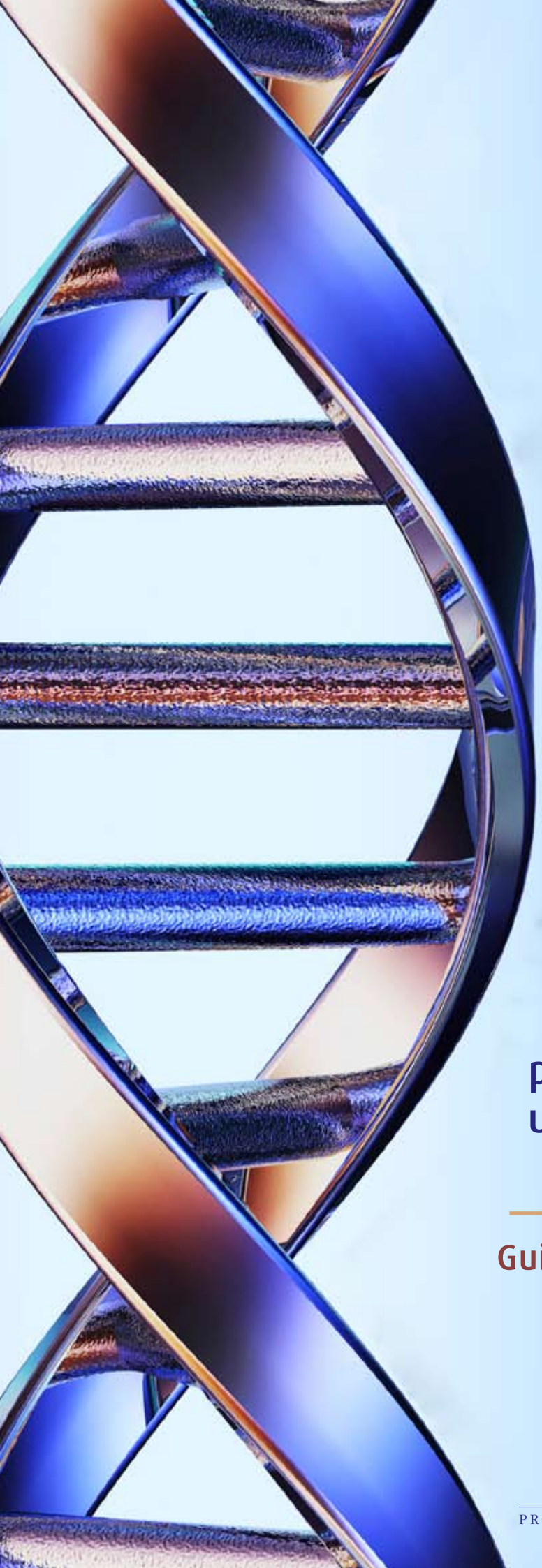

Australian Government
National Health and Medical Research Council
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Use and disclosure of genetic information to a patient's genetic relatives under section 95AA of the *Privacy Act 1988* (Cth)

Guidelines for health practitioners in the private sector

Effective from 15 December 2009

WORKING TO BUILD A HEALTHY AUSTRALIA
PROMOTING AND PROTECTING PRIVACY IN AUSTRALIA

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Contents

Introduction

The sequencing of the human genome has led to identification of the genetic basis of an ever-increasing number of conditions. Currently, the genetic basis of almost 2,000 different familial conditions has been determined (Forrest et al 2007). As a result, health practitioners will increasingly encounter people with genetic risk of disease and inherited disorders. Some of these conditions pose a **serious threat** to **life, health or safety**, and many are associated with dementia and impaired decision-making ability.

Genetic information resulting from assessment of an individual may be relevant not only to that person but also to genetic relatives, due to the shared genetic heritage within families. Depending on the nature and penetrance of the genetic condition, **genetic information** from one person can have consequences for the health of entire extended families. Because information gained through genetic testing can be seen as being relevant to a family rather than an individual alone (Davey et al 2006), people generally either notify family members themselves or give consent for health practitioners to do so. When this consent is not given, health practitioners may recognise the potential benefits of providing information to genetic relatives.

In 2003, a joint inquiry by the Australian Health Ethics Committee (AHEC) and Australian Law Reform Commission (ALRC) recommended that privacy legislation be amended to broaden the circumstances in which health practitioners may **use or disclose genetic information** without consent. The *Privacy Legislation Amendment Act 2006* (Cth) (the Amendment Act) made changes to the *Privacy Act 1988* (Cth) (the Privacy Act) to allow health practitioners **to use or disclose patients' genetic information, whether or not they give consent, in circumstances where there is reasonable belief that doing so is necessary to lessen or prevent a serious threat to the life, health or safety of their genetic relatives**. This is reflected in an additional exception to National Privacy Principle (NPP) 2 — NPP 2.1(ea) — which governs the **use or disclosure** of personal information in the private sector (see Appendix 2). NPP 2.1(ea) is more permissive than the general requirements of NPP 2.1(e) for **use or disclosure** of personal information, as the threat need not be "imminent". The inclusion of Section 95AA into the Privacy Act provides for guidelines that clarify circumstances in which **genetic information** may be **used or disclosed** without consent. The amendments **do not oblige disclosure** of information but provide the framework for this to occur under the appropriate circumstances.

The Amendment Act also introduced a requirement in the Privacy Act for the NHMRC to develop and issue these Guidelines, which must be approved by the Privacy Commissioner. In undertaking this task, the Working Committee (see Appendix 1) reviewed the amendments to the legislation, considered the ethical issues involved and developed guidelines and practical guidance.

These Guidelines came into effect on the date nominated in the approval instrument of the Privacy Commissioner. Breaches of the Guidelines may be pursued under the Complaints Procedures of the Office of the Privacy Commissioner.

Purpose

The Guidelines specify the requirements that must be met by health practitioners in the private sector if they choose to **use or disclose genetic information without patient consent** under NPP 2.1(ea). Disclosure of genetic information without consent must be in accordance with NPP 2.1(ea) and these Guidelines. In contrast to other guidelines for clinical settings developed by the NHMRC, these Guidelines have been issued with the approval of the Privacy Commissioner as the means of implementing the amendment to the legislation.

Application

These Guidelines apply to private sector **organisations** that have obtained **genetic information** in the course of providing health services to individuals (including, for example, medical specialists and general practitioners [GPs] in private practice). The National Privacy Principles[1] (NPPs) **do not** apply to the public health sector or to Australian Government, State or Territory agencies (or to **genetic information** stored in databases maintained by these agencies). Therefore, these Guidelines **do not** apply to clinical genetics services or other medical practices in the public health sector.

Section 95AA and NPP 2.1(ea) only apply to **genetic information** collected on or after 21 December 2001. They are applicable to **genetic information** about a living person.[2]

Scope

As well as reflecting the amendments to the privacy legislation, the Guidelines give general guidance that can be adapted to specific situations. These situations will differ depending on a range of factors including the genetic condition involved, relationships within the family, and the health care setting.

The scope of the Guidelines does **not** include:

- the **use or disclosure** of **genetic information** in the public health sector as this is outside the scope of NPP 2.1(ea)
- the disclosure of **genetic information** to anyone other than the patient and genetic relatives, as this is outside the scope of NPP 2.1(ea)
- situations in which consent to **use or disclose genetic information** to relatives has been given — in these cases, the provisions under NPP 2.1(ea) are not applicable as NPP 2.1(ea) is concerned with disclosure without consent[3], however, the NPPs and the **duty of confidentiality** will still need to be considered before disclosing information even with the consent of the patient
- situations concerning **genetic information** that present a **serious threat** to an unborn child, as these fall outside the intended scope of NPP 2.1(ea)
- general information about genetic assessment, clinical information to support diagnosis, use of medical records, stored genetic samples or general consent issues
- the health practitioner's professional obligation to seek, record, interpret and act on the patient's family history
- more general issues relating to the application of the Privacy Act and the **duty of confidentiality** in health
- genetic screening
- **genetic information** that is stored in databases or registers maintained by State or Territory agencies, as this is outside the scope of NPP2.1(ea)

or

- the use of **genetic information** in human research (this is discussed in Chapter 3.5 of the ***National Statement on Ethical Conduct in Human Research***).

1 Available at: www.privacy.gov.au/publications/npps01.html

2 This does not necessarily mean that genetic information about a deceased person may be disclosed to any person without restrictions. The legal duty of confidentiality that exists outside the Privacy Act may also apply to this information.

3 Scenarios 1, 2 and 3 deal with circumstances where consent has been provided or the patient chooses to contact relatives. These are included to demonstrate good practice in these more usual circumstances.

Structure of the Guidelines

The guidance in this document is intended to satisfy the purpose of Section 95AA of the Privacy Act. The document comprises four parts:

- Part A lists the nine Guidelines that specify the requirements that must be met for disclosure to take place and provides an explanation of the terms used in the Guidelines.
- Part B provides a summary of the Guidelines and key points for good practice.
- Part C includes discussion of:
  - the amendments to the Privacy Act introduced in the Amendment Act (Chapter 1)
  - ethical considerations, including factors involved in understanding specific situations (Chapter 2)
  - requirements for **use or disclosure** without consent in accordance with NPP 2.1(ea) and good practice throughout the process of decision-making and, potentially, disclosure (Chapter 3).
- Part D includes a number of scenarios, which provide general guidance on how **authorising medical practitioners** and **disclosing health practitioners** may meet the requirements under NPP 2.1(ea) and act in accordance with the Guidelines. However, it should be noted that the scenarios are to assist **organisations to** comply with NPP 2.1 (ea) and the nine Guidelines. **Acting in accordance with the scenarios does not necessarily protect against a breach of the NPPs or a breach of the duty of confidentiality (common law)** (see Appendix 2).

The appendices provide:

- information about the development of the Guidelines (Appendix 1)
- excerpts from the Privacy Act, including the NPPs (Appendix 2)
- sample materials that can be adapted for local use (Appendix 3)
- answers to frequently asked questions (Appendix 4).

Part A: The Guidelines

Guidelines for the use or disclosure of genetic information without consent

The Guidelines are presented here for easy reference. The Guidelines provide a concise outline of the requirements for acting in accordance with National Privacy Principle 2.1(ea). They should be read in conjunction with the full explanation; page references are provided in brackets.

