



9 May 2017

**Submission to the
Health and Disability Commissioner on the
Consultation on health and disability research involving adult participants who are
unable to give informed consent.**

Since I was diagnosed, I have been asking to be in a research project. I want to be a research subject but I haven't had the chance.

Alzheimers NZ Consumer advisory group member with dementia

I would have preferred a process that meant I was better informed before giving consent. It's a big responsibility to make a mistake on behalf of someone else.

Alzheimers NZ Consumer advisory group member – carer/partner of person with dementia

1. Alzheimers NZ welcomes the opportunity to comment on the consultation on research involving adult participants unable to give informed consent.
2. We recognise the importance of having a rigorous human rights and ethical approach to the question of consent for research. Abuses where consent has not been sought are well documented and outlined in the consultation document, and have resulted in the current safeguards. As noted by the HDC consultation document, people who lack the capacity to make informed choices are particularly vulnerable to abuses of their rights and interests.
3. However, Alzheimers NZ is concerned that a narrow interpretation of consent, or the capacity to give consent, can lead to situations in which people with dementia can be excluded from participation in research that they wish to be part of and wish to see take place.
4. There needs to be more research undertaken into dementia. People at different stages of the dementia journey wish to see this happen and wish to be participants in it. Members of our Consumer Advisory Group and others in the dementia community say they want to be participants in research which will provide insights into the condition and the best care and support options which will be of benefit to others with the disease. They know they themselves may not personally benefit from this research, but they want the community to benefit in the long run. We see validity in extending the boundaries of research beyond the current standard that it should only take place when it is assessed as being of direct benefit to the participant.

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5. The UN Convention on the Rights of People with Disabilities (UNCRPD) recognises **provision, protection and participation** rights. The inclusion of Article 15 specifically covers the right of people with disabilities to be protected from being subject to medical or scientific experimentation without their consent. However, it is important not to read this Article in isolation from those covering participation rights, such as Articles 5, 12 and 19. A key element of ensuring that both protection rights and participation rights are met is ensuring that communication and other processes are appropriately modified for target communities.
6. As the Consultation document notes, the UNCRPD notes the importance of a mental shift from **substituted decision-making**, where decisions are made by others on behalf of the relevant individual, to **supported decision-making**, where the individual receives support that allows them to make the decision themselves. Alzheimers NZ strongly supports this approach, which requires more than a simple assessment in the abstract of whether a particular individual is cognitively capable of making a decision. It also involves more complex assessments about whether a person is able to make a decision to participate in research in the specific context and specific conditions at the time, including their own state of wellbeing.
7. Jan Dewing¹ and other researchers working in the area of research with dementia patients argue that a narrow focus on cognitively biased informed consent and to consent taking place at the beginning of projects is exclusionary for people with dementia. She outlines a method for consent which enables people with dementia to take part in research projects, and on consent as a process that runs through the whole of a research project. We would like to see more serious examination of these options in New Zealand research, and attach a copy of her paper with this submission.
8. Obtaining consent at the start of a research project alone will not protect a person from abusive or intrusive research if no other safeguards exist. We believe there are other ways to ensure that people with dementia are safely and appropriately included in research.
9. While obtaining consent from another person with legal capacity to make decisions for people with dementia should not be overlooked, Dewing focuses on asking family members/carers rather on **permission for access** to a person with dementia. Her process may include carers in the conversation to further enhance the communication with the person with dementia and to confirm assumptions or conclusions being made about whether consent is given and continues to be given in a research context.
10. Family members in our Consumers Advisory Group recognise there are situations in which carers can be conservative and over-protective about giving permission for their family members to take place in research, out of concern about not knowing what their loved person really would like to happen. Some carers wish to see an independent advocate appointed to

¹ Dewing J (2007). Participatory research: A method for process consent with persons who have dementia. *Dementia: The International Journal of Social Research and Practice*. 6 (1) 11-25

assist the assessment of participation of a person with dementia in a research project was appropriate. This included an acknowledgement that there are times that they are too close to, and the researcher too distant from, the person with dementia to properly assess what they want and what will be of benefit to them and the wider community.

11. It is essential that there is enhanced oversight of research involving people who have reduced capacity to give consent, and not just by ethics committees at the start of research. There needs to be ongoing monitoring and assessment of whether the research was undertaken in the way originally proposed.
12. Members of the Alzheimers NZ Consumer Advisory Group wish to see the Code of Health and Disability Rights Services and Consumers' Rights coverage extend to all research undertaken with people with dementia. One example given of research involving a family member with dementia appeared to be a University design school study into design elements of dementia care facilities, which the researchers understood to be outside the Code. However, our CAG group member was surprised to find the questions covered a much wider range of issues, including how the person with dementia felt about being put into care and attitudes about the care she was receiving. He felt the researcher did not have the competence to understand and appropriately respond to the emotions being generated by the questions, and it was a traumatic experience for both the person with dementia and their family and institutional carers. This project appeared to depart significantly from the stated purpose for the research, and to have inadequate sign off and oversight by an Ethics Committee. We believe that this particular situation did fall within the Code, and this also should have been assessed as such by the Ethics Committee.
13. It is important to note that this negative experience is not an argument for not undertaking research including participants who have dementia; rather it is an argument for ensuring that the highest standards of ethical behaviour are required for research of this kind.
14. In conclusion:
 - It is important to provide ways that people with dementia can be included in research projects.
 - We believe the current guidelines can and should be extended to include:
 - Research that may not benefit directly the person with dementia but is of long term benefit to others with the same conditions and to the wider community;
 - A wider range of forms of consent, including participatory processes such as those outlined by Dewing and other researchers working on these issues;
 - Priority given to supported decision making over substituted decision making.
 - Protection of people with dementia in research projects is important and the highest standards of research and oversight by Ethics Committees need to be in place.
 - However, there also needs to be a balance of protection and participation rights. Issues around reduced cognitive capacity should not stop research projects into dementia from proceeding, or people with dementia from participating in them.

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