community mental health drug and alcohol
RESEARCH NETWORK
CMHDARN

Research Ethics:
A CMHDARN Best Practice Guide

March 2016

The CMHDARN is an initiative developed in partnership between NADA, MHCC and the Mental Health Commission of NSW.

mhcc mental health coordinating council

NADA network of alcohol and other drugs agencies

Mental Health Commission of New South Wales

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We intend to keep this resource current. Please tell us about new tools and resources as you find them. To make suggestions for the improvement of this guide, please contact:

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About This Guide

CMHDARN thanks the CMHDARN members and stakeholders who participated in consultations or contributed to the development of this guide in any way.

Initial work for this guide was undertaken by Thushara Prabesh with the support of Deb Tipper. A later version was developed by Carla Cowles, Staff Consultant with Human Capital Alliance (International) Pty Ltd. Our thanks to these contributors. The current version was prepared by Dr Angela Argent in consultation with the CMHDARN Steering Committee and Project Reference Group.

Thanks to the Drug and Alcohol Multicultural Education Centre (DAMEC), Neami National and the AIDS Council of NSW (ACON) for their assistance and for granting permission for the use of their materials in this guide. Special thanks to the Mental Health Commission of NSW for funding this resource and to NADA and MHCC for making it all possible.

Every effort has been made to ensure that the information contained here is accurate at the time of publication. However, this remains very much a work in progress and your suggestions for improvement and keeping it relevant are extremely welcome.

About CMHDARN

The Community Mental Health Drug and Alcohol Research Network (CMHDARN) is a partnership project between the Mental Health Coordinating Council (MHCC), the Network of Alcohol and other Drugs Agencies (NADA) and the Mental Health Commission of NSW.

CMHDARN was established in 2010 to broaden the involvement of the community mental health and alcohol and other drugs sectors in practice-based research, and to promote the value of research and the use of research evidence in practice. Its overall aim is to improve the quality of service delivery and, correspondingly, the outcomes for consumers of community-managed services.

CMHDARN aims to facilitate the development of a culture of research by providing opportunities and a context for the exchange of ideas, the sharing of resources, support and collaboration among community organisations, and between community organisations and research bodies, including universities and research institutes.

In order to build the research capacity of the sectors, the Network shares information via its website, workshops, forums, reflective practice webinars/webcasts, e-communications and other activities.

For further information about;

CMHDARN, go to www.cmhdaresearchnetwork.com.au

NADA, go to www.nada.org.au

MHCC, go to www.mhcc.org.au

The NSW Mental Health Commission, go to www.nswmentalhealthcommission.com.au

Acronyms

ACCHS	Aboriginal Community Controlled Health Services
ACON	AIDS Council of NSW
AH&MRC	Aboriginal Health & Medical Research Council
CALD	Culturally and linguistically diverse
CMHDARN	Community Mental Health Drug & Alcohol Research Network
HREC	Human Research Ethics Committees
LHD	Local Health District
LNR	Low and negligible risk
MH	Mental health
MHCC	Mental Health Coordinating Council
MHDA	Mental health and drug and alcohol
NADA	Network of Alcohol and other Drugs Agencies
NEAF	National Ethics Application Form
PHO	Public Health Organisation
SPSS	Statistical Package for the Social Sciences
SSA	Site Specific Assessment

Terminology

Research and evaluation

Research can be characterised as an original and exploratory investigation to obtain a deeper understanding and insight into a particular issue.[1]Evaluation involves collecting and analysing information to make a judgement about the effectiveness, efficiency and/or appropriateness of an activity or program.[2]

Research and evaluation drive innovation by growing the evidence base that informs and influences practice improvement. Research translates into improved services and outcomes for real people living with mental health and alcohol and other drugs issues. Building sector capacity for research and evaluation is therefore of crucial and growing significance in the community sector, among consumers, peer workers and carers.

Research and evaluation that involves people raises a range of ethics questions. That's why CMHDARN developed this guide.

Community Organisations

This guide uses the term 'community organisations' to refer to organisations within the mental health and alcohol and other drugs sectors.

Consumer/client/peer/psychiatric survivor/service user

In this guide, the term 'consumer' is used to refer to a person with a lived personal experience of mental health, and/or alcohol and other drugs issues. The use of the term in the mental health context has its origins in the civil rights movements of the 1960s and 1970s. Survivors in numerous contexts sought to find a counter-narrative of empowerment and resistance to negate negative experiences of 'treatment' and lack of choice within systems that served to perpetuate rather than make the systems 'human'. The use of the term 'consumer' today remains as contentious as it ever was. Many people within the mental health sector would advocate for the use of 'survivor' or 'psychiatric survivor' instead.

There also remain significant differences in language usage within and between the mental health (MH) and alcohol and other drugs (AOD) sectors. Broadly, in the alcohol and other drugs sectors, the term 'client' is still far more commonly used. These differences in usage are based on dissimilar sector histories, policy environments and service models.

The deliberate use of the term 'consumer' throughout this guide is intended to draw into question the use of medical and clinical language, and to redirect the conversation towards recovery oriented and trauma informed language, reflecting hope, optimism, and focusing on strengths.

- The meanings that each person gives to their own experience of mental health or alcohol or other drugs issues are entirely individual. No two 'consumers' are in any way the same. Active engagement and leadership in research and evaluation means that consumers and/or carers, as insiders to the processes of knowledge creation, have a better chance of having more say and control over their lives.

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[1] NHRMC, the Australian Research Council and Universities Australia (2007). *Australian Code for the Responsible Conduct of Research*. Australian Government: Canberra, ACT.
[2] Australasian Evaluation Society (2013). *Guidelines for the Ethical Conduct of Evaluations*, http://www.aes.asn.au/images/stories/files/membership/AES_Guidelines_web.pdf, (accessed 20 March 2015).

Carer

In this guide, the term 'carer' has been used to describe the people who care for, or support people who experience mental health and/or alcohol or other drugs issues. A carer may be a friend, peer, spouse, sibling, grandparent, child, neighbour or other supporter. Carers/supporters come from a diverse range of backgrounds, experiences and circumstances. They may be young or old. The individual experiences, needs and interests of carers are similarly dissimilar from one another.

Contents

Introduction to this guide

Purpose

This guide has been written for any community organisation, consumer, peer worker or carer in the mental health and alcohol and other drugs sectors who is considering engaging in research and/or evaluation.

The primary purpose of this guide is to provide you with information and support to:

- kick-start a conversation about ethics in research and evaluation, tailored to your project
- bring the question of ethics to the research table and help guide your judgement and decision making
- help you embed ethical research practices in all that you/your team do
- increase your knowledge and understanding of the specific rights and needs of consumers, peers and carers in research and evaluation
- understand formal ethics processes and the role of Human Research Ethics Committees (HRECs)
- access useful resources and links to support ethics in research and evaluation.

This guide is intended to be read alongside *Ask The Experts, a CMHDARN Best Practice Guide for Enabling Consumer and Carer Leadership in Research and Evaluation).*

Why research ethics matters

Research involving people raises a diverse range of ethical considerations. Every research and evaluation project is different in its own particular way. Most research is built on problematic or troubling traditions of one kind or another, and things can get very complicated when we include human participants in the mix.

That's why CMHDARN has developed this guide, to assist you to interpret, assess, grapple with and apply various concepts, principles, tools, guidelines and ways of seeing. We intend for this guide to empower you and your organisation to make good decisions and act on them with greater confidence in various research and evaluation situations and contexts.

Research and evaluation drive innovation by growing the evidence base that informs and influences practice improvement. Research translates into better services and outcomes for real people living with mental health and drugs and alcohol issues. Building sector capacity for research and evaluation is of crucial and growing significance in the community sector, but research ethics is very much about getting started in your research with your eyes wide open.

Research ethics is much more than just building a methodology concerned with protecting rights and minimising potential risks to participants, researchers and the broader community, although certainly the safety, wellbeing and empowerment of all participants in research is very important.

A genuine commitment to research ethics means taking the time to think about the way you behave, interpret, balance, or apply your own values, norms and life experiences against other sets of behaviours or norms.

Ethics in research is about tapping into your innate sensitivity, moral and social awareness and sense of compassion for the people you want to learn from.

