



Statement on Consumer and Community Participation in Health and Medical Research



NHMRC
*National Health &
Medical Research Council*



**Consumers' Health Forum
of Australia**

Statement on Consumer and Community Participation in Health and Medical Research

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Consumers' Health Forum
of Australia

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- 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.

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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.

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

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;
- 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 effect 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.

1. INTRODUCTION

1.1 WHY CONSUMER PARTICIPATION IN RESEARCH?

Research is a powerful tool, and those who control health and medical research have considerable influence over the health care system and a profound effect on the lives of all health consumers and their families.

Health consumers believe they have a great deal to offer health and medical research. It seems clear to them that those most affected and most intimately acquainted with the issues of health and medical services should be involved in its ongoing development. Those who are to benefit (or suffer) from the decisions made by researchers, policy makers and health care administrators should be an integral part of the decision-making process. Their perspective cannot be ignored if health research is to continue to provide best quality outcomes for today's health consumers and the health consumers of the future (Arsenault 1994; Pivik 1997; Entwistle et al 1998; CHF 1999a; Richards 1999; Taylor 2000; Williamson 1999).

Many health consumers see they have the right to participate in health and medical research, not simply as passive subjects or token representatives but as equal partners in the development of research goals, questions, strategies, methodologies, information dissemination and reporting. In this way, research can better serve the needs of its constituents, health consumers and the wider community (Matrice and Brown 1990; CHF 1998a; Wills 1999). A community that is more aware of current health research activities is also likely to provide greater support for research and researchers.

Many researchers also recognise the right of consumers to participate in research that might affect them and the contribution they can make (Chalmers 1995; Goodare & Lockwood 1999; Hanley et al 2001). Most researchers agree that research methods and results that are open to informed public scrutiny and debate ensure integrity of research and accountability to the wider community for the quality of the research they undertake. However consultations to develop this *Statement on Participation* show that researchers want their own expertise in health and medical research recognised and are concerned that their work should not be limited by lack of understanding or onerous processes for involving consumers.

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, 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 the ethics and value of the research.

1.2 Vision

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 research and their right to do so. In developing and using this *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 *Statement on Participation* is intended as a guide to consumer participation, at all levels and across all types of health and medical research in Australia.

Consumers and researchers recognise and fully support the *National Statement on Ethical Conduct in Research Involving Humans* (NHMRC 1999a) (the *National Statement*) which provides a national reference point for ethical consideration relevant to all research involving humans. The primary purpose of the *National Statement* is to protect the welfare and rights of participants in research, including those who may be affected by the research as well as those who are the focus of the research.

This *Statement on Consumer and Community Participation in Health and Medical Research* aims to provide a similar reference point for involving consumers and the community in research and in communicating about the role, benefits and results of research and consequences of new fields such as genomics. It will also include involving consumers in setting priorities across the full range of health issues and building of understanding to facilitate integrating research-based knowledge into policy and practice (based on recommendations made by Wills 1999).

1.3 What is consumer participation in research?

This *Statement on Participation* is intended to further ‘consumer and community participation in health and medical research.’ In developing this *Statement on Participation* some of the key issues canvassed were:

- the role of consumers in setting the research agenda and the research questions;
- moving beyond the notion of informed consent to informing research participants about the outcomes of the research they participate in;
- ensuring that the community has access to research results; and
- greater community involvement in research leading to greater interest from individuals in participating in research and greater support from the community for research.

However consultations showed that people think of consumer “participation” in many different ways:

- participants in clinical trials being fully informed before they consent to participate;

- informing clinical trial participants of progress and final outcomes of the trial(s);
- improving the availability of lay information about research and research results to enable consultation with informed consumers in developing particular research projects;
- researchers being better informed about how to engage with consumers and the community and to communicate with lay people;
- full collaboration between researchers and the community in research priority setting, design and methodology, including participation on research teams, research boards and funding bodies; and
- consumer led research as an important and valuable component of true consumer participation in health and medical research.

These varied views reflect the historical growth of consumer participation. So what do consumers and researchers mean by “participation” in the context of this *Statement on Participation*?

Bastian (1996) describes participation as an active process where participants have at least the potential for significant influence. Real participation implies sharing of decision-making power. Drawing on previous work by others (Arnstein 1969; Birchman et al 1989) she summarises the levels of consumer participation as follows:

LEVELS OF PARTICIPATION	
None	Consumers’ perspectives and concerns not specifically addressed. <i>From Bastian (1996)</i>
Manipulation	Consumers “educated”
Restricted scope	Experts advocating their perception of consumers’ views Possible token “consultation” with consumers
Open involvement	Consumers’ representative(s) representing consumers’ views Consumers possibly consulted
Wide Participation	Consumers’ representatives representing consumers’ views Consumers widely consulted and participating

In order to clarify what “participation” means for the purposes of this *Statement on Participation*, examples of how each of these levels apply to health and medical research are considered below.

None

Historically, consumers have been primarily involved in health and medical research as passive “subjects”. In this model, the consumer is often a “patient” whose role is to comply with the requests made by researchers. Data about them may be used without their knowledge or permission. Subjects are not necessarily aware they are involved in research, and are not informed of the outcomes. Research planning, priority setting and funding do not involve any consumer participation as researchers are considered to be the experts.

For the purposes of this *Statement on Participation*, which complements current ethical principles (NHMRC 1999a), research that is “done to subjects” is not acceptable. Goodare and Smith (1995), in their description of the notorious case of the Bristol “trial” of complementary treatment to help women with breast cancer, clearly show why it is no longer acceptable to exclude consumers from being informed and involved in the research agenda.

In many cases, research has progressed beyond this approach.

Manipulation

At this level of participation a person might be given information to encourage them to participate as a research subject, but only be given part of the story, with no continuing information during or after the research. An individual might be asked to participate in a research steering committee because contact with a particular health interest group might help the researchers with funding or recruitment. Or consumers may be invited to join committees or reference groups but their input is token, their comments are not considered or may even be discouraged, and they are not given voting rights. Their involvement may end as soon as the research is underway.

Many consumers and researchers now recognise the value of moving beyond this level of participation, which is based on assumptions that “experts,” such as doctors and biomedical researchers are the best judges of what research is needed, which does not give consumers voice (Entwistle et al 1998; Goodare & Smith 1995; Hunt 1997; Liberati 1997).

In Australia, individual research participants are protected against some forms of manipulation by the *National Statement on Ethical Conduct in Research Involving Humans* (NHMRC 1999a) which aims to protect their welfare and rights through requiring informed consent. (For debate about how this works in practice, see the discussion under “Restricted Scope”, page 5)

This *Statement on Consumer and Community Participation in Health and Medical Research* flags that low-level participation, or manipulation, is not acceptable in Australia in research priority setting, planning and funding, and identifies some strategies for progressing beyond it. This is consistent with the policy of the Commonwealth Department of Health and Ageing to foster active involvement of consumers at all levels of the development, implementation and evaluation of health strategies and programs as integral to their success (Consumer Focus Collaboration 2001). A similar step has already been taken in the United Kingdom (UK), by the National Health Service (NHS), to ensure that research and development focuses on what is important for patients and users. The Standing Group on Consumers in NHS Research, set up in 1996 as a sub-group of the Central Research and Development Committee, aims to ensure that consumer involvement in research and development improves the way that research is prioritised, commissioned, undertaken, disseminated and used (NHS 1999).

Restricted Scope

Participation with restricted scope might mean that a doctor informs a patient about a clinical trial and recommends participation without encouraging the person to think about the issues, ask questions, and discuss the issues further before making their choice. The informing doctor may not realise the influence they are exerting as a person on whom the patient relies in an ongoing relationship. Restricted participation may also mean that researchers consult with consumers when they are developing research proposals and strategies, but make decisions about research priorities and outcomes based on their own perceptions of the consumers' views, without actually giving the consumers a say.

