



The Caring Communities Program: An Introduction to Ethics

Evaluation Bulletin, Number 2, June 2003

This document provides information about ethics and ethical requirements of the individual Caring Community projects.

'The researcher has a moral and professional obligation to be ethical, even when the research subjects are unaware of or unconcerned about ethics.' (Neuman, 1997:443)

Ethics in History

Human research has occasionally been clouded by unethical practices, which in some cases have involved serious violations of human rights. Some of the most notorious examples include the so-called medical experiments carried out by the Nazis in which people were subjected to torturous treatments so that the researchers could examine the effects on the human body. Another example is the Tuskegee Syphilis Study, where infected people were allowed to progress through to advanced syphilis and die long after treatment was available, so that scientists could observe the full course of the disease (Neuman, 1997: 445). Ethical guidelines, such as those developed by the National Health and Research Council have been developed to ensure that the welfare and rights of people involved in research are protected.

Why do we have to consider ethics?

The sorts of research outlined above are very different to the evaluations that the Caring Communities projects will undertake. Why then do we need to consider ethics? Why might it be necessary for many of the projects to submit the details of their proposed

evaluation to a human research ethics committee?

Researchers must be aware of unintended effects that may be caused by their research. For example questions about carer's experiences may generate a level of grief, loss or even anger that the researcher was not expecting. In many cases, the process of submitting a project to an ethics committee will alert researchers to these potential causes of harm to subjects and make them think about strategies to deal with them if they arise. Researchers must also be aware of the need to inform people fully about their involvement and take steps to ensure that their confidentiality and privacy are respected.

Do I have to submit the details of my project to an ethics committee?

The NHMRC guidelines include a note about projects that do not require ethics approval:

"Human Research Ethics Committee approval is not required for projects which only seek to obtain publicly available information or only seeks the professional view of an office holder on the basis of that person's professional role (i.e. asking

about the official role but not asking for personal judgement or opinion)". (NHMRC 1999)

In addition, the NHMRC provides further guidelines about quality assurance (2003) activities which state that:

An activity can proceed without ethics review if:

Both:

- the activity is undertaken with the consent of patients, carers, health care providers or institutions involved;
- or
- is consistent with National Privacy Principle 2.1(a), which states:

'An organisation must not use or disclose personal information about an individual for a purpose (the secondary purpose) other than the primary purpose of collection unless both of the following apply:

- the secondary purpose is related to the primary purpose of collection and, it the personal information is sensitive information , directly related to the primary purpose of collection;
- the individual would reasonably expect the organisation to use or disclose the information for the secondary purpose';

and

- it is an activity where participants, including patients, carers, health care providers or institutions are unlikely to suffer burden or harm (physical, mental, psychological, spiritual or social).

If, however your project involves asking people outside your professional setting about their opinions, for example carers, patients, interested community members or volunteers, then you will need to obtain ethical clearances to undertake your evaluation. We understand that it may be difficult for individual projects to make a decision about the need for ethical clearance and strongly recommend that you contact your designated evaluation team member about this.

What sorts of issues will an ethics submission ask me about?

Your ethics submission will ask you to provide a brief outline of your project, and how you are going to undertake it. For example how will you recruit subjects, what sorts of research methods are you going to use (eg face to face interviews, focus groups, analysis of de-identified data).

Informed Consent

Informed Consent must be obtained from individuals or groups before research is undertaken.

There are two important components of Informed Consent:

The provision of information - Individuals or groups must be provided with enough information about the project, including an indication of the types of questions they will be asked, the time that it will take, the purpose of the research and what will happen to the results. As Neuman 1997 states:

"Participation must be voluntary. It is not enough to get permission from subjects; they need to know what they are being asked to participate in so that they can make an informed decision." (Neuman, 1997:450).

The capacity to make a voluntary choice - Consent must be obtained without coercion and individuals or groups must be assured that they have the right to withdraw entirely from the research at any time or refuse to participate in certain aspects of the research.

Confidentiality and privacy

In the majority of cases the information provided by subjects of research is given on the basis that it will be treated confidentially by researchers. In an ethics submission researchers should outline the steps they take to protect the confidentiality and privacy of subjects, for example through anonymous questionnaires.

Safe storage of results

Primary data must be stored safely for a period of five years in a secure location (for example a locked filing cabinet) within the research institution.

Ethics and Indigenous communities

There are additional guidelines for researchers who wish to conduct research with Indigenous communities. Researchers whose projects involve Indigenous people should consult the NHMRC Guidelines on Ethical Matters in Aboriginal and Torres Strait Islander Health Research (Interim 1991).

Ethics Checklist

Your project should have received a revised ethics checklist that has been updated to clarify the ethical requirements of your project. This document can also be found as an appendix to this newsletter.

