

**Office of the Public Advocate**



OFFICE OF THE  
PUBLIC ADVOCATE

**Submission to the second consultation of  
the National Health and Medical Research  
Council: *National Statement on Ethical  
Conduct in Human Research draft*  
(*January 2006*)**

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## **Executive Summary**

This submission makes comment upon and recommends modifications to the proposed consent provisions as outlined in Chapter 2.2. (Consent) Chapter 4.4.8.-.14 (Research involving unconscious people) and Chapter 4.5. (People with a cognitive impairment, intellectual disability, or mental illness), so as to facilitate the participation in research of people with cognitive disabilities.

OPA makes the following recommendations:

### **Recommendation 1**

That section 2.2.10. is amended to either refer only to minors or to read as follows:

*Where a potential participant lacks the capacity to consent, either because of age, cognitive impairment, intellectual impairment, mental illness or because they are unconscious, a person or appropriate statutory body with lawful authority to decide for the participant should be provided with relevant information and may exercise that choice.*

### **Recommendation 2**

The requirement in section 4.5.10. “respected” should be amended to read: “to give effect to” or “complied with”.

### **Recommendation 3**

That section 4.5.6. (b) is amended to add the following: In the case of non-medical research, where there is an organisation or person required by law to consent to medical research, such organisation or person may provide consent.

## **1. Purpose**

To comment upon and to recommend modifications to the proposed consent provisions as outlined in Chapter 2.2. (Consent), Chapter 4.4.8. - 14. (Research involving unconscious people) and Chapter 4.5. (People with a cognitive impairment, an intellectual disability, or a mental illness), so as to facilitate the participation in research of people with cognitive disabilities.

## **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 Guardians Program, the Community Visitors Program and the Independent Third Person Program in Victoria. Further material on the role of the Office can be sought if required by consulting the Office of the Public Advocate's (OPA's) website: [www.publicadvocate.vic.gov.au](http://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), people who are unconscious and therefore lack the capacity for communication or cognition and people with dementia.

## **3. Previous Submission**

The experience of OPA is that ethics committees seek to strictly adhere to these NHMRC guidelines in their application. Unfortunately this can at times get in the way of ethics committees applying these in terms of their overall intent. This is further complicated by the national focus of the guidelines preventing them from being too specific given the various state and territory laws relating to substitute consent involving people with a cognitive impairment, intellectual disability or mental illness. The application of the same guidelines to both medical and other forms of research also presents some challenges when state legislation sets out a specific process in relation to medical research.

The proposals outlined in this submission build on the proposals put forward in OPA's March 2005 submission regarding the *National Statement on Ethical Conduct in Research Involving Humans draft (2004)*. This submission will not repeat the rationale provided there regarding the right of people with a cognitive disability, intellectual impairment or mental illness to participate in research when they wish to do so and it is to their benefit. It will focus instead on the mechanisms designed to facilitate the procurement of informed consent on behalf of people with cognitive disability who cannot consent for themselves. It will also discuss the mechanisms to be used when a person who cannot consent does not have anyone to consent on their behalf.

## 4. Consent

In relation to consent the guidelines state the following:

*Chapter 2.2. Consent*

*Section 2.2.10. Where a potential participant lacks the capacity to consent, a person or appropriate statutory body with lawful authority to decide for the participant should be provided with relevant information and may exercise that choice (p. 15).*

It is unclear why this guideline exists (except in relation to minors), given the provisions in 4.5.6. Are there persons other than these who lack the capacity to consent? If not then there is the potential for confusion between the two provisions.

### Recommendation 1

Section 2.2.10. is amended either to apply only to minors or to read as follows:

*Where a potential participant lacks the capacity to consent, either because of age, cognitive impairment, intellectual impairment, mental illness or because they are unconscious, a person or appropriate statutory body with lawful authority to decide for the participant should be provided with relevant information and may exercise that choice.*

## 5. Who can consent on behalf of unconscious people, people with a cognitive impairment, an intellectual disability, or a mental illness?