Although the “experts” at this level of participation are informing and listening to consumers and may believe that they are acting in their best interests, they are still acting for them. Bastian (2000) explains how this must, at times, translate into different value judgements about healthcare choices, attitudes to risks and benefits, and key issues of concern. Indeed the research evidence available, much of which has been accumulated in this framework of restricted participation, may not reflect the major concerns of the consumers who have to make the choices. For example, trials on the effects of healthcare often measure mortality or easily measured outcomes such as diagnostic test results, but overlook key issues of concern for consumers, such as quality of life and long-term effects, so the evidence consumers most need to inform their choices is not available.

This restricted participation should not occur for individual research participants if current ethical requirements for informed consent (NHMRC 1999a) are being met. A consumer should make a voluntary choice about whether to participate in research, based on information provided at their level of comprehension, about the purpose, methods, demands, risks, inconveniences, discomforts and possible outcomes of the research (including the likelihood and form of publication of research results). However the level of debate generated about the acceptable limits of informed consent in medical studies by a series of comments in the *British Medical Journal*, shows that differences in practice still prevail across a range of research

circumstances (Doyal 1998; Tobias 1998; Warnock 1998; Power 1998; Goodare 1998). Perhaps the comment of most relevance to this *Statement on Participation* is from Power, a health advocate, "If informed consent is about the dignity and empowerment of trial subjects and the genuine participation of patients in our health research, then how can this be maximised throughout the trial process?"

Although current ethical requirements go some way towards minimising restricted participation for individual clinical trial participants, they do little to overcome restricted consumer participation in research more broadly. Consumers in Australia are concerned about the effectiveness of laypersons on ethics committees, where they may be outnumbered, and may not have the support of and accountability to other consumers through some sort of representative framework (Bastian 1994; CHF 1998b; McNeill et al 1994). A recent article from the UK also notes that ethics committees meet confidentially, usually with no justification (Ashcroft & Pfeffer 2001), which in effect provides another way of restricting participation and accountability, despite the role of ethics committees in protecting the public and facilitating useful research.

While some researchers fear that scientific integrity and consumer input are mutually exclusive concepts, consumers are now beginning to demand greater input, and research bodies do allow consumers restricted participation while maintaining a scientific distance (Literati 1997). Although restricted participation of consumers on research boards and ethics committees has been regarded as a positive step forward, the research is still distanced from consumers if researchers are choosing and asking the questions.

Open Involvement

Open involvement of consumers in research includes one or more consumer representatives on research steering committees, and perhaps some consultation with consumers to support the consumer representative(s) in their accountability to those they are trying to represent, with a say for the consumer representatives in some parts of the research. These consumer representatives often have no involvement in deciding the priority for this research in the first place. Wider participation, discussed below, would include consumers and researchers involved through a variety of mechanisms in setting the agenda, deciding on what questions to ask and on how results should be described and disseminated.

A number of the consumer reference groups for the first round of coordinated care trials in Australia fell into the category of open participation (CHF 2000). Consumers were invited to participate in the reference groups, once recruitment for the trials began. They gave considerable input, which was valued by the trial management committees, on matters such as how to make appropriate approaches to the participants for the qualitative evaluations and the wording of questionnaires and information materials. However representatives of several of the consumer reference groups were frustrated because they had no input during the planning stages and they only had very limited avenues for support and scrutiny from the trial participants to whom they were accountable. Other consumer representatives

were concerned that the influence of the consumer “advisory” group was limited without a consumer representative on the trial’s management committee.

Wider Participation

For wider participation, Bastian (1996) advocates building up a picture of the range of consumers’ perspectives and actions by drawing on as many of the sources of input and information as possible. For example, in the development of practice guidelines she suggests the use of three strategies in combination to consider consumers’ views: consumer representatives’ involvement in decision making, consultation, and the use of research literature describing people’s experiences. These three strategies are also relevant to consumer and community participation in health and medical research. To raise the standards for consumer participation, consumers need to be involved in decision making, no matter how much (or little) information there is about people’s views to rely on. People are needed who can concentrate solely on what affects consumers in each discussion, without having to juggle and try to differentiate their professional interests. Wider participation takes adequate time and budget for strong community consultation. And consumer representatives need two-way links with others in the community so that they are not left in isolation to represent the whole community’s hopes and fears.

Consumers’ research

Wider participation also encompasses consumers’ research, that is research undertaken from a consumer perspective, by or with consumers, arising out of consumers’ needs. To date, such research has included the evaluation of a service or treatment, the gathering of data that challenged the medical acceptance of ‘facts’ about a condition or treatment, the exploration of consumer views and experiences, and the production of resources. During the consultations to develop this *Statement on Participation*, the importance of consumers’ research in building up a more complete picture of consumers’ perspectives and actions was emphasised, particularly where research participants may be drawn from communities that are disempowered.

For example, Wadsworth and Epstein (1998) report how a statewide representative consumer organisation, the Victorian Mental Illness Awareness Council, engaged in research to explore how consumers’ voices might be heard and how staff–consumer communication about that feedback might be built into the structure and culture of acute mental health services. Stillbirth and Neonatal Death Support (SANDS) Queensland, a community-based self-help organisation for families who have experienced the death of a baby or other forms of pregnancy loss, recognised the growing need for support among women who had experienced miscarriage. This provided the impetus for a research project, in which SANDS participated, to investigate women’s and general practitioners’ perceptions of the quality of care following miscarriage, and the information and other strategies general practitioners needed to enhance their capacity to provide care of high quality (Boyle et al 1998). Bastian (1998) highlights the value of consumers’ research in putting previously unrecognised or misunderstood health issues on the agenda including conditions such as sudden infant death syndrome and Alzheimer’s disease.

Aboriginal and Torres Strait Islander communities research

A particular application of wider community participation in research in Australia is outlined in the *Guidelines on Ethical issues in Aboriginal and Torres Strait Islander Health Research* (NHMRC 1991), under the headings of consultation, community involvement, and ownership and publication of data. Backhouse (1999) provides a practical discussion about the relationship of the community, the funding body and the researcher when Aboriginal communities participate in research. She proposes a way for all parties to benefit from interaction with each other until Aboriginal communities are conducting their own research in their own community.

Consumer participation a right not an obligation

Consumer participation in health and medical research is a right, but not an obligation. At an individual level, participation in health and medical research is voluntary, based on an informed consent process. Participation of consumer organisations in health and medical research should also follow an informed consent process.

To participate in a particular research project or priority setting process, the consumer organisation will need to be informed about the project and consider the resources available, what support is offered, the consumer organisation's priorities at that time, and whether the benefits of participation outweigh the disadvantages. For example, some illness groups consulted in developing this *Statement on Participation* identified that 'research fatigue' can become a problem where there is a small pool of people with a particular condition. A consumer group with a strong interest in consumer advocacy and research explained how they considered participation at different levels for different projects. This might mean a letter of support for the general direction of research, or nominating a consumer representative on a research board to provide a focus on research relevant to consumer interests. Or it might mean contributing to design, direction, conduct and dissemination of information about research activities with potential outcomes of immediate relevance to consumers.

However 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. For example, wider participation should have been considered and appropriately canvassed, with the decision to proceed with a low level of consumer participation based on advice from relevant consumers or community members.

Progress towards wider participation

International research literature shows that researchers are beginning to focus more on the needs, wants and opinions of consumers and how consumers can be involved in research (for example, Entwistle et al 1998). A former clinician and health services researcher, Chalmers (1995), provides insight for doctors and researchers on how consumer participation in pregnancy and childbirth research

has improved the value of research, as well as other examples of more personal relevance. Consumers have been involved in the entire research project in areas such as breast cancer research (Literati 1997; Goodare & Lockwood 1999), and management of chronic illnesses such as Parkinson's disease (Baker 2000) and arthritis (Holman & Lorig 2000).

Consumer advocates and consumer representative organisations in Australia and overseas are informing and empowering individuals regarding their role in health and medical research, including best-practice principles. Key examples are in HIV/AIDS research (McCallum 1999), breast cancer research (Breast Cancer Action Group 1998; Erikson 1995) and mental health service research (Pinches 1999). Positive outcomes include people with HIV/AIDS, and the groups that represent them, participating on national research decision making bodies and on the reference groups of national research centres in Australia (for example, Dowsett & Davies 1998). Women with breast cancer have worked to institute an unprecedented multi-million dollar breast cancer research project within the US Department of Defence, which includes participation by consumers at the peer review research table (The National Breast Cancer Coalition 2001).

