



Australian Government

National Health and Medical Research Council



## Resource Pack for Consumer and Community Participation in Health and Medical Research

INVESTING IN AUSTRALIA'S HEALTH

DECEMBER 2004



Consumers' Health Forum  
of Australia



**Australian Government**

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**National Health and Medical Research Council**

Resource Pack for  
Consumer and Community Participation  
in Health and Medical Research

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## **PART ONE INTRODUCTION**

### **HOW TO USE THIS RESOURCE PACK**

This *Resource Pack for Consumer and Community Participation in Health and Medical Research* has two main audiences. The first audience is health consumers or community members wanting to get involved in the work of a research organisation. Parts 2-4 are mainly intended for this audience. These parts aim to increase readers' understanding of health and medical research and of how consumers and community members can contribute to it.

The second audience is researchers or other staff members working within a research team or organisation. This *Resource Pack* might help researchers to understand the sort of information useful to consumers and the values that underpin consumer and community participation in health and medical research. The overview provided in Part 2 should provide some useful information on how and why consumers can be involved in research. In addition, Part 5 provides some brief guidance on developing strategies for consumer participation. This *Resource Pack* is accompanied by a *Model Framework for Consumer and Community Participation in Health and Medical Research*, which provides advice for research organisations developing consumer and community participation, including a section on 'getting started.'

Though some people may find it useful to read the whole document, it is intended that readers can dip into those sections which interest them and skip topics with which they are already familiar.

Many of the references in this document are to websites. Wherever possible a telephone number or other publication details have been provided. However, organisations are increasingly providing some information only in electronic form. The Consumers' Health Forum of Australia (CHF) recognises that many consumers either do not use or do not have easy access to the Internet. In such cases, CHF is happy to assist consumer organisations to obtain hard copies of documents referenced here. CHF can be contacted on 02 6273 5444.

### **THE STATEMENT ON CONSUMER AND COMMUNITY PARTICIPATION IN HEALTH AND MEDICAL RESEARCH**

In Australia, the Consumers' Health Forum (CHF) and the National Health and Medical Research Council (NHMRC) worked together to develop a *Statement on Consumer and Community Participation in Health and Medical Research* (the *Statement on Participation*). This was developed in 2000-2001 as a partnership between consumers and researchers. They shared their hopes and concerns about consumer participation in research and learned much about each other's viewpoints. Their shared vision was:

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

CHF and NHMRC co-endorsed the *Statement on Participation* in December 2001. The *Statement on Participation* was launched by the Minister for Health and Ageing in 2002.

The *Statement on Participation* includes a series of *Objectives* to guide consumer participation at all levels and across all types of health and medical research:

- 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;
- 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;
- 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 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 facilitate dissemination of balanced information about the research and its results to the community; and
- Consumers and researchers will advocate for the resources needed for effective consumer and community participation in health and medical research.

## WHAT IS MEANT BY CONSUMER AND COMMUNITY?

The terms 'consumers' and 'community' can mean different things to different people. For example, a research organisation would be aware of health consumers but could also think in terms of non-researchers, sponsors or of the clinicians who use treatments it develops as the consumers of its research.

The following definitions were used for the purposes of the *Statement on Participation*:

- *Health 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; and
- *Community* — a group of people sharing a common interest (e.g. 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.

A variety of other terms may be used to refer to consumer and community members. Examples include:

- Patient
- Layperson
- Volunteer
- Member of the public

The key attribute that these people share is that they are not researchers or health professionals. Their main experience of health research is as a health consumer or community member.

## WHAT IS MEANT BY PARTICIPATION?

Consumer and community participation includes consumer and community involvement in policy formation and the role of consumers and community members as advocates on certain issues. The Australian Communications Authority<sup>1</sup> noted the following differences between consumer and community participation and consumer and community consultation:

*“Participation* is about being part of the process...It is about more than observing and commenting on processes but actual involvement in forums, the authoring of solutions or the development of regulatory instruments...

*Consultation* is when consumers are asked for their views...Consultation is a level of participation at which people are offered some choices on what is to happen, but are not involved in developing additional options or actions.”

<sup>1</sup> *Consumer and Community Driven Communications: Strategies for Better Representation – Issues Paper*, Australian Communications Authority [http://internet.aca.gov.au/ACAINTER.65636:STANDARD:1970703639:pc=PC\\_1661](http://internet.aca.gov.au/ACAINTER.65636:STANDARD:1970703639:pc=PC_1661)



INVOLVE<sup>2</sup>, a UK organisation which facilitates consumer participation in research, explains that:

“By ‘*involvement*’ we mean an active partnership between the public and researchers in the research process, rather than the use of people as the ‘subjects’ of research. Active involvement may take the form of consultation, collaboration or user control. Many people define public involvement in research as doing research ‘with’ or ‘by’ the public, rather than ‘to’, ‘about’ or ‘for’ the public. This would include, for example, public involvement in advising on a research project, assisting in the design of a project, or in carrying out the research.”

Consumer and community 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 and community 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 health outcomes. The degree of consumer and community participation may reflect the degree to which the research impacts upon consumers and community members. However, it should be remembered that many significant breakthroughs have been the result of basic science, such as the importance of clean water and a better understanding of how diseases spread. Similarly many of the concepts which currently challenge our society, such as the mapping of the human genome and its potential use, have their roots in basic science. Consumers and community members therefore have a legitimate interest in this area and would welcome greater public accountability and discussion.

## CONCLUSION

Consumers are already participating in health and medical research at local, national and international levels. Indigenous health research has led the way in creating a climate of close co-operation between researchers and Aboriginal and Torres Strait Islander communities<sup>3</sup>. Some consumers and researchers have learnt how to work together well but there is still a significant way to go before consumer and community participation is an expected part of research policy and practice.

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<sup>2</sup> INVOLVE – [www.invo.org.uk](http://www.invo.org.uk)

<sup>3</sup> NHMRC, (2003) *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research*, Commonwealth of Australia, Canberra, viewed 13th December 2004 <<http://www.nhmrc.gov.au/publications/pdf/e52.pdf>>.

## **PART TWO      OVERVIEW OF CONSUMER & COMMUNITY PARTICIPATION IN HEALTH AND MEDICAL RESEARCH**

### **WHY INVOLVE CONSUMERS IN RESEARCH?**

As the end users of health and medical research, consumers can provide valuable input to decisions about research policies and practices. If such research is to continue to provide high quality outcomes, it is important that consumer and community involvement in research and its ongoing development is facilitated. This includes participation by consumers as 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 and community participation in research brings with it responsibilities for consumers, community members 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, community members and researchers is to ensure that ethical requirements are met and that there is value to the research.

Until relatively recently, the main role consumers played in health and medical research was as ‘subjects’ in research studies. Ethical requirements for research involving humans have been strengthened by the National Health and Medical Research Council (NHMRC) *National Statement on Ethical Conduct in Research Involving Humans*<sup>5</sup>, which takes into account the welfare and rights of participants in research, including those who may be affected by the research<sup>4</sup> as well as those directly involved. A later section of this document discusses research ethics in more detail.

This document is not primarily concerned with the role that consumers might play as people involved as participants in a research study. It seeks to encourage a different kind of participation, where consumers and researchers work in partnership with one another to shape decisions about research priorities, policies and practices.

The *Statement on Participation* identified a number of levels of consumer and community participation in research. These range from no participation (which is no longer an acceptable approach) to wider participation, which uses a range of strategies to consider the views of consumers and community members.

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<sup>4</sup> People who may be affected by a research project include participants, their carers, and other people living with the condition being studied.

<sup>5</sup> NHMRC, (1999) *National Statement on Ethical Conduct in Research Involving Humans*, Commonwealth of Australia, Canberra, (under review).

This includes involving consumer representatives in priority setting and decision making, consultation, and the use of research literature that describes people's experiences.<sup>6</sup> 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 and community members.

## HOW COULD CONSUMERS BE INVOLVED?

The *Statement on Consumer and Community Participation in Health and Medical Research* envisages consumer and community participation in all stages of the research process. Once consumers and researchers have accepted that consumers should be involved in health and medical research, they need to consider how this will occur. There are many possibilities! In some, consumers and community members are involved at a surface level; in others they are as deeply involved as the researchers. For this to occur there needs to be mutual respect, trust and appreciation between researchers and consumers. Such relationships take time to build so if consumer and community participation is relatively new to the organisation it is likely that consumer and community involvement may start at a surface level then deepen over time.

Some possible approaches to consumer and community participation are listed below. These are suggestions only and it may be that consumers and researchers can together identify methods which would work in their particular situation. Here are some starter ideas:

- *Deciding what to research:* Consumers and community members could participate in a focus group to identify important unresolved questions about their health. Careful questioning could help to elicit consumer and community priorities for research. Researchers and consumers could then discuss which of these could form a research question. Sometimes consumers themselves identify the topic, for example, Stillbirth and Neonatal Death Support (SANDS) Queensland instigated a study of general practitioners' attitudes towards miscarriage in conjunction with the local Division of General Practice. This came about because their members reported that they felt their GPs didn't really understand the impact of miscarriage and how best to care for them.<sup>7</sup>

Consumer and community involvement at this stage could ensure the research questions reflect consumer and community priorities and are phrased in such a way as to answer their questions;

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<sup>6</sup> Wider participation also encompasses consumers' research; that is research undertaken from a consumer perspective, by or with consumers, arising out of consumers' needs.

<sup>7</sup> F Boyle, R Chapman, J Hancox, (1998) 'General Practice Care after Miscarriage: Consumer and Provider Views', Stillbirth and Neonatal Death Support QLD and the University of Queensland. Project summary available at (<http://www.sph.uq.edu.au/CPHC/research/Miscarriage.html>)> page viewed 14<sup>th</sup> December 2004.

