

# Health research and privacy: Guidance notes for health researchers and ethics committees

### *Acknowledgements*

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## 1. Introduction

The [Health Information Privacy Code 1994](#) (HIPC) is the starting point for any consideration of the privacy issues which arise in health research. These guidance notes are provided to assist health researchers and ethics committees, but they should not be relied upon as a substitute for the provisions of the HIPC.

The notes have three functions:

- (a) to highlight matters in the HIPC which are especially relevant to health research;
- (b) to provide guidance for health researchers, ethics committees and custodians of health information where the HIPC leaves them with discretion. The guidance notes indicate matters which should be taken into account in making decisions in such cases; and
- (c) to deal with matters beyond the provisions or framework of the HIPC. The notes recommend good practice in the use of personal information for research, which goes beyond the requirements of the Code.

The guidance about the matters which should be taken into account when making decisions, and the recommendations about good practice, reflect the judgments reached by a broadly based working party which in 1993 produced a draft code of practice for health research.

The draft code did not proceed but some of its provisions were incorporated in the HIPC, and some passages from the notes to the draft code now appear in the commentary which accompanies the 1994 code. However, much has not yet been utilised. Many of the judgments made by the earlier working party have been re-expressed here, in terms appropriate for a set of guidance notes and recommendations concerning good practice.

The writers have taken account of the international and other guidelines for ethical conduct of health research.

After providing guidance on the application of the HIPC to health research, these notes deal separately with the collection, use and disclosure of health information in health research.

## 2. Application of the HIPC

The HIPC applies where a *health agency* deals with *health information*. If a researcher is not a health agency, or part of a health agency, then, even though he or she might be dealing with health information, the HIPC will not apply. (However, even if the researcher is not a health agency, the record-holder usually will be, and the HIPC will apply to it.) In such a case, the researcher will need to apply the provisions of the Privacy Act 1993 itself, which make different and in many cases lesser demands. (This section does not deal with those provisions.) The Privacy Act is subject to other legislation. If a request for health information is made by a person who is not the subject of the information, the request must be considered under the Official Information Act.

### 2.1 Health agencies

There are many bodies that fall within the definition of health agency:

- (a) A health agency is a person or body which provides health or disability services. Usually a researcher will not be providing services. If, however, the researcher has a clinical or service providing role as well, then even though the information might be sought for research purposes, the researcher will fall within the definition of a health agency, and thus will be governed by the HIPC;
- (b) Any purchaser of health services is declared to be a health agency. Any research carried out under its auspices will be subject to the HIPC;
- (c) A “school, faculty, or department of a tertiary educational institution which provides the training or a component of the training necessary for the registration of a health professional” is a health agency. This definition encompasses teaching functions. It is not clear whether it incorporates all the research functions of tertiary educational facilities that provide training;
- (d) Certain specified agencies are stated to be health agencies. These include the HRC.

### 2.2 Health information

Health information has at the core of its definition the notion that information relates to an identifiable individual. If information cannot be linked to an identifiable individual it will not come within the scope of the HIPC, or within that of the Privacy Act itself. Health information is information about the health of an identifiable individual. This includes:

- (a) the medical history of the individual; or
- (b) information about any disabilities the individual has or has had; or
- (c) information about any health or disability services that are being provided, or have been provided to that individual; or
- (d) information provided by that individual in connection with the donation, by that individual, of any body part or bodily substance of that individual, or information derived from the testing or examination of any body part or bodily substance of that individual; or

- (e) information about the individual which is collected before, or in the course of, and incidental to, the provision of any health or disability service to the person.

Researchers should note that anonymised information which cannot be linked to any identifiable individual is not health information, and thus is outside the reach of the HIPC.

For the HIPC to apply in relation to health research the researcher must be a health agency; and the information must be health information. If the research falls outside either of these definitions, the HIPC will not apply, but the Privacy Act will if personal information is involved.