The value of models of partnership and greater community participation has become more widely recognised as researchers and consumers alike become more aware of the contribution consumers can make to research design and outcome.

1.4 Partnerships of consumers and researchers

The consumers and researchers consulted in the development of this *Statement on Participation* agreed that building effective partnerships between consumers and researchers was the key to consumer participation in health and medical research.

“Partnership” is a word used frequently in the literature about consumer participation in health and medical research. For example, Macaulay et al (1999) discuss participatory research as incorporating the knowledge and expertise of the involved community through collaboration of researchers and community members, mutual education, and acting on results developed from research questions that are relevant to the community. This partnership between researchers and communities is defined as “a mutually respectful relationship based on sharing responsibilities, costs, and benefits leading to outcomes that are satisfactory to all partners.”

Pivik (1997) stresses understanding of what constitutes successful partnerships as an important component in collaborative research. The explanation of a partnership she uses is “a relationship involving two or more organisations that have agreed to work cooperatively. With the common goal of addressing a human/community issue or set of issues, a partnership requires the sharing of power, work, support and information with others. Through mutual agreement and shared values, a partnership accrues benefits to each partner as well as the community, while fostering an achievement of ends which are acceptable to all participants.”

The *Guidelines for Research in Partnership with Developing Countries* (Polanka 1997) are also worthy of consideration, comprising 11 principles with a focus on action. These principles pick up the need for transparency which has been identified as critical for research:

1. Decide on the objectives together
2. Build up mutual trust
3. Share information, develop networks
4. Share responsibility
5. Create transparency
6. Monitor and evaluate the collaboration
7. Disseminate the results
8. Apply the results
9. Share profits equitably
10. Increase research capacity
11. Build on the achievements.

The nine principles of sustainable partnership developed by Birch (1999), as discussed by Murphy at the 9th National Conference on Volunteering, Adelaide 2000 (see box) were also suggested as a guide to what the partnership between researchers and consumers should encompass.

NINE PRINCIPLES OF SUSTAINABLE PARTNERSHIP

- 1. Recognition.** Effective partnerships require each partner to recognise their own organisational culture in order to be able to understand the other partner more effectively. Recognition of self-interest and others' interests are crucial.
- 2. Respect.** Partnerships require respect for each other, especially in the acknowledgment of difference in each of the organisations. This respect requires willingness to share skills, knowledge, personnel and resources – so that while the organisations may not be equal in size or finances, there is always a spirit of equality defining the partnership. This may not come easily at first.
- 3. Review.** Partnerships will not survive or develop without reflection and review. Partners need to be able to listen to each other, and speak out when necessary
- 4. Resilience.** Partnerships need to cope with the challenge of internal and external pressures. This requires effective and understanding leadership, trust, honesty and integrity, adaptability, sensitivity, flexibility, all grounded firmly in ethically and morally acceptable behaviour.
- 5. Responsibility.** Each partner needs to recognise and accept responsibilities for their part in the relationship – beyond the resource implications of a particular project, or beyond their own self-interests.
- 6. Reward.** All effective partnerships should result in rewards for all partners. These rewards may not always be equal among the participants. This is a commitment to mutual benefit which requires 'capital' to be thought of in ways other than financial.
- 7. Resolve.** Partnerships will always be faced with competing claims on priorities and it is therefore crucial that partners are able to maintain their resolve in order to keep the partnership going, even in times of adversity.
- 8. Relevance.** Partnerships should not be seen as one-off activities. They should become routine parts of the core business of the organisation. This can be achieved through the partnership becoming increasingly relevant for all participants, by opening up new opportunities, building on existing ones, and by shaping and adding to (not simply reflecting) social, cultural and economic value.
- 9. Reference.** Partnerships need to be able to set measurable objectives and to set standards against other partnerships and other social, cultural and economic priorities. They need to be able to share their experiences – to reference themselves, and to be referenced by others. They need to be able to distinguish between the partnership itself and specific program objectives. The former will always be long term while the projects themselves may have relatively short lives.

From Birch (1999)

Approach

What is meant by “partnership” is not defined in this *Statement on Participation*, as each new partnership of consumers and researchers will need to be sensitive to its specific purpose, the personalities and expertise of the people involved and the environment in which it works. Further, a partnership is not a static relationship but a continually evolving one. Consumers and researchers are encouraged to use the principles of partnership discussed above as a guide, but to consider what is fair and appropriate in each situation.

The vision for this *Statement on Participation* sets the focus and the challenge for each partnership:

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

Chapter 2, includes specific objectives to be met by consumers and researchers participating in health and medical research, and provides suggestions for how research partnerships might work in practice. The checklist in Chapter 3 and the strategies for overcoming barriers to participation in Chapter 4 support a continuous process of learning and improvement within research partnerships.

1.5 Consumers and community

This *Statement on Participation* will not mean the same thing to all people, nor should it be applied inflexibly. Consumer participation in health and medical research involves a dynamic relationship that is sensitive to changing priorities in research, to different consumers and communities, and to the requirements of different types of health and medical research. This Section outlines the approaches taken to the use of the terms “consumers” and “community”.

In the initial consultations to develop this *Statement on Participation*, a number of different interpretations of the words “consumer” and “community” were raised. “Consumer” and “community” participation were seen as bringing different perspectives, which it may be helpful to consider separately.

Some people interpreted “consumer” as an individual or a layperson. There was also concern that consumer participation in health and medical research might be interpreted as only applying to the participants (or potential participants) in clinical trials if linked too closely to ethical principles for research involving humans. However many people saw “consumer” as a member or a representative of a particular interest or disease group, who may be well placed to give input relevant to their interests, but may not be representative of the wider “community”.

Others thought “community” was too narrow, because they saw society (and “the public”) as made up of a number of different “communities” which might be based on ethnic background, disease group, residential suburb or educational level. It was

considered important to be clear about what is meant by “community”, as the term is often used to mean everything that is not “government” and this usage masks differences and divergent interests among Australians. Concerns were also raised that the community members who were most likely to become involved in research may be articulate and well-educated, or professional people themselves, who may fail to represent the wider “community”.

Consumer

In this *Statement on Participation*, the term “consumer” will be used to mean “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”. This definition was adopted by the National Health Service (NHS) in the UK at a major public conference entitled “Research, What’s in it for me?” in 1998.

Consumer representative

Another term, “consumer representative”, will be used to mean 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 (CHF 1999b).

Community

In this *Statement on Participation*, “community” will be used to mean “a group of people sharing a common interest – for example, cultural, social, political, health, economic interests – but not necessarily a particular geographic association” as used, for example, by Macaulay (1999).

However it will also be important to keep in mind more fundamental distinctions between communities that may affect their participation in health and medical research. Dowsett and Davies (1998) in their consideration of HIV/AIDS research, differentiate between communities sharing a common interest, which may often be brought together by factors outside their control, and “deeply structured communities”. For example, they suggest that people with haemophilia who are reliant on blood products have a real need for collective action, which in turn leads to the development of alliances, networks and support structures. However some communities, such as indigenous Australian communities or some groups of people from culturally diverse backgrounds, for whom race (and racism) have contributed to an almost insurmountable distance from other Australians, will already have a profound, historically formed community structure in which they operate. How these communities participate in research and the approaches they take are likely to be quite different.

Simplifying the wording

People within either of these interpretations of the word “community” would be “consumers” in the broad meaning adopted in this *Statement on Participation*. Each person or consumer is likely to fit into more than one “community”, and to contribute to different “community” views depending on which community is participating in health and medical research.

For the purposes of this *Statement on Participation* the term “consumer participation” is generally used in developing the objectives for health and medical research in Section 2 and focusing on the sorts of issues that will need to be addressed in the checklist in Section 3. However in meeting these objectives or using the checklist, relevant communities will need to be considered to ensure “community participation” is encompassed and any barriers to their participation in health and medical research are addressed.