For the purposes of National Privacy Principle 2.1(ea):

GUIDELINE 1	**Use or disclosure** of **genetic information** without consent may proceed only when the authorising medical practitioner has a **reasonable belief** that this is **necessary** to **lessen** or prevent a **serious threat** to the **life, health or safety** of a **genetic relative**.	(pp 23–33; in particular pp 23–29)
GUIDELINE 2	Specific ethical considerations must be taken into account when making a decision about whether or not to **use or disclose genetic information** without consent.	(pp 17–24)
GUIDELINE 3	Reasonable steps must be taken to obtain the consent of the patient or his or her **authorised representative** to **use or disclose genetic information**.	(pp 24–27)
GUIDELINE 4	The **authorising medical practitioner** should have a significant role in the care of the patient and sufficient knowledge of the patient's condition and its genetic basis to take responsibility for decision-making about **use or disclosure**.	(pp 27–28)
GUIDELINE 5	Prior to any decision concerning **use or disclosure**, the **authorising medical practitioner** must discuss the case with other health practitioners with appropriate expertise to assess fully the specific situation.	(pp 28–30)
GUIDELINE 6	Where practicable, the identity of the patient should not be apparent or readily ascertainable in the course of inter-professional communication.	(p 28)
GUIDELINE 7	Disclosure to genetic relatives should be limited to **genetic information** that is **necessary** for communicating the increased risk and should avoid identifying the patient or conveying that there was no consent f or the disclosure.	(pp 32–33)
GUIDELINE 8	Disclosure of **genetic information** without consent should generally be limited to relatives no further removed than third-degree relatives.	(p 33)
GUIDELINE 9	All stages of the process must be fully documented, including how the decision to use or disclose without consent was made.	(p 33)

Explanation of terms used in the Guidelines

A number of key terms are used in these Guidelines. Most of these are not defined in the Privacy Act. To aid readers, the way in which certain terms are used in these Guidelines is explained below. These explanations are included to assist clarity and do not constitute an interpretation of the legislation. Where a word or phrase is used in its defined sense, the word or phrase will appear in bold in these Guidelines. Otherwise the word or phrase should be interpreted according to its ordinary meaning.

Authorised representative

In situations where a person is legally or physically incapable of making the relevant decisions, a representative of this person is generally involved (eg parent, guardian, or person who holds an enduring power of attorney). Legislation in each State and Territory authorises certain people to make decisions for those lacking the capacity to do so. The scope of this legislation varies between each State and Territory and there are differences regarding the powers, rights and responsibilities of people who are in a position to make decisions for those lacking the capacity to do so. The authorised representative may be someone other than a genetic relative of the individual (eg his or her spouse). However, being a close relative or spouse does not automatically convey status of authorised representative.

Authorising medical practitioner

While a range of professionals may be involved in the care of a particular patient, final responsibility for decision-making on behalf of an organisation about use or disclosure should be taken by a person in the organisation who is a senior medical practitioner who has a significant role in the care of the patient, has sufficient knowledge of the patient's condition and of its genetic basis and has sought expert advice. This person may be a medical specialist or a general practitioner, as long as these criteria are met.

Cascade contact

A step-by-step process that can provide access to **genetic information** for a wider cross-section of a family, in which each genetic relative who is notified about their increased risk and makes contact with the **disclosing health practitioner**, is asked for consent to contact his or her genetic relatives. When additional genetic relatives make contact, the process is repeated.

Confidentiality

The general non-legal principle concerned with the obligation of people not to use private information – whether private because of its content or the context of its communication — for any purpose other than that for which it was given to them (definition from the *National Statement on Ethical Conduct in Human Research*; NHMRC, ARC & AVCC 2007b).

Disclosing health practitioner

Once a decision has been made that disclosure without consent is **necessary**, the process of disclosure can be undertaken by the **authorising medical practitioner**. In these circumstances, the **authorising medical practitioner** will be the **disclosing health practitioner**. Alternatively, the **authorising medical practitioner** can identify another suitably experienced and qualified professional to make the disclosure without consent (eg a genetic counsellor). In these circumstances, the person identified will be the **disclosing health practitioner**.

Duty of confidentiality

It is common for a person to disclose information to another person with the intention that the information will only be used for a particular purpose, particularly in a health practitioner/patient

relationship. In these circumstances the common law (the law developed through decision of courts rather than through legislation) recognises that an obligation or duty of confidence may arise and that the confidential information can only be used or disclosed with the consent of the party who communicated the information.

Note: The **duty of confidentiality** is in addition to the obligations set out in the Privacy Act.

Genetic information

The amendments to the Privacy Act alter the definitions of "health information" and "sensitive information" to include "genetic information", without expressly defining "genetic information". In its 2003 report, the Australian Law Reform Commission did not apply a precise or exhaustive definition to "genetic information", preferring to suggest consideration of the context to determine whether the use of genetic-related information requires any special handling or protection. It notes that genetic information is gained from a range of sources (eg clinical examination, DNA testing and chromosome studies, newborn screening, family history) and may confirm a condition that is clinically apparent, or be predictive of the likelihood of an individual developing or carrying a mutated gene causing a condition.

Genetic relative

This term is defined as follows in Section 6 of the Privacy Act: "genetic relative of an individual (the first individual) means another individual who is related to the first individual by blood, including but not limited to a sibling, a parent or a descendant of the first individual". In the context of these Guidelines, disclosure without consent is generally recommended to relatives no further removed than third-degree relatives[4], as the process of **cascade contact** should facilitate access to information for the wider cross- section of a family.

Lessen

The term "lessen', as used in NPP 2.1(ea), requires an authorised person to form a **reasonable belief** that the contemplated **use or disclosure** of **genetic information** would reduce the **serious threat** that exists to an individual's **life, health or safety**. In circumstances where a contemplated **use or disclosure** would **not** reduce a **serious threat** to **life, health or safety**, or assist in reducing that threat, the exception as described in NPP 2.1(ea) will not apply.

Life, health or safety

The phrase "life, health or safety', including as it is used in NPP 2.1(ea), ordinarily refers to both physical or psychological/emotional health.

Necessary

"Necessary" is defined by the *Macquarie Dictionary* to mean "something necessary, indispensable, or requisite". Applying this ordinary meaning in the context of NPP 2.1(ea), it can be said that **use or disclosure** of **genetic information** will be "necessary" when it is requisite to achieving the stated outcome. Deciding whether disclosure is "necessary" should therefore be based on whether it will lead to the intended outcome, that is, whether disclosure will **lessen** or prevent a **serious threat** to **life, health or safety**. See Section 3.3.3.

Organisation

All health service providers in the private sector are "organisations', by operation of sections 6C and 6D of the Privacy Act (see Appendix 2).

4 Third-degree relative has been chosen for practical reasons eg for later onset/potentially fatal disorders like familial cancer it is possible that first and second-degree relatives are deceased and so specifying third-degree relatives gives health professionals the scope needed to reach other relevant family members.

Note: Except where a health service provider is a sole trader, the obligations under the NPPs are not imposed on individual health practitioners directly. Rather, the obligations are imposed on the health service provider for whom the health practitioner works. Nevertheless, the practical effect of the Privacy Act is that health practitioners working for a health service provider are required to act consistently with NPP2.1(ea) when they seek to **use or disclose genetic information** on behalf of the health service provider. Accordingly, these Guidelines have been drafted in a way to guide health practitioners who work for health service providers.

Privacy

While the Privacy Act regulates the collection, use and disclosure, quality and security of personal information, there is no general legal right to privacy in Australian law. Therefore, when the term "privacy" is bolded in these Guidelines the term is a reference to the general, non-legal, principle used to describe the domain within which individuals and groups are entitled to be free from the scrutiny of others (definition from the *National Statement on Ethical Conduct in Human Research*; NHMRC, ARC & AVCC 2007b).

Reasonable belief

"Reasonable belief" is a belief that results from the exercise of sound judgement. If an organisation sought to rely on "reasonable belief" they would need to be able to explain, drawing on their experience, training and expertise, the basis on which they formed that belief.

Serious threat

The Office of the Privacy Commissioner guidelines on health privacy[5] states that a "serious" threat "must reflect significant danger to the individual and could include a potentially life-threatening situation or one that might reasonably result in serious illness or injury". In the context of these Guidelines, there must be a **reasonable belief** by experts in the field that the threat reflects a significant danger to the individual, which may or may not be imminent. This could include a potentially life-threatening situation, or one that might result in an illness or injury or the threat of a disease or psychological harm that may result in death or disability without timely decision or action.

Use or disclosure

The "use" of **genetic information** refers to the sharing of **genetic information** within an **organisation**, and "disclosure" refers to the sharing of information outside an **organisation** (eg with the patient's **genetic relatives**).

5 Available at: www.privacy.gov.au/publications/hg01_pdf

Part B: Summary and Practical Guide

What are these guidelines for?

These Guidelines were developed in response to changes to the Privacy Act and to NPP 2 that provide for disclosure of **genetic information** to **genetic relatives** without the consent of the patient in certain circumstances. The additional exception introduced through NPP2.1(ea):

- allows **use or disclosure** of a patient's **genetic information**, without the patient's consent, in circumstances when there is **reasonable belief** that disclosure is **necessary** to **lessen** or prevent a **serious threat** to the **life, health or safety** of his or her **genetic relatives**
- applies to private sector **organisations** that have obtained **genetic information** in the course of providing health services to individuals (these include private medical practices, pathology services, private hospitals) and their employees
- applies only to **genetic information** concerning a living person that was collected by an **organisation** on or after 21 December 2001
- does not apply to situations concerning **genetic information** that presents a **serious threat** to an unborn child.

Disclosure without consent has the potential to cause distress. Appropriately managing the patient or **authorised representative** in such situations is considered an integral part of duty of care and good practice.

When can disclosure without consent take place?

The Guidelines establish when, by whom and in what manner **use or disclosure** of **genetic information** may take place without patient consent, with particular reference to the statutory test set out in NPP 2.1(ea). That test provides for disclosure when there is:

- a **serious threat** to **life, health or safety** of a **genetic relative**
- the **use or disclosure** is **necessary** to **lessen** or prevent that threat.

In the event that this statutory test is satisfied and the patient or his or her **authorised representative** has not given consent for **use or disclosure**, conveying this information to **genetic relatives** is permitted only if done in accordance with these Guidelines. The obligations created by the other NPPs (see Appendix 2) and **duty of confidentiality** are other considerations. The application of the Guidelines is considered in more detail below.

NPP 2.1(ea) **does not** create a legal obligation to **use or disclose** a patient's **genetic information**.

As disclosure without consent represents a significant departure from normal practice and is only permissible in certain circumstances, medical practitioners may wish to consult their medical defence organisation before authorising disclosure.

To provide general guidance so that authorising medical practitioners may meet the requirements under NPP 2.1(ea) and act in accordance with the Guidelines, some scenarios are included in Part D. It should be noted that the scenarios are to assist compliance with NPP 2.1 (ea) and the nine Guidelines given here. Acting in accordance with the scenarios does not necessarily protect against a breach of the NPPs or a breach of the duty of confidentiality.

