



Summary Statement on Consumer and Community Participation in Health and Medical Research

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The strategic intent of the NHMRC is to provide leadership and work with other relevant organisations to improve the health of all Australians by:

- fostering and supporting a high quality and internationally recognised research base;
- providing evidence based advice;
- applying research evidence to health issues thus translating research into better health practice and outcomes; and
- promoting informed debate on health and medical research, health ethics and related issues.

It is planned to review this publication in 2006. For further information regarding the status of this document, please refer to the NHMRC web address: <http://www.nhmrc.gov.au>

The Consumers' Health Forum of Australia Inc (CHF), established in 1987, is Australia's peak non-government organisation representing consumers on national health care issues. CHF established policy in consultation with its members, more than 100 health consumer organisations, and other consumers. It provides a balance to the views of government, industry, service providers and health professionals.

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SUMMARY

This *Statement on Consumer and Community Participation in Health and Medical Research* has been developed because many consumers and researchers recognise the contribution that consumers can make to health and medical research and their right to do so. The vision for the development and use of the *Statement on Participation* is:

Consumers and researchers working in partnerships based on understanding, respect and shared commitment to research that will improve the health of humankind.

INTRODUCTION

The Consumers' Health Forum of Australia Inc (CHF) has a long-standing interest in health research and has promoted consumer and community involvement in health and medical research in many different forums. This has included making submissions to the Health and Medical Research Strategic Review (the Wills Review) which was carried out in 1999. The final report of the Review adopted the CHF's recommendations that:

- consumers be given the opportunity to participate in decisions about what types of research should have priority;
- consumers who take part in research be told about the outcomes of that research; and
- researchers involve the community in the research process by disseminating information about the role, benefits and results of research, consequences of new areas of research and ethical issues.

In 2000, the National Health and Medical Research Council (NHMRC) agreed to fund the CHF's proposal to develop a statement on consumer and community participation in health and medical research. The project was conducted as a partnership between consumers and researchers who were represented on the Reference Group for the project, responded to the consultation paper and participated in roundtable discussions.

The consumers and researchers who have contributed to this project have shared their hopes and concerns about consumer participation in research and have learned much about each other's viewpoints. The CHF believes that the *Statement on Participation*, from which this summary is derived, provides the key to developing stronger partnerships between consumers and researchers at all levels of health and medical research in Australia and calls for the NHMRC to continue to support this evolving process.

Consumer and community participation in research

As the users of health and medical services, consumers can provide valuable input to health and medical research. If such research is to continue to provide high quality outcomes, it is important that consumer involvement in research and its ongoing development is facilitated. This includes participation by consumers as equal partners in the development of research goals, questions, strategies, methodologies and information dissemination.

Research methods and results that are open to informed public scrutiny and debate also help to ensure the integrity of research and accountability to the community for the quality of the research.

Consumer participation in research brings with it responsibilities for consumers and researchers — the responsibility to be respectful of each other's knowledge, to share information with each other about research issues, and to be open about potential interests in the outcomes of research (such as a consumer's individual health or the researcher's financial benefits from a funder). The shared responsibility of consumers and researchers is to ensure that ethical requirements are met and that there is value to the research.

Consumers and communities

Consumer participation in health and medical research involves a dynamic relationship that is sensitive to changing priorities in research and to different consumers and communities. In the consultations to develop the *Statement on Participation*, *consumer* and *community* participation were seen as bringing different perspectives to the research.

In light of this, the following definitions were used for the purposes of the *Statement on Participation*:

- *consumer* — patients and potential patients, carers, organisations representing consumers' interests, members of the public who are targets of health promotion programs and groups asking for research because they believe that they have been exposed to potentially harmful circumstances, products or services;
- *consumer representative* — a member of a committee, steering group or similar, who voices the consumer perspective and takes part in the decision-making process on behalf of consumers. This person is usually nominated by an organisation of consumers and is accountable to them;
- *community* — a group of people sharing a common interest (eg cultural, social, political, health, economic interests) but not necessarily a particular geographic association. Within this definition, it is important to recognise that different types of communities are likely to have different approaches to participation in research.

Each person or consumer is likely to fit into more than one community and to contribute to different community views. The term *consumer participation* is more generally used in this document but relevant communities will need to be considered to ensure community participation is encompassed and barriers to participation in research are addressed.

Levels of participation

Consumer participation in health and medical research is mostly in the areas of health services research, clinical research and multidisciplinary research. The potential contribution of consumer participation to scientific discovery has been less recognised, perhaps because this type of research is more often based on the questions of researchers than improving outcomes.

