Submission to the New South Wales Law Reform Commission on Draft Proposals for the Guardianship Review

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Introduction and General Comments

1. Associate Professor Nola Ries is an expert in law, health and ageing and a member of the Law | Health | Justice Research Centre at the UTS Faculty of Law. The Centre's research addresses the question: how can law best address inequality in health and unmet health needs, in particular for vulnerable and disadvantaged populations. All of the Centre's research is directed to legal change.

2. Dr Elise Mansfield is a postdoctoral research associate in the School of Medicine and Public Health at the University of Newcastle. Her research focuses on improving wellbeing and health outcomes for older adults, with a particular focus on people with dementia.

3. This submission adds to our previous submission to the Commission of 11 May 2017. In that submission we shared some preliminary results of a study of community members aged 60 and older about their views on the participation of people with cognitive impairment in research. This submission shares some updated results from that study, as well as some key findings of another study of community members' views on supported decision-making.[1]

4. As a general comment, we agree with the focus in the Draft Proposal on "decision-making ability". Too often "capacity" and "competence" are still used to denote a bright-line distinction and people receive labels of being "incapable" or "incompetent", implying they have no ability to be involved in any decisions about their lives.

[1] Scholarly articles reporting on these studies are in preparation. For further details about this research, please contact Assoc Prof Ries, [redacted]

Medical Research

No approval role for statutory tribunal

5. In line with our previous submission, we support the proposal that the statutory tribunal would not have a role in approving research that involves people with impaired decision-making ability. We agree with the rationale for this recommendation, as stated on page 54 of the Draft Proposals.

Advance directives

6. In regard to terminology, it would be preferable to have a general definition of an advance directive (AD), then state that this definition includes ADs for healthcare and ADs for research. A general definition could cover key points – for example, an AD includes written or oral instructions on specific matters, as well as expressions of values and preferences; at the time of making an AD, a person must have decision-making ability in relation to matters covered in their AD; and the statute does not limit the common law about ADs.

7. There are conceptual and practical problems with using the term "advance care directive" or "advance healthcare directive" throughout the new Act (both terms appear in the Draft Proposals).

8. It is not ideal to use "advance healthcare directive" to refer to a directive that expresses a person's will and preferences in relation to research participation. Healthcare is provided to benefit the person; research, in contrast, aims to advance knowledge and may not offer direct benefits to the individual participant. Misunderstanding the differences between research and care is referred to as therapeutic misconception. Ethicists, researchers and clinicians have long emphasised the importance of countering therapeutic misconception among research participants.[2] Legal frameworks should not inadvertently blur these differences and we recommend that advance directives for healthcare and advance directives for research should be separate concepts in the new law.

9. Our previous submission noted that the National Statement on Ethical Conduct in Human Research (National Ethics Statement) encourages researchers to discuss with participants their preferences for future research participation should decision-making

[2] See eg, GE Henderson et al, 'Clinical Trials and Medical Care: Defining the Therapeutic Misconception' (2007) 4(11) PLoS Medicine e324, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2082641/.

ability decline.[3] This process may be particularly useful when recruiting a person in early stages of cognitive impairment into a longitudinal study that will involve research activities over a period of years. As a matter of practice, researchers may be reluctant to engage participants in advance research planning if there is an implication in law that this plan should be part of an "advance healthcare directive". Researchers are not well-placed to assist a participant with a process of planning for medical treatment matters.

10. Using a general term of "advance directive" in the new Act has the advantage of leaving the concept open to future development. For example, with the growing awareness of financial abuse and exploitation of older people in our communities, an AD for financial matters may become a useful tool for a person to express their will and preferences in relation to the types of financial decisions listed in Proposal 1.5.

11. The new Act should make it clear that an AD can express specific instructions as well as statements of values and preferences. The Draft Proposals refer explicitly to a directive as a means to consent to healthcare or research procedures. The use of an AD to express general values or preferences is addressed more implicitly in the statement that "the requirement to consider a person's will and preferences includes considering any valid advance care directive." Encouraging reflection on and communication of values could help to ensure that future decisions promote the individual's "personal and social wellbeing" - one of the new Act's principles - where a specific directive does not apply in the situation.

