The Public Advocate
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National Health and Medical Research Council
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Via email: ethics@nhmrc.gov.au

Consultation on Section 4 of the National Statement on Ethical Conduct in Human Research

Thank you for the opportunity to make a submission to the consultation on Section 4 of the National Statement on Ethical Conduct in Human Research (the National Statement).

As the Public Advocate for Queensland, I undertake systemic advocacy to promote and protect the rights and interests of Queensland adults with impaired decision-making ability.[1] There are several conditions that may affect a person's decision-making ability, including intellectual disability, acquired brain injury, mental illness, neurological disorders (such as dementia) or alcohol and drug misuse. While not all people with these conditions will experience impaired decision-making ability, many of them will at some point in their lives. For some, impaired decision-making ability may be episodic or temporary, requiring intensive supports at specific times, while others may require lifelong support with decision-making and communicating their wishes and preferences.

Due to the factors which contribute to impaired decision-making ability, including disability and mental health concerns, people may be at increased risk of harm when participating in research. It is important that these risks are considered appropriately by researchers who may include people with impaired decision-making ability in their research.

However, it is also critical that people with impaired decision-making ability are not excluded from research solely on the basis of their decision-making ability, and that, if required, they are supported to understand the research, and that they have an opportunity to participate in and to make a decision about whether to take part.

With this in mind, I would like to draw attention to a publication that I co-authored with Professor Shih-Ning Then and Mr Yuu Matsuyama that was recently published in the *Journal of Law & Medicine* titled: 'Supporting the involvement of adults with cognitive disabilities in research: the need for reform' (see attached article).

This publication explores the current legal and ethical requirements relating to the involvement of adults with cognitive disability in research, with a particular focus on the legislative frameworks in Queensland and Victoria. It highlights the complexity of State and Territory regulatory frameworks, which are not consistent across jurisdictions and may deter some researchers from including people with impaired decision-making ability as research participants.

The article outlines several recommendations for both legal and ethical guidance reform, which if implemented, could support greater involvement of adults with cognitive disability in research, and support greater engagement of adults with cognitive disability in decisions regarding participation in research.

While some of the components described have been addressed within the revised version of Section 4 of the National Statement, I would also like to put forward the following for consideration.

[1] *Guardianship and Administration Act 2000* (Qld) s 209.

Supported decision-making

As is noted in our article (p. 468):

> The requirement to support people to make their own decisions wherever possible is receiving increasing legislative recognition (eg, s 11B of the Guardianship and Administration Act 2000 (Qld); s 6C of the Powers of Attorney Act 1998 (Qld); s 8 of the Guardianship and Administration Act 2019 (Vic)) and ought to be reflected in national best practice [ethical] guidance in Australia.

Supported decision-making is briefly mentioned in Chapter 4.1 (Ethical issues in recruitment and involvement of research participants who may experience increased risk) and Chapter 4.4 (People in dependent or unequal relationships). Chapter 4.5 (People experiencing physical or mental ill-health or disability) includes the provision that:

> 4.5.32 In seeking consent from people living with disability who are able to make their own decisions about participation in research, researchers should consider which measures to support the consent process are appropriate for the specific circumstances of each potential participant.

The National Health and Medical Research Council (NHMRC) could consider the inclusion of further guidelines that may assist researchers to develop consent processes that, in accordance with Article 12 of the United Nations Convention on the Rights of Persons with Disabilities (UNCRPD), assume that people have the ability to make decisions and ensure that, where required, people are provided with appropriate support to enable them to participate in decision-making to the greatest extent possible. Our article makes some suggestions for provisions that could be included in Chapter 4.5, including (p. 469):

> Consent to participation in research by an adult with a cognitive impairment, an intellectual disability, or a mental illness should be sought from that adult.
>
> Where it is necessary to do so, an adult with a cognitive impairment, intellectual disability or a mental illness should be provided with support to enable them to determine whether to consent to participation.
>
> Where the adult's impairment, disability or illness is temporary or episodic, an attempt should be made to seek consent at a time when the condition does not interfere with their ability to give consent.
>
> Consent under paragraph 4.5.5 should be witnessed by a person who understands the merits, risks and procedures of the research, is independent of the researcher and, where possible, knows the participant.
>
> Consent to participation in research should only be sought from another person on behalf of an adult with a cognitive impairment, an intellectual disability, or a mental illness in situations where:
>
> (a) the adult is unable, even with support, to determine whether to participate; and
> (b) the other person is authorised by law to make decisions of this nature on behalf of the adult.
>
> Consent to participation in research should only be provided by another person on behalf of an adult in situations where the adult – had they the ability to do so – would likely have agreed to their participation.

The inclusion of these provisions may assist in emphasising the importance of seeking consent to participate from the adult with cognitive impairment wherever possible, and help to clarify some key issues that researchers should consider as part of that process.

Clarifying that the considerations in Chapter 4.5 concern adults

As noted in our article (p. 468):

> … the guidance, it would appear, applies equally to children and adults. Some of the terminology in that context – such as "guardian" [for example, paragraph 4.5.33 of the revised version of Section 4] – is potentially confusing. The term "legal guardian" for a child may refer to a parent, while an adult will only have a guardian if one is appointed for them by the relevant State or Territory's civil and administrative tribunal. Other people may also have powers in relation to the adult that are comparable to a guardian's, such as an attorney appointed under an enduring power of attorney and a default health decision-maker (such as a statutory health attorney in Queensland).

As Chapter 4.3 focuses specifically on children and young people, the NHMRC could consider clarifying some of the terminology within Chapter 4.5.

Key terminology

Within the article, we also discuss some other terms included within the National Statement, including the term 'best interests' (p. 459).

> … the guidance contains some outdated terminology, certainly in relation to adults with disability, such as "best interests" [paragraph 4.5.5 of the revised version of Section 4]. While a familiar standard in medicine and law, human rights discourse (and Art 12 of the *UNCRPD*) recognises this paternalistic standard as being inappropriate in relation to adults with cognitive disabilities.

I would recommend that, where it appears in paragraph 4.5.5, this term be replaced with 'health and wellbeing'.

The NHMRC could also consider replacing the term 'capacity' with 'ability' where a person's ability to consent to participation in research, or their decision-making ability, is discussed.

Withdrawal of consent

The revised version of Section 4 includes a paragraph relating to the withdrawal of consent to participate in research by people with ill-health or disability.

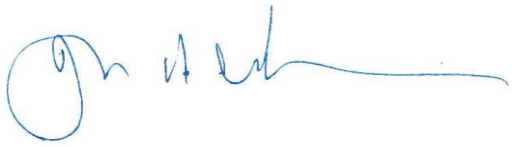
> 4.5.7 Researchers should not assume that, once engaged in the research, signs of reluctance or distress from a participant with ill-health or disability indicate a definitive desire to end participation. In this situation, researchers should consider pausing the research activity, explore the source of the distress, and, if possible, address it using strategies to calm or re-orient the participant. However, if the unwillingness to participate is sustained or unequivocal, then any refusal to continue to participate must be respected and their decision to withdraw consent is binding.

It is important that researchers communicate effectively with research participants and seek to understand their wishes regarding their participation in research. In situations where a participant may experience difficulty with verbal communication, or uses alternative forms of communication, researchers must be aware of non-verbal cues and, if a participant is expressing a preference to withdraw from the research, respect the participant's wishes.

The NHMRC may wish to consider the wording of this provision so that it centres around the needs and preferences of the research participant.

Thank you for the opportunity to make this submission. Should you require further information regarding any of the matters I have raised, please contact my office on 3738 9513.

Yours sincerely,



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