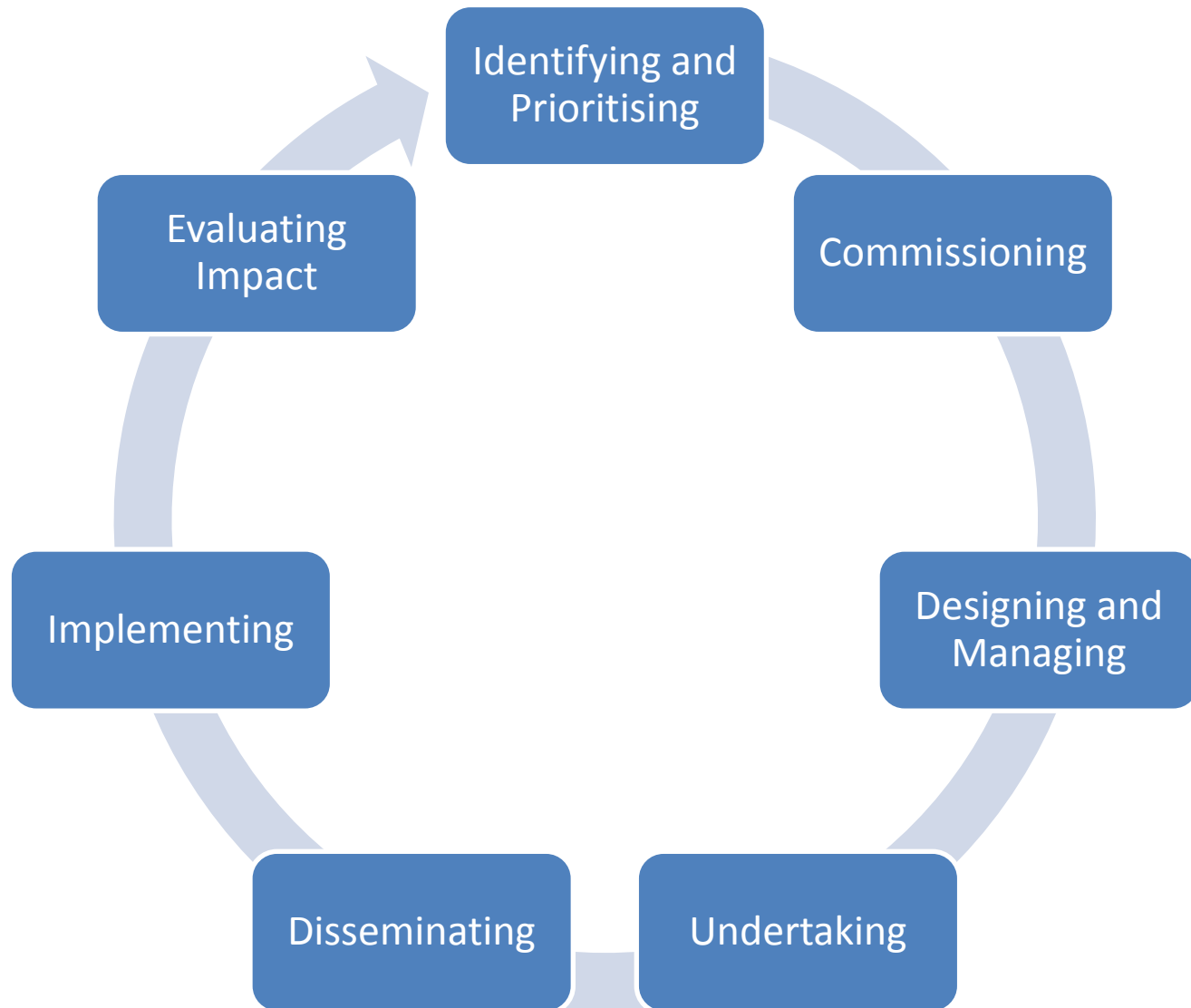
Media stories

Dissemination to charities/patients

Social media

*When to do  
PPI?*

Patients can  
be involved  
at any stage  
in the  
research  
cycle



# What can patients bring to research?

## Identify Priorities

Is this a relevant question?

