



Privacy in relation to research involving human subjects

SUMMARY

The *Privacy Act 1993* lays down a number of personal information privacy principles (PIPPs) which research proposals must comply with.

Collection of personal information must be for a lawful purpose: it is difficult to envisage a permissible exception to this principle.

Source of personal information: personal information should be collected directly from the individual concerned.

Collection of information from subject: the subject should know:

- that the information is being collected;
- by whom and
- for what purpose.

Manner of collection: personal information may not be collected in a manner that is unlawful, unfair or overly intrusive.

Storage and security of personal information: personal information should be stored securely.

Personal information shall not be retained for longer than is necessary.

Access to personal information: where the researcher holds personal information about an individual – especially where the information has been created by the research, the individual has a right to access that information. Note: particular issues arise with respect to genetic information and its release to the individual concerned.

Limits on the use of personal information: in general where information has been supplied for one purpose, e.g. a particular research project, it cannot be used for another purpose without the consent of the individual concerned.

These principles should be regarded as obligatory; any departure from them needs to be justified in the ethics application on the basis of one or more of the applicable exceptions, as recognised in the Act.

Potential exceptions:

- The information is publicly available
- The individual concerned authorises the departure from the relevant PIPP
- Non-compliance would not prejudice the interests of the individual concerned
- Compliance would prejudice the purposes of the collection
- Compliance is not reasonably practicable in the circumstances of the particular case
- The purpose for which the information is used is directly related to the purpose in connection with which the information was obtained
- The information will not be used in a form in which the individual concerned is identified

INTRODUCTION

Massey's *Code of Ethical Conduct for Research, Teaching and Evaluations involving Human Participants* is based on the following principles:

- a) Respect for persons;
- b) Minimisation of harm to participants, researchers, institutions and groups;
- c) Informed and voluntary consent;
- d) Respect for privacy and confidentiality;
- e) The avoidance of unnecessary deception;
- f) Avoidance of conflict of interest;
- g) Social and cultural sensitivity to the age, gender, culture, religion, social class of the participants;
- h) Justice.

While all these principles apply to the issues of privacy, (a), (c) and (d) are most strongly engaged when privacy of participants and others is considered.

As noted in Section 3. 9 of the Code, respect for persons includes respecting their rights including that of privacy, and hence we will focus on (d) and (c).

The Code and the Law

In New Zealand the right of individuals to privacy is a legal right conferred principally by the *Privacy Act 1993*. The Code naturally complies with the law as set out in the Act and generally that which is compliant with the law would be compliant with the Code.

These notes will endeavour to illuminate the requirements of the code with respect to privacy in terms of the legal requirement.

THE PRIVACY REGIME IN NZ

Rather than lay down a set of detailed prescriptive rules to protect the privacy of the individual in every conceivable situation, the Act provides for a set of principles which are couched in general terms. The Privacy Commissioner is empowered under the Act to issue codes of practice which provide the framework for the application of the personal information privacy principles (PIPPS) to particular areas of which the most significant one for researchers in the health and related fields is the *Health Information Privacy Code 1994*. The *Telecommunications Information Privacy Code 2003* is also potentially relevant in these days of digital information and the internet.

The Personal Information Privacy Principles and research

The PIPPs that have particular application for research are those relating to:

- collection of personal information (principles 1-4)
- storage and security of personal information (principle 5)
- retention of personal information (principle 9)
- use of personal information (principles 10 and 11),

This does not include all the PIPPs and those omitted are not necessarily irrelevant to research but for the sake of brevity lines have to be drawn.

Preliminary definitions under the Act

Personal information means information about an identifiable individual (including information relating to a death) that is maintained by the Registrar-General pursuant to the *Births, Deaths, Marriages, and Relationships Registration Act 1995*, or any former Act (as defined by the *Births, Deaths, Marriages, and Relationships Registration Act 1995*)

Individual means a natural person, other than a deceased natural person – hence information relating to companies or other incorporated entities, although regarded by the law as persons, is not protected under the *Privacy Act*.

Agency means any individual, organisation or business.

The collection of personal information

1. Collection of personal information must be for a lawful purpose

This would be a given – one would hope – but there is a connection with a later principle relating to the use of personal information which can only be for a purpose for which it was originally collected. (B.4q and B.4r *Risk Assessment*)

2. Source of personal information

Personal information should be collected directly from the individual concerned.

This is the basic principle which should always be born in mind. Personal information includes contact details of potential participants and PIPP 2 applies to them. Unless the contact details are in the public domain (telephone directory, Electoral Roll and the like) it is not permissible for researchers to be given access to the contact details through some third party agency e.g. by being given access to the membership list of the organisation through whom recruitment of participants is being done.

The appropriate way is to ask the club or other organisation to distribute the information and the researcher's contact details to members, who can then, on the basis of adequate information thus supplied, decide whether they wish to contact the researcher.