- *Deciding how to do it:* Consumers can offer practical advice to ensure that the research study is designed in a way that benefits consumers, even though they are not experts on research methodologies. For example, a research proposal to improve the mobility of people with knee problems could focus on a practical outcome important to consumers, such as regaining the ability to drive, as well as a clinical measurement such as the ability to walk a certain distance. Consumers can help to ensure that the research does not impose undue burdens on the participants. They may be able to help researchers include information on people's quality of life as well as their clinical data, as quality of life issues are an important part of consumers' decision-making about treatment options;
- *Doing it:* As members of a research reference group, consumers and community members can provide advice on how to ensure that any research participants are informed of their rights, of the timelines in the research, ethics and complaints processes. They can help to ensure participants have clear, accurate and comprehensive information on which to base their decisions about their involvement in the research. They may also provide a way for participants' experiences to be brought to the attention of the reference group. A consumer or community member of a reference group would ideally share the characteristics of those involved in the study but may not be a participant as this may constitute a conflict of interest. So if the research was focused on people with dyslexia then the consumer member on the reference group would also have dyslexia but would not be enrolled in the study itself.

Effective consumer representatives are able to move away from a personal opinion to a viewpoint that takes account of the diversity of experiences and needs of consumers. They take the time to form good relationships with the committee secretariat and with other committee members. Effective consumer representatives should be able to:

- Analyse an issue and judge its effects on consumers
  - Consider the consequences of decisions in the short and long term
  - Present an argument rationally and convincingly;
- *Letting people know the results:* Consumer or community members on a reference group can help to ensure that research participants are kept informed of the study's progress. This does not mean releasing information before proper peer review has validated its claims but could encompass explaining the study's methodology, informing people of the stage the research has reached, what the next steps will be and sharing stories from participants (with their consent) about their experience of being in the study. The *Statement on Participation* supports the rights of research participants to receive (or choose not to receive) their own results, wherever this is possible within the methodology of the study.

Once the results of the study have been analysed consumers can ensure that its findings are reported more widely than in an academic journal. They could help the researchers write up their findings in plain English for publication in consumer and community journals and newsletters. They may be able to advise on other ways of informing the local community such as radio, news programs and newspapers; and

- *Deciding what to research next:* It may be valuable to seek feedback from the participants to find out if there are any aspects of the study that could have been improved. Be creative about how to gather this feedback – there are more possibilities than the usual bland survey form.

Seeking feedback may require ethical approval. If so, it would need to be part of the original plan for the research. If this is not possible, researchers could discuss the likely issues with a consumer group representing people with the condition which was studied. Providing people with a plain English summary of the research findings may help them to identify further questions, which could form the basis of the next research project.

Consumers and community members may be able to create links with consumer representatives on committees of the local hospital or Division of General Practice. This means they are in a position to ask such consumer colleagues about how their organisation will implement the research findings to ensure that the research does lead to changes in clinical services.

It is likely that different consumers may be involved in each stage. For example, in determining priorities and designing a research study, it may be more appropriate to involve a consumer group with an interest in the condition being researched. Once the study commences, it is likely that a different set of people will volunteer as participants because such people must meet the study inclusion criteria. The checklist on page 37 of the *Statement on Participation* (reproduced below) should stimulate further ideas about how to involve consumers and community members in research.

## CHECKLISTS TO GUIDE ASSESSMENT OF PARTICIPATION

The *Statement on Participation* contains some checklists to help guide plans for and assessment of consumer participation. The checklist is not a list to be worked through and completed but a continuing cycle. The application of the principles in the *Statement on Participation* will vary depending on the sort of research being done.

### **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 receive 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.

## **FURTHER RESOURCES**

### **The CHF / NHMRC Statement on Consumer and Community Participation in Health and Medical Research**

This sets the framework for consumer and community participation in health and medical research in Australia. It was developed by consumers and researchers through both Australia's national peak body for health consumer organisations, the Consumers' Health Forum of Australia (CHF), and the national funding body for health research, NHMRC. It is available at <<http://www.nhmrc.gov.au/publications/synopses/r22syn.htm>> or by calling 1800 020 103 ext 9520. The webpage was viewed on 13<sup>th</sup> December 2004.

## **INVOLVE**

Originally named Consumers in NHS Research, INVOLVE is a UK based organisation dedicated to ensuring that members of the public should be involved at all stages of the research and development process, including deciding what research should take place; commissioning and undertaking research; and disseminating the findings. INVOLVE has produced many useful publications for both researchers and consumers, which are available on its website at <[www.invo.org.uk](http://www.invo.org.uk)>. The webpage was viewed on 13th December 2004.

### **CHF's Guidelines for Consumer and Community Representatives Working on Committees**

A consumer representative is a member of a committee who voices consumer perspectives and takes part in the decision-making process on behalf of consumers. This person is usually nominated by, and is accountable to, an organisation of consumers. CHF has produced these guidelines to help consumer representatives in their role. The guidelines are available from <[http://www.chf.org.au/Docs/Downloads/237\\_conrepguidelines.pdf](http://www.chf.org.au/Docs/Downloads/237_conrepguidelines.pdf)> or by calling 02 6273 5444. There are many other useful resources on the CHF website, which was viewed on 13<sup>th</sup> December 2004.

Ask for a copy of the research organisation's Consumer and Community Participation Policy. The *Model Framework for Consumer and Community Participation in Health and Medical Research* contains an example of such a policy.

### **The Little Purple Book of Community Repping**

This is available at <<http://www.participateinhealth.org.au/ClearingHouse/Docs/HandBook.pdf>> or in hard copy from Adelaide Central Community Health Service on 08 8342 8600. The webpage was viewed on 14<sup>th</sup> December 2004.

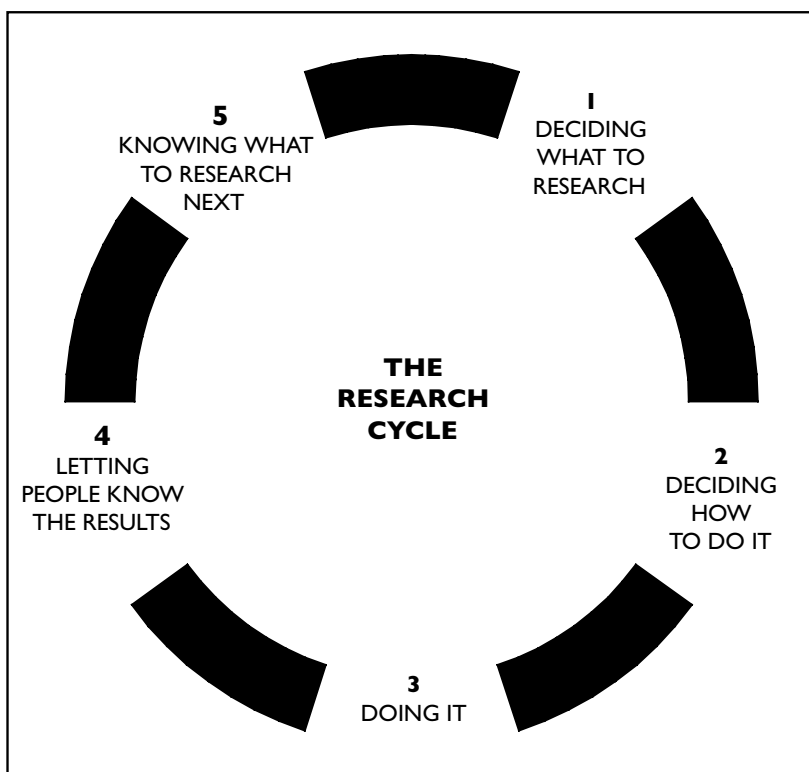


## **PART THREE AN OVERVIEW OF HEALTH AND MEDICAL RESEARCH IN AUSTRALIA**

### **WHAT IS HEALTH AND MEDICAL RESEARCH?**

We all face challenges to our health, either because of inherited susceptibility or from the environment we live in. Health and medical researchers seek to build our knowledge about health and disease and to use this knowledge to help people enjoy better health throughout their life<sup>8</sup>.

Research usually follows a cycle as illustrated below.



<sup>8</sup> Research Australia <<http://www.researchaustralia.org>>, page viewed 14<sup>th</sup> December 2004.

## HOW IS RESEARCH CARRIED OUT?

The appropriate research method will depend on the question being answered. Similarly, appropriate methods for consumer participation will depend on the type of research. The depth and scope of consumer participation in research is likely to reflect the degree to which the research imposes on consumers.

Research operates within agreed ethical guidelines, which are discussed later in this document. There are further guidelines which apply to research involving humans.

This section has been divided into four categories of research: basic research; clinical research; public health research; and health services research. This is only one way to categorise the very complex world of research. Some further 'types' of research are listed in the glossary.

### **Basic research**

Basic researchers will do their work in the laboratory using test tubes, cell samples, microscopes, chemical analysis and other methods. They will run and repeat complex experiments as they seek to understand better how the human body works at the level of its cells and molecules. More and more researchers are trying to understand how complete pathways work, rather than studying one molecule or cell type in isolation

Consumer participation in basic research could occur in the following ways:

- At a policy level, consumers could be consulted about the ethics of a particular type of research or involved in considering who owns or has access to human tissue samples<sup>9</sup>;
- Researchers could offer tours of their laboratories to the public or to schools groups to help people gain a better understanding of basic research; and
- Researchers could try to learn how to communicate the results of their work in ways that are meaningful to consumers.