Research ethics relate to every stage of your research project, including:

- conceptualising, defining and understanding the purpose and scope of your project
- thinking about the broader aims of your research, such as valuing knowledge, truth, honesty, objectivity, openness to criticism and new ideas
- designing a solid methodology – by ensuring integrity, competence, carefulness and avoidance of error
- working to involve stakeholders and participants in the values that are essential to collaborative work, such as trust, accountability, mutual respect, fairness and non-discrimination
- sharing outcomes and results that support social good and that prevent or mitigate against social harms through public education and advocacy. This in turn builds public support for research and grows research capacity
- publishing findings that grow the evidence base for evidence-informed practices and innovative thinking (and maybe even tolerance, critical thinking and understanding along the way)
- being accountable for your research – this includes taking moral and social responsibility, as well as thinking about human rights, non-discrimination, compliance with laws, health and safety and common decency
- respecting the intellectual property of others – not using unpublished data, methods or results without permission and giving credit where credit is due, i.e. properly acknowledging or crediting all contributions to research.

Ensuring that the rights of participants are protected, and that they remain empowered throughout each and every stage of research, aligns closely with the values base of the mental health and alcohol and other drugs sectors. This guide aims to increase the capacity of both sectors to support and collaborate with consumers and carers as equals, by building respectful and trusting partnerships. Growing sector capacity through meaningful collaboration increases the evidence base that can be translated into evidence-informed practices that ultimately benefit consumers and carers.

The underlying philosophy of this guide reiterates the understanding, expressed in *The National Statement on Ethical Conduct in Human Research*, 2007 (Updated March 2014)(The National Statement)that:[3]

> *"…ethical guidelines are not simply a set of rules. Their application should not be mechanical. It always requires, from each individual, deliberation on the values and principles, exercise of judgement, and an appreciation of context."* (pg. 11)

The contexts in which research and evaluation are conducted are diverse and variable. This guide serves as a starting point for community organisations to think about and undertake research and evaluation with integrity, honesty and respect for everyone involved.

The development of this guide

This guide has been informed by *The National Statement*, a key document and guide for research and evaluation in Australia. In addition, the guide has also drawn on and refers to a number of additional guides and resources, including resources from the mental health and alcohol and other drugs sectors. This list is by no means exhaustive; it is merely intended as a starting point.

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[3] NHRMC (2014). *National Statement on Ethical Conduct in Human Research 2007 (Updated March 2014)*. NHRMC, the Australian Research Council and the Australian Vice-Chancellors' Committee. Commonwealth of Australia, Canberra.

How to use this guide

This guide can be read sequentially from start to finish or dipped in and out of, depending on your needs and interests.

For community organisations, consumers or carers seeking specific guidance in relation to ethics approval processes, go straight to the section applying for ethics approval.

Embedding ethics in research and evaluation - values and principles

Before we begin, we need to think about the values and principles that underpin our desire to undertake research and evaluation.

What do we hope to gain in undertaking research? What is the benefit for participants? *Whose* ethics are we talking about? And, how do we know what is ethical or not?

The mental health and alcohol and other dugs sectors are made up of people from a diverse range of backgrounds and circumstances. There will never be a consensus on what is, or is not, ethical practice in relation to research and evaluation.

Building research capacity across the sectors is absolutely imperative. However, it is important that research ethics, that is, an awareness and questioning of our values, inform our thinking from the outset.

A good starting point is provided by The National Health & Medical Research Council (NHMRC)'s *National Statement on Ethical Conduct in Human Research, 2007 (Updated March 2014).* [4] The NHMRC outlines four values and principles that underpin *all* research and evaluation conducted with people. They are summarised below.

[4] NHMRC (2014). *National Statement on Ethical Conduct in Human Research 2007* (Updated March 2014). The Australian Research Council and the Australian Vice-Chancellors' Committee. Commonwealth of Australia, Canberra.

NHMRC Values and Principles

Research merit and integrity
The proposed research should have merit in relation to justifiable benefits, appropriate methodology and is conducted by suitably qualified and competent persons. The research should also be carried out with integrity by persons with a commitment to searching for knowledge and understanding and following recognised principles of research conduct.

Justice
Justice is expressed in the fair distribution of the benefits and burdens of research, and fair treatment of participants in the recruitment process and the review of research.

Beneficence
Researchers act with beneficence by considering the risks of harm and the potential benefits of research to participants, and to the wider community; by considering the welfare and interests of people involved in their research; and by reflecting on the social and cultural implications of their work.

Respect
Respect is the common thread that binds the ethical consideration of human research. This includes recognising the value of human autonomy, providing protection, empowerment and support.

There are instances where research ethics become particularly significant in relation to specific groups of people, such as people with mental health and/or alcohol and other drugs issues, Aboriginal and Torres Strait Islander people or people from culturally and linguistically diverse (CALD) backgrounds, and people with intellectual disability.

The six values outlined in *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research*[5] *(Aboriginal and Torres Strait Islander Guidelines)* complement the four NHMRC principles and are of great significance in a range of research and evaluation contexts. These values have been adapted and summarised below precisely because they reflect the need to recognise all participants in research and evaluation as individuals from diverse contexts and circumstances:

[5] NHMRC (2003). *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research*. Commonwealth of Australia: Canberra, ACT.

Values and special responsibilities in research and evaluation[6]

Reciprocity: Reciprocity refers to an obligation among people to achieve an equitable distribution of resources and benefits from research.

Respect: Respect includes trust, cooperation and respect for human dignity. Respectful research relationships acknowledge and affirm the right of people to have different values, norms and aspirations. In the research context, respect also includes consultation and engagement with people and valuing their knowledge and contribution to the research effort.

Equality: Equality refers to 'equal value of people.' Equality does not mean 'sameness' and in research 'equality' refers to a 'commitment to distributive fairness and justice.'

Responsibility: Underlying the value of responsibility is the obligation to do no harm; research should be beneficial and not harmful.

Survival and protection: This refers to the determination of people to protect their culture and identity from erosion by external forces. Research must not be used to undermine peoples' culture, solidarity or distinctiveness. Research must not be used to exploit people or to contribute to discrimination and derision of specific groups of people just for the sake of knowledge.

Spirit and integrity: Spirit and integrity are the overarching values that bind the other five values into a coherent whole. Research should not be used to harm or destroy the culture of any people or their core values over time.

The values and principles defined in *The National Statement* and *Aboriginal and Torres Strait Islander Guidelines* provide a good springboard for wider discussion within your organisation or research group.

The contexts in which research is undertaken are changeable and ethical considerations need to be understood as context specific, existing in a particular time and place and more importantly, invoking a particular set of meanings to dissimilar consumers and carers.

[6] These values are an amended version of the six core values within *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research.*

Identifying responsibilities in research and evaluation

Alongside the values and principles guiding research and evaluation, community organisations, research groups, researchers and evaluators have certain responsibilities.

These responsibilities include:

- **ensuring integrity and fidelity** – conducting research and evaluation with honesty and integrity and with proper governance structures in place
- **acknowledging power inequities** – recognising the power that researchers exert and work to redistribute power
- **disclosing any conflict of interest** – fully disclosing all funding sources, in-kind support and any other potential conflict of interest
- **enabling** consumers to make decisions for themselves about the extent of their participation, rather than the researcher making these decisions in isolation
- **empowering** consumers and carers to participate as expert equals at all stages of the research process – as contributors to research design, as co-researchers or as independent researchers.

Other useful resources:
NHMRC, *Australian Code for the Responsible Conduct in Research (The Code*), 2007.
Ethics of Survivor Research - Guidelines for the ethical conduct of research carried out by MH service users and survivors
National Statement on Ethical Issues for Research Involving Injecting/Illicit Drug Users - Australian Injecting & Illicit Drug Users League (AIVL).
Ask The Experts, a CMHDARN Best Practice Guide for Enabling Consumer and Carer Leadership in Research and Evaluation)

Developing a framework for research and evaluation

Developing a framework that brings together values and principles, as well as practical considerations, is a positive step that all community organisations can take to help ensure they act ethically.

A framework is a way to formalise and provide clear guidance about how all research and evaluation, both within, and in partnership with, the community organisation will be conducted and managed. A framework can help to establish ethical practices and take some of the guesswork out of starting a research or evaluation project.

