

REVISED STATEMENT ON CONSUMER & COMMUNITY PARTICIPATION IN HEALTH AND MEDICAL RESEARCH

Submission by Research Australia in response to
the NHMRC consultation

September 2014

**RESEARCH
AUSTRALIA**

AN ALLIANCE FOR DISCOVERIES IN HEALTH



ABOUT RESEARCH AUSTRALIA

Research Australia is an alliance of 160 members and supporters advocating for health and medical research in Australia. Research Australia's activities are funded by its members, donors and supporters from leading research organisations, academic institutions, philanthropy, community special interest groups, peak industry bodies, biotechnology and pharmaceutical companies, small businesses and corporate Australia. It reflects the views of its diverse membership and represents the interests of the broader community.

Research Australia's mission is to make health and medical research a higher priority for the nation. We have four goals that support this mission:

- A society that is well informed and values the benefits of health and medical research.
- Greater investment in health and medical research from all sources.
- Ensure Australia captures the benefits of health and medical research.
- Promote Australia's global position in health and medical research.

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REVISED STATEMENT ON CONSUMER & COMMUNITY PARTICIPATION IN HEALTH AND MEDICAL RESEARCH

SUBMISSION BY RESEARCH AUSTRALIA IN RESPONSE TO THE NHMRC CONSULTATION

INTRODUCTION

In August 2014 the National Health and Medical Research Council issued the *Revised Statement on Consumer and Community Involvement in Health and Medical Research*. (the *Statement*) for consultation.

The consultation invited the electronic submission of responses to a number of specific questions. The questions, and Research Australia's responses, are reproduced below.

Where a heading is in inverted commas, eg. **'Why is consumer and community involvement important?'** this is the heading of a specific section in the *Statement* and the comment in the submission relates to that section of the *Statement*.

QUESTIONS AND RESPONSES

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

The current *Statement* appears to suffer from a lack of clarity about (i) whether it is providing guidance or is mandatory; (ii) its audience; and (iii) its purpose.

Mandatory requirement or guidance?

The status of the document in this regard should be resolved. The *Statement* itself says

'In order to receive NHMRC funding research institutions are required to have written policies for accreditation purposes to ensure adherence to the Statement on Consumer and Community Involvement in Health and Medical Research...'

It is not clear that this statement is true. There is no reference to the *Statement* in the 2015 NHMRC Funding Rules, the 2011 NHMRC Administering Institutions Policy, or the 2014 Funding Agreement. The *Statement* is not included in the definition of 'NHMRC Approved Standards and Guidelines.'

There is a reference to the *Statement* in the Australian Government Code for Responsible Research.

'1.13 Consumer and community participation in research

Appropriate consumer involvement in research should be encouraged and facilitated by research institutions and researchers. This Code should be read in conjunction with the Statement on Consumer and Community Participation in Health and Medical Research (NHMRC and Consumers' Health Forum of Australia Inc. 2002).

The Code creates a general requirement for researchers and research institutions to encourage and facilitate consumer and community participation in conjunction with the *Statement*. However, there is nothing in this wording that appears to create an obligation on administering institutions to ensure adherence to the *Statement*.

This is an important point, because the status of the document determines the audience for whom it is written and the language used. If the *Statement* is to be a document that research institutions are required to comply with, then it needs to be written in a manner that gives them a clear idea of what is required of them and how compliance will be assessed. This can either be a prescriptive document which spells out detailed requirements or it can be a principles based document which specifies the broad outcomes that research organisations are required to meet in order to comply.

Audience

If administering institutions are required to comply with specific requirements, then the institutions are the primary audience, and the document should be drafted accordingly as outlined above.

To the extent that the audience is individual researchers, then any guidance provided to researchers needs to be in the context of them being required to work within the processes and structures put in place by their administering institution. The *Statement* could provide them with information designed to persuade them of the benefits of involving consumers and community members and promote active engagement with consumers and community members, including information and examples of how and why this engagement will benefit their research.

If the audience is community members and consumers already working with research institutions, the aim of the *Statement* should be to help them understand their roles, rights and responsibilities. If the audience is prospective community and consumer participants in research, the document needs also to give them a sense of why they should be involved and the kind of contribution they can make.

At the moment the *Statement* does not adequately address any of these audiences.