### **Clinical research**

Clinical researchers will usually work with human participants or their tissue samples as they seek to find better ways of identifying the causes of ill health and improving treatment. Some types of clinical research are done in the laboratory; other types involve more direct contact with consumers as participants in the research. If the research involves participants, they will be recruited and enrolled into the study according to agreed inclusion criteria (criteria for who can be in the study, which

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<sup>9</sup> The final decision is likely to rest with those running the consultation, whether at national or local level. If the research involves humans, the Human Research Ethics Committee will have the final say at the local level.

might need people of a certain age or with a certain condition). Clinical researchers' methods may include asking questions, taking blood or tissue samples, asking participants to take a particular treatment according to a trial protocol and monitoring their progress.

Consumer participation in clinical research will vary depending on whether the research is primarily laboratory based, or primarily participant based. It could include:

- Involving consumers in decisions about the ethics of a particular type of research or in decisions about who owns or has access to human tissue samples;
- Involving consumers in identifying areas for further research; and
- Communicating the results to participants and the wider community in consumer-friendly ways.

Clinical trials are one type of clinical research, perhaps the most common area for consumers to be involved in. Part 4 discusses clinical trials in more detail.

### **Public health research**

Public health research involves the study of communities or populations, typically outside health care institutions. It is undertaken to identify the factors which contribute to ill-health in populations and ways of influencing these factors to prevent disease. It includes epidemiology, health promotion, social and behavioural sciences, health services research on population-based health interventions. For example, public health researchers may look at all the people living in a certain town to determine why there has been an increase in asthma rates. Their methods include surveys, focus groups and comparison of data from health records, record linkage, electoral rolls and other sources.

Consumer participation in public health research could include:

- Identifying the need for research in a particular area and providing a groundswell of support for it;
- Developing policy, such as the privacy of medical records or other personal information;
- Helping researchers to establish and run focus groups. In some cases, researchers have trained consumers to run focus groups themselves as participants are sometimes more likely to open up to other consumers; and
- Helping to translate the results into practice, for example, campaigning for restrictions on smoking in public places.

## **Health services and health systems research**

Health services researchers examine ways of improving the delivery of health services, for example, improving equitable access to services or improving cost-effectiveness. Such research has a more operational and economic orientation than clinical research. Health systems and policy research studies health-related institutions and their role in shaping policy and improving implementation.

Consumers have often been closely involved in health services and health systems research. As users of the services, they may usually have good ideas on how improvements could be made.

## **Analysing and publishing the results of research**

All researchers use a high level of scientific, mathematical and statistical knowledge to interpret their findings. They will usually seek to publish the results of their work in a prestigious peer-reviewed<sup>10</sup> journal or at a conference of their peers. Researchers are usually under considerable pressure to publish the results of their work in a highly regarded journal as a good publication record is essential if they are to be successful in bids for further funding.

## **WHO FUNDS HEALTH AND MEDICAL RESEARCH IN AUSTRALIA?**

In Australia, health and medical research is carried out in universities, hospitals and medical research institutes as well as government agencies (such as CSIRO<sup>11</sup>), health service groups, research consortia, pharmaceutical companies, biotechnology enterprises, and other health interest groups. An increasing number of community based health groups, such as Divisions of General Practice, are undertaking research relevant to their fields of interest.

Some organisations are largely funded through the public purse. Others rely primarily on private funding from wealthy individuals and businesses for their core budget, seeking public grants for specific research projects. Some research organisations have developed strong public relations strategies to help raise their profile and funds. Such public relations activities, which seek to promote the organisation to the community, must be distinguished from consumer and community participation which seeks the engagement of the community in the organisation's work.

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<sup>10</sup> See the Glossary for a definition of peer-review.

<sup>11</sup> Commonwealth Scientific and Industrial Research Organisation

## WHAT ETHICAL STANDARDS ARE THERE IN RESEARCH?

Health and medical research operates within a framework of agreed ethical considerations. Specific guidelines cover research involving humans, or animals, and research with Aboriginal and Torres Strait Islander communities.

### General ethical principles

The Joint NHMRC / Australian Vice Chancellors' Committee's *Statement and Guidelines on Research Practice*<sup>12</sup> (under review) is a professional code of conduct for health and medical researchers. It notes that,

“Researchers have a duty to ensure that their work enhances the good name of their institution and the profession to which they belong. Researchers should only participate in work which conforms to accepted ethical standards and which they are competent to perform. When in doubt they should seek assistance with their research from their colleagues or peers. Debate on, and criticism of, research work are essential parts of the research process. Institutions and researchers have a responsibility to ensure the safety of all those associated with the research. It is also essential that the design of projects takes account of any relevant ethical guidelines.”

### Ethics in research involving humans

The *National Statement on Ethical Conduct in Research Involving Humans*, is applicable to all research involving humans, in that the key ethical principles can be used to guide the design and conduct of any research (medical, health, social science, humanities) which involves human participation. The *National Statement* is intended to be a document which provides a national standard for best practice. According to the *National Statement*, ethical considerations are as important to good research as scientific considerations are. Ethical inadequacies are as significant as scientific inadequacies.

Any organisation that receives NHMRC funding for research is bound through a contractual agreement to adhere to the *National Statement* and to obtain ethical review for research involving humans. Other funding bodies, such as the Australian Research Council, may also place a similar requirement on the funding they provide. In addition, some agencies have decided to include reference or adherence to the *National Statement* (or other NHMRC guidelines) in their legislation. For example, the Therapeutic Goods Act refers to the *National Statement* to regulate the conduct of clinical trials. There is also some legislation at the State/Territory level that also references the *National Statement* for specific purposes.

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<sup>12</sup> NHMRC / Australian Vice Chancellors' Committee's (1997) *Statement and Guidelines on Research Practice*, (under review) <<http://www.nhmrc/research/general/nhmrcavc.htm>> page viewed 14<sup>th</sup> December 2004.

Before research involving humans can proceed, it must be approved by a Human Research Ethics Committee (HREC). These exist in universities, hospitals and other research organisations. Their membership is set down by the Australian Health Ethics Committee. HRECs must include at least 7 members, comprising:

- A chairperson;
- A layman and a laywoman. These are people who have no affiliation with the institution or organisation, are not currently involved in medical, scientific or legal work, and who are preferably from the community in which the research organisation is located. They are chosen for their individual understanding rather than nominated by a consumer or community organisation. They may or may not be able to contribute the perspectives of people participating in research;
- At least one member with knowledge of, and current experience in, the areas of research that are regularly considered by the HREC (e.g. health, medical, social, psychological, public health, as appropriate);
- At least one member with knowledge of, and current experience in, the professional care, counselling or treatment of people (e.g. a medical practitioner, clinical psychologist, social worker, nurse as appropriate);
- At least one member who is a minister of religion, or a person who performs a similar role in a community, such as an Aboriginal elder; and
- At least one member who is a lawyer.

HRECs assess research proposals in the light of the *National Statement's* requirements. The three basic ethical principles are:

- *Respect for persons*: individuals should be treated as independent people; those who are dependent on others are entitled to protection. Researchers should show respect for the inherent dignity and the rights of each person. They commit not to use a person solely as a means to an end;
- *Beneficence*: this is the obligation to do as much good and as little harm as possible to the participants in the research. Harms are not only physical but could also be economic or social disadvantage or emotional distress. Researchers can exercise beneficence by assessing the potential risks and benefits to participants, by being sensitive to participants' needs and rights and by reflecting on the social and cultural implications of their work; and
- *Justice*: this addresses the question of who should receive the benefits of research and who should bear its burdens. In the early 20<sup>th</sup> Century, most participants in research were public patients but those who benefited from new treatments were mainly private patients. This is unjust. Similarly, in our times, some groups are regularly asked to participate in research but do not necessarily see its benefits for the health of their communities.

Research participants who feel they have been mistreated, can ultimately bring their complaint to the local HREC. However, there is very little public information about ethical review. Trial participants are usually provided with some information on ethical review but there is little information in the public domain – few organisations provide information about ethical review on their websites or in their public reports. Most consumers know very little about the process.

Consumer participation and ethical review are separate but complementary components of any research involving humans. Involving consumers in the planning of research may identify some ethical issues earlier, giving chance to address them before submitting the proposal to an HREC. Consumers working with a research team or organisation may find it useful to make links with the HREC, particularly with its lay members.

### **Ethics in research involving animals**

*The Australian Code of Practice for the Care and Use of Animals for Scientific Purposes*<sup>13</sup> encompasses all aspects of the care and use of, or interaction with, animals for scientific purposes in medicine, biology, agriculture, veterinary and other animal sciences, industry and teaching. It includes their use in research, teaching, field trials, product testing, diagnosis, the production of biological products and environmental studies.

The Code provides general principles for the care and use of animals, specifies the responsibilities of investigators and institutions, and details the terms of reference, membership and operation of Animal Research Ethics Committees. It also provides guidelines for the humane conduct of scientific and teaching activities, and for the acquisition of animals and their care, including their environmental needs.

The Code covers all live non-human vertebrates and higher order invertebrates. Researchers are advised to take into account emerging knowledge and ethical values when proposing to use other animal species not covered by the Code.

### **Ethics in Indigenous health research**

The National Health and Medical Research Council (NHMRC) has produced guidelines for ethical research with Aboriginal and Torres Strait Islander peoples<sup>14</sup>. In accordance with guidance from Aboriginal and Torres Strait Islander people the guidelines are written around a framework of Aboriginal and Torres Strait Islander values and principles.

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<sup>13</sup> NHMRC, (2004) *The Australian Code of Practice for the Care and Use of Animals for Scientific Purposes* 7<sup>th</sup> edition, Australian Government, Canberra. <[www.nhmrc.gov.au/publications/pdf/ea16.pdf](http://www.nhmrc.gov.au/publications/pdf/ea16.pdf)> page viewed on 13<sup>th</sup> December 2004.

<sup>14</sup> NHMRC, (2003) *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research*, Commonwealth of Australia, Canberra. <<http://www.nhmrc.gov.au/publications/pdf/e52.pdf>> page viewed 13<sup>th</sup> December 2004.

