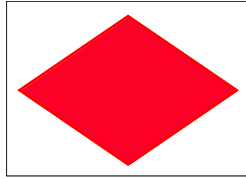


Office of the Public Advocate



**Submission to Review of the National
Health and Medical Research Council:
*National Statement on Ethical Conduct in
Research Involving Humans draft (2004)***

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**Contact: Dr David Sykes
Manager, Policy and Education
Office of the Public Advocate
Ph: 9603 9567
Email: david.sykes@justice.vic.gov.au**

1. Purpose

To recommend modifications to the current consent provisions relating to people with an intellectual or mental impairment in relation to qualitative and epidemiological research and research involving data and databanks.

2. About the Public Advocate

The Public Advocate in Victoria is appointed by the Governor in Council pursuant to the Victorian *Guardianship and Administration Act 1986* (GAA1986). The office represents the interests of people with a disability, aiming to promote their rights and dignity and to strengthen their position in society. It is a statutory office, independent of government and government services, and can highlight situations in which people with disabilities are exploited, neglected or abused.

The Public Advocate delegates his authority to his staff, who may be advocates, investigators or guardians. The office also coordinates the Private Guardian Support Program, the Community Visitors Program and the Independent Third Person Program in Victoria. Further material on the role of the office can be provided if required by consulting the Office of the Public Advocate's (OPA's) website: www.publicadvocate.vic.gov.au.

People with disabilities include people with an intellectual or physical disability, people with a mental illness, people with an Acquired Brain Injury (ABI) and people with dementia.

3. Definition of disability in the guidelines

It is recommended that the term people with "an intellectual or mental impairment" be replaced with "cognitive impairment" as this more appropriately includes people who have an acquired brain injury or dementia in the group who may have difficulty in providing consent to participation in research.

4. Participation of people with a disability in research

The Public Advocate submits that people who have a disability have the right to choose whether to participate in research as an important part of community participation. In addition to having this right to participate it is also submitted that some research may have beneficial outcomes for people with a disability. People with a disability also have the right to be protected from any undue risks associated with their participation in research.

Historically people with a disability have experienced disadvantage, overprotection and abuse in relation to research. Their right to give informed consent has typically been ignored and unwarranted assumptions made about their capacity to consent. The history of exploitation of people with a disability

in medical research has tended to affect the extent to which researchers and universities have sought to include people with a disability in research or indeed undertake research which could potentially benefit both people with a disability and the wider community.

Given this history and the extent to which some people with a disability may have difficulty in providing informed consent to participate in research, the Public Advocate acknowledges the importance of the *National Health and Medical Research Council, National Statement on Ethical Conduct in Research Involving Humans (1999)*. These guidelines help to promote clear ethical standards for the conduct of research, by protecting the welfare and rights of participants in research.

However, these guidelines need to not only acknowledge the situation of many people with a disability, but must also ensure that they do not have the effect of preventing people with a disability from choosing whether or not to participate in research.

The current guidelines importantly recognise the right of the person themselves to provide informed consent in the first instance. However, where the person is unable to provide this informed consent, the current process is both unclear and overly restrictive. There is lack of clarity in specifying the extent to which anyone can be considered at law to have the authority to provide consent for a person with a disability to participate in research. This can have the effect of being quite restrictive in that significant others involved in the life of the person with a disability may have no formal legal standing to consent but could be quite appropriate to do so based upon their knowledge of the person with a disability. There is also a clear absence of a process for enabling people who are unable to consent and who do not have anyone at law who can provide consent for them to participate in research.

The current process for including people with a disability in some types of non-medical research has become overly restrictive, and may have had the effect of discouraging researchers from undertaking research involving people with a disability.

In the United Kingdom the Medical Council's Working Party on Research on the Mentally Incapacitated (1991) put forward an ethical case for the inclusion of people with a disability who are unable to consent:

“There is a consensus, with which we concur, that a principled case can be made on ethical grounds for research involving people who cannot consent. There are a number of situations in which knowledge that is badly needed for the sake of those suffering from various forms of mental handicap or mental illness can only be acquired by research on people who are themselves suffering from these conditions and as a consequence lack the mental capacity to consent”.

