

National Health & Medical Research Council Public Consultation

Draft Statement on Consumer Involvement in Health and Medical Research

FEEDBACK ON CONSULTATION QUESTIONS

Q1. The aim of revising the Statement is to improve language and accessibility. Are there further improvements that should be considered?

In preparing this submission the Australian Clinical Trials Alliance (ACTA) canvassed views from within the ACTA community, which includes 60 clinical trials networks, trial coordinating centres and clinical quality registries around Australia. Many of these groups have dedicated consumer advisory groups, consumer representatives or other established mechanisms for engaging consumers and the community in their research programs.

ACTA's submission outlines commonly expressed views relating to the purpose and scope of the *Revised Statement on Consumer and Community Involvement in Health and Medical Research* (the Statement), along with examples of feedback on specific elements of the current draft.

The purpose and scope of the revised Statement is not clearly discernible in the current draft. Much of the content that provided context in the 2002 Statement has been removed (for example, a set of objectives) such that it is now unclear for whom the Statement is intended (individual researchers, research institutions, research policymakers or consumers and community members) and whether its purpose is to outline a set of guiding principles, mandatory requirements or measures of achievement/compliance.

If one removes the *Statement Overview* and *Definitions* (presumably intended to serve as an introductory summary and explanatory notes for the full Statement) and everything that follows from the section *Putting the Statement into Practice*, then the Statement itself (to which the former and latter parts of the document refer) has been condensed to the three sections: *Why is consumer and community involvement important?*; *Elements for consumer and community involvement*; and *Levels of involvement*.

Comments:

Why is consumer and community involvement important?

The supporting paragraphs for this section essentially only make the case for the importance of consumer and community involvement in health sector planning, policy development and service delivery; shared decision making at the level of individual healthcare decisions; and in promoting the translation of research into improved policy and practice. There is much that could be drawn from the contemporary literature to make this section more relevant to the meaningful engagement of consumers and communities in the research process, for example, research priority setting, funding allocation, identifying patient-centred outcomes, informing study design and developing recruitment strategies.

The 9 bullet points that follow under *Benefits of effective consumer and community involvement* are central to the Statement but are not given appropriate prominence. For example: ***research being conducted that is relevant to community needs.***

This is a critically important aspect of the Statement. Consumer and community involvement is important at an upper policy level as well as at the research institution and individual research project level. The Statement doesn't address how consumers and communities should be involved in determining government's research agendas and ensuring they align with the interests of the public. For example, How much of the public research dollar should be allocated to clinical versus basic research? How much of the public research dollar should be spent in areas that have a major impact on health and disability in the community, versus less common areas of poor health but in which there is existing scientific excellence?

Elements for consumer and community involvement

This section is extremely broad-sweeping given that it is the central component of the Statement as it is currently structured. According to this draft, there are only two key elements that underpin effective involvement (as the remainder of this section refers to an example of effective involvement – the *NHMRC Roadmap II: Strategic Framework for Improving the health of Aboriginal and Torres Strait Islander People through Research*). These are that:

- ***Active involvement is integral to all stages of the development of research programs, policies, guidelines and strategies.***
- ***Consumers and community members will be included on all decision-making committees.***

Comments:

One of the major challenges for researchers and consumers/communities in creating better partnerships in research is to avoid tokenistic involvement. Such broad assertions could potentially undermine the laudable vision for the Statement. For example, it is not always appropriate for consumers and community members to have decision-making capacity, especially where there is a liability relevant to professional expertise that they are unable to equally share (eg. Scientific Review Committees and Data Safety Monitoring Committees).

As currently worded, these foundation elements directly contradict the point further down the page that says "*The level of involvement selected for any research activity will depend on the purpose of the involvement, the resources available and the type and subject of the research*".

The existing *Resource Pack for Consumer and Community Participation in Health and Medical Research* (the *Resource Pack*) acknowledges this, too: "*The appropriate research method will depend on the question being answered. Similarly, appropriate methods for consumer participation will depend on the type of research. The depth and scope of consumer participation in research is likely to reflect the degree to which the research imposes on consumers.*"

It is not clear how the Statement is intended to relate to the existing supporting documents; *A Model Framework for Consumer and Community Participation in Health and Medical Research* and the *Resource Pack*. Are these to be redeveloped?

Levels of involvement

By removing much of the intended reference content to an appendix (which may not be accessed by many readers of the Statement) this section now lacks useful, readily accessible information about levels of involvement. The inclusion of at least one of the frameworks (including a schematic or graphic representation) outlining levels of involvement endorsed by the NHMRC as examples in the appendix would be helpful.

The assertion that “*To ensure the integrity of health and medical research and accountability to the community, a researcher or research organisation intending to proceed without involving consumers and community members must be able to fully justify that intention*”, is highly ambiguous. Who will researchers and research organisations need to justify this to? How will this be enforced? How will this ensure the integrity of the research and accountability to the community?

Language and accessibility

A range of differing views were expressed regarding the language and accessibility of the revised document.

Comments:

The Statement is more concise and will therefore be more accessible to consumers.

The primary audience of the Statement is not clear. It is therefore difficult to assess whether it is currently pitched appropriately.

The Statement lacks a strong internal logic and is in parts internally contradictory – for example, the last sentence “*Researchers and research institutions may consider the relative cost-benefit of these activities in order to achieve the highest level of consumer and community involvement with available resources.*” Given that much of the research effort in Australia is chronically underfunded, particularly clinical research in which consumers and community members have a high stake, including this as the last sentence of the Statement strikes an odd chord and could be viewed as an ‘escape clause’.