Will answering this question improve patients' lives?

Are there better questions you could be asking?

## Ensure outcomes are meaningful

Patient Reported Outcomes

Surrogate markers?

Quality of life

## Ensure methods are acceptable to patients

Is test uncomfortable? Too long?

Will test exacerbate symptoms?

Helps recruitment

## Improve information

Ensures fully informed consent

Improves recruitment

## Spot confounding factors

Other medication

Psycho-social interactions

Under reported side effects

## Help interpret findings

Explain unexpected findings

Alternative explanations for observed associations

## NRES and INVOLVE joint statement on the ethics of public involvement in research

<http://www.invo.org.uk/wp-content/uploads/2016/05/HRA-INVOLVE-updated-statement-2016.pdf>

You do NOT  
need ethical  
review for PPI  
even if patients  
are recruited  
via the NHS

# INVOLVE

Promoting public involvement  
in NHS, public health and  
social care research

**NHS**  
National Patient Safety Agency  
National Research Ethics Service

## Patient and public involvement in research and research ethics committee review

### Purpose

This statement has been developed by the National Research Ethics Service (NRES) and INVOLVE to provide clarity and guidance on patient and public involvement in research and the requirements of research ethics review. The statement has been approved by the NRES Advisory Group on NHS Service Users and Ethical Review.

### Active involvement vs. participation in research

Involvement in research as a research participant comes with the protection afforded by research governance arrangements that include research ethics committee (REC) review to protect the rights, safety, dignity and well-being of research participants.

However, when we talk about 'involvement' in research, in this statement, we mean getting actively involved in the research process itself, rather than being participants or subjects of the research.

### Active involvement

Many people describe public involvement in research as research that is done with or by the public, and not to, about, or for them. The public have been involved in research and development for a number of years and in a variety of different ways. For example this includes:

- identifying and prioritising research topics;
- being part of research advisory groups and steering groups;
- undertaking research projects and;
- reporting and communicating research findings.

### When is ethical approval required for active involvement?

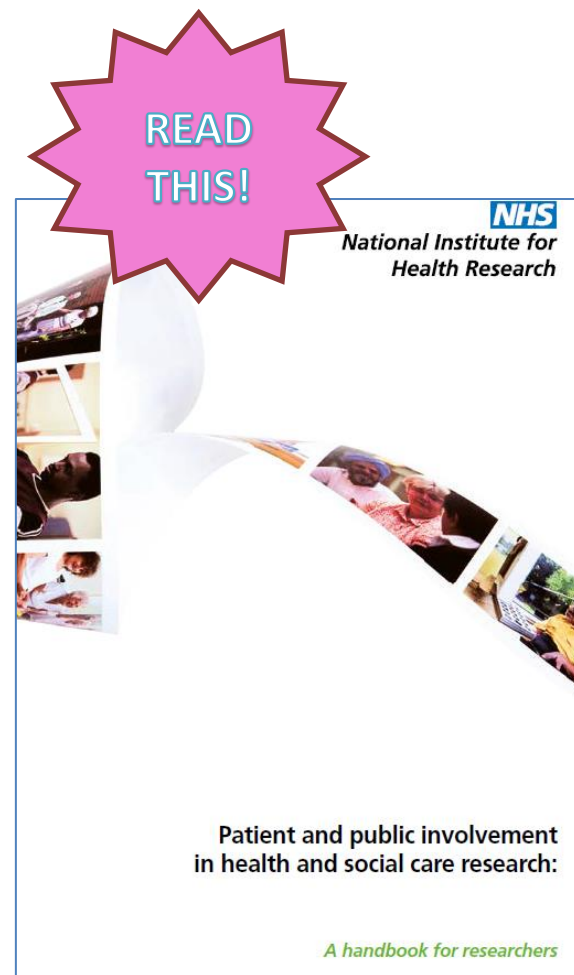
The active involvement of patients or members of the public does not generally raise any ethical concerns *for the people who are actively involved*, even when those people are recruited for this role via the NHS. This is because they are not acting in the same way as research participants. They are 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