How are the guidelines applied?

GUIDELINE 1	***Use or disclosure*** of ***genetic information*** without consent may proceed only when the ***authorising medical practitioner*** has a ***reasonable belief*** that this is ***necessary*** to ***lessen*** or prevent a ***serious threat*** to the ***life, health or safety*** of a ***genetic relative*** (see pp 28–33).

When consent is withheld, the **authorising medical practitioner** will first need to determine whether there is a **serious threat** to **genetic relatives**, taking into consideration:

- the nature of the condition, its associated risks and treatment or care options
- the probability that a **genetic relative** may also have the condition or be a carrier of the relevant mutation.

If a **serious threat** to the **life, health or safety** of **genetic relatives** is identified, it should then be determined whether the potential to **lessen** or prevent the threat exists. Considerations include:

- whether the condition is preventable or manifestations treatable (eg whether the relatives can benefit from the information)
- if the disease is incurable, whether knowledge of the condition would allow optimal management.

Before making a non-consensual **use or disclosure**, the **authorising medical practitioner** must form a **reasonable belief** that such an act is **necessary** to **lessen** or prevent the identified threat to **genetic relatives**. It must be determined whether a means other than **use or disclosure** exists to **lessen** or prevent the threat. The decision to **use or disclose** without consent must be made in good faith, with the health practitioners involved in the decision-making drawing on their experience, training and expertise.

Key points for good practice are to:

- hold further discussions with the patient and ask that they reconsider the refusal of consent if there is **reasonable belief** that there exists a **serious threat** to the **life, health or safety** of a **genetic relative** (see pp 29–30)
- allow time for review of the decision and consider arranging genetic counselling before further discussion of **use or disclosure** when patients or their **authorised representatives** choose to withhold consent — unless the nature of the condition requires an urgent response (see pp 24, 29–30)
- discuss the basis of this decision and the process of disclosure with the patient or the **authorised representative** of the person if **use or disclosure** without consent is considered **necessary** (see p 30)
- be aware of the potential for patient distress and manage this appropriately.

The **authorising medical practitioner** may decide that disclosure should not proceed. This may be because:

- the requirements for disclosure without consent have not been met
- all the requirements have been met but there are extenuating circumstances in the family to defer disclosure — in which case it may be appropriate not to proceed with disclosure without consent, or if appropriate in the clinical circumstances, to wait until the family's situation changes
- all the requirements have been met but the medical practitioner is unwilling to disclose — in which case the practitioner should consider identifying another medical practitioner to review the circumstances.

If disclosure is permissible but the health practitioner is unwilling to disclose, he or she should consult another suitably qualified and experienced health practitioner and consider whether it would be more appropriate for the information to be disclosed by another health practitioner.

Health practitioners have an ethical obligation to advise the patient or the **authorised representative** to inform relatives of the diagnosis, but are under no legal obligation to disclose the information to

genetic relatives themselves, whether consent is given or not. As the law currently stands, there is no valid basis to suggest that a doctor could be liable for non-disclosure.

Whatever decision is made, the process of decision-making must be documented in writing, including details of the reasons for the decision.

What ethical points need to be considered?

GUIDELINE 2	Specific ethical considerations must be taken into account when making a decision about whether or not to **use or disclose genetic information** without consent (see pp 17–24).
GUIDELINE 3	Reasonable steps must be taken to obtain the consent of the patient or his or her authorised representative to use or disclose **genetic information** (see pp 24–27).

In providing guidance on meeting the requirements of the NPPs, the guidelines aim to ensure that ethical considerations are taken into account throughout the process of decision-making concerning the **use or disclosure** of **genetic information** without consent.

A health practitioner has an ethical obligation to maintain the **confidentiality** of information about his or her patient. With genetic conditions, an ethical responsibility can also be seen to extend to the wider family so that every effort is made to encourage sharing of information with relatives at risk. Only if these efforts are unsuccessful and the patient or his or her **authorised representative** continues to withhold consent should the **authorising medical practitioner** consider using or disclosing **genetic information** as outlined in these guidelines.

Whether or not the patient agrees that **genetic relatives** should be notified, the process of sharing **genetic information** should aim to maintain respect, as far as is possible, for the autonomy and **confidentiality** of the patient and the **genetic relatives**.

Key points for good practice are to:

- explain to the patient the implications for **genetic relatives** and why they should be informed of any risk to them (see p 23);
- advise that in certain circumstances, **use or disclosure** may be made without consent (see p 23);
- consider referring patients to a health practitioner with expertise in conveying relevant **genetic information** or consult such an expert (see p 24);
- consider arranging timely genetic counselling for patients or referring them to an organisation that provides genetic counselling (see p 24);
- establish whether the patient is competent to make decisions concerning disclosure of his or her **genetic information** (an **authorised representative** can then be identified) (see p 25);
- take reasonable steps to enable patients who have impaired decision-making ability or are children or young people to be involved in decision-making (see pp 25–26);
- seek independent advice to ensure that the person's best interests are respected if consent to **use or disclose genetic information** concerning an adult with impaired decision-making ability or a child or young person is sought;
- ensure attempts are made to ascertain what the patient's wishes would likely have been before being affected by the disease if he or she is not competent to make decisions about disclosure of **genetic information** (see pp 25); and
- follow the principles and guidance given in the NHMRC guidelines on communicating with patients (NHMRC 2004a) and on providing patients with information (NHMRC 2004b) when communicating with patients (see p 17).

If consent is provided, the provisions under NPP 2.1(ea) are not applicable.

Who is responsible for decision-making and disclosure?

GUIDELINE 4	The **authorising medical practitioner** should have a significant role in the care of the patient and sufficient knowledge of the patient's condition and its genetic basis to take responsibility for decision-making about **use or disclosure** (see pp 27–28).
GUIDELINE 5	Prior to any decision concerning **use or disclosure**, the **authorising medical practitioner** must discuss the case with other health practitioners with appropriate expertise to assess fully the specific situation (see pp 28–30).
GUIDELINE 6	Where practicable, the identity of the patient should not be apparent or readily ascertainable in the course of inter-professional communication (see p 28).

If a patient withholds consent to **use or disclose genetic information**, timely review of the situation by a health practitioner with relevant expertise is needed to determine the nature of any threat to relatives and the necessity for **use or disclosure** to **lessen** or prevent the threat. It is required that a medical practitioner takes responsibility for the process as **authorising medical practitioner**, even if another professional (eg a genetic counsellor with requisite knowledge of the particular condition) takes on the role of **disclosing health practitioner**.

It is important that the decision to proceed with **use or disclosure** of **genetic information** is made only after discussion with experienced colleagues, even when the medical practitioner involved is experienced in the field. In such discussions, wherever practicable, the **authorising medical practitioner** should not reveal the identity of the patient either verbally or in writing.

Key points for good practice are to:

- seek advice on the nature of the threat to **genetic relatives** and on the necessity for disclosure without consent, from colleagues and relevant experts and/or committees. Document the outcomes of these discussions (see pp 28–29)
- refer the patient to another medical practitioner with the appropriate expertise or consult colleagues and outside experts if not expert in the field yourself (see p 27)
- organise discussion of the case so that all involved have time to prepare and document the outcomes of these discussions (see p 28)
- identify another medical practitioner who is able to fulfil the role if unwilling to undertake the role of **authorising medical practitioner** (see p 22).

How does disclosure take place?

Guideline 7	Disclosure to **genetic relatives** should be limited to **genetic information** that is **necessary** for communicating the increased risk and should avoid identifying the patient or conveying that there was no consent for the disclosure (see pp 32–33).
Guideline 8	Disclosure of **genetic information** without consent should generally be limited to relatives no further removed than third-degree relatives (see p 33).
Guideline 9	All stages of the process must be fully documented, including how the decision to **use or disclose** without consent was made (see p 33).

Many ethical concerns associated with disclosure can be mitigated through careful structuring of the way in which **genetic relatives** are contacted. Disclosure of **genetic information** needs to be

sensitively handled with due consideration to the **confidentiality** of the patient, the preference of **genetic relatives** not to receive unsolicited information concerning their health, the autonomous right of **genetic relatives** to receive information affecting their future health, and the importance of offering genetic counselling.

The collection of contact details of genetic relatives must accord with the Privacy Act, particularly NPPs 1 and 10.

In order to disclose information to **genetic relatives**, health practitioners would generally not be permitted to obtain contact details of the **genetic relatives** without those individuals' consent or by lawful authority.

A separate Information Sheet is available from the Privacy Commissioner in relation to obtaining the contact details of **genetic relatives** for the purpose of disclosure of genetic information.

Key points for good practice are to:

- continue to exercise a professional duty of care to the patient whether or not consent for **use or disclosure** is given (p 33)
- notify the patient that a decision has been made to disclose without consent and advise them when disclosure has taken place unless there is a contraindication (p 30)
- provide written information, which gives the recipient the opportunity to decide whether or not to seek further information (in some circumstances telephone contact may be more appropriate) (see p 32)
- take steps to ensure that any information provided to **genetic relatives** does not directly identify the patient, the genetic condition or that consent was not given for the disclosure (p 32)
- consider using a step-by-step process of **cascade contact** if contemplating making contact beyond first-degree relatives (p 33)
- fully document all stages of the process, including how decisions were made. It is also important to document situations where a decision is taken not to disclose (p 33).

A sample letter that may be used as a template for contact or as the starting point for **cascade contact** is included in Appendix 3.

FRAMEWORK FOR LEGAL AND ETHICAL USE OR DISCLOSURE OF GENETIC INFORMATION

Notes:

This framework is provided as a summary only and should be used in conjunction with the Guidelines.

- When a patient is assessed for a genetic condition that has the potential to have serious implications for **genetic relatives,** these should be discussed and the patient or the **authorised representative** of the person advised of the potential for **genetic information** to be used or disclosed without consent in certain circumstances.
- In situations where the patient's decision-making ability is limited (eg due to the impact of the disease process on memory or understanding), reasonable steps are required to ensure that the patient's understanding is as thorough as possible. It may be **necessary** to involve an **authorised representative** of the person (see explanation of terms on p 5). There are legislative differences between jurisdictions regarding the powers, rights and responsibilities of people in this role. Attempts should be made to ascertain what the patient's wishes would likely have been before he or she became affected by the disease.
- Throughout this process a medical practitioner with appropriate expertise and a significant role in the patient's care will take responsibility for decision-making. In seeking advice from colleagues, this professional should not reveal the identity of the patient.
- If disclosure without consent is to take place, the patient should be notified of this decision unless there is a contrary indication for doing so.
- All stages of the process should be documented, including reasons given if consent is withheld.
- If consent is provided, the provisions under NPP 2.1(ea) are not applicable. The NPPs (see Appendix 2) and common law apply.

