Submission to the New South Wales Law Reform Commission on the Review of the *Guardianship Act 1987*

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This submission is made in response to Question Paper 5 and focuses on the inclusion of people with cognitive impairment in research.

1. Many Australians live with conditions that episodically or permanently affect their cognition, including acquired brain injury, intellectual disability and mental illness. Dementia – the focus of this submission – is a particularly serious problem in Australia and many other countries with ageing populations.

2. Our University of Newcastle research team is currently conducting a study of community members aged 60 and older about their views on the participation of people with dementia in research. The study explores their views about taking part in research if they (hypothetically) developed dementia and experienced impaired decision-making capacity. We share some of our preliminary survey results in this submission.

The Need for Research

3. People with dementia should receive respectful, beneficent and just care that optimises their outcomes. Appropriate care depends on well-designed and methodologically rigorous research. There are notable "differences in the issues of concern, experiences and needs of people with dementia at the mild, moderate and severe stages."[1] Therefore, the "inclusion [in research] of persons with dementia at all stages is essential" to understand and respond to these varying needs.[2]

[1] K Murphy, F Jordan, A Hunter, A Cooney & D Casey, 'Articulating the Strategies for Maximising the Inclusion of People With Dementia in Qualitative Research Studies' (2015) 14(6) *Dementia* 800.
[2] Ibid.

4. Yet research is not keeping pace with the burden of dementia.[3] As a consequence, there are many gaps in the evidence base to inform care for people living with dementia. For example, Australian Clinical Practice Guidelines for Dementia were published in 2016.[4] Of the 109 recommendations in the guidelines, only 29 are considered 'evidence-based', that is, based on a systematic review and synthesis of available scientific evidence. Of these, 22 recommendations are based on evidence judged to be of very low to low quality and 7 are based on moderate quality evidence. None of the 109 recommendations are based on high quality evidence.

5. Compounding the problem of insufficient research into dementia is the fact that people living with the syndrome are often excluded from taking part in research studies. Researchers and research ethics committees are "nervous about including this population in their studies"[5] due to ethical and legal complexities, including concerns about assessing capacity to consent and the role of substitute decision makers in the research context. Yet many people living with dementia are interested in taking part in studies and "not making opportunities to participate in such studies available to patients with AD [Alzheimer's disease] would disrespect these patients."[6]

Law Reform Should Reduce Unnecessary Barriers to Research Involving People with Cognitive Impairment

6. Reforms to the *Guardianship Act* should improve clarity and consistency in the law and reduce unnecessary barriers that may exclude people with dementia – and other conditions that affect capacity – from participating in ethically approved research.

7. The law should operate harmoniously with the National Statement on Ethical Conduct in Human Research, which aims to protect vulnerable persons, empower people with reduced autonomy and advance knowledge through meritorious research.

8. Chapter 4.5 of the National Statement provides guidance on research participation for people who live with conditions that affect their capacity. It states: "People with a cognitive impairment, an intellectual disability, or a

[3] For example, a recent analysis of clinical trial activity in Australia shows that research into dementia interventions falls below the relative disease burden: J Lam et al, 'Australian Clinical Trial Activity and Burden of Disease: An Analysis of Registered Trials in National Health Priority Area' (2015) 203(2) *Medical Journal Australia* 97.
[4] The Clinical Practice Guidelines are available online: http://sydney.edu.au/medicine/cdpc/documents/resources/CDPC-Dementia-Recommendations_WEB.pdf
[5] N Pachana et al, 'Can We Do Better? Researchers' Experiences with Ethical Review Boards on Projects With Later Life as a Focus' (2015) 43 *Journal of Alzheimer's Disease* 701, 705.
[6] E Howe, 'Informed Consent, Participation in Research and the Alzheimer's Patient' (2012) 9(5-6) *Innovations in Clinical Neuroscience* 47, 48.

mental illness are entitled to participate in research, and to do so for altruistic reasons."[7]

9. The National Statement requires that researchers identify and minimise the risks involved in their studies: "Research will be ethically acceptable only if its potential benefits justify those risks."[8] The National Statement requires that all research that proposes participation by people with cognitive impairment be reviewed and approved by a human research ethics committee, unless the research involves only 'negligible risk' or the use of previously collected non-identifiable data, such as an anonymised chart review.[9] Research is considered to have negligible risk if the foreseeable risks are simply inconveniences (e.g. taking time to answer a survey) and there are no foreseeable risks of discomfort or harm.[10]

10. The *Guardianship Act* should not require a duplicative process of Tribunal review where a research ethics committee has already approved a study that will involve people with cognitive impairment. In recent statutory reforms, the ACT Government applied sound reasoning in its decision not to require approval from the Civil and Administrative Tribunal, including a desire to avoid: increased burden on the Tribunal; giving decision making authority to people who do not know the person with impaired capacity; and discouraging researchers from undertaking studies that involve people with cognitive impairment.

