



Excellence in Public Health Research

Independent Scientific Advisory Committee for MHRA database research

Patient Involvement Update



INDEPENDENT SCIENTIFIC ADVISORY COMMITTEE (ISAC)

STATEMENT ON INVOLVING SERVICE USERS/PATIENTS AND/OR CARERS

This brief note of guidance has been prepared for applicants, many of whom have said they would appreciate some advice on the 'service user' section of ISAC's protocol application form.

ISAC asks about this aspect of your work because we believe it is important in many cases to include the perspective of people of whom the research is about, alongside the perspectives of clinicians and other healthcare professionals, researchers, statisticians and others. We include it on the protocol form to encourage applicants to think about this aspect of their work.

This could be thought of as a form of peer review. It is an accepted way of working, for instance in the Cochrane Collaboration, and in healthcare research in the UK (see www.invo.org.uk).

We understand that your application does not involve primary research. We are, however, asking you to consider whether input from people with the condition or illness you are researching could add insight to your project planning, protocol development, search strategy, interpretation of the evidence and dissemination of the findings. This type of input could help ensure assumptions underlying your hypothesis and analysis are both scientifically rigorous and reflect the reality of patient behaviour.

Outcomes of such input could include, for example:

- improved understanding of patient behaviour in using different forms of medication (for instance, issues related to adherence (or 'concordance'), use of over-the-counter medicines and interactions)
- Appreciation of issues related to different forms or locations of healthcare provision (primary care and/or secondary care; specialist clinics; home care) which might affect the assumptions underlying the hypothesis and analysis
- patient insights into a hypothesis that could lead to a refinement in the hypothesis or methodology.

No one service user or patient can reflect the full range of opinion on any of these or other matters, just as no one clinician or scientist can reflect all the ranges of opinion in their particular areas of concern.

However, including a perspective from the patient's point of view can help to give a more rounded picture both to the research

proposal and the subsequent analysis and writing up.

There is also no single way of doing this. Different forms of 'involvement' will be appropriate for different types of research topic, and in different locations. You could think about:

- including someone from a relevant charitable or voluntary organization on your research steering group
- developing a list of 'peer reviewers' which includes one or more people from such an organization
- where you are a local body (for instance an academic research team or located in an NHS trust), considering testing your hypotheses with one or more people from a local patient support network. There are many of these, for instance for cancer, stroke, diabetes, and others
- gaining insights from a well researched website, such as www.dipex.org

ISAC understands that involvement of patient and/or carers in research using GPRD is not always possible or appropriate. We will want to know first, that you have given this topic some consideration in developing your protocol and second, what you plan to do (or why you have decided in this instance it will not be helpful or necessary). In commenting on your protocol we will make every effort, where appropriate, to consider what you have told us, and to comment or make suggestions on how this aspect of how your work might be carried out.

ISAC Committee