RESEARCH AUSTRALIA
AN ALLIANCE FOR DISCOVERIES IN HEALTH

REVIEW OF THE GUARDIANSHIP & ADMINISTRATION ACT 1990 (WA)



August 2013

A submission by Research Australia

ABOUT RESEARCH AUSTRALIA

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

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

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

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Table of Contents

Introduction 3
Why allow participation in research? The risks and benefits 4
Human Research Ethics Committees 4
Consent to participation 5
Research participation in the absence of a person responsible 7
Advance Health Directives 7
Conclusion 7
Appendix 8

REVIEW OF THE GUARDIANSHIP & ADMINISTRATION ACT 1990 (WA)

A SUBMISSION BY RESEARCH AUSTRALIA

Introduction

Research Australia's submission to the review of the Guardianship & Administration Act 1990 (WA) ('the Act') is confined to matters relating to the participation in human research of individuals who are unable to make a reasonable judgment or decision for themselves.

Research Australia proposes the Act be amended to make specific provision for this purpose. The aim of the amendments should be to provide a legal framework for the participation in human research of individuals who are unable to make a reasonable judgment or decision in a manner that:

- protects the individual;
- does not place an unreasonable burden on relatives and friends;
- facilitates participation in appropriate research; and
- is safe, effective, timely and efficient.

Research Australia's chief recommendations are that Human Research Ethics Committees (HRECs) be responsible for determining whether medical research is safe for individuals who are unable to make a reasonable judgment or decision for themselves to participate in; and that persons responsible be able to decide whether a person who is eligible to participate will do so.

For the purposes of this submission, Research Australia is adopting the definition of 'human research' used in the *National Statement on Ethical Conduct in Human Research*. The definition is provided as an Appendix to this submission.

Why allow participation in research? The risks and benefits

There are both risks and benefits associated with participating in human research, regardless of whether an individual has the capacity to make reasoned decisions for themselves. The risks associated with participating in human research can, in the case of medical research, include injury and death. These are risks which are also associated with conventional medical treatments (although the risks with medical research may be less well quantified or known). The risks to individuals without capacity to make decisions for themselves can best be mitigated by restricting participation to human research that has been vetted and approved by properly formulated HRECs, just as they are for individual participants who have full legal capacity.

The benefit of participation in human research can be an improved health outcome for the research participants. In the case of clinical trials, this includes access to the latest drugs at no cost. While the outcome cannot be assured with the same level of probability as for conventional treatments, the possibility of a significantly better outcome exists. While this difference is most stark in circumstances where there is no effective conventional treatment, it can be beneficial even where an existing treatment exists.

As the Act currently stands, individuals who are unable to make a reasonable judgment or decision in respect of their own treatment are effectively denied the opportunity to benefit from participation in human research.

Human Research Ethics Committees

The National Health and Medical Research Council (NHMRC) is an Australian government body charged by the National Health and Medical Research Council Act 1992 (The NHMRC Act) with considering ethical issues relating to health. The Australian Health Ethics Committee (AHEC) is also created under the NHMRC Act.

The *National Statement on Ethical Conduct in Human Research* (The National Statement) is created and issued jointly by the NHMRC, the Australian Research Council and the Australian Vice- Chancellor's Committee. Among other things, it provides for the conduct of ethical human research and the creation and operation of HRECs. While it draws its authority from Commonwealth legislation, it is generally recognised in State and Territory jurisdictions, including Western Australia.

> 'All human research conducted in WA Health must undergo ethical and scientific review, approval and monitoring by a HREC registered with the NHMRC's Australian Health Ethics Committee (AHEC) and operating in accordance with the NHMRC "National Statement on Ethical Conduct in Human Research" 2007'[1]

HRECs review research proposals involving human participants to ensure they are ethically acceptable and in accordance with relevant legislation, standards and guidelines. HRECs typically operate at a local, institutional level (eg. a hospital or university).

In undertaking this role, HRECs are guided by the National Statement, which deals with a range of issues, including

- different types of research;
- research provided as part of treatment, with treatment, or independent of treatment, and the interaction between the treatment and the research;
- confidentiality;
- conflict of interest;
- complaints; and
- consent (including types of research and circumstances in which consent is not required).