The guidelines in relation to these groups of people state that:

*Section 4.4.10.*

*Where it is not practicable to approach a person highly dependent on medical care, or the person is not capable of making such a decision, consent should*

*be sought from the participant's guardian, or organisation or person authorised by law, before inclusion in the research (p.63).*

Section 4.5.6(b)

*where at the time consent is initially sought the person lacks the capacity to consent, the person's guardian, or any organisation or person required by law (p.66).*

Section 4.5.9.

*Researchers should inform HRECs how they propose to determine the capacity of a person with a cognitive impairment, intellectual disability or mental illness to consent to the research. This information should include how the decision about the person's capacity will be made, who will make it, the criteria that will be used in making it, and the process for reviewing during the research the participant's capacity to consent and to participate in the research (p.67).*

Section 4.5.10.

*Refusal or reluctance to participate in a research project by a person with a cognitive impairment, intellectual disability or mental illness should be respected (p.67).*

OPA affirms the importance of respecting the wishes of the person with a cognitive impairment, intellectual disability or mental illness should they refuse or be reluctant to participate in research. (4.5.10). OPA assumes that "respecting" means that participation in research may not occur if a person with a cognitive impairment, intellectual disability or mental illness refuses to consent to participation, regardless of whether or not that person has capacity to consent. If this is the intention behind the guidelines then the guidelines should be drafted more definitively.

OPA also acknowledges the importance of establishing the most appropriate way of determining the person's capacity to consent to the research (4.5.9). This recognises that this may need to be assessed differently in each circumstance.

## **Recommendation 2**

The requirement in 4.5.10.. "respected" should be amended to read " to give effect to" or "complied with".

## **5.1. Medical Research**

The procedure in Victoria for seeking consent to involve unconscious people, people with a cognitive impairment, an intellectual disability or mental illness in medical research where they are unable to provide consent themselves currently involves the researcher making an application to the Guardianship List of the Victorian Civil and Administrative Tribunal (VCAT). After VCAT receives the application they decide whether or not to consent to a person

with a cognitive disability participating in medical research based upon the principles previously outlined. Similar provisions exist in the NSW and Qld Legislation.

This process can be unduly burdensome and can have the effect of discouraging researchers from including people with disabilities in their research because of the delays in obtaining consent for participation. As a result, some people with disabilities could be denied the opportunity to participate in research that may be of benefit to them.

In order to address this issue, *the Guardianship & Administration (Further Amendment) Act (2005)*, has been passed by the Victorian Parliament amending the *Guardianship and Administration Act (1986)* in relation to medical research. This amendment (when it commences operation) will enable the “person responsible” who is authorised to provide consent to medical treatment (usually the person’s next of kin or unpaid carer) under section 37 of the Act also to provide consent for participation in medical research (Department of Justice, 2005; Thompson, 2005). Section 37 of the *Guardianship and Administration Act (1986)* contains a hierarchy of people who are empowered by law to provide consent to medical and dental treatment. (See Attachment A).

Provisions similar to those provided under section 37 of the Victorian Act exist in some of the equivalent guardianship and administration Acts of the other Australian States.

Procedural authorisation procedures are also outlined in the Victorian *Guardianship & Administration (Further Amendment) Act (2005)* in the event that no person responsible is available. This authorisation is obtained by the researcher completing a prescribed form and sending it to the Office of the Public Advocate. (See Attachment B).

The recent Act also provides for involuntary patients under the *Mental Health Act (1986)* to be subject to its medical research provisions. It is recognised that involuntary patients are particularly vulnerable in relation to the provision of consent to medical research procedures (Gillam & Weedon, 2005) and these new procedures should provide necessary safeguards to ensure that the principles of best interests, justice, beneficence and respect are followed in relation to this group. (See Attachment C.).

## **5.2. Non-medical Research**

At present no such formal procedure exists for providing consent to non-medical research. The lack of a formal procedure (i.e. lawful authority) for providing consent to non-medical research for people with cognitive disabilities means that some people will be unnecessarily excluded from research.

This is because either they do not have a guardian appointed by VCAT, or when competent, they had not appointed an enduring guardian to act on their behalf if they became incapacitated. Therefore, the proposed guidelines detailed in the statement at sections 2.2.10. and 4.5.6. (b) will fail to provide a mechanism for obtaining consent to non-medical research. This is because in the absence of a guardian with plenary powers (such a guardian is uncommon in Victoria) there is no person or statutory body with lawful authority (required by law) to provide consent on their behalf. An unintended consequence of the current guidelines is that they can potentially introduce a higher standard for consent to participation in non-medical research, through some ethics committees requiring that a guardian be appointed to consent to the person participating in the research.