For further reading:

Jones, J. H., 1981, *Bad Blood: the Tuskegee syphilis experiment*, New York, Free Press

National Health and Medical Research Council, 1991, *Guidelines on ethical matters in Aboriginal and Torres Strait Islander research*. Available electronically at:

<http://www.health.gov.au/nhmrc/issues/as ti.pdf>

National Health and Medical Research Council, 1999, *National Statement on Ethical Conduct in Research Involving Humans*, available electronically at:

<http://www.health.gov.au/nhmrc/publications/synopses/e35syn.htm>

National Health and Medical Research Council, 2003, *When does quality assurance in health care require independent ethical review?* Available electronically at:

<http://www.health.gov.au/nhmrc/issues/pd fcover/qualassu.htm>

Neuman. W. L., 1997, *Social Research Methods, Qualitative and Quantitative Approaches* (3rd Ed), Chapter 17, 'Ethical and political issues in social research', pp 442-475, Allyn and Bacon, Boston.

Appendix 1
Project Name
Ethics Approval Notification

To enable the National Evaluation team to assess the need for ethics approval for your project, please tick one of the following boxes and fax this form to the number below.

- We have received ethics approval for our project
- We have applied for ethics approval for our project

If you have not ticked either of these boxes, please fill out the table on the next page.

As background to your considerations, we have included an excerpt from a NHMRC policy document for your information.

Checklist for determining whether Ethics Approval is necessary (NHMRC, 2003)

An activity can proceed without ethics review if:

Both:

- the activity is undertaken with the consent of patients, carers, health care providers or institutions involved;

or

- is consistent with National Privacy Principle 2.1(a), which states:
 ‘An organisation must not use or disclose personal information about an individual for a purpose (the secondary purpose) other than the primary purpose of collection unless both of the following apply:

- the secondary purpose is related to the primary purpose of collection and, it the personal information is sensitive information , directly related to the primary purpose of collection;
- the individual would reasonably expect the organisation to use or disclose the information for the secondary purpose’;

and

- it is an activity where participants, including patients, carers, health care providers or institutions are unlikely to suffer burden or harm (physical, mental, psychological, spiritual or social).

This same document poses a number of issues, included in the table overleaf and presented here as some quick questions for you to consider:

Is consent given?	If the participants do not know about <u>additional uses</u> of their personal details, <u>consider ethics.</u>
Increasing risk or burden?	If the activity is <u>different to routine</u> , <u>consider ethics.</u>
Is privacy & confidentiality ensured?	If information is being accessed, sent to or used <u>by others</u> , <u>consider ethics.</u>
Is it service provision or research?	If <u>new activities</u> or procedures are being done, <u>consider ethics.</u>
Are there broader issues?	If the activity <u>changes the personal status</u> , community standing or reputation of participants, <u>consider ethics.</u>

Issue	Questions to ask	Relevance to your Project?*
<p>Consent:</p> <p>If the participants do not know about additional uses of their personal details, consider ethics.</p>	<p>Would the participants (patients, family, carers, professionals) <i>expect the information collected to be used in the ways that you plan to use them?</i> For example:</p> <ul style="list-style-type: none"> Do participants realise case notes may be used in an evaluation report or conference paper? Feedback on a training program – Will the feedback be used in reports that could be used for other purposes, eg comparing effectiveness of different services/personnel? 	<p>Relevant? Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Comments:</p>
<p>Risks & burden</p> <p>If the activity is different to routine, consider ethics.</p>	<p>Does the project involve routine activities of the organisation, or does it involve different activities/procedures? Do these different activities expose the participants to any risks or burdens <i>beyond those that would be expected</i> as part of routine care or professional activity? For example:</p> <ul style="list-style-type: none"> Risks: psychological, spiritual, social harm eg stigmatisation Burdens: intrusiveness, discomfort, inconvenience, eg phone calls, additional hospital visits, completing long questionnaires 	<p>Relevant? Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Comments:</p>
<p>Privacy & confidentiality</p> <p>If information is being accessed, sent to or used by others, consider ethics.</p>	<p>Is personal information being used by someone who would not normally have access to it as part of their work? For example:</p> <ul style="list-style-type: none"> Is the agency or professional collecting information that will be passed on to another person/s for the purposes of evaluation or research? <p>Is sensitive health information being passed on, eg by letter, fax or email, to someone outside the agency which the patient attends – could this information be read by someone for whom it is not intended?</p>	<p>Relevant? Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Comments:</p>
<p>Service provision or research?</p> <p>If new activities or procedures are being done, consider ethics.</p>	<p>Does the activity include a change in routine care? Does the activity include randomisation into particular groups for different types of care? Does it involve the use of control groups or of a placebo? Is more information to be collected than would normally be collected as part of routine care or routine training?</p>	<p>Relevant? Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Comments:</p>
<p>Broader issues</p> <p>If the activity changes the personal status, community standing or reputation of participants, consider ethics.</p>	<p>Does the activity have the potential to infringe the rights, privacy or professional reputation of carers, health care providers or institutions?</p>	<p>Relevant? Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Comments:</p>

If you answer yes to any of these questions, you may need Ethics approval and should discuss this with the Evaluation Team.

Please indicate if:

- You have access to an Ethics Committee?
- You need the Evaluation Team to provide access to an Ethics Committee