The rules in the HIPC mostly apply from the date the HIPC commenced. This means that individuals can make complaints about failure to comply with the HIPC in relation to actions taken concerning their health information from 30 July 1994. However, some of the rules in the HIPC expressly apply in relation to health information obtained before the commencement date. These rules are:

- (a) Rule 5 (storage and security of health information);
- (b) Rule 6 (access to personal health information);
- (c) Rule 7 (correction of health information);
- (d) Rule 8 (accuracy etc. of health information to be checked before use);
- (e) Rule 9 (retention of health information);
- (f) Rule 10 (limits on use of health information) - does not apply to health information obtained before 1 July 1993; and
- (g) Rule 11 (limits on disclosure of health information).

### **3. The collection of health information**

**3.1 Rules 1 to 4 and 12 of the HIPC** are related to the collection of health information.

(a) *Rule 1 - Purpose of collection of health information*

The researcher should collect only information necessary for the research project: Rule 1(b).

(a) *Rule 2 - Source of health information*

Health information may be collected for research purposes from sources other than the individual concerned, if approval by an ethics committee (if required) has been given, and so long as it will not be published in a form that could reasonably be expected to identify the individual concerned: Rule 2((2)(g)(iii).

(b) *Rule 3 - Collection of health information from individuals*

Where a researcher is collecting information directly from the individual concerned, the researcher must take reasonable steps to ensure the individual knows that the information is being collected, why it is being collected, who will receive it, what consequences might follow if the information is not provided, and what are the individual's rights of access to and correction of the information: rule 3(1) (a) - (g). It is not necessary to comply with this requirement if

compliance would prejudice the interests of the individual concerned or the purpose of collection: Rule 3(4) (b) (i) - (ii).

*(c) Rule 4 - Manner of collection of health information*

Researchers must not collect health information by means that are unfair or that intrude to an unreasonable extent upon the personal affairs of the individual concerned: Rule 4(b) (i) - (ii).

*(d) Rule 12 - Unique identifiers*

Health agencies must not assign a unique identifier to an individual unless to do so is necessary to enable the health agency to carry out its functions efficiently: rule 12(1). A unique identifier is something (other than the person's name) that uniquely identifies that individual. This will usually be some sort of alpha-numeric code.

Note that the rule regulates assignment not use of unique identifiers. Thus where researchers have collected health information to which another agency has already assigned a unique identifier, the HIPC does not prevent the researcher's use of that same unique identifier.

Where there is no practical way for a unique identifier to be linked to an individual or where a unique identifier has been subject to an irreversible encryption process, the identifier may be regarded as anonymised information.

The use of unique identifiers can enhance individual privacy where the unique identifier replaces other identifying information, and thus diminishes the possibility of unauthorised persons breaching the individual's privacy. However, the HIPC contains safeguards against overuse or abuse.

### **3.2 Guidance on discretionary matters**

Ethics committee approval is required in order to rely on the exception for research in Rule 2, relating to the collection of health information from sources other than the individual concerned. This may be either from another individual or from health records. These two situations are discussed separately below.

*(a) Collection of information from another individual*

Where the researcher proposes to collect information from someone else, then this should be with the authority of the individual concerned, except in special circumstances. For instance if the researcher proposes to collect personal information from a relative or someone else, without the authority of the individual concerned, because that individual is deceased, untraceable, incapacitated, or for some other good reason, then this approach should be explained in the protocol for the ethics committee, and carried out in accordance with any conditions the committee specifies.

*(b) Collection of information from health records*

The use of health records for research without the authorization of the individual concerned should only be undertaken subject to certain extra conditions:

**1. Justification**

The reasons for not seeking consent should be justified to the ethics committee. These reasons may be scientific, practical or ethical.

1.1 The main scientific reason for not seeking consent to use health records for research is that failing to locate individuals to seek their consent may lead to less complete ascertainment of cases for study, and therefore possibly a biased (and hence incorrect) result. This is because the people who are hard to locate may differ in their health problems or the outcome of their treatment from those who are easy to locate.