12. The emphasis on an AD as a means to consent to particular procedures has two drawbacks. First, it may encourage proliferation of directives that try to be too specific and are not useful if the consent given does not match future circumstances. Second, it may detract from more holistic conversations about a person's history, values and beliefs, which some clinicians and commentators argue are more helpful in guiding decisions when a person lacks decision-making ability.[4]

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[3] National Statement on Ethical Conduct in Human Research, https://www.nhmrc.gov.au/book/national-statement-ethical-conduct-human-research, 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."

[4] M Spranzi and V Fournier, 'The Near-failure of Advance Directives: Why they should not be abandoned altogether, but their role radically reconsidered' (2016) 19(4) Medicine, Health Care and Philosophy 563.

Medical research decision-making for a person unable to give their own consent

13. If a prospective study participant does not have a person responsible to consent to the medical research procedure, the Draft Proposals provide that the Tribunal would need to appoint a representative (or supporter, if appropriate) for them to participate. Alternatively, the Tribunal may give consent on the prospective participant's behalf.

14. Our recent survey asked people aged 60 and over attending outpatient clinics at a NSW hospital who they would want to be involved in decisions about their inclusion in research if they were not able to make their own decision.[5] Nearly 90% of respondents indicated they would like their decision-maker for healthcare treatment matters to also make decisions about their participation in research. Respondents expressed more negative views about a legal tribunal being involved in these decisions: just over two-thirds of respondents either disagreed with or were unsure about a legal entity having a role in this determination.

15. Respondents were more likely to prefer that a doctor involved in the study be involved in the decision (nearly 80%), as compared to a doctor not involved in the study (around 30%). The involvement of a person's healthcare practitioner raises concerns about possible conflicts of interest, however. Ethical rules for clinician-researchers, such as the World Medical Association's Declaration of Helsinki, require doctors to be "particularly cautious" in research consent processes involving their patients.[6]

16. Over three-quarters (77%) of respondents said they would be very or somewhat interested in making an advance directive for research if they had an opportunity to do so.

Altruistic participation in research

17. Proposal 7.4 states that a person responsible or Tribunal may only give consent to research if "the drugs or techniques being tested are intended to cure or alleviate a particular condition the participant has or has had or to which the participant has a significant risk of exposure."

[5] The survey sample consisted of nearly 200 people who were representative of the Australian population in terms of gender and age split (ie, proportion of people aged 60-74 and those aged 75+). Education levels appear slightly lower than national census data, partly explained by the older age range included in our survey.
[6] World Medical Association, 'Declaration of Helsinki: Ethical principles for medical research involving human subjects' (2013) 310 Journal of the American Medical Association 2191, para 27.

18. These criteria, while an improvement on the current *Guardianship Act* provisions,[7] could unreasonably limit altruistic research participation. This would be at odds with the position of the National Ethics Statement that people with a cognitive impairment "are entitled to participate in research, and to do so for altruistic reasons" and "research involving these people need not be limited to their particular impairment, disability or illness."[8]

19. In addition, the criterion of "significant risk of exposure" could promote stereotypical or hyperbolic claims about people who have conditions that impair cognition. For example, if researchers want to involve people with dementia into a study about an issue other than dementia, they would have to establish that this population necessarily faces "significant exposure" to the problem, which seems a high threshold.

20. Emphasising frailty and vulnerability to justify research inclusion is counter to the new Act's focus on the strengths and abilities of people with cognitive impairment. Strengths-based approaches are advocated by peak bodies. For example, the Dementia Australia Language Guidelines state: "It is important to use language that focuses on the abilities (not deficits) of people with dementia to help people stay positively and meaningfully engaged, and retain feelings of self-worth."[9]

21. In support of these points, our recent survey on research participation (referred to in points 14-15 above) revealed that altruism is a very strong motivator for research participation. Thinking ahead to a period when they cannot make their own decision, approximately 90% of respondents said they would be willing to be involved in studies that would not benefit them but could help researchers understand other diseases or health problems.

Definitional issues

22. In line with our previous submission, we support the effort in the Draft Proposals to define types of research and to clarify what is and is not a "medical research procedure" for the purposes of the new Act. The categories that <u>are not</u> medical research procedures are relatively clear in the Draft Proposals, however, some things that <u>are</u> such procedures are ambiguous. For example, "use of equipment or device" is a medical research procedure. What kinds of equipment or device are envisioned here? Would it include the use of a tablet computer to guide study participants through an in-home occupational therapy intervention?