## HOW IS RESEARCH REGULATED IN AUSTRALIA?

There are several different processes which contribute to the regulation of health and medical research in Australia:

- In order to obtain funding, researchers must express their research idea in a grant proposal which is then assessed by independent scientists, for example, those on NHMRC Grant Assessment Panels. Such scrutiny enables any flaws in the scientific or ethical aspects of the proposal to be identified and addressed before funding may be granted;
- Research organisations in receipt of NHMRC funding must sign a deed of agreement which assures compliance with relevant codes, guidelines and legislation;
- As noted above, the Joint NHMRC / Australian Vice Chancellors' Committee's *Statement and Guidelines on Research Practice* (under review) is a professional code of conduct for health and medical researchers;
- As well as the formal structures, researchers as professionals (scientists) also have to abide by a set of recognised scientifically rigorous and valid techniques to ensure their approaches have credibility and results are defensible. This can mean that some research methods or practices cannot be changed, despite consumer input, because it would compromise the integrity of the research;
- In research involving humans or animals, researchers must abide by ethical requirements and are guided by the decisions of their Human or Animal Research Ethics Committees;
  - Research proposals must be submitted for ethical approval before the research can commence. If ethical approval is denied, the research cannot be done.
  - The head of the research organisation must sign a statement of compliance with the NHMRC's *National Statement on Ethical Conduct in Research Involving Humans* and / or with the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes*. Non-compliance can lead to sanctions.
  - Both ethics committees and sponsors or funders of the research have a responsibility to monitor its progress.
  - Researchers are required to produce annual reports, progress reports and final reports for their research. These are submitted to ethics committees and to the funding body.
  - Intention to publish the results of the research is an ethical requirement as this allows the transfer of knowledge and the testing of the conclusions by other scientists. Publication is encouraged in respected, peer-reviewed journals.



- At an international level, the *Declaration of Helsinki* is a statement of ethical principles to provide guidance to physicians and other participants in medical research involving humans<sup>15</sup>;
- Clinical trials involving drugs or medical devices must meet the Therapeutic Goods Administration's (TGA) requirements under its Clinical Trials Exemption (CTX) or Clinical Trials Notification (CTN) schemes (see Clinical Trials Part 4 for further details); and
- The *Note for Guidance on Good Clinical Practice*<sup>16</sup>, is an internationally accepted standard for the designing, conducting, recording and reporting of clinical trials. The TGA has adopted the *Note* in principle but has recognised that some elements are, by necessity, overridden by the *National Statement* (and therefore not adopted) and that others require explanation in terms of 'local regulatory requirements'.

## HOW ARE THE RESULTS OF RESEARCH COMMUNICATED?

Researchers usually seek to publish the results of their work in respected academic journals in their relevant fields. These can be specialised, such as a journal about gastroenterology, or more general, such as the *Medical Journal of Australia* which covers a range of topics of interest to the medical community.

A researcher's success is usually judged on his or her publication record. Funding bodies usually expect publication as an outcome of the research. However, whilst consumers can access these journal articles on the internet or can buy a copy, the articles are usually written in technical language for other specialists.

Some organisations now publish short consumer summaries of research. See <<http://www.informedhealthonline.org>> for some examples of consumer summaries of Cochrane Reviews (the role of the Cochrane Collaboration is discussed in Clinical Trials Part 4). Whilst some researchers do produce summaries of their research in lay language, they rarely receive any credit for doing so. In the busy world of health and medical research, there needs to be more incentives for researchers to communicate their work to consumers. Explanations of research findings and methods could then be published in consumer newsletters or on the internet and might help to improve consumers' understanding of research.

Some commentators<sup>17</sup> have noticed a tendency for positive results of research to be published whilst negative results are much less likely to appear in academic journals,

<sup>15</sup> World Medical Association, (1964) *Declaration of Helsinki*. Ethical principles for medical research involving human subjects, (last amended 2000). Available online at <<http://www.wma.net/e/policy/b3.htm>> page viewed 14<sup>th</sup> December 2004.

<sup>16</sup> Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95). Available at <<http://www.tga.gov.au/docs/html/ich13595.htm>> page viewed on 14<sup>th</sup> December 2004.

<sup>17</sup> P Alderson, S Green, JPT Higgins, editors. Formulating the problem. Cochrane Reviewers' Handbook 4.2.2 [updated December 2003]; Section 5. <<http://www.cochrane.dk/cochrane/handbook/hbook.htm>> website viewed on 14th December 2004.

even though their findings are also valuable. This is termed ‘publication bias.’ This is not to suggest bias on the part of individual researcher but rather to highlight that there are biases in the system which favour the publication of positive results. For example, a trial showing that a new drug worked much better than the existing treatment is much more likely to be published than a trial showing that the new drug has no advantages over the old. However, it is important to learn what doesn’t work as well as what does. Negative results should receive more attention than they do at present. Many consumers and researchers would like to see a requirement for public reporting of all research results.

Remember that research articles are designed to answer a particular research question. One research paper, on its own, is rarely accepted as *proof* of a particular proposition. Results must be supported by other studies before they are accepted by the scientific community. So, if a research article states that Drug A was better than Drug B, that doesn’t prove that doctors should be prescribing Drug A right now. There are always questions that need to be asked first, such as: What kind of people were being studied? What was used to define “better”? Have other studies found the same result? Research results must be read carefully and applied cautiously.

## DEVELOPING CLINICAL PRACTICE GUIDELINES

Many researchers are involved in developing clinical practice guidelines, which are one way of improving health care in the light of research findings. The NHMRC *Guide to the Development, Implementation and Evaluation of Clinical Practice Guidelines*<sup>18</sup> is the most recent statement on the NHMRC’s position about consumer involvement in guideline development.

It notes that, “The process of guideline development should be multidisciplinary and should include consumers. If guidelines are to be relevant, those who are expected to use them or to benefit from their use should play a part in their conception and development. Involving a range of generalist and specialist clinicians, allied health professionals, experts in methodology, and consumers will improve the quality and continuity of care and will make it more likely that the guidelines will be adopted.”

## QUALITATIVE AND QUANTITATIVE RESEARCH METHODS

There are two main types of research methods, quantitative and qualitative. Basic research relies on quantitative methods. However, social and behavioural researchers may use a mixture of quantitative and qualitative methods.

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<sup>18</sup> NHMRC, (1998) *Guide to the Development, Implementation and Evaluation of Clinical Practice Guidelines*, Commonwealth of Australia, Canberra. <<http://www.nhmrc.gov.au/publications/pdf/cp30.pdf>> page viewed 14<sup>th</sup> December 2004.

In behavioural or social research, quantitative methods involve measuring and / or the statistical analysis of data. It often involves collecting very structured information using closed questions, for example recording a person's experience of pain on a scale of 1 to 10 or measuring reactions to a treatment. Data for quantitative research is usually obtained through questionnaires or standardised tests. Quantitative research is often seen as providing greater reliability, so that if a study is repeated under identical circumstances it should produce the same results. However quantitative research is sometimes criticised as it may not look at issues in sufficient depth.

In behavioural or social research, qualitative research focuses on the way people interpret and make sense of their experiences and the world in which they live by seeking to understand why and how things happen. The information is collected in a less structured way and is analysed in a non-mathematical way. Qualitative research often involves using open questions which invite a depth of information, such as 'how did you feel about the treatment you received?' Such data can be obtained through focus groups, interviews, observations and videos<sup>19</sup>. Some people regard qualitative research as less reliable than quantitative research as it is more open to interpretation. However, consumers place a high value on qualitative research as it can identify and validate their experiences.

## ARE THERE ANY EXAMPLES OF CONSUMERS RUNNING THEIR OWN RESEARCH PROJECTS?

Yes! Consumers' research is research undertaken from a consumer perspective, by or with consumers, arising from 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 the *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<sup>20</sup> report how a state-wide 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)

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<sup>19</sup> Consumers in NHS Support Unit (now INVOLVE), (2001) *Getting Involved in Research: A Guide for Consumers*, London, <[http://www.invo.org.uk/pdfs/guide\\_for\\_consumers.pdf](http://www.invo.org.uk/pdfs/guide_for_consumers.pdf)> page viewed on 14<sup>th</sup> December 2004.

<sup>20</sup> Wadsworth Y and Epstein M, (1998) 'Building in dialogue between consumers and staff in acute mental health services' *Systematic Practice and Action Research*, vol 11, pp353-379. This was also written up as *The Essential U&I* by Y Wadsworth, Victorian Health Promotion Foundation, 2001.

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 quality care following miscarriage, and the information and other strategies general practitioners needed to enhance their capacity to provide quality care<sup>20</sup>.

Bastian<sup>21</sup> (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.

The Consumers' Health Forum of Australia (CHF) has published a *Guide for Consumers Doing Health Research*, which is available at <[http://www.chf.org.au/Docs/Downloads/269\\_researchguide.pdf](http://www.chf.org.au/Docs/Downloads/269_researchguide.pdf)> or by calling 02 6273 5444. The webpage was viewed on 14<sup>th</sup> December 2004.

## FURTHER RESOURCES

NHMRC *National Statement on Ethical Conduct in Research Involving Humans*  
This outlines what is and is not ethical in research involving humans. It governs the work of Human Research Ethics Committees. Research which does not comply with the *National Statement* cannot be approved by an ethics committee. The *National Statement* is available at <<http://www.nhmrc.gov.au/publications/synopses/e35syn.htm>> or by calling 1800 020 103 ext 9520. The web page was viewed on 14<sup>th</sup> December 2004.

### Research Bites

This series of one page factsheets is aimed at those wanting to improve their understanding of research basics. These are available at <[http://www.phcris.org.au/resources/phcred/redresources\\_frameset.html](http://www.phcris.org.au/resources/phcred/redresources_frameset.html)>. The webpage was viewed on 14<sup>th</sup> December 2004.