1.2 Another reason for not seeking consent is practical. Sometimes access to records is required in order to determine who will be potential participants in a study. The researcher must identify the names of individuals with a certain condition prior to approaching the individuals to seek their consent to take part in the study.

It is usually impracticable for the individual's own doctor to seek his or her patient's consent for the release of the name to the researcher, because the records will not usually be held by the individual's own doctor, but will be held by hospitals or disease registries. Other practical difficulties occur when there are very large numbers of records and many of the individuals may be untraceable or deceased.

In some situations the process of seeking consent may cause undue anxiety or distress to individuals. This might arise where researchers were investigating a tentative link between an exposure and a serious disease. An example is a study in New Zealand of the use of an asthma drug as a possible cause of sudden deaths from asthma. This study compared the medical records of individuals who had died from asthma with records of asthmatics who had been admitted to hospital but had not died. It would have been wrong to have sought the consent of the group who had not died, because informing these people of an untested hypothesis might have frightened and distressed them without good cause.

## 2. *Benefits*

The potential benefits of the research must be described to the ethics committee, which must weigh up these potential benefits against the loss of privacy.

2.1 The potential benefits of the research may include a contribution to the identification, prevention, or treatment of illness or injury, scientific understanding relating to health, the protection of the health of individuals or communities, or the improved delivery of health services. The loss of privacy may be regarded as more important for very sensitive information, for instance termination of pregnancy, or genetic information that might have implications for other individuals.

### 3.3 *Recommended good practice*

- (a) *Protocols* - should be developed prior to undertaking research, specifying the information to be collected, why this information is necessary for the research, and the use to which this information will be put.
- (b) *Valuable Information* - where the researcher collects information directly from individuals; and the information could in any way be considered by the person from whom the information is derived to be sensitive or valuable in a personal, social or cultural sense, the research protocol should be approved by an approved ethics committee.
- (c) *Explanation* - where information is being collected by the researchers directly from any individual, the purpose of the research should be explained to the individual. This

information should be as specific as possible without compromising the validity of the research.

There are many situations where providing very specific information about the study in advance of seeking consent would prejudice the purposes of the collection by compromising the scientific validity of the research. For example, if a mother is to be interviewed to establish whether she has been exposed to a particular medicine which might have caused a congenital abnormality in her baby, it would be wrong, when asking her to consent to the study, to give the name of the drug in question. If the name of the drug were disclosed this would have at least one scientifically unacceptable consequence.

If the mother in question had a baby with a birth defect, she would have both a reason and a longer period of time, in advance of the actual interview, to remember that she had been exposed to the drug. In contrast, a mother of a healthy baby would have less reason to remember past exposure, and would not reflect on possible past exposure during the period between the consent procedure and the actual interview. This effect could lead to a spurious association between birth defects and drug exposure in the mothers interviewed; thus if such an association were found, it could be scientifically invalid. In studies such as this, biased reporting can be minimised, and scientific validity assured, only by not disclosing in advance the complete details of the hypothesis under test.

Where specific information cannot be provided at the outset, the researcher should offer to provide results to participants, unless there are practical reasons to the contrary.

- (d) *Voluntary* - where researchers collect information directly from individuals, they should inform them that the supply of information is voluntary and (if in a health care context) that refusal to provide all or any part of the requested information will not affect the provision of health care to the individual in any way.

The supply of information by individuals for research purposes is voluntary. Hence there must be no adverse consequences for the individual, which are under the control of the investigator, of refusing to supply information. But in some research projects which are not undertaken by health care providers, it will not be appropriate to inform individuals that their provision of health care will not be affected.

- (e) *No inducements* - which could be regarded as constituting undue influence, should be offered to research participants to provide information. Any recompense for participation in health research (either monetary or in kind) should be approved by an approved ethics committee.