A framework and good governance are crucial to research success.

The *Australian Code for the Responsible Conduct of Research*[7] provides useful suggestions on how to go about developing a framework. A framework might address:

- quality, safety, privacy, risk management, financial management and ethics
- roles, responsibility and accountability for everyone involved
- any relevant laws, regulations, guidelines and codes of practice
- a policy on working collaboratively with other organisations
- a process for managing complaints associated with research and evaluation projects.

The publication, *Ethical Considerations in Quality Assurance and Evaluation Activities,* also provides recommendations for developing a framework.[8]

We have included a list of useful links to research and/or evaluation frameworks developed by community organisations in Australia:

DAMEC Research and Evaluation Framework
Drug and Alcohol Multicultural Education Centre (DAMEC)
This framework focuses on the needs and rights of research participants and provides good guidance for building the evidence base to assist CALD communities and community organisations to respond to alcohol and other drugs related issues. It outlines how research will be approached and managed by DAMEC, defines roles and responsibilities and also includes a number of useful protocols in relation to specific activities and tasks.

Neami Research and Evaluation Framework
Neami National
Neami has developed a framework intended to guide the research practices that will build the evidence base in relation to providing psychosocial rehabilitation services. The framework includes a description of broad research directions to guide the organisation's overall research and evaluation activities.
It also describes the structure and function of Neami's internal research and evaluation committee and outlines protocols for decision-making in relation to research and evaluation.

[7] NHRMC, the Australian Research Council and Universities Australia (2007). *Australian Code for the Responsible Conduct of Research*. Australian Government: Canberra, ACT.
[8] NHRMC (2014). *Ethical Considerations in Quality Assurance and Evaluation Activities.* Australian Government: Canberra, ACT.

Mind Research and Evaluation Framework
Mind Australia
The Mind framework provides an example of a mental health community organisation working in partnership with the University of Melbourne, to conduct research to improve the quality and effectiveness of services for consumers. The framework includes an overall description of how it will be applied via specific platforms with the support of 'enablers.' It outlines the community organisation's strategic goals and expectations in relation to research and evaluation, and provides a description of the research and evaluation committee responsible for reviewing and overseeing all research and evaluation.

Establishing a research and evaluation review committee

The frameworks discussed above were developed by community organisations that chose to establish their own internal research and evaluation review committees. The committees oversee, review and approve all research and evaluation activities to ensure they are undertaken in accordance with the community organisation's values and practices.

Establishing an internal review committee is a highly effective and positive step that community organisations in the mental health and alcohol and other drugs sectors can take to ensure quality and implement best practice in research and evaluation.

Building the evidence base is crucial to the sectors. The sectors needs to promote innovative practices, in order to deliver improved services for consumers and carers and to ensure that their values and principles are reflected and implemented in research and evaluation. An internal review committee can help ensure that all of this happens.

Community organisations thinking about establishing an internal review committee could choose from these options:

1. Establish an internal committee that will oversee and approve all research and evaluation conducted in partnership with and within the community organisation. The models from DAMEC, Mind, and Neami provide excellent starting points. *The National Statement* also provides guidance.
2. Establish a Human Rights Ethics Committee that is registered with the NHMRC.

The latter option is a more involved and complex pathway. It is discussed in the next section, Establishing a Human Research Ethics Committee.

Establishing a Human Research Ethics Committee (HREC)

Some community organisations may be interested in establishing their own HREC. Establishing a HREC is different and more involved than establishing an internal review committee, because the **HREC must be registered with the NHMRC**.

Universities and hospitals are the kinds of organisations that most commonly set up a HREC. Some organisations have established a HREC to support researchers who do not have one at their own organisation, or who are not affiliated with one.

The National Statement provides clear guidance on the process for establishing a HREC.

In short, community organisations looking to establish a HREC need to:

- ensure that the HREC is adequately resourced and maintained
- develop terms of reference that set out the scope of responsibilities, review processes, accountability and reporting, membership requirements and whether members will be paid
- be responsible for recruiting members with adequate experience and qualifications
- ensure that members are appropriately supported.

Once the HREC is registered with the NHMRC, the HREC is then required to report on an annual basis and demonstrate how it is complying with *The National Statement*.

You can register a HREC with NHMRC here.

Other useful resources:
NSW Users & AIDS Association (2009). *Establishment of NUAA's Research Ethics Committee: Discussion Paper.*

AIDS Council of NSW's (ACON) Research Ethics Review Committee
Presentation by ACON, 2012 CMHDARN Forum.

Planning a research or evaluation project

It is important to plan research and evaluation carefully. A plan considers the values and principles of research and evaluation as well as ethical and practical considerations such as risk, consent, privacy and confidentiality.

A plan will ensure that the research or evaluation is realistic in relation to methodology, resources and time. A plan can outline:

- purpose and objectives
- methodology
- timeframes and milestones
- people involved
- resources required
- risk assessment and management protocols
- data storage protocols
- protocols for the dissemination of results
- how the results will be used.

The following list of questions provides a starting point to help guide and frame a research or evaluation plan.[9]

Developing a research or evaluation plan

1. Is the research necessary? What are you looking to investigate and why is it important? How will it build on the evidence base? How will it translate into better outcomes for real people?
2. Is the research well designed? Have consumers been consulted in the design phase? Do researchers have the relevant expertise to conduct the research?
3. What is the context in which the research will be conducted? How will this context influence the research design?
4. Is the methodology appropriate to the context and to what is being investigated?
5. What are the potential harms and benefits for researchers and participants?
6. What information, support and reimbursement for time will be provided to participants?
7. How will free and informed consent be obtained and renegotiated throughout the research process? Do participants have control over their participation?
8. Are there other parties or partners involved in the research? What are their interests? What conflicts of interest need to be disclosed? Who will benefit directly and indirectly from the research?
9. How do you plan to protect confidentiality and anonymity? What will happen to the data? How will it be accessed and secured?
10. Have researchers received ethics training?
11. How will the findings be disseminated and used? Will participants have access to the results? What will happen when the research is complete? Will the research translate into better practices in support of real people?

[9] Australian Council for International Development (2015). *Guidelines for ethical research and evaluation in development*. Australian Council for International Development: Deakin, ACT.

Once the research plan has been developed, assess whether it is appropriate and realistic. At this stage, some community organisations may seek internal review, while other organisations may approach their own/affiliated HREC.

For those organisations that do not have internal review processes in place, research centres at universities may be able to provide valuable assistance and support.

Do we need ethics approval for our research or evaluation project?

TIP:

Contact **CMHDARN**, **NADA** or **MHCC** for assistance or support to get in touch with a research centre.

Other useful tools:
Neami National Research Approval Checklist – developed by Neami, this checklist provides a useful example of a tool used to assist in planning research or evaluation.

DAMEC Research and Evaluation Framework – research and evaluation planning checklist developed by DAMEC. See Appendix 5: Framework implementation, p.27.

Ethics in research and evaluation

Ethics in research and evaluation is about enabling and ensuring good practice.

Building on the values and principles that have been discussed in previous sections, this section addresses some specific considerations.

Three considerations are key:

1. Assessing risks and benefits
2. Obtaining consent
3. Maintaining and ensuring privacy and confidentiality.

These are core issues that ought to be considered in all research and evaluation. Each of these is explored separately in this guide. Some practical strategies have been provided.

Identifying risks and benefits

The meanings of 'risk' and 'benefit' vary greatly and the meanings given to them depend on who you ask to define them. However we choose to define these terms, risk and benefit impact on the balance of power between researchers and participants and have implications for the viability of the research project itself.

Understanding and identifying the risks of research or evaluation may involve assessing:

- potential risks
- the *likelihood* that risks will occur
- the severity of the risk
- how the risk can be minimised
- whether risks are justified by potential benefits
- how risks can be managed if they arise.

Minimising the risk of harm to participants is important. Potential harms may include physical harm, anxiety, pain and/or psychological disturbance. Participation in research may leave participants feeling devalued or that their social disadvantage is heightened. These potential harms need to be identified so that they can be avoided.

Risk in research or evaluation generally falls into one of the following categories:

- low risk – where the only likely risk to a participant may be discomfort; this may involve discomfort of body and/or mind, such as anxiety induced by an interview
- negligible risk – where there is no likely risk of harm or discomfort and it is no more than an inconvenience; for example, the time required to complete a survey
- harm - if a person's experience exceeds discomfort and they become distressed, this is considered a harm.