### A Guide for Consumers Doing Health Research

This was produced by CHF to help consumers who are considering undertaking their own research project. It is available from <[http://www.chf.org.au/Docs/Downloads/269\\_researchguide.pdf](http://www.chf.org.au/Docs/Downloads/269_researchguide.pdf)> or by calling 02 6273 5444. The webpage was viewed on 14<sup>th</sup> December 2004.

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<sup>21</sup> Bastian H, (1998) 'Speaking up for Ourselves: The Evolution of Consumer Advocacy in Health Care', *International Journal of Technology Assessment in Health Care*, 14:1

*The Australian Health Consumer*, the journal of the Consumers' Health Forum of Australia, is available at <[http://www.chf.org.au/public resources/AHC browse.asp#20011](http://www.chf.org.au/public_resources/AHC_browse.asp#20011)>. The webpage was viewed on 14<sup>th</sup> December 2004. Copies can also be obtained by calling CHF on 02 6273 5444. The following issues contain articles on consumers and research.

- 2003, Issue 3
- 2003, Issue 2
- 2001, Issue 1

The following websites may also be useful:

Australian Society for Medical Research – <[www.asmr.org.au](http://www.asmr.org.au)>

Cochrane Library - <[www.nicsl.com.au/cochrane/](http://www.nicsl.com.au/cochrane/)>

Consumers' Health Forum of Australia – <[www.chf.org.au](http://www.chf.org.au)>

Informed Health Online - <[www.informedhealthonline.org](http://www.informedhealthonline.org)>

Medicines Australia - <[www.medicinesaustralia.com.au/](http://www.medicinesaustralia.com.au/)>

National Electronic Library for Health (UK) – <[www.nelh.nhs.uk](http://www.nelh.nhs.uk)>

National Health and Medical Research Council – <[www.nhmrc.gov.au](http://www.nhmrc.gov.au)>

Research Australia - <[www.researchaustralia.org](http://www.researchaustralia.org)>

## PART FOUR ABOUT CLINICAL TRIALS

As noted above, there are several broad types of research: basic; clinical; public health; and health services research. Clinical research is only one example and clinical trials are only one part of clinical research. So why include a whole chapter on clinical trials? The reason is simply that participating in a clinical trial is a very common way for consumers to be involved in research.

### WHAT IS A CLINICAL TRIAL?

Every new drug, medical device or therapy has to be tested in a clinical trial before it can routinely be provided to consumers. Clinical trials are designed to answer questions about new therapies, or new ways of using existing treatments, to determine whether or not they are safe and effective.

Clinical trials are often funded by pharmaceutical companies as part of their development and testing of new products. This makes them one of the most significant funders of clinical trials in Australia. Industry sponsorship of clinical trials has often given health consumers early access to treatments that are not yet available through the Australian health care system.

Clinical trials of medicines are generally classified according to the phase of the medicine's development. While individual phases may not be clearly defined, the following definitions are generally accepted and are useful for considering the context in which clinical trials are undertaken:

- **Phase I** studies involve the first administration of the treatment to humans, usually to small numbers of healthy volunteers (less than 100). The purpose of Phase I studies is to find out if the treatment is safe, determine a safe dose range and identify any side effects. Phase I studies are usually undertaken in centres appropriately equipped for the specialised monitoring and the high degree of surveillance needed;
- **Phase II** studies are the first trials of the treatment in patients suffering from the condition for which the treatment is intended. The principal aim of these studies is to find out if the proposed treatment is effective and to learn more about its safety. These studies are undertaken in a small number of closely supervised patients and conducted by researchers regarded as specialists in the particular disease or condition and its treatment. Such studies may involve 100 – 300 people;
- **Phase III** studies involve greater numbers of patients (maybe 1000s) and are undertaken to
  - Confirm the new treatment's effectiveness in comparison to standard treatment

- Monitor side effects
- Collect information that will allow the drug, treatment or device to be used safely

Phase III studies are undertaken if the Phase II studies indicate the treatment has potential benefit that outweighs the hazards. If the new treatment is a medicine and the Phase III studies show it to be safe and effective, the Therapeutic Goods Administration (part of the Commonwealth government) will usually register it for use in Australia; and

- **Phase IV** studies are those studies undertaken after the treatment has been approved for use in Australia. These studies continue to collect information about
  - Any long term side effects (monitored by the Therapeutic Goods Administration)
  - Any particular effects in various populations such as different races, ages, genders.

Phase IV trials are sometimes known as post-market surveillance studies. At this stage, it has been proven that the drug or device is safe and effective. Phase IV trials are therefore done for a different reason than Phase I – III trials, which seek to establish safety and efficacy. In a Phase IV trial, the company may be keeping a watchful eye for any as yet unknown side effects. The company may also be keen to find anything that could be used to market the drug more effectively to doctors who might prescribe it to their patients.

Once a drug has been registered and can therefore be prescribed in Australia, pharmaceutical companies may employ representatives to visit GP surgeries or hospitals to promote the drug to health professionals. Pharmaceutical companies will often also sponsor training events or advertise their product in medical journals to ensure that it captures the attention of potential prescribers.

Pharmaceutical companies have agreed to be bound by Medicines Australia's voluntary *Code of Conduct*<sup>22</sup>, which sets the standards for the ethical marketing and promotion of prescription pharmaceutical products in Australia. It complements the legislative requirements of the Therapeutic Goods Act and the Therapeutic Goods Regulations.

## Timescales

A clinical trial may take several years to complete. After this testing on humans has finished, the researchers must analyse the data, write up their results and get them published in a peer-reviewed journal.

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<sup>22</sup> Medicines Australia *Code of Conduct*, edition 14, 2002. <<http://www.medicinesaustralia.com.au/public/Code%20of%20Conduct%20Edition%2014%20-%20Jan%2003.pdf>> page viewed 14<sup>th</sup> December 2004.

**What are the benefits of being in a clinical trial?**

People participating in clinical trials may benefit from:

- Access to new treatments, not yet available outside a trial setting;
- Free use of the treatment in the trial;
- Expert medical care at leading hospitals and health centres during the trial; and
- Helping others by contributing to medical research.

**What are the risks of being in a clinical trial?**

The downsides of being in a clinical trial could include:

- People not being able to choose their own treatment – participants may be randomly selected to receive one treatment instead of another (or a dummy drug instead of the trial treatment), no matter what their own preferences might be;
- People taking treatment that doesn't work for them or at a dose that doesn't suit them;
- Experiencing side effects from the trial treatment; and
- Time-consuming trips to see the researchers.

**What information should clinical trial participants receive?**

Trial participants should receive sufficient information to help them decide whether or not to join the trial. The *Note for Guidance on Good Clinical Practice* details the sort of information that consumers should receive. This includes:

- Whether the trial involves the use of an unproven drug, device or therapy;
- The purpose of the research;
- What treatment(s) will be offered in the trial and the probability that the participant will be randomly assigned to a treatment, rather than able to choose his / her own;
- Alternatives to participating in the trial;
- The reasonably expected benefits of the trial. Where there is no intended clinical benefit to the participant s/he should be made aware of this;
- The compensation available to the participant in the event of any trial-related injury;
- That participation is voluntary and that the participant may withdraw from the trial at any time without penalty or loss of benefits to which s/he would otherwise be entitled;



- Who to contact for further information about the trial and the rights of trial participants and who to contact in the event of trial related injury;
- How long the study is expected to take (and how long the participant needs to be involved for, if this is different); and
- Privacy of information gathered during the trial.

Human Research Ethics Committees may lay down additional requirements about the information that consumers should receive about the trial.

Before deciding whether or not to take part in a clinical trial, consumers may want to find out how the researcher plans to let participants know the results. Will the results be reported publicly, whether in a company report or through publication in a peer-reviewed journal? Will there be a summary of results for participants? If there are no plans to report the results publicly and in a consumer friendly manner, then consumers may need to consider carefully whether or not to participate in the research.

There is some evidence to suggest that trials with disappointing or negative results are less likely to be submitted for publication than those with positive results<sup>23</sup>. The Cochrane Collaboration (discussed below) notes that,

“The results of many studies are never published, and most of these probably remain unknown. If studies showing an intervention to be effective are more likely to be published, then any summary of only the published reports may result in an overestimate of effectiveness due to a publication bias<sup>24</sup>.”

This is known as publication bias and has serious consequences. In some cases, patients have continued to receive drugs that a study had proved to be harmful because the results were never published<sup>25</sup>.

## WHAT ARE THE RIGHTS OF CLINICAL TRIAL PARTICIPANTS?

People who participate in research have certain rights such as the right to:

- Agree or refuse to participate without pressure;
- Receive balanced information about potential risks and benefits of the trial before deciding whether or not to participate;

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<sup>23</sup> Dickersin K, (1997) ‘How important is publication bias? A synthesis of available data’. *AIDS Education Prevention*; 9: 15-21.

<sup>24</sup> Alderson P, Green S, Higgins JPT, editors. *Formulating the problem. Cochrane Reviewers’ Handbook 4.2.2* [updated December 2003]; Section 5. <<http://www.cochrane.dk/cochrane/handbook/hbook.htm>> website viewed on 14th December 2004.

<sup>25</sup> Yamey G, (1999) ‘Scientists who do not publish trial results are unethical’ *British Medical Journal*; 319:939.

- Receive (or choose not to receive) the results of any tests that are carried out on them, where this is possible within the trial's methodology;
- Bring any complaint or concern about the trial to the attention of the Human Research Ethics Committee; and
- Withdraw from the trial at any time if they wish to.