It may be hard to draw a line between exerting pressure or offering improper inducements and legitimate encouragement. Whether such inducements constitute undue influence must be assessed in the light of prevailing social norms.

- (f) *Positions of Power* - researchers who are in positions of power over individuals, as in teacher/student relationships, should not use their positions to unduly influence the decisions of individuals to provide personal information for research purposes.

- (g) *Intrusion* - where research intrudes upon the personal affairs of individuals, a judgment on whether it does so to an unreasonable extent should be made by an approved ethics committee. (The ethics committee's approval of the research does not

relieve the researcher of this obligation, but the decision may provide evidence that the action was permissible).

Where health researchers seek to enquire into the personal affairs of individuals, for instance in studies of sexual behaviour in relation to sexually transmitted diseases, in deciding whether such questioning intrudes to an unreasonable extent, the ethics committee should take into account the purposes of the research and the potential benefits in terms of the health of individuals or communities.

- (h) *Information Collection* - the following are elements of good practice concerning the collection of health information:
- i. Interviewers should be properly trained, suitable and culturally sensitive and, where appropriate, carry identification.
  - ii. If it is reasonably foreseeable that health problems previously unknown to the individual will be identified, then arrangements for referral, with the individual's consent, should be made.
  - iii. Care should be taken not to interfere with health professional/patient relationships.

#### **4. The use of health information**

**4.1 Rules 5, 8, 9 and 10 of the HIPC** deal with the use of health information.

(a) *Rule 5 - Storage and security of health information*

Rule 5 requires researchers to whom the HIPC applies to take reasonable steps to protect health information against loss, unauthorised access, use, modification, or disclosure, or other misuse. The HIPC provides details of what might be appropriate safeguards in particular circumstances. In health research, these include removing names or other identifying information from records or data while in use, and using an identifier to ensure that identification of individuals is only possible by reference to a master index which is kept securely.

(b) *Rule 8 - Accuracy etc. of health information to be checked before use*

Rule 8 requires researchers only to use information if they have taken reasonable steps to ensure that the information is accurate, up to date, complete, relevant and not misleading. This involves the researcher making a judgment. The HIPC requires that judgment to be made by considering the purpose for which the information is to be used. Whether steps taken to ensure accuracy etc. are reasonable will be judged on the circumstances of the case.

(c) *Rule 9 - Retention of health information*

Rule 9 requires health agencies to keep health information for no longer than is required for the purposes for which the information may lawfully be used. Note that this does not mean that the health agency may keep the information for only as long as required for the original purposes for which it acquired the information. The rule entitles the health agency to keep information for as long as is necessary for any lawful purpose.

Thus this rule does not prevent a health researcher who collects or uses health information for one research purpose from retaining the information for another research purpose. However, such reuse may breach rules 3, 10 or 11 if the researcher has not indicated the possibility of reuse to the ethics committee, the individual concerned, or the agency holding the information.

Note that regulations prescribing minimum periods for which information must be kept have been made by the Health (Retention of Health Information) Regulations 1996. Obligations for minimum retention only apply to health information about identifiable individuals, and only to health service providers.

#### *(d) Rule 10 - Limits on use of health information*

Rule 10 limits the use of health information. Where an agency has obtained health information for one purpose, it may not use it for another purpose, unless it can show that it reasonably believes that its proposed new use is authorised.

There are several points to note about rule 10 where it concerns health research.

- i. Firstly the rule refers to information obtained. Thus it applies to health researchers who hold information which they themselves may not have collected, but have received through some other means.
- ii. Secondly, the rule concerns information obtained for a *purpose*. This word is not defined in the Privacy Act or the HIPC. An ordinary understanding would differentiate between health information obtained for treatment purposes from that obtained for research purposes. But is health information obtained for a particular research project entitled to be used for a different research project because the common purpose of research links the two projects? The HIPC permits such use if the new use is for a purpose “directly related” to the original purpose (Rule 10(1) (b)). If this is read widely, it could permit such new research uses. The Privacy Commissioner’s commentary to the Code, however, suggests that this is not intended, and that researchers who propose to use information from one research project for another need to rely on exception to rule 10(e) (iii).
- iii. Thirdly, the health agency must, in any event, be able to show that it believes on reasonable grounds that it is entitled to use the information for a purpose different from that for which it obtained the information.