1.6 Health and medical research

During the consultations to develop this *Statement on Participation*, a number of questions were raised or assumptions made about the types of research in which consumer participation might be appropriate. Both researchers and consumers recognised the contribution consumers could make to research into delivery of health services and qualitative projects. It was also generally acknowledged that health consumers and their families have a role to play in research into disease cures, treatment and prevention, and a number of respondents assumed that consumer participation would mainly apply to clinical research, in particular, clinical trials. There were also a number of suggestions that improved consumer participation in health and medical research would support a broader range of research approaches considered more likely to effect positive changes in health and health care. In particular, the value that consumers place on qualitative research, and the aspects of health that are not easily “boxed” or expressed as facts and figures, was raised.

The potential contribution of consumer participation to scientific discovery was recognised less frequently, perhaps because this type of research is more often based on the questions or curiosity of researchers. Concerns were raised, primarily by researchers, that research should not all be focused on immediate improvement in health outcomes, as many of the major breakthroughs in health and medical research start from knowledge seeking or curiosity driven projects. Consumer organisations were also concerned that research should not be done for the sake of research, but to improve health outcomes for consumers. However where consumers have been consulted in setting research priorities they value scientific research that may result in the discovery of a cure rather than a treatment for symptoms (CHF 1999a; National Breast Cancer Coalition 2001).

Although “pure” research, which involves systematic investigation to establish facts, principles or knowledge through prospective collection of information to test hypotheses, may involve more scientific expertise in its execution, consumers still

have the right to give their informed input to strategic priority setting, direction and design.

In the literature, consumer participation is reported primarily in the areas of health services research, clinical research and multidisciplinary research.

Health services research

The value of the users of health services participating in provision of health services and in setting priorities for health services is frequently recognised. Indeed Obermann and Tolley (1997) in their survey of all health authorities in England, Wales, and Scotland found that 75 per cent of health authorities wanted to see more input in priority setting from the public. Richards (1999) writes: "A revolution is underway. After decades of patriarchal provision of services governments are now accepting that patients should have a say in what is provided. Debates on priority setting have brought the case for public participation in difficult healthcare choices sharply into focus."

Clinical research

The role of consumer participation in clinical research is also discussed widely in the literature, perhaps because it reflects the search for disease cures and treatments that characterise the doctor/patient relationship. Coulter et al (1999) reference several clinical areas where patients have been shown to benefit from a more participatory consultation style (including hypertension, breast cancer and diabetes) and emphasise the need for high quality patient information and training in communication skills and techniques for clinicians to promote shared decision making. Consumer groups often form around specific disease areas, and facilitate consumer participation in clinical research through links with researchers or through developing consumer-focused research themselves (a series of examples are included in Matrice & Brown 1990). The substantial funding of clinical research by pharmaceutical companies may also contribute to higher consumer and community awareness about this type of research.

Hanley et al (2001) in a recent survey of clinical trial coordinating centres in the UK, found that consumer involvement in the design and conduct of controlled trials seems to be growing and welcomed by most researchers. Such involvement was seen by the researchers as helping to refine research questions, improve the quality of patient information and make the trial more relevant to the needs of patients.

Multidisciplinary research

Consumers also place considerable importance on multidisciplinary research to explore ways of improving health outcomes, with a broader focus on the whole of the person, rather than treating the disease in isolation (CHF 1999a). This type of research is only now beginning to be recognised in the health and medical research literature. For example, McGrath (1999a) describes an Australian initiative to establish a permanent psychosocial research program on leukemia and associated

haematological disorders to inform service and policy development for patients and their families, but notes the “dearth of psychosocial material accessible on these diagnostic groups”. She emphasises that most of the current information available focuses on scientific medical research, despite the indications that patients and their families from these diagnostic groups are vulnerable to the stress of extraordinary demands from both the disease and the therapeutic regimens to treat it. The emphasis of her work is a reference point for medical social work practitioners, but it clarifies why the *Statement on Consumer and Community Participation in Health and Medical Research* must also recognise multidisciplinary research.

Approach taken

Traditionally, biomedical researchers have worked within a culture of hypothesis-driven research, and criteria for research funding have been developed on the assumption that this approach will be used. Public health research and research into service delivery have generally adopted a more qualitative research approach which is now more widely recognised by funding bodies. These different research cultures, which can make valuable contributions to health policy and outcomes, all have a place and are worthy of support. Constructive criticism, peer review and public accountability will enhance the quality of all research.

In furthering consumer and community participation in research, it is necessary for consumers and researchers to consider together the research strategies and approaches that might be meaningful. Researchers need to explain in plain language why they think a particular research strategy should be taken. Consumers need to be prepared to recognise the researchers’ expertise, but also to clearly identify any issues of importance to them that will not be addressed sufficiently or may need to be better clarified. Both groups need to recognise that one research approach will not answer all their questions.

Consumers and researchers are encouraged to think about who will be affected by the research, others who may have an interest, and how to ensure their effective participation in a cycle of continuous improvement of the quality of all research.

2. OBJECTIVES

The vision for this *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.

Much of the discussion by the consumers and researchers who contributed to the development of this *Statement on Participation* focused on articulating achievable objectives to assist others in taking up the challenge of effective consumer participation in health and medical research. These objectives are intended as a guide to consumer participation at all levels and across all types of health and medical research in Australia. The discussion of each objective considers the benefits and concerns raised in the consultations that will need to be considered in the development of effective partnerships, with some suggestions as to how this might be done. Key areas where additional support and capacity building may be required are also identified.

2.1 Collaborating to improve quality

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 a growing recognition that consumers and researchers have much to gain through collaboration in health and medical research. While researchers contribute their expertise and research experience, consumers have their own insights and life experiences to contribute, which may differ from those of health professionals and researchers. Both consumers and researchers are therefore able to contribute to the research cycle of questioning, then attempting to find answers, which will in turn lead to new questions.

Benefits for researchers in collaborating with consumers include a better informed community, more likely to recognise the value of research and offer public support, better able to understand why particular research strategies need to be followed and more prepared to participate in research that is seen as relevant. Benefits for consumers in collaborating with researchers include influence over research questions and priorities to ensure that research is relevant to community needs but, most importantly, contributing in a meaningful way to improvement in health outcomes.

For example, collaboration between researchers and the community provides the basis for meaningful debate about the benefits and risks of new technologies, such as stem cell research or gene technology research, where new ethical questions and challenges to community values emerge. This can help to balance sensational descriptions of such technologies given in the media.

Collaborations may occur in a range of ways, such as:

- research institutes involving consumer representatives in board discussions and decisions about such research issues
- researchers explaining (in lay terms) the potential risks and benefits they see in applying these new technologies to their specific research questions at information evenings or university open days for interested community members, including potential research participants and benefactors.

Through such approaches, consumer representatives and community members are also able to raise questions and contribute their concerns about the new technologies so that researchers become better informed of the range and complexity of community views.

Collaborations between consumers and researchers would also provide opportunities for researchers to justify the quality and relevance of their research and to account to the community for the funding they receive from the public purse or from donations and benefactors. Again this would involve researchers explaining their work and its importance in lay terms and listening to and addressing the questions, concerns and suggestions of people in the community who are effectively paying for the research and likely to be most affected by its outcomes.

Suggestions for ways to foster this collaboration include funding bodies giving weight to research proposals developed in consultation with consumers, consumer representation in decisions about funding allocations, and requirement for some form of lay reporting as a condition of funding. For example, research reports in lay terms for inclusion in annual reports are already a requirement for recipients of Cancer Council research funds.

Collaborations between consumers and researchers provide an avenue for the continuous improvement of the quality of research, similar in principle to the well-accepted peer review process, but with consumers and researchers questioning and challenging each other and looking for new approaches, interpretations and opportunities to ensure the integrity of research.

2.2 Effective 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.

This objective recognises that there are challenges for consumers and researchers in collaborating with each other, which the people consulted in developing this *Statement on Participation* believed would best be overcome through the development of effective partnerships, although there was some concern as to what these partnerships might mean. The approach to partnership between consumers and researchers in health and medical research is discussed in Chapter 1. Partnership is not defined in this *Statement on Participation* in recognition of the

differing challenges that each partnership may face, and the need for flexibility and innovation as each partnership evolves.