PART C: Considerations when deciding whether to disclose without consent

Decisions regarding **use or disclosure** of **genetic information** without patient consent should be made after careful consideration of:

- Australian privacy legislation (see Chapter 1)
- context for decision making (see Chapter 2)
- practical considerations (see Chapter 3).

1 Australian privacy legislation

The Privacy Act covers the collection, use and disclosure, access to, quality and security of personal information in Australia. As well as providing principles to regulate these areas (see below), the Privacy Act, among other things, provides a framework for complaints about breaches of the Act, and defines the role of the Privacy Commissioner.

The Privacy Act regulates Australian Government and ACT agencies,[6] most private sector businesses with an annual turnover of more than $3 million and all health service providers in the private sector. Section 6 of the Privacy Act defines "health service" as an activity performed in relation to an individual:

- to assess, record, maintain or improve the individual's health[7]
- to diagnose the individual's illness or disability
- to treat the individual's illness or disability or suspected illness or disability

  or

- the dispensing of a prescription drug or medicinal preparation by a pharmacist.

The Privacy Act applies to all private sector **organisations** that deliver these types of services, including small health service providers. This includes private hospitals and day surgeries, health practitioners in private practice, private sector pharmacists, and allied health professionals such as counsellors.

1.1 National Privacy Principles

The Privacy Act contains two sets of principles — the Information Privacy Principles, which apply to Australian Government and ACT agencies, and the National Privacy Principles (NPPs), which came into effect on 21 December 2001 and apply to **organisations** in the private sector (see Appendix 2).[8] The NPPs aim to ensure that **organisations** that hold information about people handle that information responsibly. Of particular relevance to these Guidelines are NPPs 2 and 10 and the Public Interest Determinations 10 and 10A[9] (2007), which establish exemptions from the requirements in NPP 10 in certain circumstances to allow the collection of family histories.

6 The ACT has its own privacy legislation for health information held by its agencies; therefore health information held by ACT agencies is not covered by the Privacy Act.

7 In this context, this includes matters relating to prevention and identification of illness.

8 These principles also govern most private sector organisations that earn more than $3 million annually. The handling of personal information by Australian Government and ACT agencies is governed by the Information Privacy Principles.

9 Available at www.privacy.gov.au/act/publicinterest/index.html#1

The **use or disclosure** of personal information is governed by NPP 2. Under NPP 2, a health practitioner may **use or disclose** health information only for the purpose it was collected, unless a prescribed exception applies, such as:

- for a directly related secondary purpose within the patient's reasonable expectations
- where the patient consents
- where required or authorised by law
- where any other exception applies.

NPP 10 is concerned with the collection of sensitive information, which is defined in Section 6 of the Privacy Act and includes all health information. NPP 10.1 prohibits the collection of sensitive information about individuals, unless a prescribed exception applies, such as where an individual consents. However, the collection of a family member's health information as part of taking a patient's family history is permissible (under Public Interest Determinations 10 and 10A) as long as the information collected is relevant and necessary to the direct care of the patient.

1.2 *Privacy Legislation Amendment Act 2006*

In 2006 the Privacy Act was amended to give effect to the Australian Government's decision to implement some of the recommendations of the Australian Law Reform Commission (ALRC) and the Australian Health Ethics Committee in their report *Essentially Yours: the Protection of Human Genetic Information in Australia*. The *Privacy Legislation Amendment Act 2006* (the Amendment Act) amended the law relating to the protection of genetic information so that **genetic information** can be disclosed to **genetic relatives** in certain circumstances. The amendments apply to **genetic information** collected after 21 December 2001 and prevail over State or Territory privacy legislation, to the extent that these laws are inconsistent.

Health information and sensitive information

The amendments to the Privacy Act aim to safeguard the handling of **genetic information** by amending the definitions of "health information" and "sensitive information" to expressly include **genetic information**. **Genetic information** that is (or could be) predictive of the health of an individual is now treated as health information for the purposes of the Privacy Act (see explanation of **genetic information** on p 6). **Genetic information** that is not otherwise health information, such as the result of a parentage test, is treated as sensitive information for the purposes of the Privacy Act.

The Amendment Act also includes a definition of a "genetic relative" of an individual (the first individual) as "another individual who is related to the first individual by blood, including but not limited to a sibling, a parent or a descendant of the first individual."

Changes to the National Privacy Principles

The Amendment Act introduced an additional exception to the general requirement that personal information must not be used or disclosed for any other purpose other than that for which it was collected. The inclusion of an additional exception in NPP 2.1(ea) (see Appendix 2) allows for the **use or disclosure** of **genetic information** to a patient's **genetic relatives** if the **organisation** reasonably believes that this is **necessary** to **lessen** or prevent a **serious threat** to **life, health or safety** of the relative, even if the threat is not imminent and consent has not been given.

Inclusion of Section 95AA

The inclusion of Section 95AA into the Privacy Act allows the Privacy Commissioner to approve guidelines developed by the NHMRC to clarify circumstances in which **genetic information** may be used or disclosed without consent.

NPP 2.1(ea) requires that **use or disclosure** of **genetic information** by a health practitioner without the consent of the patient be conducted in accordance with these Guidelines.

2 Context for decision-making

2.1 Meeting individual needs

2.1.1 Communication

Effective communication from the first consultation may help the patient to fully understand the implications of the **genetic information** being discussed and avoid a situation where he or she refuses consent to disclose **genetic information** to **genetic relatives**. Good communication can also help the health practitioner to understand and respect the patient's decisions about disclosure.

NHMRC guidelines on communicating with and providing information to patients (NHMRC 2004a; 2004b) identify obstacles (eg anxiety about the condition, family discord) that may make the patient less able to take in or provide information and make decisions. They also identify obstacles that may prevent the health practitioner from fully appreciating the views of the patient.

Even where there are obstacles, better communication can be fostered through:

- establishing rapport and using active listening techniques
- helping patients to express themselves and to understand and retain the information given
- using plain language that is free of clinical terms and reinforcing discussions with written and other relevant materials and services (eg video, websites, advice on relevant support groups, interpreters)
- considering the environment and length of consultation required before communicating potentially distressing news.

Patients will differ in the amount of information and support they require and there may be particular difficulties in communicating with patients with dementia or cognitive difficulties. The pace of information provision should be determined by each patient's needs and the particular situation.

2.1.2 Cultural and lifestyle factors

Health practitioners see patients from a range of ethnic, cultural and socio-economic backgrounds, and should aim to ensure good communication regardless of the social or cultural background of patients. As well as following general principles of good communication, additional strategies that may be helpful include (NHMRC 2004a):

- asking questions to appreciate the patient's understanding of health and disease
- establishing an environment that welcomes and affirms each patient regardless of background
- negotiating with the patient about using the assistance of agents such as patient advocates, family members, pastoral care workers or spiritual leaders
- seeking advice from community agencies that understand and advocate for patients.

Qualified interpreters and culturally appropriate materials should be available for people from culturally and linguistically diverse backgrounds. Where this is not possible, telephone interpreter agencies can provide relevant services. However, not all cultural groups welcome the involvement of non-family members in such circumstances and health practitioners need to be aware of and sensitive to this possibility (NHMRC 2004a).

Effective communication with Aboriginal and Torres Strait Islander patients requires consideration of cultural factors such as (NHMRC 2005):

- beliefs that the concept of a family differs from that of genetic connections
- the recognition of both "blood" and "skin" relationships
- the complexity of Aboriginal and Torres Strait Islander lore, which affects communication within families and communities
- the importance of family and community involvement in decisions about health care
- a holistic view of health that includes cause and effect arising from the body, the spiritual, the land and dreaming
- the high degree of mobility among Aboriginal and Torres Strait Islander peoples
- the unique issues relevant to people that live in remote areas of Australia.

Involving an Aboriginal and Torres Strait Islander Hospital Liaison Officer and/or Health Worker, with the patient's agreement, can help to ensure that communication takes place in a culturally appropriate way and that the patient's understanding of the term **genetic relative** is clear. In cases where disclosure without consent is a possibility, advice from senior community members or Elders may assist in decision-making about the appropriate course of action after careful consideration. Initial contact with Elders should be made with discretion ensuring protection of the individual's privacy.

2.2 Understanding the situation

2.2.1 Settings

With the increasing use and utility of genetic testing, there is a widening range of settings in which **genetic information** is discussed. Settings relevant to these Guidelines include (but are not limited to) private hospitals, specialists' private rooms and general practice. Genetics services and familial cancer units are ideally positioned to deliver pre- and post-test counselling and involve at-risk family members as necessary. Outside these settings, the advice of other health practitioners may need to be sought.

2.2.2 Diagnostic and predictive testing

The results of genetic tests are not always straightforward, which can make them difficult to interpret and explain. The degree of uncertainty will affect discussion of the implications of the results for patients and their **genetic relatives**. Family history and experience are also important in determining how an individual will react to the results of genetic testing (Evans et al 2001).

- *Diagnostic testing* — This is done for patients who have clinical signs of disease to confirm or rule out a suspected genetic condition. While a positive result confirms a clinical diagnosis, it still cannot accurately predict the exact course of the disease, and in some situations, the exact phenotype.
- *Predictive testing* — While some heritable diseases are caused by changes in specific genes, most are caused by the interaction of multiple genes with each other and with environmental factors (Petrila 2001). Predictive or presymptomatic genetic testing is done in well individuals to predict future risk of disease.

In some cases, a single test can reveal both predictive and diagnostic information. For example, a diagnostic test for fragile X syndrome in a boy with intellectual disability may reveal a full mutation in the fragile X gene that explains his disability. This result would also have implications for **genetic relatives** who may carry a pre-mutation that puts them at increased risk of developing a neurodegenerative disorder in later life.

2.2.3 Nature of the genetic condition

The type of **genetic information** being discussed will vary widely, depending on the probability that someone with the mutation will develop the condition, whether the condition is serious or life threatening if it does develop, and whether it is preventable or treatable. The risk of a person developing the familial disease may vary for many reasons, including age, gender, and degree of relationship with an affected person. For example, **genetic information** may:

- be considered by the health practitioner or the patient as being straightforward
- imply an increased risk but no certainty of developing a disease
- have serious implications for present and future generations
- concern a condition that is presently incurable but has serious manifestations of which the patient is unaware that can be ameliorated

  or
- have the potential to cause significant psychological harm.

