

PIAG

Patient Information Advisory Group

USING PATIENT INFORMATION AND INVOLVING SERVICE USERS IN RESEARCH

A guide for researchers applying to the Patient Information
Advisory Group



OVERVIEW

The Patient Information Advisory Group (PIAG) is an independent body established to advise the Government about the use of personal information about patients.

PIAG assesses applications by medical and research institutions to use non-anonymised information about patients without their consent under the provisions of Section 60 of the Health and Social Care Act 2001.

PIAG encourages all Section 60 applicants to incorporate user involvement in the development of their proposals. This leaflet outlines why PIAG takes this approach, what value it can bring and what methods might be appropriate.

WHAT IS USER INVOLVEMENT IN RESEARCH?

User involvement means engaging with the views and interests of research participants in the development, design and implementation of a study. This usually involves direct discussions with individuals and organisations who represent the interests of the patient groups that will be the subject of the study.

WHY SHOULD RESEARCHERS UNDERTAKE USER INVOLVEMENT

Generally, the prime purpose of user involvement is to improve the way research is commissioned, undertaken and disseminated because it helps to ensure that research is relevant to patients. From PIAG's perspective, however, it is fundamental for researchers to undertake user involvement because they are using patient information.

A core value of medical research is critical openness: a willingness to discuss every aspect of an investigation and to subject professional assumptions and conclusions to the rigour of peer review. User involvement extends this critical openness to embrace the interests of a wider range of stakeholders who may be involved in, or affected by, a study. User involvement makes research more robust and more effective by exposing research design to diverse views and challenges. Because users have a different perspective on research from that of professionals, their views can be useful at every stage of the research process.

User involvement is also integral to research and information governance. Although most researchers are aware of the importance of respecting the interests of research participants, this does not always extend to a considered engagement with those interests, prior to recruitment. User involvement is a means of respecting and addressing the interests of research participants, and the wider patient community, from the earliest stages of research design.

Within the NHS, user involvement is a statutory duty. Section 11 of the Health and Social Care Act 2001 established a duty to involve and consult patients and the public in service planning, operation and in the development of proposals for change.

SECTION 60 APPLICANTS

User involvement is especially valuable when ethical and related issues are considered, not least because user perspectives help professionals to see their own values and priorities in a different light.

PIAG's core concern is how Section 60 applicants address issues of consent and confidentiality within their proposals.

Your application to PIAG for Section 60 support will only be granted if you can show that the patient and public interest served by your proposal is worth the sacrifice of patient confidentiality demanded by its design. Consulting with users will help you to appreciate the character of this dilemma and potentially minimise its impact.

This quandary exists for all Section 60 applicants. It is an important issue for historical, records-based studies as well as for prospective, patient-focused studies.

If you consult with patients or patient organisations and find that the people you talk to are strongly opposed to your plans, you should rethink your research design to address their concerns. You may, however, encounter a range of views, in which case it is important that you document these views and your response to them. You do not have to act on everything you hear, but it is important that you demonstrate that you have considered everything you hear. User involvement is essentially a dialogue in which the views of both parties should be taken seriously.

Engaging with users gives you an opportunity to make your case before you make it to PIAG. You will have to explain to users exactly why you cannot seek consent and what measures you plan to take to protect information about patients during the course of the study. If users are not persuaded by how you have addressed these issues, they may be able to help you define a more appropriate approach.

METHODS OF INVOLVEMENT

There are many methods of user involvement. As in research design, your choice of methods should be appropriate to the nature and scope of your aims.

Different levels of user involvement can be distinguished, reflecting different degrees of user participation. These include:

- **information-giving, where communication is only from professionals to service users**
- **consultation, where feedback is sought but service users do not participate in decision-making**
- **partnership, where service users are actively engaged with professionals at every stage of the programme.**

Information-giving is important in all research but does not add value to the research process in the ways outlined above. Consultation can take many forms, such as questionnaires, focus groups, interviews and special events, all of which can deliver valuable insights for the researcher. The community and voluntary sector will often offer a relatively straightforward means of consulting with patients and patient representatives about your plans. However, you will need to be assured that the organisations you approach do, in fact, have effective participation from users, and that you are not wholly reliant on people who speak on their behalf. Similarly, you will need to be assured that the individuals you involve are knowledgeable about confidentiality issues and are, therefore, able to give an informed view on the research proposal.

Partnership may sound ambitious but it need not be onerous. The inclusion of patient or voluntary sector representatives on your steering group is a form of partnership that will ensure regular user input to your thinking and ensure that the findings from consultation activities are properly addressed. These roles are sometimes described as ‘critical friends’. For further advice about different methods of user involvement please see *Involving the public in NHS, public health and social care research: briefing notes for researchers* produced by INVOLVE and available on their website www.invo.org.uk.

WHAT IS APPROPRIATE FOR YOUR STUDY?

Any study that involves the recruitment of patients should incorporate significant user involvement. At the very least, patients from the target population should be consulted about the aims and design of the study. An appropriate first step is to consult with local or national patient organisations whose members are likely to be experienced in dealing with requests from health professionals. Such groups should also be able to advise you whether further user involvement is appropriate.

A study that does not involve the recruitment of patients, such as records-based research, must still address all the practical and ethical considerations described above. User involvement is therefore still likely to be appropriate. As in patient-focused research, initial discussions with patient organisations are recommended.

The more sensitive the data the greater the tension between the public interest and patient confidentiality, and the more important user involvement becomes. For example, users may be very unhappy about patient

information remaining identifiable for long periods and so may wish to discuss the range of measures you have defined to protect this information.

If the information you wish to see is of a highly sensitive nature, extra care should be taken to consult with individuals or organisations who appreciate both the implications of using the information and the potential benefits of your proposal.

In any study where significant issues of patient consent and confidentiality arise, on-going lay representation within the study's mechanisms of research and information governance is highly recommended.

Glossary

Lay - people who are not healthcare professionals, this could include both people who regularly use health services i.e. patients, and members of the public who are not frequent users of health services.

Service User - people who use health services i.e. patients and carers.

Where to get more information

Further information about PIAG and the application procedure for Section 60 support is available online at www.advisorybodies.doh.gov.uk/piag

The PIAG secretariat is based at the Department of Health and can be contacted on 0113 397 3095/3378.

Extensive information and advice about involving users in research is provided by INVOLVE, a national advisory group supported by the Department of Health. INVOLVE can be contacted on 02380 651088 or online at www.invo.org.uk

Acknowledgement

The Patient Information Advisory Group would like to thank INVOLVE for their contribution to this leaflet.

To obtain further copies of this leaflet please visit www.connectingforhealth.nhs.uk/publications or call 08453 700760 quoting reference number 2238