Until relatively recently, consumer participation in health and medical research was primarily as 'subjects', who were not necessarily aware that they were involved in research and were not informed of the outcomes. The approach to research involving humans has changed and ethical considerations as outlined in the NHMRC *National Statement on Ethical Conduct in Research Involving Humans* take into account the welfare and rights of participants in research, including those who may be affected by the research as well as those directly involved. A number of levels of consumer participation in research have been identified.

These range from no participation (which is no longer an acceptable approach) to wider participation, which uses a range of strategies to consider consumers' views. This includes involving consumer representatives in priority setting and decision making, consultation, and the use of research literature that describes people's experiences.¹

Adequate time and budget are provided to allow for community consultation and consumer representatives are provided with links with others in the community so that they are better able to represent community viewpoints.

To ensure the integrity of health and medical research and accountability to the community, a researcher or research organisation must be able to fully justify any decision to proceed *without* wider participation of consumers.

OBJECTIVES TO GUIDE CONSUMER PARTICIPATION

The *Statement on Participation* was developed in recognition of the contribution that consumers can make to research and their right to participate in research. In developing and using the *Statement on Participation*, consumers and researchers share a vision of working in partnerships based on understanding, respect and shared commitment to research that will improve the health of humankind.

The objectives discussed below are based on the consultations. They are intended as a guide to consumer participation at all levels and across all types of health and medical research.

Collaboration

Consumers and researchers will collaborate and draw on each other's knowledge to build on and strengthen the quality of health and medical research in Australia.

There is growing recognition that consumers and researchers have much to gain through collaboration based on the expertise and research experience of researchers and the insights and life experiences of consumers. Benefits from collaboration include:

- the involved community is likely to be better informed, recognise the value of research and have greater understanding of research strategies;
- consumers gain influence over research questions and priorities so that research is relevant to community needs and contributing in a meaningful way to improving health outcomes;

¹ Wider participation also encompasses consumers' research, that is research undertaken from the consumer perspective, by or with consumers, arising out of consumers' needs

- opportunities are provided for researchers to justify the quality and relevance of their research and better account to the community for the funding they receive; and
- an avenue is provided for the continuous improvement of the quality of research.

Partnerships

This collaboration will be achieved through partnerships of consumers and researchers based on mutual trust and shared social responsibility, giving consideration to what each can reasonably expect from the other.

Each partnership will need to be sensitive to its purpose, the personalities and expertise of the people involved and the environment in which it functions. Considering the following issues will help the partners to develop mutual trust and understanding:

- responsibilities that can reasonably be met by each partner;
- accountability to each other, to the consumer organisation's constituency, to the researcher's funding bodies and to society; and
- transparency of the research process.

The *Statement on Participation* includes some principles of partnership that may be of use as a guide but it remains necessary to consider what is fair and appropriate in each situation.

Role of the partnership

The partnership of consumers and researchers will shape decisions about research priorities, specific research questions and design of research projects in a way that recognises and responds to the rights of all voices to be heard.

The potential roles of research partnerships in implementing consumer participation will depend on the level and type of research. The participatory processes should recognise contributions from different points of view or types of expertise. The partnership will also need to consider the research strategies and approaches that might be most appropriate to their purposes.

Information about research

The partnership of consumers and researchers will support the rights of research participants to their own results, be accountable to them for the results of the research, and encourage and facilitate dissemination of balanced information about the research and its results to the community.

The consultation process indicated support for the ethical right of research participants to receive (or choose not to receive) their own results and overall results of the research as outlined in the NHMRC *National Statement on Ethical Conduct in Research Involving Humans*. Partnerships of consumers and researchers using the *Statement on Participation* will be uniquely placed to explore appropriate and sensitive ways of making the results of the research available for research participants in a variety of different research settings.

Partnerships of consumers and researchers may also consider ways of publicising information about research and results that are more accessible to the community than scientific journals or even the internet, which is not available to everyone. Alternatives include lay summaries in annual reports, information sessions held at universities or research institutes, publications in consumer journals and presentations at consumer meetings, books, videos and the media. Consumers and consumer organisations have a particular role to play in this process.

Resources for consumer participation

Consumers and researchers will advocate for the resources needed for effective consumer and community participation in health and medical research.

Allocation of funds for consumer participation in a project's budget should be advocated from early in the development of research projects. Funding should cover both informed participation and informing research participants and the community of research results.

Examples of funding informed consumer participation include training for consumers, providing for them to participate in steering committee meetings, enabling them to consult with other consumers about the research, or acknowledging the consumer groups who participated. Consumers' time and expertise needs to be valued in some way, which will assist with a sense of ownership and responsibility and guard against a tokenistic partnership.