The nature of the genetic condition will influence decision-making on the benefits of informing the patient's **genetic relatives** because:

- the more serious the condition, the more important it is to consider the implications for **genetic relatives** and how they should be alerted to the option of genetic assessment
- the degree of risk for different **genetic relatives** will vary depending on the underlying condition and its penetrance as well as on the closeness of the relationship with the patient.

2.2.4 Family situation

Being aware of dynamics and pressures within a family can help health practitioners understand patients' reactions when they find out that they have a genetic condition. While many patients wish their information to be available to help their **genetic relatives**, there are a number of reasons why patients or their **authorised representatives** may choose not to provide this information to relatives (Clark et al 2005), including:

- cognitive change preventing the person from organising contact
- shielding others from distress, particularly in the absence of effective therapy
- breakdown of relationships within the family
- denial about the condition leading to unwillingness to admit the situation to others
- uncertainty about how or when they should share information with their **genetic relatives**
- thinking that a **genetic relative** is too unwell or busy to hear the news
- cultural, religious and spiritual factors
- fear of the potential for discrimination or stigmatisation if anyone else is told
- not understanding or acknowledging that others in the family may be at risk
- having the perception that **genetic relatives** would prefer not to know
- financial implications (eg information compromising subsequent applications for life or disability insurance, potential impact on superannuation)
- fear of establishing or revealing non-paternity, or non-maternity.

If the patient's motivation is based on a lack of understanding or denial, exploring feelings and reactions may help him or her to reverse the decision not to share the information. However, when there is a long-term estrangement, patients may have completely lost touch with **genetic relatives** and they may be unable as well as unwilling to make contact.

2.2.5 Special situations

For some patients there may be an additional level of complexity in the decision-making process. This may be due to their limited understanding and consequent inability to give informed consent (for example, due to the impact of the disease process on memory or understanding, or maturity levels). Decision-making in situations involving adults who have impaired decision-making or children and young people is discussed more fully in Section 3.1.3.

2.3 Ethics in decision-making

2.3.1 Ethical issues raised by sharing genetic information

In the context of these Guidelines, there are a number of ethical principles underpinning the practice of sharing **genetic information**, which are discussed briefly here and are the basis of the guidance given in Chapter 3. If a patient does not give consent for **use or disclosure**, there is likely to be conflict between the practitioner's ethical obligations to the patient and to his or her **genetic relatives**, which needs to be considered as part of the decision-making process.

Justice

Health practitioners may feel a responsibility not only towards their patients but also to the relatives that share their genetic heritage, as **genetic information** can be seen to be relevant to a family rather than to an individual alone (Davey et al 2006). Clinical genetics practice aims to make the family rather than an individual the unit of care and offers access to the benefits of genetic assessment to family members when the patient gives consent for them to be contacted. The ethical principle underpinning this sharing of information is justice, which may be breached if one member of a family benefits from genetic assessment and at the same time is allowed to exclude others in the family from access to such benefits (Parker & Lucassen 2004).

Beneficence

The likely benefits to **genetic relatives** must justify any risks of harm or discomfort to patients if information is used or disclosed without their consent. Most guidelines in this area agree that a health practitioner's minimum ethical responsibility is to tell patients about the implications of their **genetic information** for their family members, and to actively encourage patients to share this information with **genetic relatives** (Forrest et al 2007). Discussion about the condition may help patients to understand their genetic risks and those of their **genetic relatives** (Forrest et al 2007), and assist in avoiding a situation where consent to **use or disclose** is withheld.

Respect

Respect for human beings is a recognition of their intrinsic value. Respect also requires having due regard for the welfare, beliefs, perceptions, customs and cultural heritage of individuals (NHMRC, ARC, AVCC 2007). In this context, **confidentiality**, which has a long-established tradition in medicine, is relevant to respecting the patient's welfare. Ethically, this is based on the widely accepted view that competent patients should have control over decisions concerning their medical care, including the right to decide what happens to information about them. A further justification for respecting patient **confidentiality** arises out of concern that breaching **confidentiality** can undermine trust in the relationship between health practitioners and patients (Parker & Lucassen 2004). The potential for harm to individuals, and ultimately society, from breaching patient **confidentiality** contributes significantly to the ethical dilemma faced by health practitioners when patients withhold consent to disclose information to their **genetic relatives**.

2.3.2 Benefits and risks of sharing genetic information with genetic relatives

The process of informing **genetic relatives** about possible risk must be managed carefully. There are ethical issues to consider even when the patient gives consent.

The possibility that **genetic relatives** may not want to be informed about their risk is also a consideration. However, in most cases the health practitioner is unlikely to know the preferences of the **genetic relatives**.

However, once relatives have been informed of a genetic risk, they may prefer not to undergo further assessment to learn their own genetic status. There is a range of reasons for not wanting to undertake such assessment, including fear of discrimination, anxiety, denial, lack of knowledge, perceptions of pressure (Swartling et al 2007) and autonomy (Malpas 2005; Wilson 2005).

The box below indicates some benefits and risks of informing **genetic relatives** about possible risk.

Potential benefits of disclosing

- Clarification of the risk status of clinically unaffected relatives so that they can consider predictive genetic testing (if available) and plan future medical and other life decisions.
- The possibility for steps to be taken to reduce the risk of disease or allow early diagnosis and management, including for the manifestations in as yet incurable conditions.
- The avoidance of the need for other investigative interventions if genetic testing identifies the relative as a non-carrier.
- The avoidance of mistaken diagnosis (of another condition) and inaccurate treatment.
- In some cases, shared knowledge of the genetic condition within the family may help to avoid family breakdown and anger.

Potential risks of disclosing without consent

- Possibility of the **privacy** of the patient being affected.
- Possibility of losing the patient's trust and confidence.
- Difficulties in the process of advising **genetic relatives** even if patient is willing to share **genetic information**.
- Potential for patient uncertainties about the practicalities of disclosure.
- **Genetic relatives** feeling that receiving unsolicited information about possible genetic risk is an invasion of **privacy**.
- Perceived pressure on **genetic relatives** to undertake genetic assessment.

Source: Adapted from Suthers et al 2006.

2.3.3 The ethics of disclosing without consent

Any departures from maintaining a patient's **confidentiality** must be taken very seriously (AMA 2006), and should be the exception rather than the rule. Accordingly, any decision to disclose **genetic information** to a patient's **genetic relatives** without the patient's consent must be made extremely carefully, weighing the patient's **privacy** and autonomy against the potential to **lessen** or prevent serious harm for **genetic relatives** (Falk et al 2003).

In addition to ensuring that **use or disclosure** meets the requirements of NPP 2.1(ea), the decision involves consideration of:

- the likely effect on the patient of breaching **confidentiality**
- the possible ambivalence of **genetic relatives** to receiving **genetic information**.

The scenarios in Part D illustrate these considerations.

2.3.4 The ethics of non-disclosure

Even in circumstances where disclosure without consent would otherwise be permissible on the basis of the decision-making process outlined in these Guidelines, the treating health practitioner may be unwilling to disclose. This may be because of a belief that it is never acceptable for a clinician to breach a patient's **confidentiality** in the interests of others, or for other reasons.

The box below indicates some benefits and risks of not disclosing.

Potential benefits of not disclosing

- Avoids breaching **confidentiality**.
- Avoids potential for disruption to patient/doctor relationship.
- Avoids causing anxiety to relatives.
- Potential to reduce harm to family relationships.

Potential risks of not disclosing

- Relatives are left unaware of potential risk.
- Potentially preventable harm cannot be averted.
- Relationships within family may be damaged when relatives discover that information was not passed on to them.
- Relatives who were not informed due to a deliberate decision by a health practitioner not to disclose may be distressed and experience harm as a result.

Guidance on the practical and legal aspects of non-disclosure is given in Section 3.3.5.

3 Practical considerations

3.1 Application of the guidelines

GUIDELINE 1	**Use or disclosure** of **genetic information** without consent may proceed only when the **authorising medical practitioner** has a **reasonable belief** that this is **necessary** to **lessen** or prevent a **serious threat** to the **life, health or safety** of a **genetic relative**.
GUIDELINE 2	Specific ethical considerations must be taken into account when making a decision about whether or not to **use or disclose genetic information** without consent.

These Guidelines establish when, by whom and in what manner **use or disclosure** of **genetic information** may take place without patient consent. They are underpinned by:

- Guideline 1, which outlines the requirements of the statutory test set out in NPP 2.1(ea)
- Guideline 2, which concerns the ethical considerations outlined in Chapter 2.

In the event that the statutory test is satisfied and the patient or his or her **authorised representative** has not given consent for **use or disclosure**, conveying this information to **genetic relatives** is permitted only if done in accordance with all of the Guidelines. Other considerations are the obligations created by the other NPPs (see Appendix 2) and **duty of confidentiality**.

This chapter outlines the process of applying the Guidelines and good practice, including:

- providing relevant information to patients or **authorised representatives**, including referral for genetic counselling as appropriate (see Sections 3.2.1 and 3.2.2) and provision of further information if consent is withheld (see Section 3.3.4)
- taking reasonable steps to obtain consent (see Sections 3.2.3 and 3.2.4)
- establishing who will take responsibility for the process if consent is withheld (see Section 3.3.1)
- involving other health practitioners with relevant experience in the decision-making process while maintaining patient confidentiality (see Section 3.3.2)
- determining whether the statutory test set out in NPP 2.1(ea) can be met and whether it is appropriate for disclosure to proceed (see Sections 3.3.3 and 3.3.5)
- providing only the necessary information and doing so in an appropriate manner, if disclosure is to proceed (see Sections 3.4.1 and 3.4.2)
- limiting disclosure to relatives generally no further removed than third-degree relatives and using a process of **cascade contact** to provide access to genetic information for a wider cross-section of the family (see Section 3.4.3)
- accurately documenting the process (see Section 3.4.4).

3.2 Discussing use or disclosure of genetic information

3.2.1 Providing information about implications for genetic relatives

In any situation when confirmation of a genetic condition or predictive **genetic information** is likely, there should be discussion with the patient about:

- the implications for **genetic relatives**
- the potential benefits of notifying **genetic relatives** or allowing the release of information
- the fact that there is legal provision for **use or disclosure** without consent in certain circumstances.

The fact that this advice has been given should be documented in the patient's record.

Consent is a continuing process. These early discussions support patients in exercising their choice and form the basis for later discussions about consent to disclose the patient's **genetic information** to **genetic relatives**.