Statement of Purpose

The document lacks a clear statement of purpose about what it is trying to achieve and why. (Resolving the above questions about status and audience will help to clarify the *Statement's* purpose.)

The *Statement's* vision is outlined in the Overview but further information is required. For example, what does it seek to achieve? Some elements of this are contained in the Overview and hinted at elsewhere in the document but there is no clear statement of purpose. As noted above, determining the audience for the *Statement* will assist in determining and articulating its purpose.

Objectives

The 2002 *Statement* set out a number of objectives: enhanced collaboration through partnerships, access to results and the provision of resources for consumer participation. The current statement does not have any objectives as such. What are the measures by which the *Statement* seeks achievement of the vision of 'Consumers, community members and researchers... improve the health of all Australians'?

'Why is consumer and community involvement important?'

The section of the *Statement* under this heading starts by quoting Item IV of the World Health Organisation's Alma Ata declaration on primary healthcare and then asserts that it is therefore important for researchers to work collaboratively with consumers and community members.

Healthcare and research are two different (although related) things. Just because there are benefits in involving consumers and community members in 'the planning and implementation of their health care' it does not automatically follow that they should be involved in the conduct of research. A case for the involvement of consumers and community members can be made, but relying on the Alma Alta declaration does not achieve this.

The next paragraph refers to wide acceptance of consumer involvement in the *'planning, policy development and service delivery (of health services)'* and asserts benefits that flow from this. Again, this is about healthcare services not research.

The following paragraph suggests that consumers should be involved in health and medical research because they benefit from its translation into research. (There is no reference in this sentence to 'community members'.) It also asserts that as beneficiaries, consumers (no reference to community members) have an interest in the translation of research and that it therefore *'naturally follows'* that researchers should *'incorporate and support sustainable consumer and community involvement.'* It is not at all clear why the self-interest of consumers in the translation of research is a reason for the involvement of consumers in health and medical research. It is a reason why consumers might want to get involved in research but it is not a reason why their involvement is important or valuable.

The real benefits of consumer and community involvement are detailed in the dot points in the final paragraph- i.e community and consumer involvement improves the quality and relevance of health and medical research. Even in this paragraph some of the suggested benefits are more intermediate steps than benefits in their own right- eg.:

- *'effective communication strategies between consumers, community members and researchers'* is not a benefit in itself- greater understanding of the science and the benefits of funding research is.
- *'Improved openness and ethical transparency in the conduct of research...'* What is 'ethical transparency'?
- How is the *'quality of research continuously improved'*?
- The valuing of consumer and community perspectives (by researchers presumably) is not a benefit in itself.

Once again this section seems to suffer from a confusion about the audience. Some of the points seem to be directed to explaining to consumers and community members why they should get involved; others outline the benefits to researchers of involving consumers and community representatives.

Interaction with the Framework and Resource Pack

How does this document interact with the Framework and the Resource Pack?

The *Statement* makes no reference to the Framework document and the Resource pack, and yet these are key to providing the whole picture. Will they be retained? If so, the relationship between the document needs to be clearly explained.

The Appendices

Appendix 1 is about the process of reviewing the Statement and does not appear to be part of the Statement itself. Appendices 2 to 4 appear to be more integral to the statement itself. Will they be included in the final statement?

2. 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?

Definitions of *community*, *consumer* and *consumer representative* are not clear or distinct.

'*Community*' is defined as a group of people with a common interest. This would appear to include groups of individuals with a particular disease.

'*Consumer*' is defined as individuals who are patients, potential patients, carers, and members of the public. It also (somewhat oddly) includes consumer organisations.

'*Consumer representatives*' are defined as individuals who voice the consumer perspective. They can be nominated by a consumer organisation, but also by a community organisation. The expression '*Consumer representative*' although defined, is not actually used in the draft statement. In other parts of the draft statement reference is made to '*consumers and community members*' without reference to them as representatives and as if these are distinct roles. All of this raises some questions.

- Do representatives appointed by consumer organisations and representatives appointed by community organisations play the same role or distinct roles?
- When would it be appropriate to involve a consumer representative appointed by a consumer organisation rather than a representative appointed by a community organisation and vice versa?
- Is it reasonable to assume that for some forms of research, especially basic research, there could be community representatives but no consumer representatives?

If community representatives (appointed by a community organisation) and consumer representatives (appointed by a consumer organisation) have distinct roles it would be useful to define these roles and the difference between 'consumer' and 'community' more clearly.