## WHAT ROLE DOES THE THERAPEUTIC GOODS ADMINISTRATION PLAY IN REGULATING CLINICAL TRIALS?

Clinical trials involving drugs or medical devices must meet the Therapeutic Goods Administration's (TGA) requirements under its Clinical Trials Exemption (CTX) or Clinical Trials Notification (CTN) schemes.

The main difference between CTN and CTX is the involvement of the TGA in reviewing data about the medicine or device involved in the trial before it begins<sup>26</sup>. In CTN trials the TGA does not review any data before the trial begins. The responsibility for this review lies with the institution's Human Research Ethics Committee (HREC) and the principal investigator. The HREC and the institution are responsible for establishing what information should be provided in support of an application and how that application will be handled by the committee.

In CTX trials the TGA reviews summary data about the therapeutic good (medicine or medical device). The TGA then provides comment to the HREC about the product. The TGA also stipulates the minimum data which must be provided to the HREC. This data includes summary information about the product, the overseas regulatory status of the product and the Proposed Usage Guidelines for the product. The HREC and the institution may require additional information to be provided in support of an application.

HRECs are responsible for reviewing clinical trial protocols for both CTX and CTN. The responsibility for the conduct of the trial rests with the principal investigator and the sponsor.

The HREC provides advice to the sponsor and the institution on the trial before it begins and during the course of the trial. Clinical trials, both CTN and CTX must be conducted according to the protocol which the HREC has approved, *Good Clinical Practice (GCP)* and the National Health and Medical Research Council's (NHMRC's) *National Statement on Ethical Conduct in Research Involving Humans*.

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<sup>26</sup> Therapeutic Goods Administration, (2001) *Human Research Ethics Committees and the Therapeutic Goods Legislation*, Department of Health and Aged Care, Canberra, [www.tga.gov.au/docs/html/hrec.htm](http://www.tga.gov.au/docs/html/hrec.htm)> Page viewed 14<sup>th</sup> December 2004.

## Vignette of a Consumer Involved in Research

I was diagnosed with breast cancer in 1987 and introduced to consumer advocacy when I became a volunteer with the Queensland Cancer Fund following my diagnosis. My perspective as a consumer was sought for a variety of projects, including the development of resources and speaking to the media about what was important for women diagnosed with breast cancer.

Over time, my involvement in breast cancer issues has expanded and opportunities to participate in a variety of aspects of breast cancer advocacy including collaboration with researchers on specific research projects have presented themselves.

My commitment to improving outcomes for women has opened doors that may not otherwise have been opened and I consider myself extremely fortunate to have been given opportunities to work in partnership with a wide network of researchers, health providers and the members of the community.

When the National Breast Cancer Centre was established I became a member of its Consumer Advisory Board and it was this group of women who were instrumental in advocating for the establishment of the Breast Cancer Network Australia. I am a member of the Consumer Advisory Panel of the Australian New Zealand Breast Cancer Trials Group (ANZBTG) and am the Consumer Coordinator of IMPACT (Improving Participation and Advocacy for Clinical Trials), an initiative of the ANZ BCTG, which acknowledges the input of women who participate in breast cancer research, raises awareness in the community and advocates for breast cancer clinical trials. In addition, I am assistant coordinator of the Wesley Hospital Kim Walters Choices Program which offers free community support to women diagnosed with breast cancer and their families. It is through these organisations and many others like them that I am able to continue to contribute in my way, to improve breast cancer outcomes.

My goal is to continue to broaden these networks whilst promoting an atmosphere of mutual respect between researchers and consumer advocates. It is exciting to witness and to have been a part of the growth of consumer advocacy in Australia, however, the reward of being involved in the community in this way is not limited to personal satisfaction. It has led to lasting friendships and I value the opportunity of sharing the goal of improving outcomes for women and their families who experience breast cancer.

*Leonie Young*  
*IMPACT, December 2004*

## HOW DO RESEARCHERS MINIMISE BIAS?

Bias is defined as ‘a particular tendency or inclination, which prevents the unprejudiced consideration of a question.’ Biases can be positive or negative but we all have some. Bias can creep into research because of the way a study is designed or because of what the people running it expect to find. Some particular research methods have arisen in order to minimise the likelihood of bias.

### **Selection Bias**

This occurs in two ways:

- In the choice between those people who are suitable to participate in the study and those who are not. This can be minimised by carefully deciding on who is eligible for enrolment in the research study; and
- In the allocation of people to a particular arm of a trial, e.g. to receive the new treatment or to receive the standard treatment or a placebo. There is an obvious risk of bias if providers or participants are left to choose who will be in which arm. This is why researchers often randomly allocate people to each arm of the trial. In many cases, researchers will run a ‘blind’ trial where the participants, the researchers, or both do not know who is receiving which treatment.

### **Attrition bias**

Research participants are free to leave a study whenever they wish. However, it is important that their data informs the conclusions. For example, a sub-group of those in the trial may drop out of it because they experience problematic side-effects, which others in the trial do not experience. This is very important information about the drug and should be reflected in the overall conclusions. It would be a worry if the trial reported that there were few side effects, simply because those who remained in the trial did not experience them.

### **Publication Bias**

As discussed above, this is the bias towards reporting ‘successful’ studies rather than publishing unfavourable results as well. This is not to suggest bias on the part of individual researcher or sponsor but rather to highlight that there are biases in the system which favour the publication of positive results. There are many important influences, in particular the desire of journals to have exciting positive results and the high rejection rates this involves. Researchers who are motivated to publish negative results can find it very difficult to find a publisher.

## WHAT IS A SYSTEMATIC REVIEW?

Only rarely is a single trial big and strong enough to provide, on its own, a reliable answer about the effects of a health care treatment. One small trial could suggest something works – but it could be outweighed by another 10 trials showing the opposite. It is more common for trials showing benefit from treatment to be publicised, while the results of trials showing no benefit remain unpublished. This can make healthcare treatments look more effective than they really are. A systematic review can combine the results of many trials and provide a comprehensive view of that healthcare treatment.

Often, a systematic review will conclude that there is not enough strong evidence to give an answer. This provides a guide to where more research is needed, so that if not now, then at least in the future there may be an independent, scientifically rigorous and reliable answer about what treatments might be able to help<sup>27</sup>.

## WHAT IS THE COCHRANE COLLABORATION?

The Cochrane Collaboration is an international non-profit and independent organisation, dedicated to making up-to-date, accurate information about the effects of healthcare readily available worldwide. It produces and disseminates systematic reviews of healthcare interventions and promotes the search for evidence in the form of clinical trials and other studies of interventions. The Cochrane Collaboration was founded in 1993 and named for the British epidemiologist, Archie Cochrane.

The major product of the Collaboration is the Cochrane Database of Systematic Reviews which is published quarterly as part of the Cochrane Library. Those who prepare the reviews are mostly health care professionals who volunteer to work in one of the many Collaborative Review Groups, with editorial teams overseeing the preparation and maintenance of the reviews, as well as application of the rigorous quality standards for which Cochrane Reviews have become known. Many review groups also include consumers, who comment on the consumer aspects of the work.

Cochrane reviews go through all the steps of systematic review – and they go one step further. The reviews are updated. The Cochrane Collaboration's goal is to check every review at least every two years and update them when new research or other information emerges. A Cochrane review provides the most reliable answer known to the question of "Does this treatment work?"

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<sup>27</sup> Informed Health Online, *About reviews* <<http://www.informedhealthonline.org//item.aspx?tabid=8&pagerequest=1>> page viewed on 14<sup>th</sup> December 2004.

## The Cochrane Library

The Cochrane Library is an on-line database of scientific research drawn from around the world. It is renowned for being one of the best sources of reliable evidence about health care interventions. The Australian Government and the National Institute for Clinical Studies have ensured that all Australians can have free access to the Cochrane Library. Go to <http://www.nicssl.com.au/cochrane/> to find out more.

## Cochrane Consumer Network

The Cochrane Consumer Network (CCNet) supports consumers to provide their perspectives to the Cochrane Collaboration and its systematic reviews by facilitating communication, training and guidance. The Network encourages consumers throughout the world to give their perspectives and have their say on priorities for health care and encourages the concept of evidence-based practice with a forward thinking approach to improvement of health care.

The Cochrane Consumer Network believes that consumer participation aids the development of high-quality and relevant systematic reviews, and that these reviews can actively inform evidence-based practice in health care with effective dissemination. The Consumer Network also:

- provides links for consumers to Cochrane groups;
- develops materials, training materials and workshops to facilitate effective consumer participation and accessibility to Cochrane reviews by consumers;
- maintains these web pages;
- publishes regular newsletters; and
- provides an avenue for consumer representation, including from developing countries.

Further information about the Cochrane Consumer Network is available at <http://www.cochrane.org/consumers/homepage.htm>.

## WHAT LEVELS OF EVIDENCE ARE THERE?

Not all research is equal! Some findings are based on observations of a small group of people whilst others are drawn from very large, carefully controlled trials. In other situations, there may never have been any systematic research and doctors may have to rely on the advice of their more experienced colleagues.

Because of this, evidence from medical research is categorised into 4 different levels:

- **Level I:** evidence is obtained from a systematic review of all relevant randomised controlled trials (this is the gold standard);

- **Level II:** evidence is obtained from at least one properly designed randomised controlled trial;
- **Level III:** evidence is obtained from well-designed controlled trials without randomisation; or from well-designed cohort or case-control analytic studies, preferably from more than one centre or research group; or from multiple time series with or without the intervention; and
- **Level IV:** represents the opinions of respected authorities based on clinical experience, descriptive studies or reports of expert committees.

## FINDING OUT MORE ABOUT CLINICAL TRIALS

Research Australia has produced a very useful booklet on clinical trials which is available at <<http://www.researchaustralia.org/files/clinical%20trials%20new%20banner.pdf>> or by calling (02) 9227 0875. The webpage was viewed on 14<sup>th</sup> December 2004.