When applying for ethics approval from a HREC, it is important to note that research or evaluation will not be prevented because risks have been identified. Thinking about ethics is about developing a methodology that minimises risk and responds to risks as they arise.

Challenges in defining, identifying and managing risk

The mental health and alcohol and other drugs sectors are diverse and changing, therefore assessing risk means listening to and taking into consideration the experiences and values of a range of different people, environments and contexts.

The right to participate in research is recognised and acknowledged in *The National Statement*.[10] Consumer participants are expert knowledge holders. However, people with mental health and alcohol and other drugs issues may also have 'distinctive vulnerabilities' in that they could be more susceptible to various kinds of discomfort and stress, even though they are capable of providing informed consent.

The nature of mental health and alcohol and other drugs issues, the impact of any medication or treatment, the emotional investment in research itself, or fluctuations in conditions, are all matters for consideration that are used to flag risk when undertaking research or evaluation with participants experiencing mental health and/or alcohol and other dugs issues.

The National Statement has identified that people involved in illegal activities, such as taking drugs, may be vulnerable to distinct risks.[11] The participant, but also the researcher or evaluator, must remain mindful of their legal obligations, especially if there is a potential for information relating to the illegal activity being obtained by relevant authorities and linked to specific people. There may also be risks for any dependents of the participant if personal information disclosed in relation to research participation leads to criminal conviction.[12] These considerations are extremely important.

However, it is worth highlighting that many consumers and carers do not see themselves as having 'distinctive vulnerabilities.' Many consumers and carers have a strong desire to be listened to, precisely because they bring particular insights and expertise to research.

All research participants want to feel that their lived experience is acknowledged and validated. Lived experience qualifies consumer and carer researchers as key contributors to research design, co-research and/or independent research. Consumers and carers need not be passive research participants. With good planning, they can be equal partners and leaders in in research.

Being aware of potential risks, minimising risks, and empowering participants are crucial to all research and evaluation.

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[10] NHMRC (2014). 'People with a cognitive impairment, an intellectual disability or a mental illness, ' in *National Statement on Ethical Conduct in Human Research* 2007 (Updated March 2014). NHRMC, the Australian Research Council and the Australian Vice-Chancellors' Committee. Commonwealth of Australia, Canberra.
[11] NHRMC (2007). *Ethical Issues in Research into Alcohol and Other Drugs: an Issues Paper Exploring the Need for Guidance Framework*. NHRMC, the Australian Research Council and the Australian Vice-Chancellors' Committee. Commonwealth of Australia, Canberra.
[12] NHRMC (2007). *Ethical Issues…*

Practical strategies for managing risk

Anticipating and managing risk can be achieved by:

- facilitating participation
  - involve consumers and carers in every stage of the planning and development of research and evaluation, including survey development, methodology and planning (e.g. determining the location and timing of interviews or surveys) - see *Ask the Experts, A CMHDARN Best Practice Guide for Enabling Consumer and Carer Leadership in Research and Evaluation* *http://www.cmhdaresearchnetwork.com.au/data/files/d0/10/00/00/BPG-CCPIR-FINAL-20151201.pdf*
  - real participation means sharing decision-making power
- planning
  - seek assistance and guidance from research bodies such as universities to develop appropriate methodologies
  - collect and store data appropriately (see Privacy and confidentiality)
- informed consent
  - give people the choice to participate or not, to determine the extent of their participation, highlight and identify risks and any other information that may influence the decision to participate (see Obtaining consent)
  - protect the rights of consumers
- providing support
  - support participants as valued experts and uphold duty of care
  - develop protocols or procedures to manage risk. For example, if a participant becomes distressed during an interview, make sure there is a procedure for providing support or referral
  - consider duty of care in relation to research or evaluation conducted online.[13]

DAMEC has outlined some useful approaches for responding to participants when they are distressed. While it is not the role of the researcher or interviewer to act in a counselling or support role, the following strategies may prove helpful: [14]

a) ask the participant if there is anything the researcher can do to help

b) ask the participant if there is anyone they would like to contact to seek help

c) explain that the interview or focus group can stop if the participant wishes it to

d) inform the participant that they can choose to have the information they have provided erased

e) reiterate the role of the researcher

f) offer to put the participant in contact with a clinician or welfare worker

g) provide helpline numbers

h) contact emergency services.

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[13] NHRMC (2007). *Ethical Issues...*
[14] Drug and Alcohol Multicultural Education Centre (2011; 2014) *DAMEC Research and Evaluation Framework*. Sydney: Drug and Alcohol Multicultural Education Centre.

Useful tool:
Example Distress Protocol – University of Technology
http://www.cmhdaresearchnetwork.com.au/data/files/41/10/00/00/Example%20distress%20protocol.doc

Obtaining consent

Ethics in research and evaluation involves obtaining informed consent from all participants from the outset and *throughout* a project.

Informed consent means:

- participants are provided with clear and timely information about the project, the scope of their involvement, and agree to participate voluntarily and without coercion
- participants have been provided with an understanding of the potential risks and benefits (if any) of participating
- participants understand that it is **their right to withdraw at any stage** of the research
- participants provide written, or where necessary verbal, consent to participate.

TIP:

Attach a business card with the research details and contact details to the participant information sheet. This way it is more likely that the contact details will be retained and the participant can follow up with you if necessary.

Consent should always be obtained at the very beginning of a project. It may also be renegotiated throughout the course of the project, particularly if the research changes direction.

It is good practice to provide a Participant Information Sheet that clearly outlines what the research will involve, as well as the rights described here. The information that can be included on an information sheet is listed below.

What information do we need to provide to participants in research and evaluation?

- a plain language explanation of the purpose of the research or evaluation - avoiding the use of complex 'scientific' words and jargon
- an outline of the research or evaluation that includes:
  - aims and objectives
  - methods and procedures; for example, interviews, surveys or focus groups
  - any risks, including potential harms, inconveniences and/or discomforts – will the research deal with sensitive or challenging issues that can cause discomfort?
  - practical requirements or demands on participants; for example, time and travel requirements
- a statement explaining what support and information will be provided to participants if they have any questions, concerns or they experience distress before, during and/or after the research or evaluation, and how and when they can access support
- contact details for:
  - a person to receive complaints
  - the researcher or evaluator
- a truthful assurance regarding how privacy and confidentiality will be protected, including details about:
  - how information will be collected
  - how information will be stored
  - how and for what purposes information will be used
  - what happens to the information once the research or evaluation finishes
- an explanation about the participant's right to withdraw at any stage, along with any implications of withdrawal, and whether it will be possible to withdraw data
- full disclosure in relation to the funding body of the research or evaluation and any other relevant information, including potential conflict/s of interests in relation to researchers, sponsors or institutions
- reimbursements/payments for participation (if any)
- an explanation about how the information will be shared and disseminated, including publication
- any expected benefits; for example, to individuals, the wider community or improvements to services. It is important not to overstate any potential benefits.

Challenges in obtaining consent

Obtaining informed consent is not always as simple as providing written information and asking participants to sign a form. Informed consent is about establishing a mutual understanding between researchers and participants.[15]

It may be important to consider:

- **literacy** – providing information verbally and then recording verbal consent if a potential participant is illiterate or has limited literacy
- **language** – providing interpreters and/or translation services for people from CALD communities who may have limited written and spoken English
- **rescheduling** - if a person is feeling unwell, experiencing withdrawal, or is under the influence of alcohol or other drugs, it may be necessary to reschedule to meet with the person at another time and obtain their consent then.

Practical strategies for obtaining consent

Balancing **the right to participate** in research or evaluation with the broader rights and interests of consumers and carers can be achieved by:

- providing clear information
  - provide information in a range of ways; for example, verbally, in writing, via information sessions, etc.
  - provide opportunities for participants to ask questions and seek clarification, including the opportunity to discuss, or be supported in their decision-making[16]
  - be honest and realistic about the benefits and outcomes of the research or evaluation
  - ensure that consent is renegotiated and discussed throughout the project; this is particularly important when a consumer is unwell or experiencing difficult circumstances, or when there are changes to the project
  - be clear about how the outcomes and results will be shared at the end of the project and involve participants in the dissemination of results
  - ask to contact participants once the project is completed and determine how they would prefer to receive research outcomes; for example, project report, short information sheet, one-to-one briefing, an information session, etc.
- planning
  - involve consumers and carers in research planning and development (see *Ask The Experts, a CMHDARN Best Practice Guide for Enabling Consumer and Carer Leadership in Research and Evaluation*)
  - have clear complaints procedures and provide the contact details of a person who is independent of the research or evaluation – a support worker, service manager, etc.