Many of the challenges to developing research partnerships raised in the consultations related to the rights and responsibilities of consumers and researchers and how to balance these in the sharing of power and decision making within a partnership. Consumers believe they have rights to hold power over what is done to them, what is researched, how it is researched and how the research is used. Researchers are concerned that empowering consumers should not unfairly limit their capacity to carry out research by imposing requirements that they are not able to meet. They are particularly concerned for it to be recognised that the natural curiosity of an individual researcher may be a driving force towards outcomes that have never been explored, and that basing research priorities only on the likelihood of tangible improvements in health may limit potential medical breakthroughs. Researchers need the right to use their own skills and follow their own intuition, while maintaining the rights and role of consumers in this process.

The key to addressing these challenges was seen as the building of mutual trust and understanding within each partnership through considering issues such as:

- who the consumers represent and their accountability to their constituency;
- what the consumers can realistically bring to the partnership;
- how the consumers and researchers will be accountable within the partnership;
- how to ensure transparency of research processes; and
- researchers' funding benefits and obligations.

Sharing social responsibility for the work of the research partnership, while taking into consideration what consumers and researchers can reasonably expect from each other, will also contribute to the building of mutual trust. Researchers will have obligations to their organisations and to funding bodies. Consumers will be accountable to the constituency they represent. Partners will be accountable to each other, but they must also share accountability to the society in which they are working. Informing the community about the results of research is a key aspect of research (see Section 2.4).

To fulfil its social responsibility, the partnership will also need to consider ways of ensuring equitable participation. Participation in health and medical research should not be limited to well-informed members of the community, or those who are easiest to work with. The partnerships must also take responsibility for ensuring that people who are already disadvantaged in their ability to participate in decisions about their health care are not further disempowered. Special consideration will need to be given to ways of maximising participation in research involving children, people with mental illness, people in dependent relationships, people who do not speak English, and so on.

The partners will need to consider how to enable participation, empower the partners and reach mutually agreed, transparent goals and processes, as the partnership evolves. As well as the principles and approaches to partnership discussed in Chapter 1, there are a number of tools available to assist in this process (see Appendix 1). Some of the frequently raised barriers to consumer participation in research (such as not being sure about which consumers to ask) are discussed in Chapter 4. Informed participation is also recognised as important to the partnership and ways to provide information in lay terms about the current research status for consumer partners and their constituencies will need to be considered early in the development of the partnership. Researchers will also need to be informed about ways of engaging with consumers and providing lay information (see Sections 2.4 and 2.5).

2.3 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 fair way that recognises and responds to the right of all voices to be heard.

This objective identifies the potential roles of research partnerships as they consider the most effective ways of implementing consumer participation in health and medical research at different levels and in different research areas. Further, the objective guards against participatory processes that are selective or token, or that fail to recognise contributions from different points of view, or types of expertise.

For example, a national committee setting research priorities may seek nominations for consumer representatives from national peak consumer organisations and provide resources for these consumer organisations to consult with their members, as well as funding public consultation about national research priorities. Decision-making committees of funding bodies may seek nominations for consumer representatives relevant to the funding area, for example from specific disease of population groups, and provide resources for them to consult with their constituencies to provide input on community relevance of proposed research directions. Institutional research committees may focus on their accountability to the community that they serve, ensuring that local community members are involved in their specific research programs through information exchange. At the research project level, researchers may involve representatives of self-help groups of people likely to be affected by the research to ensure that they are measuring key outcomes for consumers and that information provided to participants is appropriate and understandable.

The nature of consumer participation will also vary with the type of research that is being conducted. For example, research to improve a mental health service may directly involve research participants who use the service as partners. Representatives of relevant illness or self-help groups may provide an effective means for consumer participation in clinical research or even applied gene technology research. However consumer participation in basic research may

involve the researcher(s) or research institutions building their accountability to society for the direction of their research through information exchange and discussion with people from the wider community, as well as with their peers.

Consumer participation in breast cancer research has become a reality, in Australia as well as overseas (Reaby 2000; Goodare & Lockwood 1999; National Breast Cancer Coalition 2001) and provides a useful model. One of the most important changes has been acceptance of the idea that breast cancer survivors must have a say when policies are formed and decisions about research funding are made. Basic scientific and leadership training to empower and inform consumers and patients so they can effectively and responsibly influence decisions related to breast cancer research was a major contributor to this change (Liberati 1997; Goodare and Lockwood 1999). Liberati concludes “The challenge now is for the medical profession to develop alliances with consumers to move forward toward a wider recognition of the uncertainty and weaknesses of medicine and the biases in the process of setting research priorities”.

Partnerships of consumers and researchers are encouraged to consider who will be most affected by the research, others who may have an interest, and how to ensure effective consumer participation in a cycle of continuous improvement of the quality of research. After all health consumers, as the end users of health and medical research, have a strong commitment to improving the relevance and quality of health and medical research in Australia.

2.4 Informing people about research results

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.

This objective explores the role of partnerships of consumers and researchers in supporting and delivering the rights of research participants to their own results and the results of the research in which they participate. It also highlights the social responsibility of the partnership to provide information about the research and its results to the community.

The *National Statement on Ethical Conduct in Research Involving Humans* requires that researchers inform participants of the outcome of research and undertake a process of publishing their results in scientific journals (NHMRC 1999a). This *Statement on Consumer and Community Participation in Health and Medical Research* supports the ethical right of research participants to receive (or choose not to receive) their own results and overall results of the research. Further, it recognises that partnerships of consumers and researchers developed to further consumer participation in health and medical research will have opportunities and a social responsibility to influence and improve the ways in which information about research results is provided to research participants and the community.

Information for research participants

How and when research participants will receive information about their own results and the overall results of the research is important for partnerships of consumers and researchers to consider in planning research projects, taking into account any limitations such as experimental design, timeframes for finalising data and so on. This information will assist people in making an informed choice about whether to participate in the research. The partnership will also need to consider what the implications of research findings may be for individual research participants, and plan for appropriate counselling, treatment or referral as required. Participants will also need to be given information to help them understand how their own results relate to the overall results of the research.

The partnership will be instrumental in ensuring that the results of the research are made available to participants when the research is completed. It will need to consider timing, content and effective ways of informing people about progress, any reasons for delays, and the results of the research. Even if the results are provided in “understandable” language and format, there are still likely to be questions, so the partnership may consider having someone familiar with the project on hand to answer questions, and other ways of disseminating information (eg through relevant consumer groups). An interpreter will also be essential for people from non-English speaking backgrounds. The expectation is for interactive and appropriate sharing of knowledge.

Perhaps the most frequently cited example of the need for research participants to know the results is the paper by Goodare and Smith (1995) on the Bristol breast cancer trial. Patients knew nothing of the results until they heard on the evening news that those of them who had been to the centre conducting the trial were twice as likely to die and three times as likely to relapse as women who had not been to the centre. Although the interpretation of the results in the media was flawed, the women paid a high emotional cost and had no opportunity to question those who conducted the research because they were not informed of the results first.

The right of a clinical trial participant to the results of the research is seen as a basic right by consumer groups (McCallum 1999; Breast Cancer Action Group 1998) and is seen generally as an ethical requirement (NHMRC 1999a). However during the consultations to develop this *Statement on Participation*, practical and ethical questions for researchers were still raised, as they are in the literature (Marshall 1996; Snowdon et al 1998). Snowdon et al conducted a study on the views of parents about feedback on trial results in a sensitive trial of experimental ventilatory support in critically ill babies. They showed that the feedback of results of randomised controlled trials can be an open and inclusive approach to participation in medical research, with the procedure for offering feedback considered at the start of the trial. However they suggested that similar evaluation should be done in a variety of contexts.

Partnerships of consumers and researchers using this *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. Some guidance on strategies to try may be derived from collaborative research, which already has a stronger focus on ensuring that consumers know about the results of research they have participated in, for example, Pivik (1997). This is a major strength of consumer led research (for example see Short [1998] on the Australian consumer research development program).