11. Half of the respondents in our survey of older people in the community disagree with a legal entity such as a tribunal making decisions about research participation in a situation where the individual no longer has capacity to make these decisions. Rather, many respondents prefer that someone they choose to make health-related decisions should also be able to decide whether they are included in a research study if they lack capacity to do so in the future.

12. Statutory reforms should also advance the national decision making principles advocated by the Australian Law Reform Commission. These principles emphasise the rights of all adults to make their own decisions and for those with impaired capacity to have access to appropriate supports to help them make decisions that affect their lives.[11] We discuss below strategies to support individual decision making, including the use of advance directives for research.

[7] National Statement, p 58, para 4.5.3.
[8] National Statement, Chapter 2.1, p 12.
[9] National Statement, p 69, para 5.1.6.
[10] National Statement, p 15, para 2.1.7.
[11] Australian Law Reform Commission, *Equality, Capacity and Disability in Commonwealth* Laws Report No 124 (2014).

Categories of Medical Research

13. We agree with preliminary submissions to the Commission that the current definition of "clinical trial" in the *Guardianship Act* is vague and open to interpretation.[12] We support eliminating the need for Tribunal approval of ethically approved research. If this role for the Tribunal is retained, the Act should define more than one category of medical research based on the degree of risk involved. For example, a lower risk study might investigate the use of educational materials or social supports to improve quality of life and involve data collection methods such as surveys, interviews or observations. A higher risk study might involve the testing of new experimental drugs. The Tribunal approval role, if retained, should be limited to higher risk research. If new legislative provisions will define different categories of research we recommend further community consultation about the proposed definitions.

14. Definitions of research should not preclude altruistic participation for people with cognitive impairment by requiring that the research must offer the prospect of ameliorating the person's condition, especially for low risk research. Preliminary results of our study show that a majority of respondents are altruistically motivated and would participate in a wide range of studies without an expectation of direct benefit.[13] Our findings show that, if diagnosed with dementia, most people would be willing to take part in studies that would not improve their own quality of life but would advance knowledge to improve the wellbeing of others with dementia.

15. It would also be helpful to distinguish between experimental care aimed at ameliorating the person's condition (i.e. an adjunct to their medical treatment) and participation in research that aims to advance scientific knowledge. The latter may include low risk research that informs future interventions/models of care, but may offer no prospect of direct benefit

Consent Processes to Promote Individual Autonomy in Decisions About Research Participation

16. After an ethics committee has approved a study involving participants with fluctuating or reduced capacity, we recommend the following processes to promote individual autonomy in decisions about research participation.

17. When inviting prospective participants, researchers should first establish the person's capacity to consent to participate. Screening tools are

[12] We refer to preliminary submissions from NSW Health and the South Eastern Sydney Local Health District Human Research Ethics Committee.

[13] Other research supports this finding: see e.g. Howe, above n 6; AL Jefferson et al, 'Clinical Research Participation Among Aging Adults Enrolled in an Alzheimer's Disease Center Research Registry' (2011) 23(3) *Journal of Alzheimer's Disease* 443; J Karlawish et al, 'Older Adults' Attitudes toward Enrollment of Non-Competent Subjects Participating in Alzheimer's Research' (2009) 166 *American Journal of Psychiatry* 182.

available for this purpose.[14] These tools assess the prospective participant's understanding of the purpose of the research, what they are being asked to do, the voluntary nature of their participation, and the possible risks and benefits of participation. Researchers should then seek consent directly from prospective participants if they have capacity to consent to the study. When inviting participants with cognitive impairment, researchers should explain the study in a manner that is easy for prospective participants to understand; simplified information materials, decision aids and multi-media resources can be helpful.[15]

18. The statutory definition of capacity should recognise that capacity may fluctuate. If it is expected that a person assessed as lacking capacity will regain capacity within a reasonable timeframe for making a required decision, decisions should be delayed until that time.

19. The law should formally endorse a supported decision making approach to decision making for people with reduced or fluctuating capacity. Supports should be available to assist such individuals who are invited to participate in research.