The Australian Injecting & Illicit Drug Users League (AIVL) suggests taking a more flexible approach to gaining informed consent:[17]

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[15] NHMRC (2014). *National Statement on Ethical Conduct in Human Research 2007 (Updated March 2014)*. The Australian Research Council and the Australian Vice-Chancellors' Committee. Commonwealth of Australia, Canberra.

[16] Australian Injecting & Illicit Drug Users League (AIVL), (2002). National Statement on Ethical Issues for Research Involving Injecting/illicit Drug Users. Canberra, ACT.

[17] Australian Injecting & Illicit Drug Users League (AIVL), (2002).

A flexible approach to obtaining consent in research with people who use drugs MEANS

- actively involving research participants and peer-based drug user organisations in all stages of the research process to significantly aid understanding of the aims, processes and outcomes of the research
- supporting peer-based drug user organisations to develop and disseminate information about the research that is accessible, credible and trusted by participants. This information must be disseminated with sufficient lead time to allow potential participants to absorb the information and ask questions. The use of peer networks would also support the distribution and credibility of the information.
- supporting peer-based drug user organisations to run information sessions for potential participants in an environment that is comfortable and safe for drug users.
- developing other forms of recording consent that may feel safer than written consent for participants, including recording verbal consent.
- developing the communication skills of researchers to support better two-way dialogue between researcher and participant.
- engaging more peer researchers in all stages of the research process and asking them to play a role in obtaining consent. This may involve peer researchers working in small groups to support better exchange of information and facilitating discussion.
- involving potential participants in qualitative peer-based processes over a period of time will help support participants who are highly intoxicated, as their participation will be regarded as a 'natural' aspect of peer interaction rather than an expression of 'dangerous' or 'out of control' behaviour.

Other useful tools:
Template Participant Information and Consent Form – NHMRC, Human Research Ethics Portal
Example Participation Information Sheet – Mental Health Coordinating Council (MHCC) and Sydney University
http://www.cmhdaresearchnetwork.com.au/data/files/61/10/00/00/Template%20-%20participant%20information%20and%20consent%20form.doc

Example Participation Flyer – MHCC and Sydney University
http://www.cmhdaresearchnetwork.com.au/data/files/51/10/00/00/Example%20Participant%20Information%20Sheet%20-%20MHCC.pdf

Respecting privacy and ensuring confidentiality

Respecting and maintaining privacy and ensuring confidentiality in research and evaluation is a significant and complex issue.

Participants should be able to freely participate in research without fear of their identity or responses being identifiable. This is especially important in relation to instances where:

- illegal activity is disclosed; for example, drug use
- negative comments may be made about a particular service or staff member that can have negative repercussions for the participant.

Some participants may be reluctant to be involved in research due to the stigma and discrimination they have experienced in the past. This needs to be respected. Participants will also want to know that they will not face additional stigma or discrimination because of their participation in research.

Ideally, researchers and evaluators should be independent of participants. Where this is not possible, a guarantee needs to be made and protocols developed and communicated, making it clear that participants will not be identified in relation to:

- recruitment
- the information collected
- information storage
- information dissemination, such as a published report or journal article.

Challenges around privacy and confidentiality

While researchers should ideally be independent of the participant and the setting in which the research or evaluation is taking place, this is not always possible.

For example, if a community organisation is conducting an internal evaluation of a particular program for the purpose of improvement and quality assurance, it is more than likely that this will be undertaken by a staff member who is an employee of the organisation. In this case, every effort needs to be made to ensure that participants will not be identified by their responses.

Other contexts where there are challenges around maintaining privacy and confidentiality might include:

- residential services – residents may be coerced to participate in research. It is important for participants to be able to speak freely, refuse to participate or determine the extent to which they are willing to participate
- where participants would prefer support or assistance from someone they know and trust, for example, a support worker, to complete a survey or to participate in an interview
- where online methods for recruitment and data collection are used – this is increasingly an area of research that is raising ethical concerns in relation to confidentiality.[18]

[18] NHRMC(2007). *Ethical Issues in Research into Alcohol and Other Drugs: an Issues Paper Exploring the Need for Guidance Framework*. NHRMC, the Australian Research Council and the Australian Vice-Chancellors' Committee. Commonwealth of Australia, Canberra.

Practical strategies for maintaining privacy and confidentiality

Privacy and confidentiality can best be ensured by collecting only the information that is absolutely necessary and directly relevant to the research or evaluation. Researchers should not request unnecessary information such as the names and addresses of participants, or collect information for the sake of interest, for example, drug use, sexual history, etc.

Sector examples: managing privacy and confidentiality

Example 1 – Research into problematic substance use by consumers accessing mental health services

Research conducted by Rose *et al.*[19] into problematic substance use among consumers accessing mental health services, provides a good example of methodology for maintaining the privacy and confidentiality of participants. The methodology includes:

- supporting staff individually in approaching and inviting consumers of the service to complete a survey, emphasising that the survey is anonymous and participation voluntary
- not collecting identifying information beyond age and gender
- asking participants to return the completed survey directly to the researchers in a reply paid sealed envelope.

Example 2 – Project evaluation with small sample sizes

A community organisation undertook an evaluation of a youth homelessness project and was looking to report on the experiences of some of the young people involved. Due to the small number of young people involved in the project, the service needed to be mindful that names and other identifying details were sufficiently changed so that individuals could not be identified.

Example 3 – Staff wellness survey

During the development of a survey by a community organisation to measure staff wellness, careful consideration of what information to collect ensured that staff could not be identified by their responses. For example, for some teams where there was only one male or female staff member, staff could be easily identified. In this instance, questions about gender and team name were not asked.

Additional strategies intended to maintain the privacy and confidentiality of participants have also been outlined by DAMEC in relation to data storage and handling procedures.[20]

[19] Rose, G., Beale, I., Malone, J., Higgin, J., Whiticker, M., & Brener, L. (2012). Problematic Substance Use in Two Mental Health NGOs, and Staff, Client and General Public Attitudes Towards Problematic Substance Use Amongst People with Mental Illness, *Mental Health and Substance Use*, 5:4, 275-286. http://dx.doi.org/10.1080/17523281.2012.702518

[20] Drug and Alcohol Multicultural Education Centre (2011; 2014) *DAMEC Research and Evaluation Framework*. Sydney: Drug and Alcohol Multicultural Education Centre. http://www.damec.org.au/images/DAMEC_Research_Framework_2014_v7.pdf, (accessed 9 April 2015).

DAMEC Data Storage & Handling Procedures

The following measures are taken to ensure the security of information from misuse, loss, or unauthorised access during the research project:

a) hand written interview notes and the digital recorder are to be physically stored in a locked filing cabinet at DAMEC.

b) computer files, such as interview transcriptions or SPSS (Statistical Package for the Social Sciences) data files will be stored on an external hard-drive that is to be stored in a locked filing cabinet when not in use.

c) personal details of respondents are to be saved locally on a password protected electronic file for the sole purpose of making contact with respondents to provide them with a copy of the results, this file will be deleted once the research has been disseminated.

d) data collected and stored on Cloud and other online systems, that is, surveys or digital forms, will be password protected.

e) the only people who should handle information involved in the research process are project researchers, interview transcribers (if applicable), interpreters (if applicable) and members of Ethics Committees whose role it is to monitor the conduct of l research.

f) where a third party has been contracted to hold data involved in a project, for example an online survey, the terms of DAMEC's contract with them will require that information privacy be maintained.

Considering practicalities

Practical and logistical considerations form an integral part of research ethics.

Research merit and integrity, the first value outlined in *The National Statement*, is specifically concerned with the appropriateness of the research or evaluation methodology. It considers issues such as whether there are adequate resources available and whether the research or evaluation is being carried out by competent and suitably qualified people.