# Research Design Service

- Patient Involvement Fund - grant of up to **£500** for pre-proposal patient involvement activity. You can apply for this if you are planning to submit a proposal to a national, peer reviewed funding body. Apply for support at <http://www.rds-wm.nihr.ac.uk/How-can-we-help/Support-Request-Form.aspx>
- Contacts
  - Jonathan Mathers (UoB)  
[J.M.MATHERS@bham.ac.uk](mailto:J.M.MATHERS@bham.ac.uk)  
01214146024
  - WM Agnieszka Igantowicz (Warwick)  
[A.Ignatowicz@warwick.ac.uk](mailto:A.Ignatowicz@warwick.ac.uk)



<https://www.nihr.ac.uk/about-us/CCF/funding/how-we-can-help-you/RDS-PPI-Handbook-2014-v8-FINAL.pdf>

# Payment for PPI

- **Always** Pay Expenses
- **Always** provide refreshments/lunch
- Payment for time should **always** be considered – use
  - “Should Money Come into it” toolkit <http://www.changefoundation.ca/patient-compensation-report/>
  - “Budgeting for Involvement” <http://www.invo.org.uk/resource-centre/payment-and-recognition-for-public-involvement/>
- People on benefits may not be allowed to receive money – check with INVOLVE
  - <http://www.invo.org.uk/resource-centre/benefits-advice-service/>
  - <http://www.invo.org.uk/wp-content/uploads/2018/01/INVPayInfSheet-Jan18.pdf>
  - <http://www.invo.org.uk/resource-centre/payment-and-recognition-for-public-involvement/>



## Should money come into it?

A tool for deciding whether to pay patient-engagement participants



National Institute for Health Research

## Budgeting for involvement:

Practical advice on budgeting for actively

**INVOLVE**



National Institute for Health Research

## INFORMATION SHEET

**Payment for public involvement with INVOLVE  
for those in receipt of welfare benefits**

Updated: January 2018

# The 4 R's

## REACH

- Who are you involving?
- Does diversity reflect patient population?

## RELEVANCE

- Is your work something that patients want and will benefit from?

## REFINEMENT

- Aim for fewer poor quality studies which don't lead to patient benefit
- Patients can help to focus on research directions that matter to them

## RELATIONSHIP

- Don't bring patients in at short notice
- Build a partnership

# INVOLVE



National Institute for Health Research

## Going the Extra Mile

The National Institute of Health Research is 10 this year and prior to this the Breaking Boundaries Review was commissioned to inform the public involvement strategy for the next 10 years. The results from this review formed the Going the Extra Mile Recommendations. This document is designed to provide you with an update on these recommendations including the key strategic leads.



FIGURE 1 NIHR's GOING THE EXTRA MILE ROSETTE. ILLUSTRATING THE SYSTEM WIDE ROLES AND RESPONSIBILITIES FOR EACH OF THE COMMUNITY RAISED PRIORITY AREAS. WHERE POSSIBLE STRATEGIC LEADERSHIP IS ALIGNED TO THE KEY ORGANISATION THE OVERARCHING VISION IS FOR THE NIHR TO ACT AS ONE SYSTEM TO DELIVER THE vision and mission OF NIHR.



## Patients', clinicians' and the research communities' priorities for treatment research: there is an important mismatch

Sally Crowe<sup>1\*</sup>, Mark Fenton<sup>2</sup>, Matthew Hall<sup>3</sup>, Katherine Cowan<sup>4</sup> and Iain Chalmers<sup>5</sup>

Home

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## The James Lind Alliance

The James Lind Alliance (JLA) is a non-profit making initiative established in 2004. It brings patients, carers and clinicians together in [Priority Setting Partnerships \(PSPs\)](#) to identify and prioritise the [Top 10 uncertainties](#), or unanswered questions, about the effects of treatments.