[1] http://www.health.wa.gov.au/researchdevelopment/home/hrec.cfm, accessed on 15 August 2013

The Statement also deals directly with the ethical considerations specific to vulnerable people:

- in dependent or unequal relationships;
- who are highly dependent on medical care and unable to give consent; or
- who have a cognitive impairment, an intellectual disability, or a mental illness.[2]

Proposal 1

Research Australia submits the Act should be amended to require an HREC to determine whether individuals who are unable to make a reasonable judgment or decision for themselves are eligible to participate in research the HREC has been asked to approve, and to place appropriate conditions, restrictions and requirements on that participation. This includes a determination by an HREC that the consent of individuals to participation in the research is not required.

Research Australia is of the view that the HRECs are best placed to make these decisions. Requiring the HREC to make these decisions as part of the approval process for any human research to be conducted in Western Australia has several advantages:

- The participation (or not) in research of individuals who are unable to make a reasonable judgment or decision for themselves will be integrated in the design and approval of the research.
- It facilitates the participation of Western Australia in national research- a requirement to obtain additional specific approval from state based bodies could act as a disincentive to including Western Australia in human research.
- HRECs have expertise in the design, conduct and approval of human research.

The Office of the Public Advocate would retain the ability to investigate concerns about the conduct of research or the participation of a particular individual, and the State Administrative Tribunal would be able to review decisions made in relation to the conduct of the research and the participation of particular individuals.

Consent to participation

Where a HREC has determined that a certain group of individuals who are unable to make a reasonable judgment or decision for themselves are eligible to participate in human research, the requirement to obtain individual consent remains. (The exception is where an HREC has determined in accordance with the National Statement that because of the nature or circumstances of the research, consent of participants is not required.)

Part 9C of the Act already provides for a person responsible to make treatment decisions for a person who requires treatment and is unable to make a reasonable judgment about the treatment. It also provides a hierarchy for determining who the responsible person is. Making a decision in relation to treatment has a number of similarities with making a decision in relation to participation in human research.

Participation in human research will usually relate to a condition for which a person is receiving treatment, although there are circumstances in which the research may relate to a condition that is currently unable to be treated, or to a condition that a family member has.

Treatment may be provided at the same time as, or instead of, other conventional treatment.

[2] The National Statement on Ethical Conduct in Human Research, Chapters 4.3, 4.4 and 4.5

Participation in the research may offer the opportunity to improve or cure the condition or to alleviate related symptoms to an extent.

The risks associated with participation in research, for example injury or death, are the risks that also accompany treatment.

Proposal 2

Research Australia submits that the same provisions of the Act that apply to consent to treatment decisions should be applied to the greatest extent practicable to consent to participation in health related research. Application of the provisions will need to be broadened to include individuals who do not meet the definition of 'patient'.

While it might be argued that asking a responsible person to consent to research is imposing a different, or greater obligation than is currently imposed on these individuals in medical situations, Research Australia does not believe this is the case.

In fact, responsible persons (usually family members) are commonly asked to make decisions in relation to a conventional medical procedure that has grave consequences for the patient. For example, consent might be sought from a family member to amputate a limb in an effort to prevent the spread of a life threatening infection, or consent to a hysterectomy to prevent blood loss.

Consent is also often sought in circumstances where there is not even a clear benefit to the patient. Organ and tissue transplants are heavily reliant on the consent of family members to the removal of tissue and organs to save the life of another person. This altruism is also the hallmark of many participants in medical research who are aware the results of the research will be too late to benefit them but may help other people with their condition in the future.

Using the same process to seek consent for research and medical treatment also has the benefit of simplicity. This is particularly important in circumstances where consent to treatment and to research is being sought at the same time, or in relation to the same condition.

Proposal 3

Research Australia submits that the test for consent to research should remain 'the person's opinion of the best interests of the (patient)'.

Research Australia further submits that the Act should be amended to provide guidance to the person responsible as to the matters to be considered in determining the 'best interests'. This should include consideration of:

- whether participation would not be contrary to the best interests of the person;
- the potential benefits and risks to the person (the benefits do not have to be certain);
- consideration of what the person might have wanted in the circumstances; and
- the potential future benefit to a class of people to whom the person belongs.