Some of the key practical factors that need to be considered include **time, resources** and **funding**, all of which are interrelated. These relate to;

- developing an appropriate methodology
- applying for ethics approval, if required
- recruiting qualified and competent people to undertake the research and evaluation
- paying or remunerating people to participate in research or evaluation
- responsibly and conscientiously undertaking the research or evaluation
- disseminating results and feedback via publication and other means.

It can be challenging for community organisations to allocate enough time, resources and funding to research and evaluation, but there are various ways to build capacity to undertake research and evaluation ethically. These include:

- **reaching out to established research** centres – some research centre, such as those within universities, may be able to assist community organisations with:
  - developing appropriate and workable methodologies
  - providing support and mentoring in research skills
  - accessing funding opportunities
  - developing partnerships
  - writing and applying for ethics approval, if required.

TIP:

Contact **CMHDARN**, **NADA** or **MHCC** for assistance or support to get in touch with a research centre.

- **accessing free training** – there are a number of training courses and resources to assist in improving and developing a better understanding of ethics in research. These include:
  - Macquarie University's *Online Ethics Training Module* – a free educational resource that examines the ethical issues raised in social science and humanities research
  - fhi360's *Research Ethics Training Curriculum for Community Representatives* – this free online course, designed by Family Health International (fhi360), is specifically for community representatives who may be involved in the development of a research methodology within their community
  - *fhi360's Research Ethics Training Curriculum* – a training curriculum designed to be delivered to researchers conducting research with people.

Payment and remuneration

Providing reimbursement or remuneration to participants in research or evaluation needs to be built into planning and methodology.

The National Statement provides the following guidance in relation to payment:

> *"It is generally appropriate to reimburse the costs to participants of taking part in research, including costs such as travel, accommodation and parking. Sometimes participants may also be paid for time involved. However, payment that is disproportionate to the time involved, or any other inducement that is likely to encourage participants to take risks, is ethically unacceptable".*[21]

Inciting participants to potential risk-taking behaviours should be avoided. However, payment, or at the very least reimbursement of costs incurred in participating in research or evaluation, is extremely important. It confers a simple acknowledgement that each participant's time and effort is valued, respected and appreciated.

Issues are often raised in relation to remunerating people with alcohol and other drugs issues. The NHMRC publication, *Ethical Issues in Research into Alcohol and Other Drugs: an Issues Paper Exploring the Need for a Guidance Framework,* raises the following concerns:

- people experiencing withdrawal or people who are under the influence of alcohol or drugs may be overly influenced by offers of payment
- remuneration may be used to purchase drugs or alcohol.[22]

The latter concern is not shared by many people with alcohol or other drugs issues or researchers in the sector. Many people wish to participate in research or evaluation in order to contribute to a greater good. Not being paid can be perceived as judgemental and denies the right to autonomy, dignity and self-determination.

Research has found that the vast majority of people with alcohol or other drugs issues who were paid to participate in research spent their money on essential items such as such bills and household items. The amount or mode (cash or voucher) of payment did not have an impact on alcohol or drug use, nor was payment seen as having been coercive.[23] Brogan (2010) suggests that paying participants for research and evaluation:[24]

- should reflect real value
- should be in cash, wherever possible
- signifies respect for participants as autonomous individuals
- can lead to better participation, representativeness and quality findings.

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[21] NHRMC (2014). *National Statement on Ethical Conduct in Human Research 2007 (Updated March 2014)*. NHRMC, the Australian Research Council and the Australian Vice-Chancellors' Committee. Commonwealth of Australia, Canberra, p. 17.

[22] NHRMC (2007). *Ethical Issues in Research into Alcohol and Other Drugs: an Issues Paper Exploring the Need for Guidance Framework*. NHRMC, the Australian Research Council and the Australian Vice-Chancellors' Committee. Commonwealth of Australia, Canberra.

[23] Festinger D.S., Marlowe, D.B., Dugosh, K.L., Croft, J.R. and Arabia, P.L. (2008). Higher Magnitude Cash Payments Improve Research Follow-up Rates Without Increasing Drug Use or Perceived Coercion. *Drug and Alcohol Dependence,* 96:128-135.

[24] Brogan, D. (2010). Incentive Payments (reimbursements) for People Who Use Drugs Participating in Research. AIVL Research & Policy Update: Issue 6 (Sept-Oct 2010). http://www.aivl.org.au/wp-content/uploads/AIVL-Research-Policy-Update-Issue-6.pdf, (accessed 29 April 2015).

Applying for ethics approval

Overview

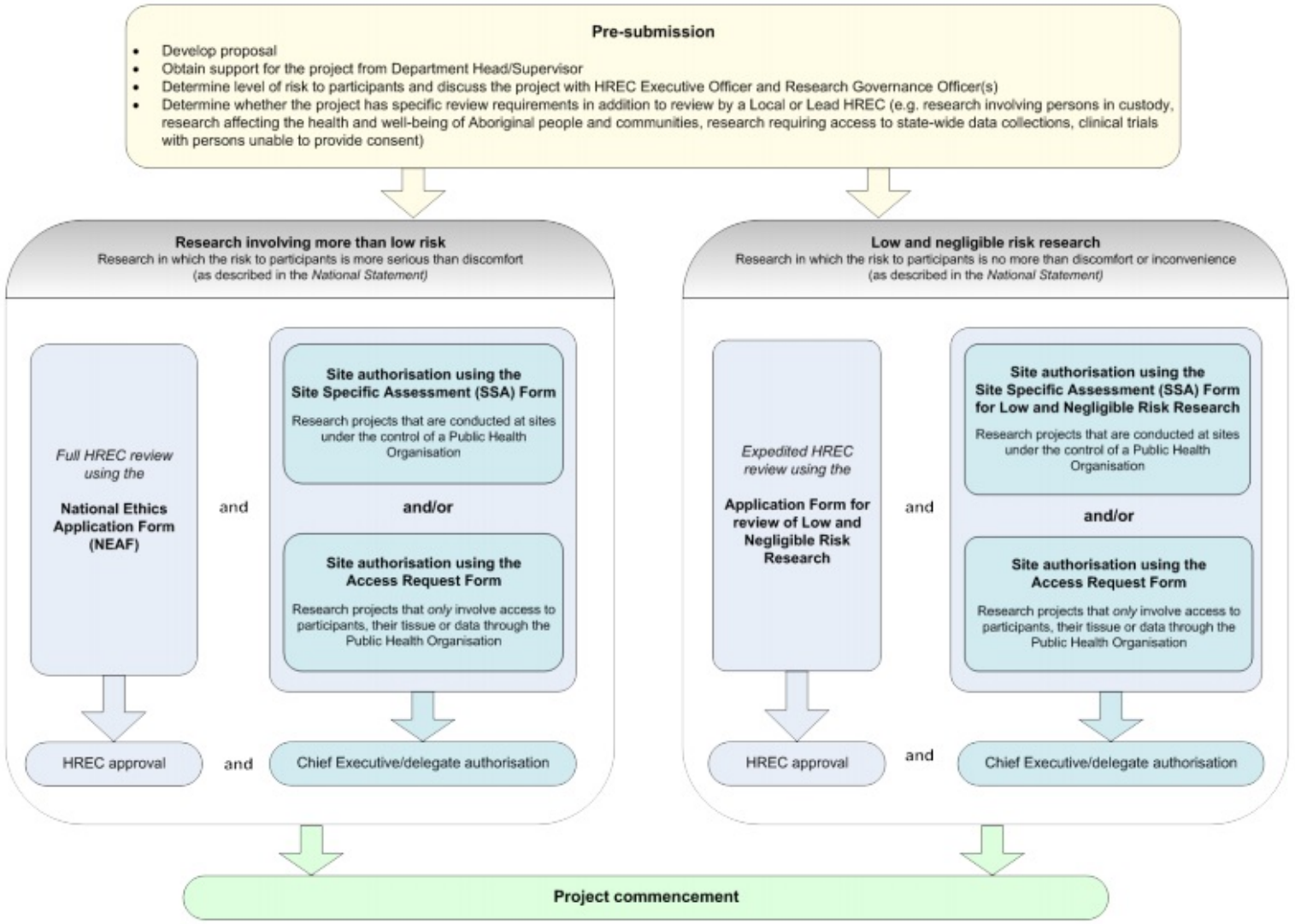
The purpose of this section is to help community organisations and individuals understand how to navigate and build ethics approval into research or evaluation plans.