A particular area of difficulty raised during the consultations to develop this *Statement on Participation* was sponsored research, where the funder rather than the researchers may have control over the release of results. This is another area where partnerships of consumers and researchers in health and medical research may be able to exert influence. Although there are mechanisms to keep trial investigators informed of progress and results, there are no such mechanisms for keeping research participants informed, nor is this required by the regulatory guidelines in Australia. Further, although current ethical guidelines generally support provision of the results of research to the participants, as discussed above (NHMRC 1999a), in practice it would appear that institutional ethics committees may not follow up to ensure that this occurs.

Information about research for the community

Partnerships of consumers and researchers will be well placed to go beyond ethical requirements for reporting and consider a range of ways of publicising information about research and results that would be more accessible to consumers than scientific journals or even the internet which is not available to everyone. Numerous suggestions were given by consumers and researchers during the consultations to develop this *Statement on Participation*. These included 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 were suggested as having a particular role to play in this process as “interpreters.”

The role of the media, although recognised as extremely important during the consultations, was questioned as difficult to harness constructively except through targeted proactive relationships with relevant media workers, for example through the Australian Medical Writers’ Association. Partnerships of consumers and researchers nationally may need to consider ways of improving the skills of consumers and the community generally to question media reports and to analyse their validity, as well as consider developing and publicising places for people to go for an unbiased evaluation.

National research registers, including both positive and negative results, were often suggested as an effective way of making information more readily available for consumers. Another variation on this was a directory of information resources, or an index of projects with easy to understand access points. This type of directory

was also seen as useful for communities of non-English speaking background, with the support of facilitators who could inform people about research projects in their native tongues. However ways to overcome barriers to communication such as literacy, spoken language and cognition or communication disorders, will need particular consideration in all aspects of reporting. For example, the Australian Research Centre in Sexual Health and Society employs a community liaison person to develop innovative ways of communicating the results of the Centre's work to research participants and communities.

Some researchers had concerns that they were already expected to go through a highly demanding process to have their results published in refereed medical or scientific journals, and that wider dissemination of results would constitute an unreasonable burden for many who were already struggling with funds. In addition, many researchers saw translating research findings into understandable lay terms as a challenge (see Section 2.5). However guidance is now becoming available for researchers and health care professionals on how to provide better information for consumers in written form (Coulter et al 1998; NHMRC 1999a; 1999b), with a focus on producing information materials which start with needs defined by consumers. There is also a range of published literature on collaborative research and participatory research, where discussing and informing consumers about research is part of the research. For example, Macaulay et al (1999) summarise a number of community and researcher collaborations in North America and Europe.

The Cochrane Collaboration involves consumers in its review process and also aims to help consumers understand and use health care research (Bastian 1994; Cochrane Collaboration 1996; 1998). Consumer groups also contribute to providing the results of research to the people who are most likely to be affected (Oliver 1995; Pivik 1997). The internet has provided opportunities for many consumers to access health information for themselves, but many consumers are looking to their health care providers for support with evaluating the information (O'Connor & Blackmore 2000). Some consumer organisations and researchers have begun to develop criteria for evaluating the health information from the internet which includes promoting authoritative websites. Commens (2001) also provides a recent discussion of some of the issues of transparency associated with pharmaceutical industry sponsored research, such as publication bias, confidential payment arrangements and public accountability for results including adverse effects.

2.5 Resources for consumer participation

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

Some of the resources needed for effective consumer and community participation have been identified in the discussion of the objectives for this *Statement on Participation* and others will emerge as more partnerships of consumers and researchers in health and medical research develop.

A first step will be to advocate for budget lines for consumer participation from early in the development of research projects, at institutional level and nationally. In part this budget line should address the issue of informed participation by consumers, which both consumers and researchers agree is the key to effective consumer participation in health and medical research. The cost of informing research participants and the community about the results of research will also need to be considered.

At an individual project level this budget line is not necessarily large, as communications between researchers and consumers to provide an understanding of research and relevant research issues may well involve discussions between the researchers and an interested consumer or community group. Results of the research may also be shared in this way, with consumers giving input on ways and content for any wider dissemination. However consumers' time will need to be valued in some way, for example through acknowledgment of their contribution in grant applications, reporting and publication, or assistance with information resources for their members, or travel costs to enable them to participate.

At institutional or national level, other strategies for informing consumer participation may be needed and should be budgeted for early in the planning process. These might include briefing of consumer representatives, supporting their accountability to their organisations through mailing or meeting costs, wider consultations, recompense for consumer representatives for travel costs and the time and expertise they contribute, and the costs of information for the wider community.

Training consumers and paying them for their involvement assists in providing them with a sense of ownership and responsibility for the research and is important in guarding against a tokenistic partnership. Depending on the research methods and situation, payments for consumers may include travel costs, child care costs, sitting fees for participation on a steering committee, or a simple acknowledgment of the population from which a sample was drawn. Of course, available research funds must also be considered, but as a guide for future advocacy for funding of consumer participation rather than as a barrier.

Some consumers in Australia are already attending training courses on science and advocacy to help them develop the necessary skills to support their participation in breast cancer research and are being included on management committees and scientific advisory committees of large research groups as well as being consulted on specific issues such as informed consent in breast cancer trials (Goodare & Lockwood 1999). Well-informed communities have also contributed to HIV/AIDS research (Dowsett & Davies 1998). Advocacy for provision of resources for this type of activity is also required. Areas of training that would be welcomed by consumers included provision of consumer friendly information about the research area(s) being considered, the interpretation of statistics, training for lay people on ethics committees and helping them to make connections with consumer or community groups.

A number of suggestions to inform and educate researchers about consumer involvement were also made during the consultations to develop this *Statement on Participation*. These included how to communicate with “non-specialists”, how to engage with consumers and the community in practice, and why this might add value to their work. In particular, there were suggestions to cover these areas in undergraduate courses in Universities, for research students and also for the medical profession and allied health professionals. The focus of the discussions was around better equipping researchers and the community to relate to each other.

Evaluation

It was also suggested in the consultations that resources for consumer participation in research should also cover evaluation of the participation in terms of positive social and medical change. The development of evaluation tools to measure these outcomes may need to be considered. These evaluation tools should include areas such as improvement in patient outcomes judged by the patients themselves, effective spending on research in terms of benefits to consumers and the community, and oversight of research to guard against fraud and abnormal behaviour, as well as to minimise unnecessary duplication.

3. CHECKLIST

Consumers and researchers reaching agreement on a set of principles for consumer and community participation in health and medical research is a first step. However the principles will not make any difference unless they are adopted. The following checklist is being developed to help with adoption of the principles, not to be used as an easy list to “tick off” in a tokenistic way, but as a guide to thinking about and planning for consumer and community participation and making it happen.

It is acknowledged that consumer participation in health and medical research will be implemented in a range of different ways. For example, a national committee setting research priorities may seek nominations for consumer representatives from national peak organisations and provide resources for them to consult with their members, as well as fund public consultation. Decision-making committees of funding bodies may seek nominations for consumer representatives relevant to the funding area, and provide resources for them to consult with their constituencies. Institutional research committees may focus on their accountability to the community that they serve. At the research project level, consumer participation may involve representatives of groups of people likely to be affected by the research.

The nature of consumer participation will also vary with the type of research that is being conducted. For example, research to improve a mental health service will directly involve research participants who use the service. Representatives of relevant illness or self-help groups may provide an effective means for consumer participation in clinical research or even applied gene technology research. Consumer participation in basic research may involve the researcher(s) or research institutions building their accountability to society for the direction of their research through information exchange and discussion with people from the wider community, as well as with their peers.

The checklist is seen as a starting point, based on the consultations to develop this *Statement on Participation*, for an evolving document as consumer participation in research evolves. Some respondents noted the similarity to the action research cycle (for example, as summarised by Wadsworth 1991) or to consumer research (Matrice & Brown 1990; Short 1998). The checklist is not a list to be worked through and completed, but a continuing cycle.

Have consumers been involved at each of the following stages:

3.1 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?

3.2 Deciding how to do it

- 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, multi-disciplinary 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?

3.3 Doing it

- 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?

3.4 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?

3.5 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 have 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.