In order to facilitate opportunities for people with cognitive impairment, an intellectual disability, or a mental illness to participate in non-medical research, when appropriate, OPA recommends that:

### **Recommendation 3**

That section 4.5.6. (b) is amended to add the following: In the case of non-medical research, where there is an organisation or person required by law to consent to medical research, such organisation or person may provide consent.

## **6. References**

Department of Justice (2005). *Medical research procedures involving patients under a legal incapacity: consultation paper*. The Department, Melbourne.

Gillam, L. & K. Weedon (2005). "Medical research and involuntary mental health patients: implications of proposed changes to legislation in Victoria". *Monash Bioethics Review* (Ethics Review Supplement) vol. 24 no. 4: 45-49.

*Guardianship Act* (1987) (NSW)

*Guardianship and Administration Act* (2000) (Qld)

*Guardianship and Administration Act* (1986) (Vic.)

*Guardianship and Administration (Further Amendment) Bill* (2005).

Thomson, C. (2005). "Medical research and participants with disabilities". *Monash Bioethics Review* (Ethics Review Supplement) vol. 24 no. 4: 56-63.

## **Attachment A: Guardianship & Administration Act (1986) Section 37: Person Responsible**

### **37. Person responsible**

(1) In this Part, “**person responsible**”, in relation to a patient and in relation to proposed medical or dental treatment, means the first person listed below who is responsible for the patient and who, in the circumstances, is reasonably available and willing and able to make a decision under this Part—

- (a) a person appointed by the patient under section 5A of the **Medical Treatment Act 1988**;
- (b) a person appointed by the Tribunal to make decisions in relation to the proposed treatment;
- (c) a person appointed under a guardianship order with power to make decisions in relation to the proposed treatment;
- (d) a person appointed by the patient (before the patient became incapable of giving consent) as an enduring guardian with power to make decisions in relation to the proposed treatment;
- (e) a person appointed in writing by the patient (being the person appointed last in time before the patient became incapable of giving consent) to make decisions in relation to medical or dental treatment which includes the proposed treatment;
- (f) the patient's spouse or domestic partner;
- (g) the patient's primary carer;
- (h) the patient's nearest relative within the meaning of paragraphs (a) to (g) of the definition of "nearest relative" in section 3.

(2) The circumstances in which a person is to be regarded as having the care of a patient include, but are not limited to, the case where the person, other than wholly or substantially on a commercial basis, regularly—

- (a) provides domestic services and support to the patient; or
- (b) arranges for the patient to be provided with domestic services and support.

(3) A patient who is cared for in an institution (such as a hospital, community residential unit, residential care service, supported residential service or State funded residential care service within the meaning of the **Health Services Act 1988**) at which he or she is cared for by some other person is not, by reason only of that fact, to be regarded as being in the care of that other person and remains in the care of the person in whose care he or she was immediately before being cared for in that institution.

(4) For the purposes of this section, a reference to the spouse or domestic partner of a patient—

- (a) is a reference to a spouse or domestic partner who is not under guardianship and with whom the patient has a close and continuing relationship;

## **Attachment B: Guardianship and Administration (Further Amendment) Bill (2005): Procedural Authorisation**

### **42T. Step 4—Procedural authorisation**

(1) Step 4 is procedural authorisation for the carrying out of the medical research procedure on the patient, which applies only if the person responsible for the patient cannot be ascertained or contacted.

Note: This section does not apply to a medical research procedure under section 42A— see section 42P(3).