The aim of this is to make sure that health research funders are aware of the issues that matter most to patients and clinicians.



### The PSPs

Find out about the areas in which



### Top 10s

See the top priorities for future



### The JLA Guidebook

Read a step-by-step guide to the

### What's new.....

This [October 2016 report](#) presents the wide range of themes and experiences that patients, carers and clinicians cared about when responding to the initial survey from the Palliative and end of life care PSP

### Mailing list

Sign up to our newsletter and stay up to date on the latest news from the JLA

Sign up

### JLA on Twitter

Tweets by [@LindAlliance](#)

# Finding Patients

## In Clinic

- Direct approach
- leaflets

## Support Groups & Charities

- News@QEHB has list of patient support groups
- Check for national/local charities

## Clinical Research Networks

- WM CRN has young people's group
- Mary-Anne Derby PPI lead for CRN

## Local NIHR bodies & UHB

- BRC – Liver & GI, 1000 elders, R2P2 – rheumatology (James Ferguson)
- SRMRC – ABC (Accident, Burns, Critical Care) (Karen Piper)
- Renal Research group UHB (Mary Dutton)
- Ophthalmology (Alastair Denniston)
- Vasculitis (Matt Morgan)

## Social Media & Internet

- [www.peopleinresearch.org](http://www.peopleinresearch.org)
- Twitter
- Facebook

## Traditional Media

- Newspaper
- Posters



# 4 PI Framework for Involvement

<http://www.nsun.org.uk/about-us/our-work/national-involvement-partnership/4pi-blog/>

The group  
decides,  
not the  
researchers

## PRINCIPLES

- eg inclusivity, no hierarchy, freedom to speak, respect, honesty

## PURPOSE

- What do you want from the patients, how do you envisage they can help you with your research

## PRESENCE

- Who is in the room? Do they represent the patient population?

## PROCESS

- How will we proceed? How often to meet, means of contact, one-off or ongoing?

## IMPACT

- How will we know we have achieved our aims?  
How to feed back to the patients about progress?



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# Assessing & Reporting Quality and Impact of PPI

**INVOLVE**



National Institute for  
Health Research

Exploring the impact of public involvement on  
the quality of research: examples

Staniszewska et al. *Research Involvement and Engagement* (2017) 3:13  
DOI 10.1186/s40900-017-0062-2

Research Involvement  
and Engagement

## METHODOLOGY

Open Access



## GRIPP2 reporting checklists: tools to improve reporting of patient and public involvement in research

S. Staniszewska<sup>1\*</sup>, J. Brett<sup>2</sup>, I. Simera<sup>3</sup>, K. Seers<sup>1</sup>, C. Mockford<sup>4</sup>, S. Goodlad<sup>5</sup>, D. G. Altman<sup>6</sup>, D. Moher<sup>7</sup>, R. Barber<sup>8</sup>,  
S. Denegri<sup>9</sup>, A. Entwistle<sup>4</sup>, P. Littlejohns<sup>10</sup>, C. Morris<sup>11</sup>, R. Suleman<sup>4</sup>, V. Thomas<sup>12</sup> and C. Tysall<sup>4</sup>

## Critical appraisal guidelines for assessing the quality and impact of user involvement in research

David Wright PhD,\* Claire Foster PhD,† Ziv Amir PhD,‡ Jim Elliott PhD,§ and Roger Wilson¶

\*Research Programmes Lead, Macmillan Cancer Support, London, UK, †CPsychol, Reader and Head of the Macmillan Survivorship Research Group, School of Health Sciences, University of Southampton, Highfield, Southampton, Hampshire, UK, ‡Director of the Manchester Macmillan Research Unit, School of Nursing, Midwifery and Social Work, The University of Manchester, University Place, Manchester, UK, §Research Management Consultant, INVOLVE Advisory Group, London, UK and ¶Associate Director (Patient and Public Involvement) UK Clinical Research Network, and member of NCRI Consumer Liaison Group, Shropshire, UK



