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## Public involvement in research: impact on ethical aspects of research

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This resource provides examples of the impact of public involvement in the ethical design and conduct of research.

Before a research study can start, ethical approvals need to be obtained from the National Research Ethics Service (NRES) and others (for example University Ethics Committees). Research Ethics Committees (RECs) frequently raise a broad range of ethical concerns about the design and conduct of research. A research project looking at NRES RECs' decisions showed the most common concerns to be: informed consent; care, protection and recruitment of research participants; and the provision of information such as patient information materials and lay summaries of the research (Angell et al. 2007).

A recent study carried out by INVOLVE and NRES examined the nature and extent of public involvement in research applications that had been assessed by NRES RECs (Tarpey 2011). This study highlighted that the information provided by researchers on public involvement can help to inform RECs about the ethical probity of studies.

Drawing on findings from three reviews (Brett et al. 2010; Staley 2009; Smith et al. 2008) and more recent literature, this supplement illustrates how public involvement throughout a study can help to make research more ethical by:

- **Making research more relevant**
  - so that research is a valuable and respectful use of people's time and the results are more likely to be useful to patients/ the public.
- **Helping to define what is ethically acceptable**
  - particularly in controversial or risky research.
- **Improving the process of informed consent**
  - making it easier for prospective participants to understand the research and potential risks.
- **Improving the experience of participating in research**
  - checking that the practical arrangements for participants are appropriate.
- **Dissemination of research to both the participants and the wider public**
  - providing information on the progress of the research as well as the final results.

## Making research more relevant

Patients and the public frequently prioritise topics for research that are different to those of academics and health professionals (Elwyn et al. 2010; Hewlett et al. 2006; Lindenmeyer et al. 2007). People living with a health condition are often in a better position to know what questions remain unanswered about their treatment or condition, and what research would most likely improve their quality of life (Evans et al. 2011).

Public involvement right at the beginning of a project helps researchers to identify new research topics and to modify their research questions (Fisher 2002). It can help shift the focus of the research design to become more in line with the public's interests and concerns. Working with members of the public requires researchers to be clearer about why they want to conduct their research and how it is relevant to the public (Hewlett et al. 2006; Lindenmeyer et al. 2007). It may challenge researchers' aims and assumptions.

Public involvement can also influence what research outcomes are measured as well as how they are measured (Ali et al. 2006; Hanley et al. 2001; Hewlett et al. 2006), helping to make the research findings more relevant and valuable to the people who want to use them (Wykes 2003).

Taking part in research that is more likely to benefit the participants and / or their peers is a more respectful and ethically acceptable use of people's time (Staley & Minogue 2006).

## Helping to define what is ethically acceptable

Sometimes the risks involved in researching a new treatment make it questionable whether the research should go ahead (Evans et al. 2011; Marsden and Bradburn 2004; Koops and Lindley 2002). By working with patients and carers and communities who might be asked to take part in high risk projects, researchers can find out:

- whether they would be willing to participate given the risks involved
- what potential participants consider to be the most serious risks and how best to explain these to their peers.

Involving the public early on during a project also helps researchers to design and conduct their research in a way that potential participants consider to be ethically acceptable (Caldon et al. 2010; Koops and Lindley 2002; Marsden and Bradley 2004). It helps researchers to identify:

- ethically acceptable processes for obtaining consent, for example when consent is required at difficult times (Morris et al. 2004) or the process is unusual, for example requiring people to opt out of a trial (Forbes et al. 2010)
- the trial design that is most likely to be acceptable to potential participants (Boote et al. 2011; Edwards et al. 2011)
- the most appropriate times to contact patients to invite them to take part in a study or for follow-up interviews / assessments; based on their own experience, patients will know when this is least likely to cause anxiety or distress (Boote et al. 2009; Forbes et al. 2010)
- any ethical concerns that may be specific to a particular community (Blackburn et al. 2010), which is important when carrying out research with people from diverse cultural backgrounds.