4. HELPING CONSUMER PARTICIPATION HAPPEN

To enable meaningful participation of consumers in health and medical research in ways that will enhance individual research projects and overall research directions, there will be many issues to be addressed and barriers that may arise. Some of these issues are outlined below alongside examples of approaches that have been taken. The examples are derived from the literature or from feedback and references provided during the consultations to develop this *Statement on Participation*. Many more examples and suggestions for follow up were given; this Chapter is written as a starting point for building up experience with consumer participation in health and medical research.

4.1 Which consumers?

Initiating communication between researchers and consumers is an obvious first step in ensuring community and consumer participation. Consumers need to be aware of why they in particular have been approached, what it is that the researcher wants to learn and what is expected from them in participation in the study (McCallum 1999). Consumers representing the community or group that the research is targeting and/or the people most likely to be affected by it (Backhouse 1999; Wadsworth 1991; Baker 2000) will need to be involved.

Consumer organisations are able to contribute consumer input on a range of topics relating to health. Organised groups of people with a particular illness can provide a range of expertise that is greater than individual input. Their representatives are accountable to the wider group and can consult with the organisations' members (CHF 1999b). These organisations vary in size and structure from small community-based groups to national representative bodies with varying resources to support their representatives. However concerns are sometimes raised that the "right" consumer organisation is not always available, or that the consumer organisation approached may not wish, or have the capacity, to participate in the research project or priority setting.

Researchers are sometimes concerned that consumer representatives should not simply be those who are the most vocal, eloquent or communicative, because a range of opinions, viewpoints and experiences will need to be considered (Pivik 1997). Consumers responding to the consultation paper were also concerned that participation in research should not be limited only to those consumers who were most articulate and informed. For example, people from non-English speaking backgrounds, older people who used a lot of medicines, or people from areas where health services were limited might have different issues and a pressing need to have them addressed.

People who use health services, or have a particular diagnosis or set of symptoms and are not involved in formal consumer groups, or organisations may not identify themselves as "consumers" although within the definition of the word proposed in Section 1. Ways of consulting these people also need to be explored (Arsenault 1994; Hunt 1997).

In practice, one of the roles of consumer representatives in a research team, or of a consumer organisation, might be to ensure that a range of approaches for consulting consumers are considered and that there is a process to ensure that their voices are heard.

The Australian Hepatitis Council supported moves to rationalise hepatitis C related research efforts into a nationally coordinated biomedical research response. However peak bodies such as the Australian Hepatitis Council and the Australian IV League need the capacity to intermittently commission smaller scale research projects which befit the needs of specific education and policy initiatives. For example, these organisations deal directly with people with or at risk of hepatitis C infection and can contribute to educational research that focuses on the people at risk rather than on the educators.

(Australian Hepatitis Council
Social Research. October 2000)

4.2 Use of language

The discrepancy in the amount of power consumer participants have in research is often implied in the language through “giving” consumers power or “allowing” them to sit on boards or ethics committee. This language, although framing progressive ideas and usually with sound intent, reinforces the notion of researchers experimenting on subjects, instead of working with consumers. The use of language, although sometimes seen as excessive political correctness, is an important one as it demonstrates the underlying values held by scientific and other community groups (Manderson et al 1998; Neuberger 1999; Tallis 1999).

If the terms used denote an underlying superiority of one group and hence inferiority of another, then inequality will result and the quality of the activity will be diminished (Coulter et al 1998; Hunt 1997).

As Boynton (1998) writes to the *British Medical Journal* (BMJ), 202 structured abstracts published by *BMJ* in 1997 include the term “subjects” as a heading, but only three included the term “participants.” But the Standing Group on Consumers in National Health Service (NHS) Research, recommended a “firm commitment to involving consumers in research – not as “subjects” of research but as active participants in the process of deciding what research should take place, commissioning research, interpreting the results and disseminating the findings”. Boynton reminds the editors and readers of *BMJ* that language is important and that people should be participants in research, not “subjects.”

This is the approach taken by the *National Statement on Ethical Conduct in Research Involving Humans* (NHMRC 1999a).

The Australian Longitudinal Study on Women's Health (otherwise known as "Women's Health Australia") aimed to conduct longitudinal surveys of Australian women from a variety of backgrounds over a period of approximately 20 years. The study was to include Indigenous women, migrant women, parents, women with disabilities and so on.

At first Indigenous women were reluctant to participate. There was a general problem with terminology use to describe Indigenous communities. ATSI, standing for Aboriginal and Torres Strait Islanders, was a term perceived to diminish the importance of the many variations of culture and distinct cultural communities. The term ATSI was seen as an oversimplification and homogenisation of a diverse group of women. The developers needed to step back and acknowledge that they should have consulted the women earlier and respected them for their knowledge. They then needed to discuss benefits of the study in ways that were meaningful to their different communities and methods of disseminating research results that could benefit Indigenous communities.

(Manderson et al 1998)

4.3 Culture

Any research relating to health of an individual or a community must take into account the cultural environment, including race, country of origin, religious beliefs and so on. In order for consumers to be involved in research, their culture must be understood, respected, known and worked within (Gauthier & Clarke 1999; Manderson et al 1998; Goodare & Lockwood 1999; NHMRC 1991). For example, when approaching an Indigenous community to ask permission to conduct research it may be culturally important (if not necessary) to conduct such a meeting over a meal (NHMRC 1996). It may be culturally important to know to whom to speak and who not to address (for example women or older community members), what to bring, what to ask and how to communicate with the community that is being invited to participate (NHMRC 1991; Macaulay et al 1999).

A Melbourne study describes a project with women who had immigrated from the Horn of Africa who were concerned about the impacts of gambling on their community's health. Members of the Horn of Africa community designed ways of consulting with their communities and were trained and employed as co-researchers and cultural consultants to the project. They conducted focus groups, assisted in the data analysis and used the findings to develop and implement strategies that were aimed at reducing the negative effects of gambling for their community. Women were then trained and employed as peer educators. The project involved collaboration between women, community elders and mainstream support services. Management of the project was undertaken by the community and the women evaluated the project themselves.

(Brown et al 2000)

4.4 Stage of life

It is also important to acknowledge the stage of life of the person who is asked to participate in research. Many individuals who have a serious or life threatening illness are very supportive of research. This may be research that could save their life or the lives of friends or family. However, those individuals who are near the end of life will also have a number of priorities for their time including family, memories and reflection which may rightly take precedence over lengthy participation in research (McCallum 1999). In developing or proposing research methodologies focussing on individuals with life threatening illness it is important to ensure that research is done as quickly and easily as possible and that communication with the individual and/or their family is maintained.

A participant's stage of life must be considered in developing ways of involving them in research in a meaningful way. Young people, older people, parents and so on will each have different considerations such as school hours, transport, access or time to consider when engaging in research (Pivik 1997; Baker 2000). These stage of life concerns must be addressed to ensure meaningful participation and to gain the vital insight of individuals' experiences of health and ill health.

Palliative care research examines issues that are at the core of the human experiences of life and death. The ideology originated as a reform movement that challenged the dehumanising practices in the institutionalised biomedical care of the dying. There are many difficulties for the researchers working at the interface between sensitive holistic care and biomedicine. One of the primary roles of palliative care research is to ensure that decision making is informed and based on reliable data about the experiences of those needing, and providing, care. It is easy to forget that the real experts are those whose needs are to be met. If you want to know about the process of dying, it is important to talk to, among others, the dying.

(McGrath 1999b)

4.5 Overcoming bias

Researchers may base reluctance to involve consumers in research development and direction setting on the claim that consumers are biased in a particular direction and thus cannot be included on what should be an objective research development team (Entwistle et al 1998). However to exclude individuals on the basis of their own bias from their experiences, you would have to exclude everyone as each researcher, each member of the scientific or professional team also has a lived experience of research and of health (Shavers-Hornaday et al 1997; Coulter et al 1999; Hanratty & Lawlor 1999; Williamson 1999).

The argument can be made that being human equates to having a bias. The key to ensuring effective engagement in research development is ensuring that those biases are acknowledged, brought to the table and considered, then put aside to create a collective, objective viewpoint. Consumers are no less capable of putting

aside their personal interest than any other members of a research team (Entwistle et al 1998; Taylor 2000; Pivik 1997; Bastian 1996).