PiiAF

The Public Involvement Impact  
Assessment Framework  
Guidance

Popay, J and Collins, M (editors) with the PiiAF Study Group

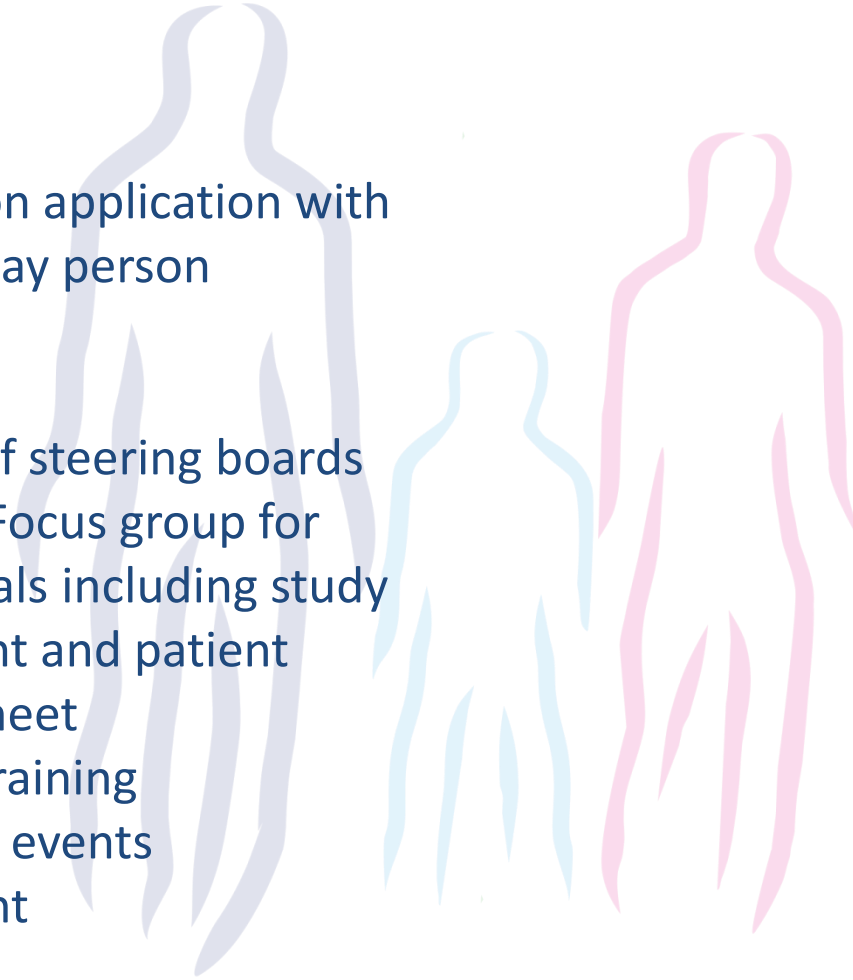
January 2014



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## Case study: NIHR Invention for Innovation

- Co-applicant on application with review of the lay person summary
- Patient video
- Involvement of steering boards
- Formation of Focus group for review materials including study design, consent and patient information sheet
- Lay member training
- Dissemination events
- Twitter account





# Get Social

- @NIHRINVOLVE
- @People\_Research
- @SDenegri
- @Tessajrichards
- @DavidGilbert43
- @ePatientDave
- @Sally\_crowe
- @Know\_HG
- @jonathonboote
- @KristinaStaley2



# Key points

- There is lots of literature out there for further reading
- Its never too early or too late to involve patients or lay members in your work
- Share your stories of PPI



“We see two types of PPI in our applications – **genuine PPI** where it is clear how researchers have worked with patients to plan better research for the NHS, and **token PPI** where a patient has been drafted in to agree with the team’s preconceived ideas. Try to be the former.”  
*Prof Hywel C Williams, Chair, HTA Commissioning Board*