## Improving the process of informed consent

Public involvement is valuable in shaping the entire consent process, not just in writing or commenting on the patient information sheet. This is because the process is as much about the conversation between the researcher and the potential participant as it is about the written information (Donovan et al. 2002; Langston et al. 2005).

Involving the public in designing the consent process ensures that:

- potential participants receive the information they want and need
- the information is delivered in a way that reflects their interests and concerns
- any written or verbal information is clear and accessible.

This makes it more likely that consent will be genuinely 'informed' and that people fully understand what taking part in a project will involve (Donovan et al. 2002).

When carrying out research with people from diverse backgrounds, public involvement ensures that the process of obtaining consent is culturally appropriate and is sensitive to a community's concerns (Bryant and Beckett 2006; Smith et al. 2008; Tetley et al. 2003). For example, public involvement can check that the language used is not stigmatising to people with mental health difficulties or to people with a disability. Involving the public at this stage helps to make sure that the recruitment process is respectful of potential participants.

## Improving the experience of participating in research

Public involvement in research design will help to make sure that the practical arrangements meet the needs of the participants (Hanley et al. 2001; Paterson 2003). This makes it easier for patients / members of the public to take part in research and ensures they are not unduly burdened by their participation. It also shows that researchers respect and value the time given by the participants (Staley & Minogue 2006), for example, by making sure that:

- questionnaires are an appropriate length
- appointments are scheduled at times and places that are convenient for participants to attend
- participants are not asked to undergo too many assessments at one time.

# **Dissemination of the findings of research to both the participants and the wider public**

It is important that the progress and findings of the research are disseminated to participants and the wider public as well as the research community (Evans et al. 2011; Trivedi and Wykes 2002). To inform participants, some research teams produce newsletters to keep people informed of progress, as well as publicising the findings by giving talks to patient groups and publishing lay summaries. This ensures that participants interests are recognised and addressed (Staley and Minogue 2006).

Public involvement in the dissemination of findings to participants and the wider public helps to ensure that information is presented in a variety of accessible and useful formats, and that the questions that patients and other members of the public may have are properly answered (Evans et al. 2011; Trivedi and Wykes 2002).

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## Useful resources

### **INVOLVE Evidence Library – an online database of references that cover:**

- the nature and extent of public involvement in research
- the impact of public involvement in research
- reflections of public involvement in research

[www.involve.nihr.ac.uk/resource-centre/evidence-library](http://www.involve.nihr.ac.uk/resource-centre/evidence-library)

### **Staley, K. (2009) Exploring Impact: Public involvement in NHS, public health and social care research. INVOLVE, Eastleigh**

[www.involve.nihr.ac.uk/posttypepublication/exploring-impact-public-involvement-in-nhs-public-health-and-social-care-research](http://www.involve.nihr.ac.uk/posttypepublication/exploring-impact-public-involvement-in-nhs-public-health-and-social-care-research)

### **INVOLVE (2012) Briefing notes for researchers: public involvement in NHS, public health and social care research. INVOLVE, Eastleigh**

[www.involve.nihr.ac.uk/resource-centre/resource-for-researchers](http://www.involve.nihr.ac.uk/resource-centre/resource-for-researchers)

### **Patient and public involvement in research and research ethics review. Joint INVOLVE and National Research Ethics service (NRES) statement. 2009**

[www.involve.nihr.ac.uk/posttypepublication/patient-and-public-involvement-in-research-and-research-ethics-committee-review](http://www.involve.nihr.ac.uk/posttypepublication/patient-and-public-involvement-in-research-and-research-ethics-committee-review)

### **Tarpey, M. (2011) Public involvement in research applications to the National Research Ethics Service. INVOLVE, Eastleigh**

[www.involve.nihr.ac.uk/posttypepublication/public-involvement-in-research-applications-to-the-national-research-ethics-service-nres](http://www.involve.nihr.ac.uk/posttypepublication/public-involvement-in-research-applications-to-the-national-research-ethics-service-nres)

## About this resource

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