The Privacy Act requires that providers give notice to their patients about certain matters when they first collect health information. These matters include why the information is being collected, how it may be used and to whom it may be disclosed. The full notice requirements are set out in NPP 1.3 and NPP 1.5 (see Appendix 2). It is therefore important to update patient information leaflets relating to the application of the Privacy Act to include possible **use or disclosure** of **genetic information** without consent. A sample patient privacy information leaflet is given in Appendix 3.

3.2.2 Genetic Counselling

In situations where **genetic information** has implications for individuals and their families, patients may be referred to a genetics service. If this is not possible within a reasonable timeframe, for example because of distance or waiting lists, the treating medical practitioner can seek advice from the genetics service about an appropriate course of action. If the patient is distressed or the situation calls for immediate action, an urgent appointment or telephone counselling may be arranged.

3.2.3 Seeking consent for use OR disclosure

GUIDELINE 3	Reasonable steps must be taken to obtain the consent of the patient or his or her authorised representative to **use or disclose genetic information**.

It is important that health practitioners seeking consent in these situations have the appropriate expertise to do so. Those who do not may elect to refer the patient to a colleague with such expertise. Where timely referral is not possible (eg in rural or remote areas), the treating medical practitioner should seek advice from suitably qualified professionals about the condition and its implications for **genetic relatives**, without revealing the identity of the patient.

Patients should be given the necessary information and assistance regarding **use or disclosure** that complements information they have already been given about their own condition and/or treatment, and allows them to make an informed decision. Such information will include:

- which **genetic relatives** are likely to be at risk
- the likelihood of each relative developing the familial disease (relevant factors may include age, gender, and degree of relationship with the patient)
- the likely threat to those relatives if they are not advised of their risk and therefore do not seek health advice
- potential preventive and early intervention measures and possible benefits of these to **genetic relatives**
- the availability of genetic counselling for the patient and family members
- the patient's involvement in the process
- the potential for information to be used or disclosed to **genetic relatives** without identifying the patient or condition.

In some circumstances, it may not be appropriate to seek consent from the patient, such as when:

- an individual has impaired decision-making ability (see below)
- seeking consent may itself cause a serious risk to the **life, health or safety** of the patient; or
- it is not possible to contact the patient.

Scenario 1 (see p 34) illustrates good practice in discussing **use or disclosure** in the more usual situation where consent is given.

Seeking consent from adults with impaired decision-making ability

Patients may have impaired decision-making ability due to a psychiatric illness or disability, intellectual disability, acquired brain injury, or some form of dementia. Impaired decision-making ability may be the result of the genetic condition of interest (eg dementia associated with the neurological degeneration of Huntington disease, Wilson disease, myotonic dystrophy).

Impairment to an individual's capacity to consent may be a permanent or temporary condition. In some cases, it may only affect decision-making ability some of the time, for example where a person has a psychological illness that is episodic in nature. In other cases, the impact on the person's decision-making ability may be incremental, such as with dementias. However, it may be that the patient can make decisions about the handling of his or her **genetic information**, if they are provided with the necessary support.

Establishing competency

A first step would be to assess the patient's ability to give informed consent. Questions to consider include the following.

- Is the patient aware that he or she has the condition?
- Is the patient aware that his or her decision-making ability is impaired?
- Is the patient able to consent to inform **genetic relatives**?
- If not, would the patient have the capacity if enough time were spent explaining the issues in simple language?

It may also be useful to seek independent advice from a colleague or other relevant expert (eg psycho-geriatrician).

Involving the patient in decision-making

- There may be difficulties in conveying the necessary information to patients with impaired decision-making ability, particularly if they attend consultations alone. The treating practitioner may encourage the patient to bring a spouse, relative, friend or advocate (such as a social worker or health worker with whom the patient is familiar) as a support person during consultations.
- The Privacy Act adopts a common law approach to consent, whereby any individual with capacity may exercise choices over the handling of his or her personal information. Efforts are therefore required to ensure that every patient's understanding is as thorough as possible. For patients who are not competent to make decisions concerning disclosure of their **genetic information**, attempts should be made to ascertain what their wishes were before they became affected by the disease (Bernat 2008). Even in situations where individuals lack legal capacity, they should be involved as far as practicable in the decision-making process.

Involving the authorised representative in decision-making

If it is determined that a patient is not capable of understanding relevant matters, an **authorised representative** of the person[10] is generally involved. It is important that the **authorised representative** is provided with adequate advice, information and genetic counselling to assist them in understanding relevant matters and reaching an informed decision.

Scenario 4 (see p 37) describes a situation in which consent to disclose is sought from an **authorised representative**.

Seeking consent for use or disclosure of genetic information concerning children and young people

In situations where a genetic condition or genetic status is confirmed in a child or young person, the involvement of that child or young person in decision-making about sharing **genetic information** will depend on his or her age, maturity, emotional readiness and mental capacity. It is most likely that at least one parent will be involved in the consultation and will also be involved in decision-making.

The Privacy Act does not specify an age at which young people may make their own decisions about how personal information about them is handled. Under the Privacy Act, the capacity of children and young people to make a decision is assessed on a case-by-case basis rather than on attaining a prescribed age.

A child or young person can give or withhold consent if he or she has sufficient understanding and maturity to understand what is being proposed. The responsibility for exercising a child or young person's rights under the Privacy Act falls to a parent or guardian, until the child reaches a level of maturity where they are able to make decisions independently.

Children may have a limited role in decision-making either because they are too young to understand or because they have mental impairment as a result of illness, injury or disability. Generally, older children should be encouraged to take a more active part in decision-making than younger children.

Involvement of a child or adolescent psychiatrist or psychologist may be of assistance, as these professionals are well placed to assist the parents and **authorising medical practitioner** by assessing the child's emotional maturity and perception of the situation. Resources are also available to assist in talking to children about illnesses (eg Hennig 2009).

When parents refuse consent to disclose information to **genetic relatives** because they wish to protect the child with the genetic condition, health practitioners may need to seek independent advice or refer the family to a genetics service.

The fact that the patient is a child does not reduce the requirement for a health practitioner to carefully consider the implications of **use or disclosure** without consent for the patient both now and in the future.

The situation can be more complicated if there are adopted children or children born through artificial reproductive technology (ART) where gametes have been donated. The implications of contacting unknown **genetic relatives** to inform them of possible genetic risk would need to be carefully considered.

Scenario 8 (see p 42) describes a situation where the patient is a child and a parent decides not to give consent to disclosure.

10 See definition on p 5.

When the genetic relative is a child

Issues of competency are also relevant when determining whether **genetic information** should be disclosed to a child. In situations where a child does not have the maturity to make his or her own decisions under the Privacy Act, disclosure to the child's parent or guardian is permitted.

3.2.4 Documenting the process of consent

Documenting the process of consent should include notation in the patient's record of:

- when and by whom the patient or his or her **authorised representative** was informed of the implications of the identified condition or genetic status for the patient's **genetic relatives**
- involvement of any other professionals (eg GPs, specialists, counsellors, ethicists) in the consent process
- written consent if given by the patient
- if consent is withheld, the reasons given by the patient or the **authorised representative**
- any particular issues that may have had an impact on the consent process such as the patient's language or capacity and what steps were taken to address these issues.

3.3 Following appropriate processes when consent is withheld

Most patients freely give consent for their **genetic information** to be disclosed to **genetic relatives** but, as discussed in Chapter 2, some may have reasons to withhold this information. In these situations, the patient's decision should be respected by allowing time for review of the decision and considering referral of the patient to a genetics service. In circumstances where an element of urgency exists, it may not be possible for expert counselling to be provided at a face-to-face appointment (particularly in rural and remote areas) but telephone counselling and support should be available.

3.3.1 Who is responsible for decision-making and disclosure?

GUIDELINE 4	The authorising medical practitioner should have a significant role in the care of the patient and sufficient knowledge of the patient's condition and its genetic basis to take responsibility for decision-making about use or disclosure.

A range of health practitioners may have a role in decision-making. However, throughout the process one senior medical practitioner will act as the **authorising medical practitioner.** The **authorising medical practitioner** should have a significant role in the care of the patient and will usually also take responsibility for disclosure. In some cases, he or she may choose to identify another professional to undertake the disclosure. In identifying professionals suitable for the role of authorising or disclosing practitioner, consideration should be given to whether they:

- have sufficient expertise in the relevant condition and its genetic basis to be able to determine whether a **serious threat** to the life, health or safety of **genetic relatives** exists and whether disclosure may **lessen** or prevent this threat
- have legitimate access to this health information about the patient and family under the NPPs
- must access expert advice from colleagues who have specific expertise (see Section 3.3.2); and
- have an understanding of the patient's individual needs, the family situation and any factors contributing to the complexity of the situation (eg when a patient is a child or has impaired decision-making ability).

A medical practitioner must take responsibility for the process as **authorising medical practitioner**, even if another professional (eg a genetic counsellor with requisite knowledge of the particular condition) takes on the role of **disclosing health practitioner**.

It is essential that all health practitioners involved in the decision-making process have a clear understanding of their roles.

3.3.2 Taking a collaborative approach

GUIDELINE 5	Prior to any decision concerning use or disclosure, the authorising medical practitioner must discuss the case with other health practitioners with appropriate expertise to assess fully the specific situation.
GUIDELINE 6	Where practicable, the identity of the patient should not be apparent or readily ascertainable in the course of inter-professional communication.

Use or disclosure of **genetic information** without consent involves consciously acting against the patient's expressed wishes. It is therefore imperative that the decision to **use or disclose** is made only after discussion with experienced colleagues, even when the health practitioner involved is experienced in the field. In such discussions, wherever practicable, the **authorising medical practitioner** should not reveal the identity of the patient either verbally or in writing.

On each occasion, discussion of the case should be organised so that all involved have time to prepare. When a face-to-face meeting is not possible (eg for professionals in rural or remote areas consulting specialists in other areas), telephone conversations or conferences may be required. The outcomes of each discussion should be documented, signed, and retained in the patient's records.

In some circumstances it may also be advisable to seek ethical advice or consult a medical defence organisation.

Scenario 6 (see p 39) describes a complicated situation where considerable consultation between experts is needed to assess the necessity for disclosure without consent.

3.3.3 Decision-making about use OR disclosure without consent

Is there a serious threat to life, health or safety of genetic relatives?

When consent is withheld, the **authorising medical practitioner** will first need to determine whether there is a **serious threat** to **genetic relatives**. A serious threat reflects significant danger to the individual and could include a potentially life-threatening situation or one that might reasonably result in an illness or psychological harm without timely decision or action.