Advance directives – for research

20. If the person has capacity to give consent for the study and does so, researchers should follow the process recommended in the National Statement and discuss with the person their views on continued participation during future periods of incapacity. These wishes should be documented. In effect, this is the making of an advance directive for research.[16] Taking the initiative to discuss the participant's preferences will advance the right "to choose what he or she wants, but may also have significant meaning for the" person.[17]

21. If a statutory regime is developed in NSW for advance care directives, we support the Victorian approach of recognising both instructional and values directives. Directives should allow for advance statements of wishes and

[14] For example, see: BW Palmer et al, 'Determinants of Capacity to Consent to Research on Alzheimer's Disease' (2017) 40(1) *Clinical Gerontologist* 24; JB Seaman et al, 'Psychometric Properties of a Decisional Capacity Screening Tool for Individuals Contemplating Participation in Alzheimer's Disease Research' (2015) 46(1) *Journal of Alzheimer's Disease* 1; DV Jeste et al, 'A New Brief Instrument for Assessing Decisional Capacity for Clinical Research' (2007) 64(8) *Archives of General Psychiatry* 966.

[15] See e.g. JC Brehaut, 'Using Decision Aids May Improve Informed Consent for Research' (2010) 31(3) *Contemporary Clinical Trials* 218.

[16] National Statement, para 4.5.7 states: "The process of seeking the person's consent should include discussion of any possibility that his or her capacity to consent or to participate in the research may vary or be lost altogether. The participant's wishes about what should happen in that circumstance should be followed unless changed circumstances mean that acting in accordance with those wishes would be contrary to the participant's best interests." Paragraph 4.5.8 recommends that this advance form of consent "should be witnessed by a person who has the capacity to understand the merits, risks and procedures of the research, is independent of the research team and, where possible, knows the participant and is familiar with his or her condition."

[17] Howe, above n 6, 50.

preferences concerning research participation during future periods of incapacity. For example, a statutory template for a directive could include space for the person to record such wishes. Legislation would need to be clear about the status of directives; for example, Victoria's law indicates that advance consent to a research procedure as documented in an instructional directive is sufficient to include a person who lacks capacity in an ethically approved study.[18]

22. Some studies report that older adults favour more education and supports for making research directives early in a dementia diagnosis.[19] The preliminary results of our research indicate that close to 70% of our survey respondents (who are aged 60 and older) are interested in an opportunity to make an advance research directive.

23. As with all advance planning on health and personal matters, people should be encouraged to discuss their wishes and share directives with their family members and others close to them. If these individuals are later called on to make a decision for the person, whether for treatment or research, this communication will increase the likelihood that the decision will accord with what the person who lacks capacity would want.

Alternate decision-makers

24. If a prospective participant is assessed as not having capacity to make a decision about taking part in a study, consent is sought from a legally authorised decision maker for the person. Ideally this decision maker should be someone appointed by the person as such an appointee may be better placed to make a decision consistent with what the person would want. Enduring guardian appointments in NSW should clearly enable people to appoint a guardian for research decisions, with relevant information communicated on the appointment form. The medical research power of attorney adopted into ACT law provides a useful model. Victoria's *Medical Treatment Planning and Decisions Act 2016* also clearly articulates the role of a medical decision maker in making decisions about participation in medical research.

25. If a person has not appointed a decision maker, the law should make it clear that a 'person responsible' may make decisions about participation in ethically approved research.

26. When called on to make a decision for a person who lacks capacity to make their own choice about research participation, the decision maker should so far as possible make a decision that accords with what the person would want. This determination should be guided by any views the person previously expressed about taking part in research (e.g. values documented in a directive or an enduring guardian appointment) as well as current indications that the person who lacks capacity objects to the

[18] *Medical Treatment Planning and Decisions Act 2016* (Vic), s 75.
[19] R De Vries, et al, 'Public's Approach to Surrogate Consent for Dementia Research: Cautious Pragmatism' (2013) 21(4) *American Journal Geriatrics Psychiatry* 1.

research activity (e.g. dissent expressed through verbal utterances or body language).[20]

27. Some people living with cognitive impairment do not have supportive family members, carers or friends to take on a substitute decision making role. Australian research reports that older people with reduced capacity are often excluded from studies if there is no relative or carer to provide consent.[21] The law should set out clear rules for how opportunities for inclusion in research are managed in such circumstances. For example, Victoria legislation permits a registered practitioner (defined as a registered medical practitioner or dentist) to carry out research procedures without consent provided specific safeguards are met.

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[20] The National Statement requires respect for the dissent of the person who lacks capacity. Para 4.5.11 states: "Refusal or reluctance to participate in a research project by a person with cognitive impairment, an intellectual disability, or a mental illness should be respected."
[21] Pachana et al, above n 5.