Resources for consumer participation in research should also cover evaluation of the participation in terms of positive social and medical change. The development of tools to measure these outcomes may need to be considered.

PUTTING IT INTO PRACTICE

Facilitating consumer participation

Effective consumer participation in research or priority setting requires that consumer organisations are informed about the project. The consumer organisation should consider the resources available, support offered, the organisation's priorities at that time, and whether the benefits of participation outweigh the disadvantages (for example, 'research fatigue' can be an issue where there is only a small pool of people with a particular condition).

The organisation may choose to vary the way in which it participates depending on the project.

There are a number of issues to be considered to ensure that participation of consumers in health and medical research will enhance individual research projects and overall research directions and that the consumer's experience of participation in research is a positive one:

- avoidance of language suggestive of an underlying superiority of one group (eg 'giving' consumers power or 'allowing' them to sit on an ethics committee);

- understanding and working within consumers' culture (eg it may be culturally important to know who to speak to, what to ask and how best to communicate with the community);
- concerns of participants at different stages of life (eg people with life-threatening illnesses will have other priorities such as spending time with family and young people may need to consider the restrictions of school hours and transport);
- possible biases resulting from individual experience (whether consumer or researcher), which should not be a basis for exclusion from the research group;
- the effects of stigma and stereotyping, which extend to many groups (eg people with mental health problems or disabilities) but should not affect the process of participation.

Continuous improvement of the quality of research

Consumers and researchers are encouraged to consider who will be most affected by the research, others who may have an interest, and how effective consumer participation in a cycle of continuous improvement of the quality of research can be ensured. Health consumers, as the users of health and medical services, have a strong commitment to improving the relevance and quality of health and medical research in Australia. The diagram below illustrates the quality improvement cycle and the following sections list considerations that can guide planning for consumer and community participation and putting it into action.



Deciding what to research

- Have consumers been involved in identifying their issues and concerns?
- Do consumers see how they will benefit from the research?

- Have the people who will be most affected by the research been consulted?
- Who else should be consulted?
- Have consumers been involved in deciding how to consult?
- How have consumers been involved (eg representation on steering group, focus groups etc)?
- Have formalised links been set up between consumer groups and academics?
- Has a flexible collaboration process been established between consumers and researchers?

Deciding how to research

- Has the research project involved consumers in its design? How? Who?
- Does the research proposal have outcomes that will benefit consumers?
- Have consumers been involved in deciding on the research methods?
- Have research methods valued by consumers been included (eg qualitative methodologies)?
- Has a holistic, multidisciplinary approach been taken?
- Have consumers' rights been defined and addressed in the research proposal?
- Are opportunities for consumer involvement incorporated in the implementation plan?
- Has funding to ensure ongoing consumer involvement been sought (including innovative sources)?
- Have consumers' needs for skills development been planned for to ensure effective participation?
- Have strategies to disseminate results to consumers been planned?
- Has an action plan for the research outcomes been incorporated in the design?

Carrying out the research

- Have the consumers involved in or affected by the research been informed of the timelines, boundaries, security and confidentiality, and likely uses of the information obtained?
- Are consumers informed of the research as it unfolds including progress according to schedule, problems and delays?
- Are peer researchers being used wherever possible?

- Are participants in the research project (eg steering committee members) receiving sitting fees for their time?
- Is an action plan for the research outcomes being incorporated into the process?

Letting people know the results

- Are the results available in a timely manner? Have participating consumers been informed about delays?
- Are the results available in layperson and relevant community languages?
- Have the participants and their health care providers, such as general practitioners and pharmacists, been informed about the results?
- Are the results accessible to consumers through a variety of media, not just professional journals?
- Are the results of community interest? Have a range of ways of providing the results been considered (eg newspaper, radio talk-back programs that allow a two-way discussion, programs that allow a regular update, news items on television, newsletters, consumer and community organisations)?
- Has care been taken to ensure that preliminary results are not provided in a way that is misleading for consumers?
- Have consumers been involved in reality testing of the researchers' interpretations and in discussion and evaluation of the results?
- Do consumers and participants have some control over the dissemination of the results?

Knowing what to research next

- Does the feedback loop include implementing the research findings and assessing the outcomes of the implementation?
- Do consumers have questions which the research does not answer?
- Do the target group feedback on the research?
- Have consumers been involved in identifying and considering the limitations of the current research to guide subsequent research?
- Are consumers being supported to take the next step with their own research or implementation plans?
- Go back to the beginning for a continuous cycle of quality improvement in research.