[7] The *Guardianship Act* currently provides that a person responsible or Tribunal may consent if "the drugs or techniques being tested in the clinical trial are intended to cure or alleviate a particular condition from which the patients suffer" (ss 45AA and 45AB).
[8] National Ethics Statement, 58.
[9] Dementia Australia, Dementia Language Guidelines, https://www.dementia.org.au/sites/default/files/NATIONAL/documents/language-guidelines-full.pdf.

23. The Draft Proposals also refer to "techniques being tested" (Proposal 7.4). What is meant by "technique" in the context of the new Act?

24. Similarly, who is a "researcher"? Is this term meant to be restricted to researchers who meet the definition of "registered health practitioner" in Proposal 6.3?

25. In regard to categories of research, our recent survey on research participation asked about respondents' willingness to be included in various types of research activities during future periods of impaired decision-making ability.[10] An overwhelming majority of the survey respondents – generally over 90% – would be agreeable to participating in the range of research activities listed below. The notable exception was taking part in a study of experimental drugs; agreement dropped to just under 60% for research of that nature.[11]

I would be willing to be included in a research study that involves:
a) **Asking me questions in a survey or interview** (example: asking about my experiences or opinions)
b) **Observing my behaviour** (example: watching how I act if I listen to music as part of a therapy program)
c) **Testing my memory or thinking** (example: asking me to draw a picture or remember specific words)
d) **Giving me psychological therapy** (example: counselling for anxiety or depression)
e) **Giving me physical therapy** (example: moving my arms or legs, massaging my muscles)
f) **Giving me experimental medicine** (example: an experimental drug that might reverse damage in my brain)
g) **Taking x-rays or scans of my body** (example: to help researchers see how dementia is affecting my brain)

[10] The selection of these activities was informed by the types of research often included on research ethics application forms.

[11] This finding is consistent with a recent American study: M Calamia, JP Bernstein and JN Keller, 'I'd do anything for research, but I won't do that: Interest in pharmacological interventions in older adults enrolled in a longitudinal aging study' (2016) 11(7) PLoS ONE.

h) **Taking a measurement about my body** (example: my weight, blood pressure)
i) **Putting something on my body, like a bracelet, that keeps track of information** (example: how much time I spend in bed)
j) **Taking a sample of my blood or other body fluid for genetic research** *[A plain language definition of genetic research was provided in the survey]*
k) **Taking a sample of my blood or other body fluid for non-genetic studies**
l) **Looking at my personal records, such as medical records or test results stored in a hospital**
m) **Using my blood or other body fluid or tissues taken in the past and stored in a hospital or other facility**

Filing records with the Public Advocate

26. Proposal 7.6 is a requirement for researchers to file a record with the Public Advocate when a participant who lacks decision-making ability is included in medical research. The intent is for the Public Advocate to monitor and report on research that involves such participants. The National Ethics Statement requires researchers to make reports to the ethics committee that approved their study. Such reports include details such as the number of people recruited in a study, the progress of the study, compliance with the approved protocol, and the occurrence of any adverse events.[12] The potential burden of duplicative reporting to the Public Advocate may outweigh the benefits.

Supported Decision-Making

27. We generally agree with the Draft Proposals regarding supported decision-making as well as enduring representation.

28. In another recent survey, we elicited community members' views on supported decision-making. As with the previously mentioned survey (points 14-15), the respondents were approximately 200 people aged 60 and older attending outpatient clinics at a NSW hospital. An overwhelming majority (95%) agreed or strongly agreed that allowing people to legally appoint a supporter is a good idea.

[12] National Ethics Statement, Chapter 5.5., Monitoring Approved Research and provisions in Chapter 3 on monitoring approved clinical research, paras 3.3.19-3.3.22.

29. Around 90% or more agreed that being able to appoint a supporter would be beneficial by: enabling them to make their own decisions; have their wishes respected; increase their confidence in their decision-making ability; and not be taken advantage of by others.

30. When asked about things that would worry them about a relationship with a supporter, the most prominent concern was having disagreements with the supporter (nearly three-quarters of respondents) and between 50-60% of respondents cited concerns such as the supporter trying to influence their decisions, not having enough time to fulfil the role, and not being trustworthy. The possible cost of having a supporter was also a concern.

31. When asked about whom they would appoint as a supporter, respondents' order of preferences was: spouse/partner; adult child/children; another family member; a lawyer; a case worker/disability services worker; a friend; a community volunteer. While over 80% would choose a spouse or adult child, only 30% would appoint a community volunteer.

Thank you for the opportunity to comment on the Draft Proposals.

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