As well as the exception in rule 10(1) (b) noted above, rule 10 also permits new uses of health information for purposes different from the original purpose for which the information was obtained:

- i. where the individual concerned agrees (rule 10(1)(a));
- ii. where the source of the information is a publicly available publication (rule 10(1)(c));
- iii. where the information is used for research purposes, an ethics committee has, if required, given approval, and only if the information will not be published in a form which could reasonably be expected to identify the individual concerned (rule 10(1)(e)(iii). (This is known as the research exception.)

The HIPC does not specify when ethics committee approval is required.

## **4.2 Guidance on discretionary matters**

Ethics committee approval may be required in order to rely on the exception for research in Rule 10, relating to the limits on use of health information.

### *(a) Research*

Ethics committee approval is required for the use of health information collected for clinical purposes for research, and for the use of health information collected for one research purpose

for another purpose not directly related to the original purpose. (If the new research purpose is directly related to the original research purpose then such use is in accordance with Rule 10(1) (b) and there is no need to rely on the research exception).

The considerations which should guide an ethics committee in deciding whether the use of health information for research without the authorization of the individual concerned is justified are specified under **5.3.2(b) Collection of information from health records**.

The use of medical records (including disease registries) to identify and approach individuals is another research purpose for which ethics committee approval is required. The research protocol and the method of approach should be reviewed by the ethics committee. It should determine whether the approach may be made directly, or by the participant's medical adviser. If the approach is to be made directly, the consent for the individual to be invited to take part should be sought from the participant's medical adviser. In this circumstance, the individual should be informed of the name of the person who had given consent for them to be approached.

Certain types of research, for instance research into the causes of injury, may only be able to be undertaken if the individuals who have had a particular injury are identified, contacted, and interviewed (with their agreement) to obtain information on possible causative factors. For example, research on falls from playground equipment has been undertaken to determine the dangers of equipment height and ground surface. To obtain accurate information on the circumstances surrounding such falls it is necessary to interview children and parents identified through hospital attendance data.

The reason for seeking the consent of the person's medical adviser for an individual to be invited to take part in research is not to usurp the individual's right to make the final decision about whether to take part, but to minimize the possibility of harm or distress to any individual. The medical adviser should be aware of the person's situation and be able to forbid a direct approach in the unusual situation that the person could be unduly distressed. Where there is uncertainty, the medical adviser should check with the individual that an approach is acceptable.

### *(b) Audit/Monitoring*

Normally, ethics committee approval is not required for the use of health information for monitoring or internal audit undertaken by staff involved in the institution or service.

Health information may be used for monitoring in accordance with rule 10(1) (b) as monitoring may be regarded as directly related to the purpose in connection with which the information was originally obtained.

This exception for ethics approval may also apply to some research where the information will not be published in a form that could reasonably be expected to identify the individual concerned. See also *Section 22(c) (2)* of the Health Act 1956.

The [National Ethics Advisory Committee](#) has developed guidelines on conducting observational studies. The guidelines specify:

- i. All observational research requires ethics committee review.
- ii. Public health investigations do not require ethics committee review.
- iii. Audits and related activities do not require ethics committee review, unless they reach a threshold of risk.

### **4.3 Recommended good practice**

#### *(a) Storage and security*

- i. The principal investigator of the research group is responsible for the security and control of health research records and information.
- ii. Anyone who is to have access to health research records and information should give a written undertaking to maintain confidentiality.
- iii. Appropriate arrangements should be made and enforced at all times for the adequate physical security for housing of confidential information both when in use and when in storage.
- iv. Measures should be taken to prevent unauthorised access to identifying data held on computer systems.
- v. Wherever practicable personal identifiers should be removed from records so that personal linking can be achieved only through the use of a separate cross-index.
- vi. Consideration should be given to deleting links to records by the irreversible removal of all personal identifiers but this should only be done where the retention of personal identifiers is considered unnecessary.

