Q & A
Ethical review of research in the disability services sector

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INTRODUCTION

For a while now, some of us in the disability sector have struggled with understanding the rules of the game for the ethical conduct of research[1]. An example illustrates the range of challenges:

> *Phoebe works part time at an after-school homework club for teens. Most of the children accessing the service are aged 12-17, and have intellectual disability. Phoebe wishes to interview a couple of the teens for an assignment as part of her Masters course. She indicated to you, her manager, that she would perhaps include some background information from their files and, because she has "known these people for ages", might include some other information but isn't sure yet. Phoebe has asked you if this would be ok.*

This example raises some important questions: "Is it research?" "If it is research, what approvals and protocols might be necessary?" "If it isn't research, what responsibilities still apply?", "Consent issues?", "Confidentiality issues?"…and many more.

We also have a variable understanding of the *National Health and Medical Research Council Act (1992)* (NHMRC Act). The legislation requires that if we do, or participate in research, program evaluation, or even internal quality improvement activities, our service delivery agencies must have relevant policies and procedures in place to oversee these projects.

We need to make sure that we all fully understand, and follow, the rules of the game.

As a first step to ensuring consistency, on 4th June 2012 the Australasian Society for Intellectual Disability (ASID) NSW/ ACT, and Northcott Disability Services co-convened "Research Ethics into Practice: A Roundtable Discussion for Disability Service Providers". Forty-five participants attended, representing government, not-for-profit agencies, and universities. The purpose of this meeting was to discuss the inconsistencies, and plan for a way ahead. Arising from the roundtable, a working party was formed, and one of its tasks was to develop guidelines for agencies in the disability sector to ensure consistency

[1] We acknowledge the debate about the distinction between research and evaluation. The NHMRC Act addresses both in its requirements. See over page for further information.

in the ethical conduct of research. Drafts were fed back to all attendees of the roundtable meeting. This document is the outcome.

QUESTIONS & ANSWERS

1. Why is ethical review of research important in the disability sector?

First, it's the law.

Second, although our sector is well versed in ensuring that people with disability maintain their rightful and equal place in society, the sector also has a responsibility to ensure that all people involved are treated with respect and protected when they participate in, or do research.

Third, with the advent of individualised funding and the National Disability Insurance Scheme (NDIS), interest in research is growing. The sector needs to make sure it is ready for this increased interest AND, it needs to advocate for the right sort of research. We can only do this if we have the correct policy and procedures in place, and that these are consistent across our sector.

2. So what is research?

The participants at the roundtable kept coming back to this fundamental question, so we thought we'd summarise the key points from the NHMRC. When involving humans, research is "with or about people, or their data or tissue"[1] (p. 8). It includes the conduct of surveys, interviews, focus groups, psychological/ physiological/ medical testing or treatment, observations, access to personal documents, collection of body tissue/ organs/ fluids, and information stored on databases [1].

3. What if a project isn't called 'research'?

Sometimes agencies participate in program evaluation, quality improvement, root cause analysis or reviews. These projects often fall under the NHMRC's definition of Quality Improvement (QI) activities[2].

According to the NHMRC QI activities are subject to the same ethical conduct requirements as research. In this document we talk about research, but it's important to remember that the rules are the same for research and QI activities.

4. So what is ethical conduct?

Ethical conduct is acting in the right spirit, with respect and concern for others[1]. For the purpose of research, it means:

- **Merit and integrity:** the research has benefit, uses the right research methods, and is respectful, honest and transparent.
- **Justice:** the research is fair and honest in recruiting people, does not exploit, and ensures fair distribution and access to the benefits.
- **Beneficence:** the benefit of the research justifies any risk or harm to participants.
- **Respect*:*** recognises the intrinsic value of all human beings.

5. What is a HREC?

The NHMRC has a national system for the ethical review of research projects, known as Human Research Ethics Committees (HRECs). There are more than 200 HRECs in Australia and their role is to ensure that research is being conducted ethically, in accordance with NHMRC guidelines. All disability agencies that do or participate in research must know about HRECs, when their approval is necessary, and how to access one.

Find more about HRECs at: http://www.nhmrc.gov.au/health-ethics/human-research-ethics-committees-hrecs/overview-human-research-ethics-committees-hrecs

6. What do I need to do now?

You should be aware of two important publications:

1. National Health and Medical Research Council, Australian Research Council, Australian Vice-Chancellors' Committee (2007 and amendments 2009). *National statement on ethical conduct in human research.* Canberra. Government of Australia[1].

   Commonly referred to as "the National Statement", and for the rest of this document, we'll use that term.

2. National Health and Medical Research Council, Australian Research Council and Universities of Australia (2007). *Australian code for the responsible conduct of research.* Canberra: Government of Australia[3].