This guidance enables the person responsible to consider the sorts of factors the person would likely have considered for themselves, including weighing the risks against the potential benefits, and the altruism which can be just as strong a driver of individuals' decisions to participate in medical research as is self interest.

Research participation in the absence of a person responsible

The Act currently makes provision for a health professional to provide a treatment to a patient in circumstances where the patient is unable to consent and a person responsible is not present and cannot be found.

There are circumstances, for example in emergency medicine, where research may be occurring in environments where treatment is being provided without the consent of the patient or a person responsible. There are only very limited circumstances where it would be appropriate for such a patient to participate in research. These include situations in which the consent of patients generally is not required (for example the assessment of the efficacy of two different conventional treatments). It might also include some situations where the research is an adjunct to the treatment (it involves conducting an additional test on a blood sample taken as part of the treatment), or it involves a very minor additional procedure (such as taking 5ml more of blood than is required to be taken as part of normal treatment).

The participation of an individual in research in such circumstances would require very clear direction from an HREC, and an explicit consideration of the issues involved in such a situation. To the greatest extent possible, any discretion on the part of the health professional to include a patient in research in the absence of the patient's or a responsible person's consent should be avoided.

Research Australia does not consider the Act needs to be further amended in any way to achieve this outcome, and is confident the National Statement adequately covers these circumstances. In the event a researcher was not satisfied with the decision of an HREC to restrict participation of patients who are unable to provide consent, the researcher would be entitled to seek review of that decision by the State Administrative Tribunal. The matter is raised to ensure the Department is aware of this circumstance, and that amendments are not made which would inadvertently or deliberately be in conflict with this.

Advance Health Directives

Research Australia is uncertain of the extent to which an Advance Health Directive can deal expressly with decisions in relation to participation in human research. Research Australia is of the view that participation (and non participation) in human research should be able to be included in an Advance Health Directive.

Conclusion

Research Australia appreciates the opportunity to make a submission to the Review. Health and medical research has the capacity to improve people's lives, including the lives of those who participate in research. The absence of suitable provisions in the Guardianship & Administration Act means that Western Australians who are unable to make a reasonable judgment or decision for themselves are excluded from participation in research. Amending the Act to provide a framework that would allow such participation brings benefits for those individuals and for broader society while ensuring that the individuals' interests are protected.

Utilising the expertise of Human Research Ethics Committees and extending the decision making power of responsible persons provides an effective and streamlined mechanism for these decisions while ensuring that the individual's interests and safety remain paramount. Retaining the capacity of the Public Advocate and the State Administrative Tribunal to intervene provides a further level of protection and oversight.

Research Australia would welcome the opportunity to discuss this submission further and to clarify or elaborate on any of the submissions made in this paper.

Appendix

National Statement on Ethical Conduct in Human Research- 'Human Research' defined[3]

Human research is conducted with or about people, or their data or tissue. Human participation in research is therefore to be understood broadly, to include the involvement of human beings through:

- taking part in surveys, interviews or focus groups;
- undergoing psychological, physiological or medical testing or treatment;
- being observed by researchers;
- researchers having access to their personal documents or other materials;
- the collection and use of their body organs, tissues or fluids (eg skin, blood, urine, saliva, hair, bones, tumour and other biopsy specimens) or their exhaled breath;
- access to their information (in individually identifiable, re-identifiable or non-identifiable form) as part of an existing published or unpublished source or database.

The term 'participants' is therefore used very broadly in this National Statement to include those who may not even know they are the subjects of research; for example, where the need for their consent for the use of their tissue or data has been waived by a Human Research Ethics Committee (HREC).

In addition, the conduct of human research often has an impact on the lives of others who are not participants. When this impact is reasonably foreseeable, it may raise ethical questions for researchers and for those ethically reviewing research.

[3] NHMRC, ARC and Australian Vice Chancellor's Committee, National Statement on Ethical Conduct in Human Research 2007, Updated May 2013, p.8. Available at http://www.nhmrc.gov.au/guidelines/publications/e72

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