3. Collection of information from subject

The subject should know:

- that the information is being collected,
- by whom and
- for what purpose.

As well as privacy this relates to informed consent – in this case to the supplying of personal information which in the case of a good deal of research will be the entirety of the individual's participation.

Generally if the information sheet template is followed then there will be compliance with this privacy principle.

4. Manner of collection

Personal information may not be collected in a manner that is unlawful, unfair or overly intrusive.

Ethical approval cannot be given for the collection of personal information by any means that are not lawful. An example would be the audio recording of conversations

without the knowledge and consent of the parties where the researcher is not a party to the conversation.¹

The recording, whether audio, visual or both, of persons in a public place raises some particular issues and researchers would be advised to consult appropriate peers where such a method of collection is proposed.

5. **Storage, security and retention of personal information**

Obviously there would be little point in ensuring that the privacy of the individual was respected during the collection process, if through inattention or carelessness the personal information thus obtained was not safeguarded from improper access or use. This is the reason for the application seeking assurance that this will not be the case.

A related principle (PIPP 9) is that **personal information shall not be retained for longer than is necessary**. In the case of student research this would be at least until the research output e.g. thesis or research paper has been assessed. With staff research, overlong retention would need to be justified and if the justification put forward was potential use in other research then this raises serious ethical and legal issues in relation to PIPP 3 that the purpose of collection must be disclosed and PIPP 10 that personal information can only be used for the purpose for which it was collected.

6. **Access to personal information**

Where an agency holds personal information in such a way that it can readily be retrieved, the individual concerned shall be entitled to have access to that information. Thus audio or video recordings of participants would normally be offered back to the participants to whom they refer. Recordings should be reviewed prior to release to ensure that they do not breach the privacy of another individual. Where the research produces new information about the participants they would be entitled to receive this unless its non-disclosure can be justified.

A particular issue exists with respect to genetic information about participants. New Zealand has no law prohibiting the use of genetic information to make decisions on matters such as insurance cover. *Currently there is no prohibition on an insurer requesting a would-be insured to provide the results of any genetic testing to which they have been subjected.* Currently insurers in New Zealand have agreed not to require applicants for insurance to undergo genetic testing. This is not the case in other jurisdictions such as that of United States of America where GINA *Genetic Information Non-discrimination Act 2008* prohibits discrimination in the provision of health insurance on the basis of genetic information.

Where research will produce genetic information about participants it is suggested that the following note be included in the information sheet:

Note: As a participant you can agree to receive your genetic information. Before agreeing to this you should be aware that under New Zealand law an insurance company could ask you to disclose such information should you apply for life or health related insurance – such as medical cover. You could be obliged to disclose it even if the insurer does not ask for it expressly.

¹ Section 216B *Crimes Act 1961*.

Not disclosing it could result in the insurer not having to pay out under the policy.

Should you choose not to receive this information for your protection and should the current insurance situation change, the possibility of identifying your genetic information will be removed one month after it becomes available.

CONSENT FORM

“I understand that if my genetic information obtained by the researcher is disclosed to me, I may have to pass this information to an insurance company should I seek life or health related insurance cover in the future. I understand that failure to disclose the information could invalidate my insurance policy.”

7. Limits on the use of personal information

In general where information has been supplied for one purpose, e.g. a particular research project, it cannot be used for another purpose without the consent of the individual concerned. This includes biological samples and information derived therefrom as well as more mundane information such as contact details.

A solution where the researcher may wish to retain personal information for later research projects, is to obtain a release or permission at the time consent to the original collection is obtained. For instance, the consent form may include an option for the participant to consent to their sample or information being used in subsequent research projects. It would be good practice to anonymise this data, or replace identifying information, such as name, with a unique identifier.

In relation to the collection of personal information for research purposes, *these principles should be regarded as obligatory; any departure from them needs to be justified in the ethics application* on the basis of one or more of the applicable exceptions recognised in the Act.

Exceptions – where compliance with certain of the above principles is excused.

The restrictions on collection (PIPPs 2 and 3) and use (PIPP 11) may not apply if certain conditions are met.

1. The information is publicly available

Personal information may be collected from other sources or without appropriate informed consent where the researcher *believes on reasonable grounds* that the information is publicly available. The interpretation section of the Act provides guidance as to the meaning of the terms:

Publicly available information means personal information that is contained in a publicly available publication

Publicly available publication means a magazine, book, newspaper, or other publication that is, or will be, generally available to members of the public and includes a public register

Public register means any register, roll, list, or other document maintained pursuant to a legislative provision requiring the register to be kept and for it to be available for inspection by the public.

Obvious examples of personal information that is publicly available are telephone directories which are also covered by the next exception – consent and electoral rolls.