5. Guardianship legislation and consent to participate in medical research

Given the history surrounding medical research and people with a disability, Victoria, Queensland and New South Wales have legislated a clear role for their respective Tribunals with responsibility for guardianship in relation to providing consent, in instances where the person with a disability is unable to provide informed consent to participation in medical research. Given this, the guidelines should make reference to the existence of such legislation and ensure that they are not inconsistent with these different pieces of legislation.

Given the level of risk and degree of intrusiveness associated with clinical research and clinical trials it is acknowledged that the Tribunals with responsibility for guardianship have an important role to play in ensuring that rights of people with a disability who are unable to consent are adequately protected in this type of research.

6. Non-medical research

Whilst acknowledging the role of guardianship tribunals in relation to medical research (which is defined in the guidelines as: clinical research and clinical trials, human tissue samples research and human genetic research) a different regime can be applied to research of a more social nature. This includes qualitative and epidemiological as well as data and data bank research. This research often provides people with a disability an important opportunity to tell their story, which can be of benefit to the person with the disability and indeed the wider community. In addition this research does not carry the type of risk involved in medical research, and is usually less intrusive. This is not to deny that there can be an emotional impact of this type of research upon the participant; however, an appropriately designed research, project with suitably qualified and experienced researchers should minimise the extent to which this is likely to be a problem for the individual.

7. Ethical research and people with a cognitive disability

There are a number of considerations when contemplating research involving people with a cognitive impairment which the New Zealand Human Research Council have included in their guidelines on ethics for health research, which this office endorses:

- a) In the case of disability specific research what is the proposed sample and range of disabilities to be included?
- b) How will the researcher determine competence to provide informed consent?
- c) A rationale for the decisions on competence in terms of the complexity of the research and the risks and benefits associated with the research?
- d) How the research will deal with the tendency of some people with an intellectual disability to comply with the perceived demands of authority figures, such as researchers?

- e) How information about the research will be provided to potential participants in a format they can understand?
- f) What input there has been from people with a disability in the design, development and implementation of the research to ensure that it is easily understood and likely to be of benefit to people with a disability?
- g) What level of experience the researchers have in working with people with a disability. (New Zealand Human Research Council Guidelines on ethics for Health Research, 2002, Appendix).

Any discussion of consent issues for people with a cognitive impairment in relation to research needs to consider these important elements of the research process.

8. Capacity to consent

It is important to acknowledge that people with a cognitive impairment vary widely in their capacity to make decisions and provide informed consent, depending upon the decision which needs to be made. Therefore it is important that all people with a cognitive disability should be presumed to have the capacity to consent until it can be demonstrated otherwise.

9. Role of significant others as a source of substitute consent

The importance of existing informal substitute decision-making networks in the lives of people with a cognitive impairment needs to be acknowledged. These informal networks include friends, family or indeed primary carers (where they are not paid to undertake this role). In the guardianship context in Victoria the obligation to consider these informal networks is recognised through the principle of “least restrictive option”. This principle generally requires the Tribunal to consider the appointment of a guardian or administrator only where these informal networks do not exist or there is considered to be a problem with the way in which they operate which may not be in the best interests of the person with a disability. Indeed in the Victorian Supreme Court case of Moore, a decision by Justice Gobbo, acknowledges the important role of informal decision-making processes in the lives of people with a disability. (1) The recognition of the role of these informal networks is highlighted by the fact that only a relatively small percentage of Victorians with a cognitive impairment that affects their decision-making capacity has a legally appointed guardian.

In relation to consent for medical treatment the role of these informal networks is formally recognised in Victoria through the “person responsible” hierarchy in which partners, family members and primary carers are all recognised as possible sources of consent to medical treatment where the person is unable to consent themselves.

However, it is recognised that there are difficulties in tightly defining friends or “significant others” even though there will be cases in which such a person is the most important, constant and caring person in the life of someone with a cognitive disability. It is therefore not proposed that such persons can be included in the list of substitute decision-makers.