Trials Central also provides information on clinical trials, including a suite of frequently asked questions and a database of trials. Trial Central's website is <<http://www.trialscentral.org/>>. The webpage was viewed on 14<sup>th</sup> December 2004.

In addition, Current Controlled Trials provides two databases of current controlled trials at <<http://www.controlled-trials.com/>>. The website was viewed on 14<sup>th</sup> December 2004.

The Clinical Study Results site at <[www.clinicalstudyresults.org](http://www.clinicalstudyresults.org)> is a central repository for clinical study results which has been established to make clinical trial results for U.S.-marketed pharmaceuticals more transparent. The website was viewed on 14<sup>th</sup> December 2004.

In the UK, the National Electronic Library for Health has produced a website on clinical trials at <<http://www.nelh.nhs.uk/clinicaltrials>>.

The Therapeutic Goods Administration provides information on the CTN and CTX schemes at <<http://www.tga.gov.au/docs/html/clintrials.htm>>. The webpage was viewed on 14<sup>th</sup> December 2004.

## **PART FIVE RESEARCH TEAMS OR ORGANISATIONS**

### **Current practice**

In Australia, health and medical research is carried out in universities, hospitals and medical research institutes as well as government agencies (such as CSIRO<sup>28</sup>), health service groups, research consortia, pharmaceutical companies, biotechnology enterprises, and other health interest groups. An increasing number of community based health groups, such as Divisions of General Practice, are undertaking research relevant to their fields of interest.

Some organisations are largely funded through the public purse. Others rely primarily on private funding from wealthy individuals and businesses for their core budget, seeking public grants for specific research projects. Some research organisations have developed strong public relations strategies to help raise their profile and funds. Such public relations work, which seeks to promote the organisation to the community, must be distinguished from consumer and community participation which seeks the engagement of the community in the organisation's work.

Australian health and medical research includes basic, laboratory based research, clinical research, public health research, and health services research. In some projects, participants will undertake a one-off procedure such as the completion of a survey or the donation of a blood or tissue sample. These bring the accompanying ethical issues of privacy, use of biological material and the nature of genetic information that can be obtained.

Other projects may require more active participation over a longer period of time, such as taking a particular course of treatment in a particular way, or making a significant lifestyle change. Some researchers therefore have far greater contact with participants in their research than other researchers do. Some researchers are far more comfortable with the idea of consumer and community participation in their work than others.

Structured consumer and community participation in health and medical research is still quite rare in Australia. Several organisations have taken steps to develop consumer and community participation but most organisations do not involve consumers as yet. Some possible obstacles to consumer and community participation are:

- Researchers being unconvinced of the value of consumer and community participation or fearful that consumers will obstruct their work rather than working in partnership with them

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<sup>28</sup> Commonwealth Scientific and Industrial Research Organisation



- Researchers lacking the time or money to initiate consumer and community participation
- Researchers who are willing to involve consumers but feeling unsure of how to do so

### **Building consumer and community participation into the research team or organisation**

Developing consumer and community participation will take time and effort on behalf of the research team or organisation and on behalf of consumers. Progress is made more easily when there is a high level champion of consumer and community participation who can influence others in the team or organisation. However, such influential people will not usually have the time to do the groundwork necessary to bring about change. Other people are required with the capacity to reflect on current practice, reach out to the community, develop policies, organise training and bring together researchers and consumers. In some organisations, these tasks may be split across existing staff. In other cases, it may be necessary to employ someone with the right mix of skills, contacts and experience to create partnerships between researchers and consumers. Such a person needs to have credibility with both consumers and researchers.

Progress may be slow initially as researchers' beliefs about consumer and community participation are uncovered. It is important to work with staff in the research organisation to ensure that their views are considered and, if possible, their perceived barriers addressed. Working in partnership requires both parties to be willing to work together, therefore imposing consumer and community participation on researchers is unlikely to be successful. The challenge is to nudge people out of their comfort zones of working without consumers but not to push them faster than they are capable of moving.

If there are areas where both consumers and researchers are willing to work together, then it could be helpful to focus attention there initially. As the relationships develop there may be a greater interest in developing consumer and community participation in other aspects of the organisation's work.

### **Finding consumers**

Does the team or organisation have any existing links with consumer and community groups? If so, what are they? Are there mailing lists for newsletters, groups who have requested a researcher to speak to them, organisations or individuals which have donated funds or volunteered to help the organisation on previous occasions? Such existing links can provide a basis for developing closer relationships with consumers and community members.

Another approach is to consider the work done by researchers in the team or organisation. Who is it relevant to? Which individuals or groups might the research benefit? From this information it should be possible to compile a list of consumer groups who might be interested in the work. It could be helpful to think of the following types of consumer or community groups:

- *Population groups* with an interest in health, such as women's groups, older people's groups, culturally and linguistically diverse groups
- *Condition specific groups*, for example asthma, diabetes, chronic fatigue, cancer, mental health groups
- *Health interest groups*, such as carers' organisations

To find local groups, it may be helpful to contact the national offices of relevant groups (such as Council on the Ageing or the Arthritis Foundation) to find out if they have a local branch. The local Council or library may have listings of community groups which meet locally. This can be a good way of finding smaller support groups.

Some States have a state level health consumer organisation which can provide advice on locating consumers in the area. These are:

<b>South Australia</b>	Health Consumers' Alliance GPO Box 2248 ADELAIDE, SA 5001 Tel: 08 8232 0422
<b>Western Australia</b>	Health Consumers' Council of WA GPO Box C134 PERTH, WA 6001 Tel: 08 9221 3422 < <a href="http://www.hcc-wa.global.net.au/index2.html">http://www.hcc-wa.global.net.au/index2.html</a> >
<b>Australian Capital Territory</b>	Healthcare Consumers of the ACT PO Box 171 MAWSON, ACT 2607 Tel: 02 6290 1660 < <a href="http://www.actcommunity.org/hcca/hcca.htm">http://www.actcommunity.org/hcca/hcca.htm</a> >

Another organisation, which might be useful in Victoria, is the Health Issues Centre, which can provide a consumer view on research issues.

Health Issues Centre  
Level 5, Health Sciences 2  
La Trobe University  
VIC 3086  
Tel: 03 9479 5827  
<<http://www.healthissuescentre.org.au>>

The Consumers' Health Forum of Australia (CHF) can also offer advice on locating consumer groups in Australia. CHF's membership comprises around 100 health consumer organisations across the country reaching nearly one million health consumers. The member list on CHF's website provides links to websites of member organisations, some of whom may have people interested in the work of the research organisation or team.

Consumers' Health Forum of Australia  
PO Box 3099  
MANUKA, ACT 2603  
Tel: 02 6273 5444  
<[www.chf.org.au](http://www.chf.org.au)>

In the early stages, one or two interested and experienced consumers could be asked to help identify other consumers and community members in the area.

This *Resource Pack* is accompanied by a *Model Framework for Consumer and Community Participation in Health and Medical Research*. The Model Framework is written specifically for researchers or organisations wishing to develop consumer and community participation in their work. Copies of the *Model Framework* can be obtained from CHF.

## GLOSSARY

Health and medical research is a very complicated and specialised field of study. It is difficult to break it into categories as there will always be research that does not fit neatly into the options given. The following<sup>29, 30</sup> is an attempt to describe certain research methods and to categorise the different types of research, to help people learn more about them. It is not an exhaustive list.

<i>Adverse reaction</i>	An unpleasant or dangerous effect in response to a treatment. (Also known as a side effect.)
<i>Arm</i>	A controlled trial has at least two arms: that is, at least two groups of people experiencing different treatment. A control arm or group is a group of people not receiving an experimental treatment. They might be getting the current standard treatment or a placebo (dummy) treatment. Experimental arms are the groups of people getting the treatment (or treatments) being tested.
<i>Applied research</i>	Original work undertaken in order to acquire new knowledge with a specific application in view. It is undertaken either to determine possible uses for the findings of basic research or to determine new methods or ways of achieving some specific and predetermined objectives <sup>31</sup> .
<i>Basic research</i>	Experimental and theoretical work undertaken primarily to acquire new knowledge without a specific direct application in view. It consists of pure basic research and strategic basic research. Pure basic research is carried out without looking for long-term benefits other than the advancement of knowledge. Strategic basic research is directed into specified broad areas in the expectation of useful discoveries. It provides the broad base of knowledge necessary for the solution of recognised practical problems <sup>32</sup> .

<sup>29</sup> Extracted from the Primary Health Care Research and Information Service at <[http://www.phcris.org.au/resources/research/research\\_frameset.html](http://www.phcris.org.au/resources/research/research_frameset.html)>, page viewed on 14<sup>th</sup> December 2004. PHCRIS drew on *The Virtuous Cycle: Working together for health and medical research*, Health and Medical Research Strategic Review, Commonwealth of Australia, Canberra, 1999.

<sup>30</sup> Abridged from the Informed Health Online *Dictionary of Research Terms for Consumers* at <<http://www.informedhealthonline.org/item.aspx?tabid=15>>. Page viewed 14<sup>th</sup> December 2004.

<sup>31</sup> Australian Bureau of Statistics, *Australian Standard Research Classification (ASRC) 1998, Chapter 2: Type of activity classification*, <<http://www.abs.gov.au/ausstats/abs@.nsf/66f306f503e529a5ca25697e0017661f22e4c184ca111129ca25697e0018fd78!OpenDocument>>

<sup>32</sup> Australian Bureau of Statistics, *Australian Standard Research Classification (ASRC) 1998, Chapter 2 Type of activity classification*, <<http://www.abs.gov.au/ausstats/abs@nsf66f306f503e529a5ca25697e0017661f/22e4c184ca111129ca25697e0018fd78!OpenDocument>>, accessed 14 December 2004.