Guidance could then be provided on when it is appropriate to engage consumer representatives rather than community representatives and vice versa.

Presumably a person can be involved as an individual consumer or community member without representing either a community or consumer organisation. What role does the statement envisage for such a person and how does it differ from a community or consumer representative?

3. 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.

‘Elements for Consumer and Community Involvement’

What is meant by ‘*all decision making committees*’? Some explanation of the scope of this would be useful.

The last dot point under this heading states ‘*This framework is considered to be equally appropriate and applicable to all health research affecting Australians.*’

Some elements of the Strategic Framework for improving the Health of Aboriginal and Torres Strait Islander People through Research go beyond the scope of the *Statement*, for example the requirement for community involvement in the conduct of research. The requirement that all research aims to be of ‘practical value’ also seems inappropriate in the context of health and medical research generally, with ‘practical value’ implying an applied or translational bias. If the aim is to incorporate certain elements of the Strategic Framework into the *Statement*, it would be better to specifically include these elements in the *Statement* (and to re-word them where appropriate).

‘Levels of Involvement’

The first paragraph under this heading refers to ‘*consumers and community members designing and leading research projects.*’ This appears to be a level of involvement that goes beyond what is contemplated elsewhere in the *Statement*.

‘*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 research.*’ While Research Australia agrees, these would seem to be exactly the matters on which the statement should provide guidance, especially if adherence with the statement is to be mandatory. Such guidance is absent from the *Statement*.

And if a researcher or research organisation proceeds without involving consumers and community members, to whom must they ‘*be able to fully justify that intention*’, and what sorts of reasons would provide justification? Lack of funds? Lack of time? ‘We advertised and no-one was interested?’ Again, guidance on these matters is important if the audience for the document is researchers or research institutions.

Reference is made to Appendix 2 and models that illustrate different levels of involvement but there is no guidance as to when and where the different models are appropriate/acceptable.

4. 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.

Once again, the question of the status of this document and the intended audience are raised by the points outlined under this section, which states *'The following points are a guide to facilitating...'* (i.e. non mandatory).

- **'consumer and community involvement must add value to the research'**

Who determines whether it is adding value, and what do you do if it doesn't? If a researcher concludes that consumer and community involvement won't provide any benefit, can he/she decide to discontinue the involvement, or even not involve the community and consumers in the first place? Including further guidance about this in the Statement would be useful.

What are *'inclusive processes'*?

Appendix 4 provides examples, but with the exception of the Lowitja Institute none of the organisations provided as examples undertake research. If the *Statement* is directed at Administering Institutions, providing examples from research organisations would be useful.

Other issues....

What role does the *Statement* play for a researcher as opposed to the institution? Research Australia suggests that these are two very different audiences and that the ways in which an institution involves the community and consumers in its research are different to the ways in which researchers are able to do so. For example, community involvement for an institution can (and usually does) start with the appointment of community members to its governing body as directors, board members etc. Is this what is contemplated by the *Statement*?

If the Administering Institutions are required to have written policies on how they adhere to the *Statement* isn't the researcher's obligation to comply with their institution's policy (and procedures)? If this is the case, what importance should they place on the *Statement*?

'The Statement and Consumer and community members'

This section of the report refers to the *'benefits and shared responsibilities of all parties'*, and then provides a dot point list of these for consumer and community members which fails to distinguish between things that are benefits and things that are shared responsibilities. If the *Statement* is intended for consumers and community members it should clearly describe the role and differentiate the benefits, rights and responsibilities, preferably under separate sub-headings.

‘Resources for Consumer and Community Involvement’

‘*Research Institutions should allocate funds to support consumer and community involvement...*’. Once again, is this mandatory (‘must’) or is it guidance?

‘*...This will ensure that Australian communities continue to support the highest quality national health and medical strategies.*’ What does ‘strategies’ mean in this context? (Without the word ‘strategies’ this sentence is a clear articulation of a reason for encouraging consumer and community participation in research, and it should be given far greater prominence.)

‘*...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.*’ This is an ambiguous statement and requires further explanation and guidance. When is the cost outweighed by the benefit?

Research to benefit overseas communities

How does the *Statement* apply to research undertaken for the benefit of overseas communities, eg. on diseases endemic in the third world?

5. 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.

Research Australia has no response to this question.

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