Though the deletion of links to records from personal identifiers is desirable as a method of safeguarding the security of personal information, there are a number of situations where it would be wrong to delete them. For instance the names of persons in drug trials should be kept long term, because of the possibility of delayed effects of the drug.

An example of the importance of this practice occurred with the drug stilboestrol, which has been demonstrated to cause cancer and congenital anomalies in the daughters of women who had been administered the drug in pregnancy. Several trials were conducted in the 1950s to test the effectiveness of the drug in preventing miscarriage. After the association with cancer was first shown, many years later, many of the participants in the trials were traced and warned and more information was gained on other adverse effects of stilboestrol.

#### *(b) Accuracy*

If there are doubts about the accuracy of information to be used for research, the researcher should take reasonable steps to check the information before use.

A particular problem might arise in using special disease registries to identify persons and contact them for research purposes. The accuracy of the diagnosis should be checked before contact with the individual is made.

#### *(c) Retention and disposal*

- i. Researchers wishing to keep identifying information or identified specimens longer than required for the original research project should obtain the agreement of an approved ethics committee.
  - A special reason for keeping personal information linked to specimens (e.g. blood or other tissue) may be the likelihood of developing a new test which might make these specimens valuable for research in the future. Another reason for keeping identifying information will arise in clinical trials of drugs or procedures. Unsuspected long-term effects may become apparent after many years, thus the period of time regarded as essential for the original purpose may be long. Records should often be kept past the end of the

research project in case other long term effects are suggested from elsewhere. These records can then be used to test this hypothesis and, if applicable, to warn the research participants.

- Organisations should ensure that the use, return and disposal of samples/ sample information is compliant with the [Human Tissue Act 2008](#), [Health Information Privacy Code 1994](#), [NZS 4304:2002](#) (Management of Healthcare waste) and [NZS 8135:2009](#) (Non-therapeutic use of human tissue).
- ii. Intact records should not be disposed of other than by shredding or burning on the premises, or by supervised transfer to a shredder or incinerator elsewhere.
- iii. Where the principal investigator ceases to be responsible for the project, responsibility for the security or disposal of the information will pass to the principal investigator's successor if any, or else to the head of the department or institution.
- iv. For the disposal of records involving Māori health information, where a Kaitiaki group has been established to act as guardian of Māori information in the area or research, the Kaitiaki group should be consulted on provisions for taongatukiho.

## 5. The disclosure of health information

### 5.1 *Rules 6, 7 and 11 of the HIPC* deal with the disclosure of health information.

The HIPC regulates disclosure of health information with two sets of rules designed to reflect the different situations of (1) the individual who requests access to his or her own information, and (2) other disclosures. These may be either to third parties, in response to a request or at the volition of the health agency, or to the individual concerned at the volition of the health agency (i.e. not in response to a request from the individual).

#### *(a) Rules 6 and 7 - The individual's rights of access to and correction of his or her health information*

Individuals have rights of access to their own health information. These rights entitle the individual under rule 6 to obtain from the health agency confirmation of whether the agency holds the information and to have access to it. As well, the individual must be told of his or her rights under rule 7 to request correction of the information.

Before the right can be triggered, the agency must hold the information in such a way that it can readily be retrieved.

With a few minor exceptions concerning the private sector only in the cases of copies of X-rays, CAT scans, or video recordings or for repeated requests for the same information, individuals are entitled to free access to their health information (HIPC, clause 6, and s 35, Privacy Act 1993).