It is recommended that the following changes be made to the guidelines:

- a) That in relation to qualitative and/or epidemiological research consent to participation in the research may be given on behalf of a person who themselves is unable to provide informed consent by a person in the following list which is in descending order of priority;**

Guardian

Person appointed under an Enduring power of guardianship

Person appointed under an Enduring Power of Attorney for Medical Treatment

Next of kin

Unpaid carer.

(Note: It may also be appropriate to list a hierarchy of relatives to ensure a uniform application of the term next of kin).

This proposed change recognises the important role that formal and informal decision-making processes play in the lives of many people with a cognitive impairment. It is consistent with the least restrictive principle of the *Guardianship and Administration Act* (1986) Vic. Where a person is providing consent on behalf of another they must be provided with sufficient information in relation to the risks and benefits of participation in the research so as to be able to make an informed decision.

This change will make the guidelines consistent with guardianship legislation which encourages the use of informal networks around the person with a disability, and only as a last resort to seek the appointment of a guardian. It also recognises that individuals with a cognitive impairment include both those who lack capacity from birth or did not make a power of attorney prior to losing capacity as well as those who were able to and did make an enduring appointment.

It is also important to acknowledge the difference between consent and compliance in that where a third party may have the authority to consent, but if the person does not wish to participate in the research it is not possible or indeed appropriate to compel them to do so.

- b) That where there is no person authorised to consent on behalf of a person who is themselves unable to consent to participation in qualitative and/or epidemiological research, research may still be authorised upon completion of a process of authorisation. The researcher should complete an “unable to consent” form. This form should require the researcher to answer the following questions for each individual namely:**

- a. How did the researcher determine that the person was unable to consent?**

- b. What efforts they have made to locate a person who is authorised to consent on the person's behalf.**
- c. The actions they have taken to explain the research to the person. This should include any support offered to assist the persons understanding of the research.**
- d. What views or actions the person has in relation to participation in the research or previously expressed views or actions in relation to this?**
- e. What the views of friends and/or "significant others" are in relation to the person's participation in the study?**
- f. What potential risks are there to the person in participating in the research?**
- g. What potential benefits are there to the person participating in the research?**
- h. What is considered to be in the persons best interests and why?**
- i. Any other questions specific to the research which pose particular issues in relation to risks or benefits.**
- j. Name of researcher and signature of the researcher who will be undertaking the research.**

Based upon these questions the researcher can decide on reasonable grounds, whether participation in the research is or is not consistent with the informed choice the person would make if they were competent (Bray, 1998).

If the researcher is so satisfied then they may include the person in the research. In this context the researcher is not providing substitute or proxy consent but rather has provided a process for including or excluding people with a disability from non-medical research where they are unable to provide informed consent.

This form once completed should be forwarded to the ethics committee.

- c) that if a researcher considers that (i) a person who is authorised to consent to participation in research is unreasonably refusing or failing to consent or (ii) that having completed an "unable to consent" form they are not able to decide whether to proceed to include a person with a disability in the research, then the researcher may apply for the appointment of a guardian for the purpose of deciding whether or not consent should be given.**

10. Conclusion

These recommendations are intended to operate in addition to other safeguards contained in the research which enables a participant to opt out at any time and be provided with appropriate support in doing this.

These changes, if adopted, will help to remove an unintended barrier which currently exists to the participation of some people with a disability in non-

medical research. This will help to affirm the rights of people with a disability to choose whether to participate in non-medical research as well having their rights protected from any undue risks from participation in research. The National Health and Medical Research Council and appropriately constituted Human Research Ethics Committees have an important role to play in encouraging ethical research which benefits people with a disability and the wider community.

11. References

Bray, A., (1998). *Research Involving People with intellectual disabilities: Issues of informed consent and participation*, Donald Beasley Institute Inc., New Zealand.

Medical Research Council. (1991). Working Party on Research on the Mentally Incapacitated. *The Ethical Conduct of Research on the Mentally Incapacitated*. London.

Moore v Guardianship and Administration Board and Another [1990] V.R. 902.