INVOLVE

NHS Health Research Authority

Public involvement in research and research ethics committee review

Purpose

This statement has been developed by the Health Research Authority (HRA) and INVOLVE for researchers who will be submitting applications for ethical review to provide clarity and guidance on public involvement in research and the requirements of Research Ethics Committee (REC) review. It will also be of relevance and interest to research funders and sponsors, organisations providing advice and support to researchers and members of RECs.

The relevance of public involvement to the role of Research Ethics Committees

RECs will draw on the information provided about how the public have been involved for assurances on aspects of the design and ethical probity of the proposed research. In doing so, the REC will consider how the involvement of the public has or will contribute to the following:[1]

- making research more relevant to the people it is trying to help;
- helping to define what is acceptable to participants;
- improving the process of informed consent;
- improving the experience of participating in research; and
- communicating the findings to participants and the wider public.

Based on the available evidence the HRA and INVOLVE believe that research that has involved the public is more likely to be relevant and good quality; and therefore more likely to receive an outright favourable opinion and to lead to better recruitment and retention of participants.

What we mean by public involvement in research?

When we talk about 'involvement' in this statement we mean the public[2] being involved in the research process so that the work [or elements of it] is done ***with*** or

[1] Evidence to support these statements is provided in INVOLVE, Health Research Authority (2016) The impact of public involvement on ethical aspects of research – see supporting reading list.

[2] In this statement we use the terms 'public involvement' and 'involving the public' where 'public' includes patients, potential patients or members of the public including those with known genetic dispositions, carers and people who use health and social care services as well as people from organisations that represent people who use services.

by the public and not to, about or for them. This is not the same as taking part in research as a research participant, or subject of the research, which comes with the protection afforded by regulation and other standards that include REC review to protect the rights, safety, dignity and well-being of research participants[3].

Within the research process, the public may be involved in:

- identifying and prioritising research topics;
- being part of research advisory groups and steering groups;
- identifying outcome measures which are meaningful and relevant to patients;
- commenting on or developing patient information sheets and other documents which are used to communicate with participants;
- commenting on the feasibility of the research design including the burden placed on participants and the levels of risk/distress that participants might be exposed to;
- undertaking research projects; or
- commenting on or helping to develop end of study information sheets for participants and lay summaries of findings.

Is ethical approval required to involve the public in research?

You do not need to apply for ethical approval to involve the public in the planning or the design stage of research,[4] for example helping to develop a protocol, questionnaire or information sheet, being a member of a research advisory group, or preparing an application for funding or ethical review, even when those people are approached for this role via the NHS.

How do I record the involvement of the public in my application for ethical review?

When you submit an application for ethical review for your research, you should fully describe how the public have contributed to the planning and design of the proposed research and will continue to do so in its conduct and management. In reviewing an application, the REC will need to address any ethical issues which may arise from how the public will be involved in conducting and managing the research.

When ethical issues may arise in the involvement of the public

Involving the public in the design and development of research does not generally raise any ethical concerns. This is because they are not acting in the same way as research participants. They are acting as advisers, providing valuable knowledge and expertise based on their experience of a health condition, and/or use of NHS/social care or public health services or in their role as a carer.

---

[3] The HRA website provides further information on ethical review. www.hra.nhs.uk.

[4] This will be made clear in the new UK Policy Framework for Health and Social Care Research, which will replace the Research Governance Framework for Health and Social Care and be issued by the Health Research Authority and the UK Health Departments later in 2016.

However, there are some situations where the involvement of the public may raise ethical concerns, for example, when they will be involved with collecting and analysing data, such as helping to analyse survey data, conducting interviews, facilitating focus groups or recruiting participants.

In these situations, the REC will be seeking assurances that the following ethical issues have been fully addressed by the applicant:

1) The well-being and safety of the *people who are actively involved as researchers.* They may find that looking at and discussing the data or talking to other people with a similar condition 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;

2) The well-being, safety and preferences 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 or concerns for people taking part in a study. A REC will also need to consider any additional issues or sensitivities that may arise for those taking part in the research, for example some patients are not comfortable being recruited by other patients as opposed to staff; and

3) In consideration of the well-being and safety of the *people involved as researchers* and *those taking part in the research as study participants*, the REC will also check that any patient or member of the public carrying out the research has adequate training, support and supervision appropriate and proportionate to the circumstances in the same way as they do for any other member of the research team.[5] They will also consider whether the proposed contribution including any direct contact with study participants is appropriate.

For further information about public involvement in research please go to the INVOLVE website*:* www.involve.nihr.ac.uk

Supporting reading:

INVOLVE (2012) Briefing Notes for Researchers, INVOLVE: Eastleigh.

INVOLVE, Health Research Authority (2016) The impact of public involvement on ethical aspects of research, INVOLVE: Southampton.

INVOLVE, Health Research Authority (2015) Public involvement in research applications to the National Research Ethics Service: Comparative analysis of 2010 and 2012 data, INVOLVE: Eastleigh.

[5] Where the public are involved in collecting and analysing data or in the recruitment or consenting of participants the training they receive should cover confidentiality and giving and withdrawing consent. However, this is rarely if ever likely to need to include training in ICH GCP (International Conference on Harmonisation of technical requirements for registration of pharmaceuticals for human use Good Clinical Practice – www.ichgcp.net).

Faulkner, A. (2004) The ethics of survivor research: Guidelines for the ethical conduct of research carried out by mental health service users and survivors, Joseph Rowntree Foundation.

Staley, K. & Minogue, V. (2006) User involvement leads to more ethically sound research, Clinical Ethics, 1, 95-100.

Nuffield Council on Bioethics (2015) Children and clinical research: ethical issues, Ch 3, Nuffield Council.

National Social Care Research Ethics Committee resource page, Health Research Authority (HRA).

This is an update of the Joint NRES / INVOLVE statement published in 2009.

This publication should be referenced as:
Health Research Authority / INVOLVE (2016), Public involvement in research and research ethics committee review. www.invo.org.uk/posttypepublication/patient-and-public-involvement-in-research-and-research-ethics-committee-review

Health Research Authority

The HRA protects and promotes the interests of patients and the public in health and social care research. We work to make the UK a great place to do research where more people have the opportunity to participate in health and social care research and continue to feel safe when they do. For more information about the HRA visit the website: www.hra.nhs.uk/

The **Research Ethics Service** is a core function of the **Health Research Authority**: www.hra.nhs.uk/about-the-hra/our-committees/res/

INVOLVE

INVOLVE is a national advisory group that is funded by and part of the National Institute for Health Research (NIHR). INVOLVE supports public involvement in NHS, public health and social care research.

Telephone: 02380 595628
Email: involve@nihr.ac.uk
Website: www.involve.nihr.ac.uk

Version 2 (May 2016)