The initial membership of the subcommittee responsible for the implementation of the Graham Report, Ontario's current blueprint for community mental health, did not include consumers. A consultation process was undertaken but consumers did not feel that their needs had been addressed.

A consumer group hired a consultant to establish new communications between consumers and the members of the subcommittee, who were predominantly public servants and government officials.

The subcommittee agreed to a discussion forum where consumers would present their views on the proposed legislation and provided consumers with set questions to frame their responses. Consumers were intimidated by the consultation document and the response sheet and unwilling to present their stories. Consumer organisations encouraged people to ignore the response form and just come and tell their story.

The forum was a very emotional experience for all concerned. Some subcommittee members felt attacked and that the consumers were simply presenting horror stories designed to get attention to their cause. Some felt that the consumers' approach, language and tone was offensive and "bad mannered". Consumers had approached the forum assuming no one would listen to them. However they felt afterwards that they had been listened to and were able to express their deep and long held dissatisfaction with the current mental health system.

Following this forum, subcommittee members on the whole felt that although it had been very hard, personally, to listen to consumers' stories, they had learnt a great deal about the reality of the mental health system and what it was doing to peoples' lives. Although some maintained a resentment towards consumers for being so "ill mannered" as to express their anger and their negative experiences of the system in such an emotive way, many had also come to realise that they had not previously had the full picture.

The biased belief of subcommittee members that consumers opinions were emotive and exaggerated to make it sound horrible may have prevented the critical message of consumers' stories from getting through. Their biased view that the mental health system while having flaws, was predominantly a good system that helped people, was as much a barrier as the consumers' bias towards the system being entirely unhelpful and that subcommittee members would never listen to them or their stories. The importance of accepting different experiences, different means of expression and different life experiences is very clear in this study. It was only through confronting the committee members in a personal way and confronting their own prejudice and stigmatising thoughts and behaviours that the changes in attitude were possible.
(Church 1996)

4.6 Stigma and stereotyping

Consumer participation in health and medical research in the field of mental health was slow to develop, which has often been attributed to the stigma and assumptions that surround people with mental health problems. Mental health consumers, often more than any other consumer group have been assumed to be incapable of voicing valid opinion and unaware of their own needs and ambitions and hence excluded from participation as partners in research or included in a token fashion (Pinches 1999; Valentine & Capponi 1998).

McGuinness & Wadsworth (1992) involved consumers and staff in evaluation of an acute psychiatric hospital, swapping material so staff saw what consumers thought and consumers saw what staff were trying to do for consumers. Then the further comments were swapped and the consumer group began to develop recommendations for change.

Feedback from CHF's consultations to develop this *Statement on Participation* reported involving and training mental health consumers as researchers in the evaluation of unmet needs for people experiencing mental health problems.

The adverse effects of stigmatisation and stereotyping extend to many groups such as people with disabilities who may be assumed to be intellectually disabled because they use a wheelchair or those who are assumed to be unintelligent because they have a brain injury or an intellectual disability (Newell 2000). Oliver (1998) considers the influence of theories and values on interventions and research involving disabled people, coupled with their increasing insistence that their voices be heard at all stages of research about their lives.

The list can go on of assumptions, presumptions and stereotypes held by the wider community for a range of marginalised groups such as injecting drug users, gay men, sex workers. In bringing together researchers and consumers it is important that these stereotypes and stigmatising presumptions are acknowledged, addressed and dispelled from the research. If this is not done, research will be biased and poorly informed and result in further perpetuation of false and damaging perceptions of various consumer groups.

4.7 Making the most of the research team

Research teams are made up of a number of individuals with specialised skills and experience. There may be specialist scientists, social workers, technical staff, data managers, consumer liaison officers and so on. In pulling a team together, it is important to acknowledge the skills and abilities of each team member. When consumers are employed as research team members their ability to relate to other consumers is one of their key skills. This skill should not be underestimated and should be used and acknowledged as equally as valid as skills of scientific discovery and analysis (Backhouse 1999). However, it cannot be assumed that any one member of the team will have only one skill to contribute. Consumers will also bring their own academic knowledge and experience and their own analytical skills just as individual researchers will. It is good practice to ensure that the team works together and fully uses all the skills of all of its members.

5. CONCLUSION

Historically patients were involved in health and medical research as “subjects”, but research has progressed beyond the days of experimentation on prisoners and also beyond the passive patient. Recognised ethical principles for research involving humans have ensured significant steps in the protection of the welfare and rights of “participants” in research. These steps include providing information for consumers considering participation in research to support their informed consent, issues of safety for research participants, and lay involvement in ethics committees. However more and more researchers, as well as consumers, see this progress continuing further towards involvement of consumers and community in the various stages of research and informing them of the results of research. That is, working forward from the currently accepted ethical principles, which focus on protection of individuals, to build and strengthen partnerships between researchers, the community and the individual participants in research.

There are benefits to consumers, the community and researchers in following this path. Consumers have first-hand experience of the health and research outcomes that will make most difference to them and can contribute this experience to research. Involving the community in setting the research agenda can inform the community about research and help to tailor research to be more relevant to community needs. Researchers can benefit from wider discussion of research hypotheses and from the support of a more informed community for health and medical research.

Consumers and researchers are encouraged to consider who will be most affected by the research, others that may have an interest, and how to ensure effective consumer participation in a cycle of continuous improvement of the quality of research. After all, health consumers, as the end users of health and medical research, have a strong commitment to improving the relevance and quality of health and medical research in Australia.

The vision for this *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.”

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APPENDIX

SOME ADDITIONAL CONTACTS AND TOOLS TO ASSIST WITH CONSUMER PARTICIPATION IN HEALTH AND MEDICAL RESEARCH.

Consumer Focus Collaboration Publications:

Feedback, participation and consumer diversity. A literature review. AGPS June 2000.

Education and training for consumer participation in health care. Resource guide. AGPS June 2000.

Improving health services through consumer participation. A resource guide for organisations. AGPS June 2000.

The Evidence Supporting Consumer Participation in Health. AGPS May 2001.

The National Resource Centre for Consumer Participation in Health:

Provides quality information, advice and consultancy about methods and models of community and consumer participation and feedback to health consumers and providers.

Level 5, Health Sciences Building 2
LaTrobe University
BUNDOORA VIC 3086

Toll free telephone number: 1800 625 619

Website: <http://nrccph.latrobe.edu.au>

Support for consumer representatives:

Consumers' Health Forum (1999) *Guidelines for consumer representatives.*
Consumers' Health Forum of Australia, Canberra.

Support for consumers doing research:

Consumers' Health Forum (2001) *A guide for consumers doing health research.*
Consumers' Health Forum of Australia, Canberra.

The National Health and Medical Research Council

The National Health and Medical Research Council (NHMRC) is a statutory body within the portfolio of the Commonwealth Minister for Health and Ageing, established by the *National Health and Medical Research Council Act 1992*. The NHMRC advises the Australian community and Commonwealth, State and Territory Governments on standards of individual and public health, and supports research to improve those standards.

The NHMRC advises the Commonwealth Government on the funding of medical and public health research and training in Australia and supports many of the medical advances made by Australians.

The NHMRC also develops guidelines and standards for the ethical conduct of health and medical research.

The Council comprises nominees of Commonwealth, State and Territory health authorities, professional and scientific colleges and associations, unions, universities, business, consumer groups, welfare organisations, conservation groups and the Aboriginal and Torres Strait Islander Commission.

The Council meets up to four times a year to consider and make decisions on reports prepared by committees and working parties following wide consultation on the issue under consideration.

A regular publishing program ensures that Council's recommendations are widely available to governments, the community, scientific, industrial and educational groups.

The Council publishes extensively in the following areas:

- Aged care
- Child health
- Clinical practice guidelines
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- Dentistry
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- Health procedures
- Health promotion
- Infection control
- Men's health
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- NHMRC – National Health and Medical Research Council
- Nutrition
- Public health
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A list of current publications is available from:

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