Ethics review and approval help ensure that research or evaluation will be conducted to the highest standards of quality. Ethics approval is also about ensuring that the rights, safety and dignity of participants, and researchers, have been considered and that the methodology is solid and appropriate.

Ethics review does not imply that most individuals, community organisations or research bodies conducting research or evaluation are not acting ethically. The ethics approval process simply offers an outside perspective and a check-and-balance to make sure that all the possibilities have been considered.

The following is a flow chart from the New South Wales (NSW) Ministry of Health that provides a useful overview of how the ethics approval process occurs in New South Wales Public Health Organisations (PHOs), such as in Local Health Districts (LHDs). It relates primarily to medical research undertaken within clinical settings, but still provides a useful and relevant overview for the mental health and alcohol and other drugs sectors in NSW.

Ethics Approval Flow chart for Research in NSW Public Health Organisations



Government Health (2011). Summary of routes to obtaining Human Research Ethics Committee (HREC) approval and site authorisation, *Research Governance in NSW in Public Health Organisations*. Doc no GL2011_001. http://www0.health.nsw.gov.au/policies/gl/2011/pdf/GL2011_001.pdf, (accessed April 2015).

Other useful resources:
Dwyer. S. (2014). Ethics Schmethics – How to Apply and Keep Your Sanity.

Scott, D (2013). *Demystifying Ethical Review*. Australian Institute of Family Studies, February 2013.

Do we need ethics approval?

While ethics approval by a HREC is important and helps ensure best practice in research and evaluation, it is not always necessary or required.

The following table provides some specific examples to guide your decision about when ethics approval is required.[25]

Ethics approval IS needed if:	Ethics approval may NOT be needed if:
▪ there is an intention to publish the results in a research journal ▪ potential harms and risks to anybody involved go beyond what is deemed 'low' or 'negligible' ▪ information to be collected goes beyond that which is routinely collected ▪ privacy and confidentiality of those involved may be compromised ▪ there will be 'secondary use' of the data, that is, the data collected will be used for purposes other than what was originally intended ▪ the data will be used for a purpose beyond program improvement ▪ the methodology includes a comparison of groups, randomisation, use of control groups or placebos ▪ minority or vulnerable groups (as deemed by *The National Statement*) will be involved and the intended use of the data will go beyond program improvement.	▪ there is no intention to publish the results in a research journal ▪ information collected is already routinely collected using well established operating procedures and/or existing protocols (such as those applied to evaluation processes) ▪ the purpose of collecting the information is to maintain and improve standards, including quality improvement and assurance activities, where work is already being undertaken, or programs are already being delivered ▪ information collected cannot be linked to any individuals – for example names, demographic information, responses provided, services that they access, etc.

[25]Australian Council for International Development (2015). *Guidelines for ethical research and evaluation in development*. Australian Council for International Development: Deakin, ACT.

The following table provides useful guidance in relation to understanding different types of investigations and methodologies and when it may be necessary to go through ethics review.

Differentiating clinical audit, service evaluation, research and usual practice/surveillance work in public health

RESEARCH	SERVICE EVALUATION*	CLINICAL AUDIT	SURVEILLANCE	USUAL PRACTICE (in public health)
The attempt to derive generalizable new knowledge including studies that aim to generate hypotheses as well as studies that aim to test them.	Designed and conducted solely to define or judge current care.	Designed and conducted to produce information to inform delivery of best care.	Designed to manage outbreak and help the public by identifying and understanding risks associated.	Designed to investigate outbreak or incident to help in disease control and prevention.
Quantitative research – designed to test a hypothesis. Qualitative research – identifies/explores themes following established methodology.	Designed to answer: "What standard does this service achieve?"	Designed to answer: "Does this service reach a predetermined standard?"	Designed to answer: "What is the cause of this outbreak?"	Designed to answer: "What is the cause of this outbreak?" and treat.
Addresses clearly defined questions, aims and objectives.	Measures current service without reference to a standard.	Measures against a standard.	Systematic, statistical methods to allow timely public health action.	Systematic, statistical methods may be used.
Quantitative research – may involve evaluating or comparing interventions, particularly new ones. Qualitative research – usually involves studying how interventions and relationships are experienced.	Involves an intervention in use only. The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference.	Involves an intervention in use only. The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference.	May involve collecting personal data and samples with the intent to manage the incident.	Any choice of treatment is based on clinical best evidence or professional consensus.
Usually involves collecting data that are additional to those for routine care but may include data collected routinely. May involve treatments, samples or investigations additional to routine care.	Usually involves analysis of existing data but may include administration of interview or questionnaire.	Usually involves analysis of existing data but may include administration of simple interview or questionnaire.	May involve analysis of existing data or administration of interview or questionnaire to those exposed.	May involve administration of interview or questionnaire to those exposed.
Quantitative research – study design may involve allocating patients to intervention groups. Qualitative research – uses a clearly defined sampling framework underpinned by conceptual or theoretical justifications.	No allocation to intervention: the health professional and patient have chosen intervention before service evaluation.	No allocation to intervention: the health professional and patient have chosen intervention before audit.	Does not involve an intervention.	May involve allocation to control group to assess risk and identify source of incident but treatment unaffected.
May involve randomisation.	No randomisation.	No randomisation.	No randomisation.	May involve randomisation but not for treatment.
Normally requires REC review. Refer to www.nres.nhs.uk/applications/approval-requirements for more information.	Does not require REC review.	Does not require REC review.	Does not require REC review.	Does not require REC review.

* Service development and quality improvement may fall into this category.

Health Research Authority (2013). *Defining Research: NRES Guidance to Help you Decide if Your Project Requires Review by a Research Ethics Committee*. Health Research Authority, NHS, London: UK.

Other useful tools:
Ethics Review Checklist – Marie Stopes International
Assists with assessing which research, monitoring and evaluation activities do not need to be reviewed by an ethics committee.

Human Research Ethics Committees (HRECs)

HRECs are committees established to ensure that research is conducted ethically. A HREC is composed of a group of people to whom ethics approval applications are sent.

There are more than 200 HRECs in Australia registered with the NHMRC, and their purpose is to ensure that all research conducted in Australia is in line with the principles and values of *The National Statement* and *The Code*.

Section 5.1.29 of *The National Statement* outlines the following composition of HRECs:

Composition of HRECs

Minimum membership of eight:

a. equal numbers of men and women
b. at least one-third of the members should be from outside the institution for which the HREC is reviewing research.

Membership should include:

a. a chairperson
b. at least two lay people, one man and one woman, with no affiliation with the institution and do not currently engage in medical, scientific, legal or academic work
c. at least one person with knowledge of, and current experience in, the professional care, counselling or treatment of people; for example, a nurse or allied health professional
d. at least one person who performs a pastoral care role in a community, for example, an Aboriginal elder, a minister of religion
e. at least one lawyer, where possible, one who is not engaged to advise the institution
f. at least two people with current research experience that is relevant to research proposals to be considered at the meetings they attend.

See section Establish a HREC for information on how community organisations can establish their own HREC.

How to find a HREC

Once you have developed your research or evaluation proposal and have identified that you may need ethics approval to proceed, you need to find and approach a relevant HREC.

TIP:

If you are having trouble finding and making contact with a HREC you can contact **CMHDARN**, **NADA** or **MHCC** for assistance.

For community organisations or individuals who are partnering with a research institute or group, there may already be an affiliated HREC, so the process is straightforward.

If you do not have access to an affiliated HREC, a full listing of all HRECs currently registered with the NHMRC can be found here.

What do we need to provide to HRECs?

Once you have made contact with the relevant HREC, find out about *all* the documentation that you will need to provide in relation to your application.

Applying for ethics approval does not necessarily have to be a time-consuming task – if you have already spent the time developing a robust methodology you are already more than halfway there (see Planning a research or evaluation project.)

The following is a list of forms you may be required to complete, depending on the level of risk identified in your proposal.

National Ethics Application (NEAF) Form: applications for ethical and scientific review in which the risk to participants is going to be more serious than the risk of discomfort.

