

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

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

Research requires ethical approval as determined by the Governance Arrangements of Research Ethics Committees (GAFREC) and legislation including the Clinical Trials Directive and Mental Capacity Act. The NRES website provides guidance on the requirements for ethical review. www.nres.npsa.nhs.uk.

The ethics committee will not need to consider within its review the active involvement of patients and members of the public in **carrying out** research that involves **no direct contact** with study participants e.g. helping to analyse survey data, postal surveys etc.

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.

What is the relevance of active involvement to the role of research ethics committees?

If patient and public involvement in research is carried out to a high standard, it is more likely to result in ethical research. This is because the research is more likely to be:

- Relevant to the people it is trying to help;
- Beneficial in terms of delivering meaningful outcomes for patients and/or;
- Conducted in a way that is sensitive to the needs of the participants – through better patient information, recruitment processes and general management of the project.

It is therefore in the interest of RECs to promote and support high quality active involvement in research.

For further information about active involvement in research then please go to the INVOLVE website: www.invo.org.uk
INVOLVE is funded by the National Institute for Health Research

Supporting reading:

Boaz, A. (2002) '**Department of Health consultation on research ethics in social care: A summary of the consultation event with social care service users and their representatives**' INVOLVE

Boaz, A. (2003) '**Department of Health consultation on research ethics in social care: A summary of the follow up consultation event with social care service users and their representatives**' INVOLVE.

Chalmers, I. Lancet (2000) 356 774 A guide to patient-led good controlled trials

Faulkner, A. (2004) '**The Ethics of Survivor Research: Guidelines for the ethical conduct of research carried out by mental health service users**' Joseph Rowntree Foundation

Hanley, B. (2004) '**Involving the public in NHS, public health, and social care research: Briefing notes for researchers.**' INVOLVE

Tallon, D. (2000) '**Relation between agendas of the research community and the research consumer**' The Lancet - Vol. 355, Issue 9220, 10 June 2000, Pages 2037-2040

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Version 1 (January 2009)