

Adults with Developmental Disability Participating in Research

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A joint initiative of Monash University and The University of Melbourne



Examples of Research

- Alzheimer's disease and Down syndrome
 - Adults with Down syndrome (direct)
 - Paid or family carers (direct)
- Development of a Victorian Population Health Survey
 - Adults with intellectual disabilities (indirect)
 - Paid support workers (direct)

Factors Influencing Capacity for Consent

- Cognitive capacity
 - Underlying language skills
- Experience with self determination
- Opportunities

Indicating Consent

- Literacy skills
- Comprehension skills
- Methods of communication
 - Speech
 - Signs
 - Graphic symbols
 - Text

Why Include People with DD in Research?

- Right to contribute to the knowledge base
- Right to be included in a valued activity
- Ensure research addresses the spectrum of abilities and needs
- Broaden their range of experiences
- Provide opportunity for decision-making and self-determination

Deciding on Capacity

- 2-part consent form?
- Pre-participation assessment?
- Checklist – completed by a familiar person

Capacity to Consent Checklist Example

Can the person understand...

Aims

- We want to get information about health and use of services

What will happen

- The support worker will give information about them.
- They will see a nurse for a medical check up
- They may miss out on an activity in the house when they see the nurse

The risks or discomforts

- No real risks or discomfort.

What will happen to the information about them, e.g.,

- All their information will be confidential.
- The information will be used to write a report for the Department of Human Services

Who decides

- They can decide if they want to participate.
- They can choose not to participate

This person routinely makes independent judgements about:

- His/her healthcare or use of services.
- Participation in research

Proxy Consent vs Acknowledgement

- Legalities
 - Can one person give consent on behalf of another?
 - Distinction between consent and acknowledgement of a family member's participation often causes confusion
 - DHS HREC tends to use acknowledgement

Medical Research Procedures

Guardianship & Administration Act (1986)

- Procedure carried out for the purposes of medical research
 - Part of a clinical trial
 - Administration of medication
 - Uses of equipment or device
- Excludes
 - Non-intrusive examinations
 - Observing activities or conducting surveys
 - Collecting or using information
 - Any other procedure prescribed by regulations not to be a medical research procedure (none at the time of amendment, 2006)

Participation of Adults without Capacity to Consent: Medical Research

- Guardianship Act 42S
 - Seek consent of person responsible
 - Agent appointed by participant (NA for people with ID)
 - Person appointed by VCAT
 - Guardian appointed by VCAT with health care powers
 - Person appointed in writing by participant to make health care decisions
 - Primary carers (not paid)
 - Next-of-kin

Participation of Adults without Capacity to Consent: Medical Research

- National Statement (2007)
 - “person’s guardian or any person or organisation authorised by law” (S4.5.5)

Medical Research

- No person responsible
 - Notification to Office of Public Advocate by medical practitioner – Section 42K



Adobe Acrobat
Document

Accessibility of Next-of-Kin

- Ageing parents
- Relatives in conflict
- Responsibility taken by other relatives
- Relinquishment of duties
- Variation in level of involvement
- Level of wariness

Reactions of Next-of-Kin – Risks!

- Cautious of privacy
- Fear of losing services or putting a service off side
- Confusion about paperwork
- Confusion about reason for being contacted
- Need to tell their story
- Attitude that researchers using their relation
- Altruistic motivations

Non-Medical Research

- If no next-of-kin
 - No person or organisation authorised by law to provide consent for participation of an adult with developmental disability (National Statement, 2007)
 - Paid person responsible for daily care of the adult is excluded by the Guardianship Act (1986)
 - Only alternative is to apply to VCAT for the appointment of a guardian for this purpose
 - Onerous for all parties

Waiver for the Consent Requirement

- HREC can give approval to waive the requirement of informed consent if the research is
 - Low risk
 - In public interest

National Statement, 2007

Statutory Guidelines for the Health Records Act 2001 (Vic)

Waiver for the Consent Requirement

- DHS and SCERH HRECs
 - Seeking legal advice
 - Tending to ask for documentation that a next-of-kin or other person responsible is not available or can't be located
 - Issue of 'How?'

Balancing Laws against Human Rights

- Participation in research
- Violations of privacy
 - Personal or health information
 - Being observed, tested, etc.
- Excluding involved next-of-kin
 - Risk relationships between – disability organisation, family, researchers

Supported Decision-Making

- Considers that most of us consult with those we trust, have confidence in
 - Make decisions within a social context

Roeher Institute Model (1996)

- Researcher asks potential participant if s/he would like a trusted person present
- Individual who knows the person well determines if the person could make an informed decision
 - If not, family member or advocate identified

Roeher Institute Model (1996)

“The individual and the person providing decision-making support review information about the proposed research and, together, determine whether or not the individual will consent to participate.”

Bach & Rock (1996)

Responsibilities of Researchers

- Educate and work with HRECs about the complexities of involving people with DD in research.
- Maintain a balance between supported decision-making and avoiding coercion.
- Ensure feasibility of the research while maintaining respect for Human Rights of adults with DD and their next-of-kin and those who support them.
- Provide opportunities for adults with DD to participate in research through varied valued roles.