Low and Negligible Risk (LNR) Application Form: application form for ethical and scientific review of LNR research.

Site Specific Assessment (SSA) Form: for research in which the risk to participants is more serious than discomfort.

LNR SSA Form: SSA form for ethical and scientific review of LNR research.

Access Request Form: for research projects which only require access to participants, their tissue or data through a NSW PHO and does not involve conducting research at any facilities, locations or services under the control of that PHO.

All of these forms can be completed and submitted via the Australian Online Forms website. The website also provides guidance and information about which forms you need to complete. However, it is best to obtain clarification from the HREC from which you are seeking approval.

The following is a *checklist from the Aboriginal Health & Medical Research Council* (AH&MRC) guidelines.[26] It gives examples of the kind of documentation you might be required to provide.

TIP:

- allow plenty of time for the approval process – it can take a few weeks or more
- get familiar with the process to save time
- reach out to research centres or institutes for assistance
- ask the HREC to attend a review meeting to make your case.

[26] Aboriginal Health & Medical Research Council (2011). *Guidelines for Submitting an Ethics Application to the AH&MRC Human Research Ethics Committee.* Aboriginal Health & Medical Research Council: Surry Hills, NSW, http://www.ahmrc.org.au/index.php?option=com_docman&task=doc_download&gid=14&Itemid=45, (accessed 17 April, 2015).

AH&MRC Ethics Application Checklist

Have you consulted with relevant Aboriginal Community Controlled Health Services (ACCHSs) or appropriate Aboriginal organisations?
Have you included all of the following with your application?

Application Forms
1. Application Cover Sheet
2. A brief statement addressing the AH&MRC's five criteria
3. A completed ethics application form - this can be a copy of an application to another HREC
4. A copy, or summary of the research study protocol
5. Checklist – have all necessary signatures been obtained?
6. A copy of any requests from other HRECs for further information about your application, together with your response to the request.
7. A copy of Approval letters from other HRECs
8. Participant Information Statement(s)
9. 'Aboriginal Health and Medical Research Council Ethics Committee' included on the Participant Information Statement as a body to which participants can raise concerns or complaints
10. Pro forma Consent Form(s) for Individual Participants
11. Signed Organisational Consent Form or Letter of Support from all relevant ACCHSs or appropriate Aboriginal community bodies

Attachments
12. All attachments numbered or lettered
13. A summary list of attachments provided
Form and Number of Copies
14. Four (4) hard copies of the application have been provided as follows:
- Three (3) hard copies, stapled and presented in final form
- One unstapled copy, in the same order as the stapled copies
15. An electronic copy has been sent to ethics@ahmrc.org.au

Other useful resources:
NHMRC research examples – Challenging Ethical Issues in Contemporary Research on Human Beings – NHMRC case studies

Dwyer. S. (2014). Ethics Schmethics – How to Apply and Keep your Sanity.

Scott, D (2013). *Demystifying Ethical Review*. Australian Institute of Family Studies, February 2013.

Site Specific Assessments (SSAs)

A Site Specific Assessment (SSA) is required for all research that is conducted in any NSW PHO. A SSA is more about logistical and practical issues than ethical issues. A SSA focuses on whether an organisation has the capacity to conduct the research at a site and takes resources, staff, insurance and indemnity requirements, etc., into consideration.

A SSA is required if a project involves one or more of the following activities at a site under the control of a NSW PHO[27], such as a LHD:[28]

- enrolling participants into research (e.g. obtaining informed consent, screening)
- carrying out protocol-specific research procedures with, or on, participants
- managing and analysing data, tissue and responses from surveys and questionnaires collected for, or from, research.

Importantly, SSAs **are not required** for research or evaluation conducted with community organisations across different LHDs; they are only required if the project includes a NSW PHO.

Key points about completing SSAs:

- HREC and SSA approval must be obtained before research can start – both processes can occur simultaneously, you do not have to wait for one to be completed before the other
- for projects taking place at a number of different PHO sites
  - a SSA is required for **every site**; there is no way around this requirement
  - **time** needs to be factored into research plans to obtain approval
  - SSA approval can take a number of months, depending on how many sites are to be included
  - in one research example, it took 12 months to obtain SSA approval to conduct research with health staff from three LHDs
- applications for SSAs must be submitted using one of the following forms:
  - SSA Form - if a full HREC review is required; or
  - SSA Form for LNR research (LNR SSA Form) - for research projects that have been determined to be LNR by a HREC
- SSAs need to be submitted to the Research Governance Officers of each site.

TIP:

Conducting research across a number of LHDs is an optimal approach for a methodology; however it is important to consider the time required to obtain appropriate approvals.

Instead, it might be useful to consider the following alternative approaches:

- for projects with a 12 month timeframe include only 1-2 LHDs
- for projects with more than 12 months, 2 or more LHDs could be included or just one metropolitan and one regional LHD
- focus on health staff from other community organisations – this approach does not require SSA approval.

[27] A Public Health Organisation, as defined in the NSW Ministry of Health Policy Directive, Research - Authorisation to Commence Human Research in NSW Public Health Organisations is: "…an Area Health Service, statutory health corporation or affiliated health organisation in respect of their recognised services". http://www.health.nsw.gov.au/ethics/Documents/PD2010-056.pdf, (accessed 1 June 2015).

[28] NSW Ministry of Health. *FAQ: Site Specific Assessment*, NSW Ministry of Health website. http://www.health.nsw.gov.au/ethics/Pages/faq-ssa.aspx, (accessed 17 April 2015).

SSA forms can be completed at the Australian Online Forms website.

For more information and further details, go to the Site Specific Assessment page on the NSW Ministry of Health website.

The site includes detailed information and a useful Frequently Asked Questions page.

Conclusion - Putting your evidence in to practice

Bringing about organisational and practice changes based on findings from research or evaluation is the most important issue that community organisations, researchers and evaluators need to consider once a research or evaluation project has been completed. In fact, the implications of what happens after research or evaluation is completed, should form part of the initial planning process. The best evaluation means a commitment to an ongoing cycle of continual learning, translation and improvement.

The pursuit of knowledge, and the desire to gain a deeper understanding of particular issues, drives research and evaluation. However, these considerations alone are insufficient justifications for research.

Research and evaluation should be underpinned by the values and principles of merit, integrity justice and beneficence, and these should continue to be applied once research or evaluation is concluded. Let your investment in research and evaluation make a real difference.

Ethics in research and evaluation is about developing sound methodologies that uphold the rights and protect the safety and wellbeing of everybody involved. It is also about providing meaningful opportunities for participants to contribute, collaborate and have their voices heard.

Putting the information and evidence collected into practice is integral to good practice. It demonstrates:

- respect for all involved
- that the research or evaluation was conducted with care and integrity
- a genuine commitment to building the evidence base in the mental health and alcohol and other drugs sectors
- a genuine intention to improve the quality and effectiveness of practices and services
- a genuine commitment to improving outcomes and opportunities for people with mental health and alcohol and other drugs issues.

Thinking through the implications of what is going to happen after research and evaluation is completed is really important. We need to ensure that a participant's time and contribution are highly valued and their time not wasted. Shelved or incomplete research and/or evaluation represents a missed opportunity for developing the capacity of the mental health and alcohol and other drugs sectors to effectively respond to the needs of consumers and carers. Completed research and evaluation that isn't translated into better practices amounts to a significant opportunity lost as well.

Let's recap. All research and evaluation should originate from a clear aim and purpose. Researchers and evaluators should ask:

- why are we doing this research or evaluation?
- what are we going to do with the information we collect? Are we going to use this information to change/improve practices/programs/services?
- do we have the resources to change practices? If not, how and where can we get them?
- how can we add to the evidence base?
- how can we increase sector capacity and information exchange?
- can this research make a difference to the lives of real people?

Research and evaluation is so much more than just a way of meeting formal requirements or ticking a box for quality improvement. Above all, research and evaluation in the mental health and alcohol and other drugs sectors should be conducted with the primary purpose of building the evidence base to improve the quality of service delivery and, correspondingly, improved outcomes for consumers of community-managed services.

We hope this guide gets you thinking and talking about research ethics. Let us know when you have something to add so we can keep this resource relevant.

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