The rights are not absolute. There are grounds for withholding information. Three circumstances are relevant to health research, but are not likely to be invoked often. The health agency can refuse to disclose where:

- i. Disclosure would involve the unwarranted disclosure of the affairs of another individual (s 29(1) (a), Privacy Act 1993).
- ii. Disclosure of the information would be likely to prejudice the physical or mental health of the individual requesting the information (s 29(1) (c), Privacy Act 1993).
- iii. Disclosure would, in the case of an individual under the age of 16, be contrary to that individual's interests (s 29(1) (d), Privacy Act 1993).

Note that prejudice to the conduct of a research project is not a ground for refusing a person access to their health information. If a person insists on access to their health information in the course of a research project, and if to grant access would prejudice the validity of the research design, the Privacy Commissioner's commentary to the HIPC suggests that the research participants should be made aware of this consequence at the time when their consent is sought to participate in the project. If the person still insists on access, access must be given, even if this has to be treated as a withdrawal from the project. This might apply in blind randomized trials.

The rights under rule 7 are to request correction of an individual's health information, or that a statement of a correction sought but not made be attached to the file. Health agencies must take reasonable steps to ensure that the health information they hold is accurate, up to date, complete and not misleading. If an individual makes a request for correction, the agency must determine, by reference to these requirements for accuracy etc., whether to make the correction sought.

However, the Privacy Act does not set out reasons for not making corrections. Where the researcher chooses not to make a correction, the researcher must inform the individual what was done and why, and advise the person that he or she may complain to the Privacy Commissioner about the refusal. The researcher must also advise the person that he or she may have a statement attached to the information of the fact that he or she had wanted the researcher to make a correction.

#### *(b) Rule 11 - Limits on disclosure of health information*

In all situations other than where an individual seeks access to his or her own health information, rule 11 applies. Thus where a health agency proposes to volunteer information to the individual or to a third party; or the third party has requested access to a person's health information, rule 11 applies.

The underlying premise of rule 11 is that health agencies must not disclose individuals' health information unless they have good reason in terms of the exceptions that the rule provides.

For health research, the following exceptions are likely to be applicable:

- i. The researcher might disclose the information to the individual concerned: Rule 11(1) (a).
- ii. The individual concerned, or the individual's representative, may authorise disclosure: Rule 11(1) (b). This might be done at the time that the individual's consent to participate in the research is obtained, or at some other time.
- iii. The disclosure of the information is itself a purpose for which the information was obtained: rule 11(1) (c).

If these exceptions are not available, a health researcher may also rely on the following exceptions, but only if the researcher believes on reasonable grounds that it is not practicable or desirable to obtain the individual's authorisation to disclose the information.

- i. The disclosure is directly related to one of the purposes with which the information was obtained: Rule 11(2) (a).
- ii. The information is to be used for research purposes (for which approval by an ethics committee, if required, has been given) and will not be published in a form which could reasonably be expected to identify the individual concerned: Rule 11(2) (c).

Where either of these exceptions is used, disclosure is permitted only to the extent necessary for the particular purpose: Rule 11(3).

Researchers should note again that the HIPC applies only to identifying health information. If they have obtained or are using health information which cannot lead to the identification of the individuals to which it relates, the researchers may use and publish the information free of the restrictions of the Code.

## **5.2 Guidance on discretionary matters**

Ethics committee approval will be required in order to rely on the exceptions for research in Rule 11, relating to the limits on disclosure of health information. In order for this exception to be applicable the health agency must also have reasonable grounds to believe that it is either not desirable or not practicable to obtain authorization from the individual concerned.

The considerations which should guide an ethics committee in deciding whether the disclosure of health information for research should be permitted are specified under **5.3.2(b) Collection of information from health records**. The ethics committee should also consider whether obtaining the authorisation of the individual(s) concerned is not desirable or practicable.

## **5.3 Recommended good practice**

*(a) Authorisation* - in general health information should not be disclosed without the authorisation of the individuals concerned. It may not always be possible or desirable to obtain individual consent, in which case the safeguards set out below are particularly important. The overriding consideration should always be that no harm or distress will ensue for the individual or for the family, and that professional relations (for example, doctor-patient) will not be impaired in any way.