Consideration of the seriousness of a threat to the **life, health or safety** of **genetic relatives** will include identification of which relatives are at risk. A one in two risk of developing a serious disease in a close relative represents a **serious threat** but lower risk in a more distant relative is less serious, particularly as the risk starts to approach that in the general population. In some circumstances such a quantitative approach will be possible. In many situations the estimation of risk will rely on a number of factors and a range of expertise will need to be involved.

Issues for consideration when determining whether a threat is sufficiently serious to warrant **use or disclosure** without consent include:

- the nature of the condition, its associated risks and treatment or care options
- the probability that a genetic relative may also have the condition or be a carrier of the relevant mutation.

Scenario 9 (see p 43) describes a situation where the risk to **genetic relatives** is difficult to define and other measures are available to assess the risk to **genetic relatives** making disclosure without consent unnecessary.

Psychological harm

In some circumstances a **serious threat** to a genetic relative's psychological health could justify **use or disclosure** without consent. For example, it may be warranted to **lessen** or prevent a serious psychological threat to a woman associated with repeated miscarriage.

Scenario 7 (see p 41) describes a situation where there is a risk of psychological harm to **genetic relatives** from both disclosure and non-disclosure.

Financial harm

Generally, under the Privacy Act, a risk of financial harm is not considered to be a serious risk to **life, health or safety**. However, in some cases, a risk to an individual's financial status may result from psychiatric illness or dementia. Those psychiatric consequences may meet the test of a serious risk to **life, health or safety**.

Can the threat to genetic relatives be lessened or prevented?

Many inherited conditions can be treated and symptoms lessened. If a **serious threat** to **genetic relatives** has been identified, the treating practitioner, in consultation with colleagues, needs to determine whether the potential to **lessen** or prevent the threat exists. Considerations include:

- whether the condition is preventable or manifestations treatable (eg whether the relatives can benefit from the information)
- if the disease is incurable, whether knowledge of the condition would allow specific management, treatment of distressing manifestations (eg depression), and better understanding of the patient through recognition of cognitive and physical impairment (McCusker 2003).

Are use or disclosure without consent necessary?

Before making a decision about non-consensual **use or disclosure**, the **authorising medical practitioner** must form a **reasonable belief** that such an act is **necessary** to **lessen** or prevent the identified threat to **genetic relatives**. Consideration should also be given to whether or not a means other than **use or disclosure** exists to **lessen** or prevent the threat (for example by including **genetic relatives** in a screening program).

> The decision to use or disclose without consent must be made in good faith, with the practitioners involved in the decision-making on behalf of the organisation drawing on their experience, training and expertise.

Compliance with confidentiality requirements

Health practitioners should be aware that information that can be disclosed consistent with the Privacy Act and these Guidelines may still be subject to the **duty of confidentiality** that exist outside the Privacy Act framework. Health practitioners may wish to seek legal advice from a medical defence **organisation** before making a disclosure.

3.3.4 Providing further information to a patient who has withheld consent

If the authorising health practitioner believes that the disclosure is **necessary** to **lessen** or prevent a **serious threat** to the **life, health or safety** of a genetic relative, a further discussion should be held with the patient. By this stage, the patient will have had some time to come to terms with his or

her own prognosis, may have attended genetic counselling and may have had a change of mind about contacting **genetic relatives**.

If not, discussion of the possible **use or disclosure** without consent should be initiated. This will include explanation of:

- the provision in legislation for health practitioners to provide information to **genetic relatives** in such circumstances
- the basis of the **authorising medical practitioner's** belief that a **serious threat** exists and that the release of the information is **necessary** to **lessen** or prevent this threat, including the expert advice of relevant health practitioners
- the fact that the information would be shared without directly identifying the patient or the condition or genetic status
- the treating practitioner's continued duty of care towards the patient whether consent is given or not
- the continuing availability of genetic counselling for the patient, if desired.

The discussion should be factual and non-coercive, and can be reinforced with written information or other relevant materials. If consent is still not given, the patient's reasons for continuing to withhold consent should be documented. It may be advisable to request that the patient reads and signs a formal statement acknowledging that he or she:

- has been informed of the risk to **genetic relatives**;
- has chosen not to give consent for **use or disclosure**; and
- is aware that **use or disclosure** can take place without this consent.

A sample statement is included in Appendix 3.

If **use or disclosure** without consent is to take place, the **authorising medical practitioner** should notify the patient of this decision unless there is a contrary indication for doing so. The **authorising medical practitioner** should explain to the patient that if the patient is unhappy with the health practitioner's decision to use or disclose their genetic information without consent, and this difficulty cannot be resolved between the patient and the health practitioner, that the patient can make a complaint to the Office of the Privacy Commissioner (see p 64 for further information).

The medical practitioner should be aware of the potential for patient distress and manage this appropriately.

Scenario 3 (see p 36) highlights the importance of ongoing provision of information, with the **authorised representative** of the person in the scenario deciding to pass on information to family members after several months of discussion and counselling.

3.3.5 Non-disclosure

In considering the details of a particular situation, the **authorising medical practitioner** may decide that disclosure without consent should not proceed. The decision not to proceed may be required under the Privacy Act, or may be an elective choice by the practitioner.

Non-disclosure when the guidelines cannot be met

Disclosure without consent can only proceed if the Guidelines in this document are met. For example, the **authorising medical practitioner** may conclude that:

- there has been insufficient ethical consideration of the issues in this situation (see Section 2.3)
- there may be additional reasonable steps that could be taken to obtain the patient's consent (see Sections 3.2 and 3.3.4)

- he/she does not fulfill the essential criteria required of the **authorising medical practitioner** (see Section 3.3.1)
- there has been inadequate consultation with expert professionals (see Section 3.3.2)
- relatives are not at risk of a **serious threat** to **life, health or safety** (see Section 3.3.3)
- there are no interventions that could assist in the clinical care of the relative (see Section 3.3.3)

  or
- means other than disclosure are available to **lessen** or prevent the threat (see Section 3.3.3).

In any of these situations, the Privacy Act does **not** authorise disclosure without consent.

When the health practitioner chooses not to disclose or is unwilling to disclose

There may be situations in which the requirements of these Guidelines are met, but the **authorising medical practitioner** chooses not to disclose, for example when:

- there are extenuating circumstances such that disclosure may be of little benefit to relatives
- other services are already undertaking notification of relatives

  or
- relatives have already stated that they do not wish to have this information.

Other considerations might include:

- the emotional impact of disclosure on the patient (eg the potential for suicide or violence)
- the potential negative impact on the patient's relationship with the family
- the potential for disclosure without consent to erode the trust between the health practitioner and patient and the ramifications of this on ongoing treatment and counselling of the patient
- cultural factors (see Section 2.1.2).

In such situations, it may be appropriate not to proceed with disclosure without consent. Disclosure in the future may be possible if the patient changes his or her mind or the family situation changes.

It is important to remember that a health practitioner **does** have an ethical obligation to advise the patient to inform relatives of the diagnosis but is under no legal obligation to contact relatives about the diagnosis in the family.

Circumstances may arise in which disclosure of **genetic information** to **genetic relatives** without consent is permissible on the basis of the decision-making process and criteria included in the guidelines, but the health practitioner is unwilling to disclose (for example, because the health practitioner has a personal view that patient **confidentiality** should never be breached).

However, if disclosure is thought to be appropriate, the health practitioner should consult another suitably qualified and experienced health practitioner, keeping in mind the NPPs and the **duty of confidentiality**, and consider whether it would be more appropriate for the information to be disclosed by another health practitioner.

As the legislation does not compel a health practitioner to disclose information to a genetic relative, the question may be asked whether an aggrieved relative, who has not been notified about a risk for a serious genetic condition, can take legal action against the organisation or health practitioner. As the law currently stands, there is no valid basis to suggest that the organisation or health practitioner could be liable for non-disclosure.

Documentation

Irrespective of the decision made, the process of decision-making in relation to disclosure must be documented in writing. The reasons for the decision must be detailed. The fact that the patient has been advised to inform relatives must be documented.

3.4 The process of disclosure to genetic relatives

3.4.1 How does disclosure take place?

Even after a decision is made to disclose without consent, the practicalities of doing so can be complicated. It is not possible for health professionals to ascertain objectively the extent of a patient's knowledge about other family members, making it particularly important to manage disclosure very carefully.

If the patient has not given consent for disclosure, the **authorising medical practitioner** will usually not have access to contact details for **genetic relatives**. While the collection of information about family members related to the direct care of the patient is an important part of history taking and often in making a diagnosis of a familial condition, this does not include the collection of identifying information such as contact details. The collection of contact details must accord with the Privacy Act, particularly NPPs 1 and 10. In order to disclose information to **genetic relatives**, health practitioners would generally not be permitted to obtain contact details of the **genetic relatives** without those individuals' consent or by lawful authority. This is because the contact details, when associated with information or opinion about the health of the **genetic relative**, may be 'health information' as defined in the Privacy Act.[11] A separate Information Sheet is available from the Privacy Commissioner in relation to obtaining the contact details of **genetic relatives** for the purpose of disclosure of genetic information.

A variety of circumstances will influence how contact takes place. Written contact gives the recipient time to consider whether to seek further information, and in this sense can be perceived as non-coercive. It is suggested that a request for verification of receipt be included with written contact (see the sample form letter in Appendix 3). In some cases telephone contact may be suitable (eg when the recipient may know that the condition exists in the family and information concerning the potential risk to themselves is likely to cause distress). However, it is not appropriate to leave messages concerning private information on telephone answering machines or with someone who is not the intended recipient of the information.

Not all people who have been contacted will respond. Repeated attempts should not be made to contact non-responders because they may have made a choice not to seek further information.

If disclosure without consent is to take place, in general, the patient should be notified of this decision and advised when the disclosure has taken place.

3.4.2 What information should be provided?

GUIDELINE 7	Disclosure to genetic relatives should be limited to genetic information that is necessary for communicating the increased risk and should avoid identifying the patient or conveying that there was no consent for the disclosure.

Information provided to **genetic relatives** when first contacted should be worded in general terms but clearly indicate the importance of the communication. It should:

- not identify the patient or the genetic status or genetic condition that has been identified
- simply state that a tendency to develop a potentially serious heritable disorder has been identified in the family
- state that notification of relatives under such circumstances is permissible under the Privacy Act
- suggest that the recipient use the contact details provided to receive further information (for example by taking the letter to their GP who could make contact for them)
- include details of the nearest genetic counselling services
- if possible, use a letterhead that does not identify the condition.

11 See the Privacy Act definition of 'health information' in Appendix 2.

The information provided should not convey the fact that consent was not given for disclosure to genetic relatives.

A sample letter that may be used as a template is included in Appendix 3.

