ENGAGING IN RESEARCH: A RISKY BUSINESS?

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THE STUDY

This presentation is part of a PhD study titled:

‘The lived experience of risk for people with early stage dementia (Alzheimer’s type): A longitudinal phenomenological study’

HREC- Human Research and Ethics Committee
CDAMS- Cognitive Dementia and Memory Services
RESEARCH AND DEMENTIA: THE AUSTRALIAN LEGISLATIVE CONTEXT

• National Statement on Ethical Conduct in Human Research (NHMRC)
• Australian Code for the Responsible Conduct of Research

• International standard (World Medical Association Declaration of Helsinki, 2008)
WHAT ARE THE GAPS?

- How capacity (competence) is determined
- Informed consent - when, why and by whom?
- What defines ‘best interests’?
- How can assent and dissent by someone with dementia should be determined?
- Whether or not people with dementia ought to be included in research?
RESEARCH with PEOPLE living with DEMENTIA

- Helps improve its quality and relevance
- Provides a unique perspective on research and the knowledge based on their experience of having dementia
- Benefits outweigh the risks
- Changes perception → attitudes → enabling policy
In relation to ‘high risk’ research with people with dementia, the National Statement says:

“the greater the risk to participants in any research for which ethical approval is given, the more certain it must be both that the risks will be managed as well as possible, and that the participants clearly understand the risks they are assuming”

This seems to indicate that people without capacity should be excluded from ‘high risk’ research.
WHY IS RESEARCH ‘RISKY’ FOR PEOPLE WITH DEMENTIA?

- Gatekeepers
- Assumption that all people with dementia are the same
- Problems with terminology –
  * autonomy
  * freedom
  * choice
  * power
Discussion Point 2

A new source of power is PEOPLE

- [www.alz.co.uk/icaniwill](http://www.alz.co.uk/icaniwill) The International I can! I will! Alzheimer's Disease International
WHY IS RESEARCH ‘RISKY’ FOR RESEARCHERS?

- Dementia research is the ‘poor relation’ of medical research
- It can be ethically challenging due to the effects of dementia on cognitive function
- Unclear guidance from the National Statement on many issues is a disincentive
WHY IS RESEARCH ‘RISKY’ FOR HRECS?

- Lack of guidelines
- Concern about the balance between potential risks and benefits.
- Vested interests may be highjacking the debate
WHAT IS THE PRICE OF EXCLUSION?

- People would become ‘therapeutic orphans’ and medically abandoned (Post, 1988).
- Over-protection has its own dangers
- For people with dementia, it would be ‘an affront to their dignity’ (Hellström et al, 2007)
A RESEARCHER’S REFLECTIONS

- Gidden’s ‘reflexive actor’ treats persons with dementia as autonomous.
- CAPACITY - A basic, but important question to ask oneself is: can this person say “no”?
- INFORMED CONSENT - is a process not an outcome to be achieved.
- Keep abreast of changes to governance and legislation
FINAL DISCUSSION POINT

‘Research... often generates ethical dilemmas in which it may be impossible to find agreement on what is right or wrong. It is important that all those involved in research and its review bring a heightened ethical awareness to their thinking and decision-making’ (National Health and Medical Research Council, Australian Research Council & Australian Vice-Chancellor’s Committee).


http://www.youtube.com/watch?v=L16DyGGy6BA&feature=player_embedded (Helga Rohra)


Email your feedback on NHMRC ethical guidelines to ethics@nhmrc.gov.au


www.thecamdensociety.co.uk/upload/public/.../sp-news-oct09.pdf (example of Service User Reference Group)