*(b) Ethics Committee Approval* - the disclosure of personal records which are not publicly available should be made only after the proposed research has been considered by an approved ethics committee. Where the researcher is the custodian of the records, disclosure to anyone else should be made only with the approval of an approved ethics committee.

*(c) Custodian's consent* - the disclosure of any part of the health records of identifiable persons requires the consent of the custodian of the record. The custodian may be the person's own health care professional (or other clinician), or in the case of health care facilities such as hospitals the custodian of the records will be the medical practitioner or other person who is the designated holder of that responsibility.

*(d) Confidentiality* - the disclosure of personal records should only be made to persons who have given a written undertaking to ensure confidentiality. A named investigator of the research group to whom the records are disclosed should accept responsibility to ensure the safety and confidentiality of the records.

*(e) Kaitiaki group* - for records involving Māori health information, where a kaitiaki group has been established to act as guardian of Māori information in the area of research, the kaitiaki group should be consulted.

(f) *Publication* - no information used for health research purposes should be published in a form that could reasonably be expected to identify the individual concerned, unless the individual has consented to publication.

(g) *Awareness of research* - reasonable steps should be taken by the custodians of health records to publicise (through notices or pamphlets) the fact that health records may be used, under conditions of strict confidence, for research purposes.

(h) *Test results* - investigators should always seek permission of the research participant to send to the participant's medical practitioner any relevant test results or abnormal findings that may be detected. If these findings suggest serious disease, research participants who have not given permission for the transfer of the information to their medical adviser should be urged to seek further advice.

Investigators should normally avoid expressing opinions about findings to the research participant, or appearing to commit a patient's doctor to any particular course of action, but the individual rights of the research participants must be respected, particularly their right to be made aware of any information obtained about them in the course of the research.

## 6. Complaints

The Privacy Act 1993 provides that individuals may complain to the Privacy Commissioner of "interferences with privacy". For an action to constitute an "interference with privacy" it must both breach an information privacy principle of the Act or a provision of a code of practice and have caused, or may cause, harm, loss, detriment, damage, injury, or otherwise adversely affect the individual's rights, benefits, privileges, obligations, or interests, or result in significant humiliation, loss of dignity, or injury to the feelings of the individual. Thus "technical" breaches which do not cause harm to the individual cannot lead to successful complaints (s 66(1), Privacy Act 1993).

As well, individuals may complain to the commissioner if an agency, in response to a request, refuses or fails within the statutory time period (ordinarily a maximum of 20 working days, but in any event as soon as reasonably practicable within that period) to make personal information available, or imposes charges or conditions on the use of personal information it discloses, or refuses to correct personal information.

The HIPC requires health agencies to designate a person to deal with complaints (clause 8) and the commentary encourages individuals to refer their complaints to the health agency first. It suggests that a satisfactory complaints procedure includes a clear entry point for complaints, independence, an opportunity for both sides to be heard, expertise in handling complaints, and prompt responses to complaints.

The Privacy Commissioner has a wide discretion not to investigate complaints that appear to be of no substance, or if the matter is stale, or if the complainant has some other adequate remedy available, or if the matter has been satisfactorily resolved. The Commissioner attempts to conciliate agreed outcomes between complainant and agency, and can, for example, call compulsory conferences for both parties to attempt to identify and resolve the issues at stake.

If the commissioner cannot obtain an agreed outcome between the parties, or if the commissioner does not consider that the complaint has substance and the aggrieved individual does not agree, the matter can be referred to the Complaints Review Tribunal. If the Tribunal finds the complaint has substance, it can order a wide range of remedies, including damages up to \$200 000, declarations, restraining orders, orders compelling the agency to redress the loss

or damage the complainant suffered, or any other relief that the Tribunal thinks fit. It can also order the unsuccessful party to pay costs.