(2) A registered practitioner may carry out, or supervise the carrying out of, a medical research procedure on a patient without the consent under section 42S of the person responsible for the patient if—

(a) the patient is not likely to be capable, within a reasonable time as determined in accordance with section 42R(2), of giving consent to the carrying out of the procedure; and

(b) steps that are reasonable in the circumstances have been taken—

(i) to ascertain whether there is a person responsible and, if so, who that person is; and

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(ii) if the person responsible is ascertained, to contact that person to seek his or her consent to the proposed procedure under section 42S— but it has not been possible to ascertain whether there is a person responsible or who that person is or to contact that person; and

(c) the practitioner believes on reasonable grounds that inclusion of the patient in the relevant research project, and being the subject of the proposed procedure, would not be contrary to the best interests of the patient; and

(d) the practitioner does not have any reason to believe that the carrying out of the procedure would be against the patient's wishes; and

(e) the practitioner believes on reasonable grounds that the relevant human research ethics committee has approved the relevant research project in the knowledge that a patient may participate in the project without the prior consent of the patient or the person responsible; and

(f) the practitioner believes on reasonable grounds that—

(i) one of the purposes of the relevant research project is to assess the effectiveness of the therapy being researched; and

(ii) the medical research procedure poses no more of a risk to the patient than the risk that is inherent in the patient's condition and alternative treatment; and

(g) the practitioner believes on reasonable grounds that the relevant research project is based on valid scientific hypotheses that support a reasonable possibility of benefit for the patient as compared with standard treatment.

(3) Before, or as soon as practicable after, the medical research procedure is carried out, the practitioner supervising the carrying out of the procedure (or, if there is no such person, the practitioner carrying out the procedure) must sign a certificate—

(a) certifying as to each of the matters set out in sub-section (2); and

(b) stating that the person responsible (if any) or the patient (if the patient gains or regains capacity) will be informed as required by sub-section (4).

(4) A registered practitioner involved in the relevant research project must inform the person responsible (if any) or the patient (if the patient gains or regains capacity) as soon as reasonably practicable of—

(a) the patient's inclusion in the relevant research project; and (b) the option to refuse consent for the procedure to be continued and withdraw the patient from future participation in the project without compromising the patient's ability to receive any available alternative treatment or care.

(5) The registered practitioner supervising the carrying out of the procedure (or, if there is no such person, the registered practitioner carrying out the procedure) must—

(a) forward a copy of the certificate referred to in sub-section (3) to the Public Advocate and the relevant human research ethics committee as soon as practicable (and in any event within 2 working days) after supervising the carrying out of, or carrying out, the procedure; and

(b) ensure that the certificate is kept in the patient's clinical records.

(6) If—

(a) the medical research procedure is a procedure extending over a period exceeding one month after a copy of the certificate is forwarded to the Public Advocate and the relevant human research ethics committee under subsection (5); and

(b) the registered practitioner supervising the carrying out of the procedure (or, if there is no such person, the registered practitioner carrying out the procedure) believes on reasonable grounds that—

(i) the requirements of sub-sections (2)(b) and (8) (if applicable) have been met but the person responsible has not been able to be ascertained or contacted; and

(ii) the patient has not gained or regained the capacity to consent—

the practitioner must, at intervals of not more than one month while the procedure continues, sign a certificate, and forward a copy to the Public Advocate and the relevant human research ethics committee, certifying that each of the matters set out in subsection

(2) continue to apply.

(7) The registered practitioner supervising the carrying out of the procedure (or, if there is no such person, the registered practitioner carrying out the procedure) must ensure that each certificate under sub-section (6) is kept in the patient's clinical records.

(8) If a medical research procedure is being carried out on a patient under the authority of this section, steps that are reasonable in the circumstances must continue to be taken (as the case requires)—

(a) to ascertain whether there is a person responsible and, if so, who that person is; and

(b) if the person responsible is ascertained, to contact that person to seek his or her consent to the proposed procedure.

Note: If the person responsible is contacted and is willing and able to make a decision (see section 37), section 42S applies. If the patient gains or regains capacity to consent, his or her consent must be sought, as he or she will no longer be a person to which this Division applies.

## **Attachment C: Guardianship and Administration (Further Amendment) Bill (2005): Amendment of Mental Health Act 1986**

### **12. Consequential amendment of Mental Health Act 1986**

(1) In section 83(1) of the **Mental Health Act 1986**, after "special procedure" **insert** "or medical research procedure".

(2) At the foot of section 83(1) of the **Mental Health Act 1986 insert—**  
"Note: Part 4A of the **Guardianship and Administration Act 1986** applies to the carrying out of a special procedure or medical research procedure on persons who are incapable of giving consent to that procedure."