Where information is contained in public registers then access to them as well as the use that can be made of the information is governed by the Public Register Privacy Principles under s59 and by the legislation that provides for the creation of the public register in question. Thus access to birth information, death information, marriage information, civil union information, or name change information is governed by Part 9 of the *Births, Deaths, Marriages, and Relationships Registration Act 1995*.

An example being ss106 and 107 of the *Electoral Act 1993* which provide for the compilation of the main and supplementary electoral rolls for each district and s110 which provides for public inspection subject to certain limitations.

Note: although access to publicly available information is permitted by the *Privacy Act*, any proposed use of such information for research should still be ethical. The Code applies to “All research involving either the participation of humans or where the research impacts on individuals, groups or communities.”

Much of the research involving publicly available information does not “involve the participation of humans” e.g. research using the decisions of the Courts either in subscription sources, or in the public access sites such as the New Zealand Legal Information Institute.

2. The individual concerned authorises the departure from the relevant PIPP

Where the individual consents to their personal information being available such as an entry in a telephone or other directory would come within this exception as well as the previous one.

Increasingly, personal information is available via the internet; the individual consent to the information being available is in general tacit, rather than express. In accessing such information PIPP 10 should be borne in mind, that generally, information supplied or made available for one purpose should not be used for another.

3. Non-compliance would not prejudice the interests of the individual concerned

If this is combined (as it often is) with use in a form that will not identify the individual concerned then it is difficult to see how its use would prejudice the individual concerned. This is certainly true where the identity of the individual will not be known to the researcher.

4. Compliance would prejudice the purposes of the collection

This would apply to collection including the recording of images without the consent of the individual, such as the observed responses to a display for market research.

In essence it must be shown that the value or utility of the research outweighs the infringement of an individual’s right to privacy. Factors that would be taken into account would include whether the collection was to take place in a public place which would include places to which the public have access such as supermarkets. Given the ubiquity of CCTV surveillance to which no one explicitly consents, such visual data collection would not be objectionable.

Where the collection takes place in circumstances in which the reasonable individual would have an expectation of privacy (e.g. a fitting room) data collection without consent could hardly be seen as ethical.

5. Compliance is not reasonably practicable in the circumstances of the particular case

This generally relates to obtaining the consent of the individuals concerned in relation to PIPPs 2 and 3; in the context of research ethics this is often paired with the next exception which relates to use under PIPP 10. Where the research will involve the use of data collected for other purposes from a large number of individuals at some time in the past, obtaining consent from the individuals concerned is impossible rather than merely impracticable. This of itself is not determinative of whether approval should be given. Other factors such as the nature of data being accessed, how the information will be used, whether the individuals would be prejudiced by permitting access to the particular data and the utility of the research would all have to be weighed against the individuals' rights to privacy. For example, if a doctor urgently needs to collect information about a patient's medical condition in order to treat them for a heart attack, the doctor is unlikely to be able to give details about who will receive the information later. Once the emergency has passed, the doctor can then let the person know it collected information from them, why it was collected and how it will be used.

6. The purpose for which the information is used is directly related to the purpose in connection with which the information was obtained

There are a number of situations in which this exception may be applicable, especially if coupled with use in a form which does not identify the individuals involved.

Education-related research into participation or outcomes in university or other education provider's products would be an example. Information on pass rates is collected (generally by a computer programme) for number of reasons, such as to measure the provider's productivity, to assist in validating the methods of instruction and assessment and to enable the provider to make improvements where required. Thus a project which examined participation and outcomes across ethnicities could be said to be in furtherance of the last objective. The fact that the research has other objectives such as publication and/or obtaining a qualification would not be an issue, especially if exception 7 (below) applies, which in the case of such research, it generally would.

7. The information will not be used in a form in which the individual concerned is identified

(Or it will be used for statistical or research purposes and will not be published in a form that could reasonably be expected to identify the individual concerned.)

This is the saving exception for many research projects where there is lack of compliance with one or more of the PIPPs outlined above. Two points need to be made in relation to this exception.

- a. If the identities of the individuals to whom the information relates is known to the researcher i.e. the data accessed includes names, addresses etc., then the nature of the information has to be examined as well as the relationship of the researcher to that information. The more sensitive the information, the more significant this issue would be. If the researcher would have access to the information anyway, say by virtue of their employment, then this would be a factor in favour of approval.

If the researcher does not have access to data then there are issues for the agency which is being asked to grant access to information under PIPP 11 which limits disclosure of personal information. While the other exceptions may be applicable, in general the more sensitive the information the less likely it would be that approval would be granted, unless the data to which the researcher will have access has been anonymised.

- b. The nature of the information may mean anonymity could be compromised. The nature of the information that is published coupled with the number of participants involved may mean that the identity of individuals may be known, at least to others whose information was the subject of the research. A simplistic example would be research that related outcomes in a particular course to age or ethnicity. If there were only two students over 60 and they were of different ethnicities – then their fellow students could easily identify them and thus their right to privacy would be breached.

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