Basic research is undertaken to address fundamental questions about the biological, behavioural and social mechanisms, which underlie wellness and disease.

*Blind / blinding*

Blinding (also called masking) refers to the process of preventing people from identifying whether a particular person is receiving an experimental treatment in order to minimise possible biases. There are several types of blinding:

- A single blind trial: only one party (eg participants or practitioners administering treatment) has been masked;
- Double blind: both the experimenter and the people ('patients') in the trial do not know to which arm of a trial the person has been assigned; and
- Triple blind: experimenters, participants, and those assessing outcomes are unaware of what treatment the participant received.

*Clinical research*

Research involving clinical patients or tissue samples from patients. It is undertaken to find better ways of identifying and caring for people in ill health. Has a more biomedical orientation than health services research.

*Clinical trial*

A clinical trial involves administering a treatment to test it. It is an experiment. Clinical trial is an umbrella term for a variety of health care trials, whether controlled or uncontrolled. Types include uncontrolled trials, controlled clinical trials (CCT), community trials, and randomised controlled trials (RCT). A clinical trial is also sometimes called a 'therapeutic trial'.

*Consent*<sup>33</sup>

In most cases, the potential research participants must give their consent before the research goes ahead. The researcher or institution must provide information about the purpose, methods, demands, risks, inconveniences, discomforts and possible outcomes of the research. The potential research participant has the right to decide against participating, without any need to justify themselves. Coercion, influence or pressure of any kind by the researchers or institution is unethical. If the individual decides to participate, they must record their agreement in some way, such as signing a form. They have the right to withdraw from the research at any time. Certain types of research, such as anonymous surveys, don't require prior consent from participants.

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<sup>33</sup> Taken from Better Health Channel, <<http://www.betterhealth.vic.gov.au>> page viewed 14<sup>th</sup> December 2004.

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<i>Control</i>	The people in a 'control' group or arm in a controlled trial or a case-control study (also called the comparison group). In a trial, people who are the 'controls' represent the status quo (current standard treatment) or placebo (dummy) treatment, against which the effectiveness of a treatment is tested. In a case-control study, the controls are the people who do not have the condition being studied: the 'cases' are the people who have the condition.
<i>Development and evaluation research</i>	Creates and assesses products (vaccines, drugs, diagnostics, prostheses or equipment), interventions (public or personal health services) and instruments of policy that improve on existing options.
<i>Generalisability</i>	Whether or not the results experienced by people in a study can be presumed to apply (be applicable or generalisable) to another group of people or population.
<i>Health policy and systems research</i>	Research about health-related institutions and their role in shaping policy and improving implementation. Range of approaches includes: clarification of concepts and issues; data sets on systems performance; retrospective case studies; and prospective evaluations and experiments.
<i>Health services research</i>	Research into health services to examine ways of improving delivery of health services, e.g. cost benefit studies of health programs. Has a more operational and economic orientation than clinical research.
<i>Intention to treat analysis</i>	Analysing the results according to the intended treatment which someone chose or was allocated to, as opposed to looking at the results according to the treatment they actually received.
<i>Investigator-initiated research</i>	Research that allows someone with a strong desire or bright idea to pursue it, whether it is perceived as a priority or not.
<i>Multi-centre</i>	Research is mostly conducted within a prescribed area, or within a single institution. A trial is sometimes conducted between a number of collaborating institutions - particularly when very large numbers of people are needed to complete a trial. Those trials are called 'multi-centre' trials, or trials conducted at several or multiple 'sites'.

*National Health and Medical Research Council (NHMRC)*

NHMRC is Australia's leading public funder of health and medical research. According to the NHMRC Act (1992), its role is:

- to raise the standard of individual and public health throughout Australia;
- to foster the development of consistent health standards between the various States and Territories;
- to foster medical research and training and public health research and training throughout Australia; and
- to foster consideration of ethical issues relating to health.

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 Indigenous groups.

*Number needed to treat*

A number which gives an estimate of how many people need to receive a treatment before one person would experience the beneficial outcome. Example: If a stroke prevention drug needs to be taken by 20 people before one stroke is prevented, then the NNT for that stroke prevention drug is 20.

*Observational study*

A survey or non-experimental study. The researchers are examining and reporting on what is happening, without deliberately intervening in the course of events.

*Open label trial*

This is a non-blind / non-masked trial - one where everyone knows what drug is being used, and at what dose.

*Placebo*

A fake (sham, dummy, inert) treatment, given to people in a control group so they can't know whether or not they are in an experimental or control group. A placebo is meant to be both useless and harmless.

*Population*

The group of people being studied, which may or may not be the population of a particular geographical area. The population in question in a research study, for example, may be 'people with ovarian cancer'. The study of the health of populations, as opposed to health of individuals, is epidemiology.

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<i>Prevalence</i>	The proportion of a population having a particular condition or characteristic, for example the percentage of people in a city with a particular disease, or who smoke.
<i>Peer-review</i>	Peer-review is a process by which independent experts analyse the results of the research. A researcher will usually submit an article to a journal that will send it on to a team of experts for review. These independent experts comment on the strengths and weaknesses of the research and may suggest amendments to the researcher. If the peer-reviewers judge the research to be of good quality, they will usually recommend that the journal should publish it.
<i>Priority driven research</i>	Where there is a need to make a concerted medium to long term effort to address a specific question or issue.
<i>Protocol</i>	Trials and systematic reviews should be undertaken according to a clearly defined protocol, which prospectively sets out what is being tested, why, and how it will be done. The trial or review should then adhere strictly to the pre-set actions in the protocol to maintain uniformity and minimise bias.
<i>Public health research</i>	Research involving communities or populations, typically outside health care institutions. It is undertaken to identify the factors which contribute to ill-health in populations and ways of influencing these factors to prevent disease. It includes epidemiology, social and behavioural sciences, health services research on population - based health interventions, and health promotion.
<i>Randomised controlled trial</i>	<p>In a randomised controlled trial, participants are assigned by chance to receive experimental or control treatment. When randomised trials are done properly, the effect of treatments can be studied in groups of people who are:</p> <ol style="list-style-type: none"><li>1) the same at the outset, and</li><li>2) treated the same way, except for the intervention(s) being studied.</li></ol> <p>Any differences then seen in the groups at the end can be attributed to the difference in treatment alone, and not to bias or chance.</p>



*Risk (absolute)*

Risk is presented in two different ways. The main factor to bear in mind is the size of the original risk – if the risk of suffering a condition is large then any reduction in risk might be beneficial; if the risk of suffering a condition is small, then potential side effects of treatment may mean it is better to avoid the treatment.

Absolute risk refers to the real numbers (e.g. 4 people out of every 100 will get a particular disease – an absolute risk of 4%). An effective drug might reduce this risk to 3 people out of every 100, giving an absolute risk reduction of 1%.

*Risk (relative)*

Relative risk is another way of presenting risk. In the absolute risk example above, the same drug can be said to have reduced the risk of getting the disease by 25% as the original 4 cases have been reduced to 3. In absolute terms though, this is still a reduction of only 1%, meaning it might be better not to take a treatment if the side effects were bad. Had the absolute risk been higher to begin with a person might decide differently. For example, if 40 people out of each 100 got the disease (40% absolute risk) and the drug lowered this to 30 people out of each 100, this would still be a relative risk reduction of 25% but would represent an absolute risk reduction of 10%.

*Strategic research*

Interpreted in Australia as research that focusses on important issues that require special attention from Australian researchers, beyond what can be expected from fundamental investigator-initiated research in Australia or around the world. In the context of our relatively small research capacity, these issues should be those that are unique to or significantly over-represented in Australia, or more severe than in other developed nations, and consequently under-researched.<sup>34</sup>

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<sup>34</sup> The Virtuous Cycle – Working together for health and medical research – Health and Medical Research Strategic Review, 1999 (Wills Review)

# The National Health and Medical Research Council

The National Health and Medical Research Council (NHMRC) was established in 1936 and is now a statutory body within the portfolio of the Australian Government Minister for Health and Ageing, operating under the *National Health and Medical Research Council Act 1992* (NHMRC Act). The NHMRC advises the Australian community and the Australian Government, and State and Territory governments on standards of individual and public health, and supports research to improve those standards.

The NHMRC Act provides four statutory obligations:

- to raise the standard of individual and public health throughout Australia;
- to foster development of consistent health standards between the states and territories;
- to foster medical research and training and public health research and training throughout Australia; and
- to foster consideration of ethical issues relating to health.

The NHMRC also has statutory obligations under the *Prohibition of Human Cloning Act 2002* (PHC Act) and the *Research Involving Human Embryos Act 2002* (RIHE Act).

The activities of the NHMRC translate into four major outputs: health and medical research; health policy and advice; health ethics; and the regulation of research involving donated IVF embryos, including monitoring compliance with the ban on human cloning and certain other activities. A regular publishing program ensures that Council's recommendations are widely available to governments, the community, scientific, industrial and education groups. The Council publishes in the following areas:

- Aged Care
- Blood and Blood Products
- Cancer
- Cardiovascular Health
- Child Health
- Clinical Practice Guidelines – Standards for Developers – Topics
- Communicable Diseases, Vaccinations and Infection Control
- Diabetes
- Drug and Substance Abuse
- Environmental Health
- Ethics in Research–Animal
- Ethics in Research–Human
- Genetics and Gene Technology
- Health Procedures
- Health Promotion
- Human Cloning and Embryo Research
- Indigenous Health
- Injury including Sports Injury
- Men's Health
- Mental Health
- Musculoskeletal
- NHMRC Corporate documents
- NHMRC Session Reports
- Nutrition and Diet
- Oral Health
- Organ Donation
- Poisons, Chemicals and Radiation Health
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- Women's Health

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