The Statement doesn’t adequately position the involvement of consumers and communities in research within the context of consumer engagement as a key priority within the Australian healthcare system and one of the National Safety and Quality Health Service Standards. Adhering to this standard is well understood and in practice across all accredited health services in Australia. This is a missed opportunity to use the existing resources developed by the Australian Commission on Safety and Quality in Health Care (ACSQHC) and convey equal significance to the engagement of consumers and communities in health and medical research –the majority of which is conducted within (or in partnership with) healthcare services and is an integral component of high-quality service delivery.

The *Statement Overview* indicates that “*the Statement provides key elements for research institutions, researchers, consumers and community members...*” In its current form, the document is likely to be missing all four key audiences by trying to adopt a one-size-fits-all approach to providing information to these distinct groups.

Q2. The draft revised Statement contains five definitions: Community, Consumer, Consumer Representative, Involvement and Stakeholders (refer page 4). Are the definitions satisfactory? Are additional definitions required?

Comments:

Consumer

Shouldn’t include consumer organisations; these should be defined separately.

Doesn’t capture people who access healthcare services but aren’t commonly referred to as patients, such as women accessing maternity care.

By including a general reference to ‘members of the public’, the definition crosses into what is commonly conceived as the community (ie. members of the community and members of the public

are used interchangeably in society) and fails to capture the societal and cultural significance of defined communities that are sub-populations within Australian society.

Adoption of a definition used by, or similar to, that used by the ACSQHC may be helpful:

“Consumers and/or carers are members of the public who use, or are potential users, of healthcare services. When referring to consumers and/or carers, the Commission is referring to patients, consumers, families, carers, and other support people.”

http://www.safetyandquality.gov.au/wp-content/uploads/2012/10/Standard2_Oct_2012_WEB.pdf

Consumer Representative

The last sentence of this definition implies that consumer representatives must be an officially nominated representative of a special interest group (consumer/community organisation). This definition should encompass individuals who partner with researchers to provide a personal lived experience perspective of the particular field of study.

The addition of **Community Representative** would define the role of an individual who has the capacity to legitimately represent the views and needs of a broader group of stakeholders sharing a common interest (a ‘community’ as defined by the current document). This role is very different to that of a consumer representative.

Involvement

Is this definition really required? The Statement itself should be sufficiently well crafted to provide clear outline of what involvement of consumers and communities means. Currently, the definition leads the reader to believe that decision-making is the only aspect of involvement which is contrast with the continuum of involvement later referred to in the appendices.

Research

It would be helpful to provide a definition of research. Are Quality and Audit activities covered by the Statement? Is population-level data collection covered?

Q3. The draft revised Statement outlines the Key Elements that underpin effective involvement and Levels of Involvement (refer page 5). You are invited to comment on the identified Key Elements and Levels of Involvement.

Please consider the relevant comments under Question 1.

Q4. The draft revised Statement includes information about how the Statement should be put into practice (refer page 5). You are invited to comment on this section, including whether additional information should be added.

There were a range of differing views expressed about both the format and context of the three subsections that make up “Putting the Statement into practice”. Again, this relates largely to the absence of clearly articulated purpose, scope and objectives of the Statement.

Comments:

Splitting this section into different sections for research institutions, researchers and consumers/community is excellent and highlights the shared responsibility for increasing consumer/community at all levels.

The bullet points throughout this section are too general and offer no practical support or guidance

to help achieve appropriate and meaningful levels of consumer and community involvement.

The Statement should more clearly articulate the role of consumers and communities in shaping (and arguably driving) the agenda for more Patient–Centred Outcomes Research. There is a need for researchers, funders and health policymakers to have much stronger guidance around patient-reported outcome measurements, and a role for consumers to be leading research to inform future directions in this area.

Specific issues related to the selection and appointment of consumer and community representatives.

The Statement doesn't adequately address the issue of selection of consumer and community representatives or provide guidance to ensure that representatives are appropriately selected to ensure they have the skills and ability to understand the subject matter and have meaningful input. This is a key issue and one that is relevant to avoiding tokenism.

Many institutions and organisations have implemented formalised programs to ensure that volunteers and consumer representatives undergo appropriate screening and training. Miracle Babies (www.miraclebabies.org.au) provides an excellent example of this in action at the community level, and many hospitals would have similar programs that could be provided as exemplars.

The Statement doesn't address the issue of managing self-interest or conflicting views between members of a community or interest group. It is not always the loudest voice that represents the most commonly held view.

It should not be inferred that established consumer organisations are the only legitimate means for identifying consumer representatives. There are other ways that representatives can be legitimately sourced (e.g. public advertisements).

Q5. NHMRC is considering placing Appendix 4: Useful Resources on our website so that stakeholders can access examples of consumer and community involvement in health and medical research. Please tell us about exemplars that should be included.

The Patient-Centred Outcome Research Institute (PCORI) in the US has an exemplary model of engaging consumers in the research process that adopts both a top-down (consumers informing national priorities and funding allocation for patient-centred outcomes research) and bottom up approach (both requirements for, and practical support for, researchers and consumers to partner at the individual study level). The PCORI website has a range of resources that would be useful to consider. In particular, the PCORI Engagement Rubric may be of value to the committee in reviewing the next draft of the Statement and supporting documents.

www.pcori.org