   Commonly referred to as "the Code", and for the rest of this document, we'll use that term.

Find the Statement at:
http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e72_national_statement_130207.pdf

Find the Code at: http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/r39.pdf

If your agency is doing, or participating in research or QI activities, then as a minimum you need to know about three things described in the Statement or the Code:

- Research governance.
- Risk.
- Consent.

7. What is Research Governance?

Research Governance is your agency's system to ensure that human research is conducted in accordance with the NHMRC Statement and Code.

The NHMRC is not prescriptive about how research governance should look in each agency, but does outline the essential responsibilities. In line with the Code, it is essential that:

- The CEO/Senior executive is aware of ethical responsibilities under the NHMRC Statement and Code.
- The agency has a clear research policy and procedure.
- Staff are aware of their responsibilities.
- The agency ensures that the people doing the research are adequately experienced, qualified and monitored.
- Structures are in place to ensure research projects are conducted with integrity.
- Processes are in place to manage conflicts of interest and complaints.
- The agency has appropriate data storage systems for all research data.

Find more about Research Governance in:	Section One of the Code Section Five of the Statement

8. What does risk mean in ethical review?

Every person who is a participant in research is exposed to some level of risk, and the extent of this risk requires assessment. This assessment determines the extent of ethical review required, ranging from internal review to a HREC review.

Agencies are responsible for ensuring that they have:

- Structures in place to assess risk.
- A risk review panel comprising suitably qualified personnel.
- An up-to-date register of all research projects and QI activities reviewed by the panel, including documentation of ethical review and justification for the level of review determined.
- Access to a HREC.

Find more about risk and ethical review in:

Sections Two and Five of the Statement.

Public consultation draft: Using the National Statement: Ethical review of quality improvement activities in health services at: http://consultations.nhmrc.gov.au/files/consultations/drafts/draftethicalreviewofqualityimprovementactivitiesinhealthservices.pdf

9. What do I need to remember about consent?

Gaining consent means that the participant understands what he or she is agreeing to. The participant's choice to participate should be based on sufficient information, and be voluntary. Agencies are responsible for ensuring that:

- Participants receive information about the research project or QI activity in an accessible format.
- Participants understand that their consent can be withdrawn at any time.
- Informed consent has been gained from the participant.

Find more about consent in: Section Two of the Statement

10. Are there particular ethical issues when working with people with disabilities?

Yes, in the disability sector we often work with people who might be considered vulnerable. In the context of ethical conduct, this vulnerability is mainly about determining informed and voluntary consent, and the participants' ability to participate in the project without undue discomfort or stress. There are guidelines to ensure ethical conduct of research and QI activities with vulnerable people, and agencies are responsible to ensure that these guidelines are followed.

Find more about the ethical considerations specific to people with disabilities at:

Section Four of the Statement:

Chapter 4.4: People highly dependent on medical care who may be unable to give consent

Chapter 4.5: People with a cognitive impairment, an intellectual disability or mental illness.

CONCLUSION

So, to go back to the example of Phoebe, given on p. 1 of this document, and repeated below…

> *Phoebe works part time at an after-school homework club for teens. Most of the children accessing the service are aged 12-17, and have intellectual disability. Phoebe wishes to interview a couple of the teens for an assignment as part of her Masters course. She indicated to you, her manager, that she would perhaps include some background information from their files and because she has "known these people for ages" might include some other information but isn't sure yet. Phoebe has asked you if this would be ok.*

What should happen?

The minimum required by the Statement and Code arising from the NHMRC Act would be…

1) Phoebe would know that she has to seek the advice of her manager before planning *anything* to do with the proposed project.
2) Phoebe's manager would know that the agency they both work for has a formal mechanism for the ethical review of the proposed project and Phoebe would have to meet the requirements of that mechanism.
3) Phoebe would not approach any of her clients about the project until she'd met these requirements.
4) Those in charge of the ethical review would conduct and document their review and decisions arising.
5) If Phoebe's project is endorsed, the agency would monitor the project to make sure it is conducted with ethical integrity.

These requirements might seem onerous. Therefore the mechanisms that an agency puts in place should be simple, but do the job. The disability sector has a responsibility to encourage research, but we also have a responsibility to make sure that it is conducted ethically.

REFERENCES

National Health & Medical Research and Council Australian Research Council and Australian Vice-Chancellors' Committee. (2007 and amendments 2009). *National statement on ethical conduct in human research*. Government of Australia: Canberra, ACT.

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National Health and Medical Research Council Australian Research Council and Universities of Australia (2007). *Australian code for the responsible conduct of research*. Government of Australia: Canberra.