Scenario 5 (see p 38) describes a situation in which there is **reasonable belief** that disclosure is **necessary** to prevent harm to **genetic relatives** but difficulties arise in maintaining the **confidentiality** of the patient.

3.4.3 Process of cascade contact

GUIDELINE 8	Disclosure of **genetic information** without consent should generally be limited to relatives no further removed than third-degree relatives.

The sample letter in Appendix 3 can be used as the starting point for **cascade contact**.

Scenario 2 (see p 35) describes a situation where the patient advises some family members to attend a genetics service and **cascade contact** is used to contact other **genetic relatives**.

3.4.4 Documenting the process

GUIDELINE 9	All stages of the process must be fully documented, including how the decision to **use or disclose** without consent was made.

The process of disclosure with or without consent should be documented, including details of:

- preliminary discussions with the patient or his or her **authorised representative** concerning the familial nature of the condition or genetic status
- the recommendation to the patient or his or her **authorised representative** that **genetic relatives** be notified
- request for consent to disclose to **genetic relatives**
- refusal of consent and reasons for it
- the identity of the **genetic relatives** contacted
- the process used to contact those **genetic relatives** (including a copy of any letter mailed to them).

If consent has been withheld and disclosure considered **necessary**, an accurate record of how the decision to disclose without consent was attained should be kept. This includes:

- the process of seeking advice from colleagues and the outcomes of these discussions;
- the basis for the belief that there is a **serious threat** to the **life, health or safety** of **genetic relatives**
- the basis for the belief that disclosure was **necessary** to **lessen** or prevent the threat to the genetic relative.

Situations where a decision is taken not to disclose should also be documented.

3.4.5 Continuing support for the patient and family

The decision of a patient to disclose, or not disclose, **genetic information** to relatives should have no bearing on the availability and quality of continuing care to the patient. However, if **genetic information** is disclosed to relatives without the patient's consent, the patient may prefer to have their continuing medical care provided by another health practitioner. The assurance of continuing care by either the same or a different health practitioner should be discussed with the patient.

Part D: Scenarios

This section includes a number of scenarios that provide general guidance for authorising medical practitioners and disclosing health practitioners about meeting the requirements under NPP 2.1(ea) and acting in accordance with the Guidelines. While the scenarios centre on DNA-based testing, the Guidelines relate to genetic information irrespective of its source.

It should be noted that the scenarios are to assist compliance with NPP 2.1 (ea) and the nine guidelines. Acting in accordance with the scenarios does not necessarily protect against a breach of the NPPs or a breach of confidence (common law).

When the patient chooses to contact relatives or provides consent

In the following scenarios the patient provides consent for relatives to be contacted. The process therefore falls beyond the scope of NPP 2.1(ea). Elements of standard good practice (such as documenting the process in patient records) are assumed and not highlighted in the scenarios.

Scenario 1

This scenario describes a situation where consent is given and the provisions under NPP 2.1(ea) are not applicable. It is included here to illustrate good practice in discussing **use or disclosure** in the more usual situation where consent is given.

A patient who had recently been diagnosed with autosomal dominant polycystic kidney disease was referred by her nephrologist to a genetic counsellor. The patient had some knowledge of the pathophysiology of the condition and the counsellor was able to provide her with a clearer understanding of its heritability. The woman was concerned about the future health of her two children and future grandchildren. She was keen to pass any information on to her own children and was also interested in whether the condition was likely to affect her cousins and their children.

Points for consideration

- *What factors support disclosure in these circumstances?* — This is an autosomal dominant disorder with high penetrance, and each child is at 50 per cent risk of inheriting the causative mutation and of developing polycystic kidney disease. The disease can be life-threatening, often leading to chronic renal failure, and is associated with cerebral aneurysms.
- *What factors weigh against disclosure?* — Even though the patient is keen to pass on the information, she should be counselled to do so carefully and with due consideration to whether it is in her relatives' best interests (for example taking into account the age and maturity of her children and the views of their father about disclosing the information).
- *What information could be given to the patient?* —In this case, it is possible to quantify the risks to the woman's children and to give an indication of likely risks to the other relatives. Available preventive measures and treatment options could also be discussed.

- *Who might be involved in decision-making?* — In this case, a genetic counsellor has already become involved. This professional has the expertise to inform the woman of the genetic implications of the condition for herself and for her **genetic relatives**. The counsellor may also discuss the importance of informing **genetic relatives** of their increased risk in such a way that they can choose whether or not to seek more information.

- *How might disclosure take place?* — Because the patient has consented to disclosure, the use of these Guidelines is not required. The patient could be supported with appropriate written materials, including information about support groups and counselling. The process of disclosure must be documented as part of the patient's medical record.

Scenario 2

This scenario describes a situation where the patient advises some family members to attend a genetics service and **cascade contact** is used to contact other **genetic relatives**.

Suzanne, whose maternal grandmother died of breast cancer in her thirties, tested positive for a mutation in the BRCA2 gene. Suzanne was advised to contact ***genetic relatives*** and suggest that they make contact with the genetics service. She refused to contact her sisters or her mother, Margaret, for personal reasons, but advised her daughters to attend the service. One of the daughters came to the service for testing and readily agreed to advise Margaret. Margaret contacted the service and made an appointment. She too tested positive for the mutation. It was suggested that Margaret (now the patient) notify ***genetic relatives***. Margaret contacted the two sisters. Both sisters attended the genetics service and Carol, the younger of the two, tested positive for the mutation. Carol gave consent for the genetics service to contact her children and grandchildren.

Points for consideration

- *Why might disclosure be advisable in these circumstances?* — The mutation identified increases the risk of breast cancer and ovarian cancer. Prophylactic mastectomy and/or oophorectomy can reduce the risk. Selective oestrogen receptor modulators (eg Tamoxifen) can also be used to reduce risk and early detection methods (eg mammography) can be used to detect the cancer when it is most treatable.

- *What factors weigh against disclosure?* — Suzanne did not consent to disclose to her mother or sisters. However, the fact that she did inform her daughters meant that a process of **cascade contact** could be used and there was no requirement for disclosure without consent.

- *What information could be given to the patient?* — In each case, the women need to be advised of the risks to themselves and the potential for disclosure to reduce the risk to **genetic relatives**. Genetic counselling should be offered to each patient.

- *How might disclosure take place?* — The process of **cascade contact** employed in this scenario allowed contact to be made with consent for a number of women who had the potential to carry the BRCA2 mutation, with only first or second-degree relatives being contacted in each instance. Any process of **cascade contact** needs to be carried out with due regard to the **confidentiality** of all patients involved.

Scenario 3

This scenario highlights the importance of ongoing provision of information with the **authorised representative** of the person deciding to pass on information to family members after several months of discussion and counselling.

A patient with significant dementia and a history of psychosis of late onset had been diagnosed with Alzheimer disease before being seen by a neurologist in private practice. The man had a movement disorder and progressively slurred speech consistent with Huntington disease. Genetic testing documented a pathogenic mutation in the Huntington disease gene. Initially, the patient's wife (as his ***authorised representative***) decided not to pass on information to those at potential risk, as she was concerned about the impact of this information on her children. However, after several months of discussion and counselling, she decided to pass the information to other family members.

Points for consideration

- *What factors support disclosure in these circumstances?* — Even in incurable, slowly progressive illnesses, there is some urgency to inform **genetic relatives**. If they choose to have it, predictive testing for Huntington disease would allow the man's **genetic relatives** (siblings and their children and adult grandchildren) the potential to plan for the disease's onset and ability to make major life decisions.
- *What factors weigh against disclosure?* — The likely effect on relationships within the family and between the family and health practitioner are considerations, especially in this case where being informed of risk may cause great anxiety.
- *What information could be given to the patient or* ***authorised representative?*** — Reasonable steps have been taken to determine whether the patient has the mental ability to understand this particular situation sufficiently to make an informed decision. As he has impaired decision-making ability, the information is given to his wife as **authorised representative**. This would include information about the course of the disease and treatment or care options.
- *Who might be involved in decision-making?* — Expert advice (eg from a psychiatrist, neurologist, geriatrician) may be required in this case to assess the mental ability of the patient and to assist in decision-making regarding the seriousness of the threat to **genetic relatives** and ways in which the threat could be **lessened** or prevented.
- *How might disclosure take place?* — In this case, the **authorised representative** changed her mind after being given more information and decided on his behalf that the information should be disclosed to **genetic relatives**. However, with or without consent, disclosure of information about progressive degenerative disorders such as Huntington disease should be done with great care and in a timely manner so that relatives can be informed of the possibility of being at risk but choose whether or not to undertake testing to find out their genetic status. Continuing family and genetic counselling may assist family members to understand the nature of the risk and come to terms with the situation.

When consent is not given and disclosure without consent takes place

The following scenarios describe situations in which consent is not given and there is potential for disclosure to take place following the process outlined in these guidelines. The scenarios are provided to illustrate certain principles. They do not highlight every aspect of the process and cannot be used as templates.

Scenario 4

This scenario describes a situation where an **authorised representative** of the patient does not give consent for disclosure. In the light of the **serious threat** to **genetic relatives**, a decision is taken to disclose to the relatives without the consent of the **authorised representative**.

A man with dementia came to a private clinic accompanied by his wife. In the past he had been shown to have a mutation for the Huntington disease gene. The husband was severely demented and could not communicate. Assessment confirmed that he was unable to understand his situation and give consent to inform ***genetic relatives*** of their risk and his wife was identified as his ***authorised representative.*** Information about the implications of the diagnosis for ***genetic relatives*** and consideration of disclosure that would have been given to the patient was then given to his wife. During the course of these discussions, the neurologist ascertained that the patient and his wife had not told their adult children or the patient's siblings of this risk. When the father was admitted to hospital, the three adult children supplied names and addresses for contact in the event of deterioration.

Despite careful explanation from the neurologist and the social worker on a number of occasions, as well as by other clinicians when the husband was admitted to hospital, the wife (as ***authorised representative***) continued to refuse to notify her children of their risk.

Points for consideration

- *What factors support disclosure in these circumstances?* — The ***authorising medical practitioner*** has a reasonable belief that disclosure to the man's children is ***necessary*** to ***lessen*** or prevent a ***serious threat*** to the adult children's ***life, health or safety***. The couple's adult children and other ***genetic relatives***, if informed of their risk of inheriting the Huntington disease mutation, may wish to consider undertaking predictive testing. Knowledge of this risk would allow planning for the disease's onset. If a predictive test is taken, the risk of inheritance is further clarified and may influence major life decisions, as well as allowing early recognition of manifestations, such as treatable depression and cognitive changes.
- *What factors weigh against disclosure?* — Despite counselling, the children's mother, as **authorised representative** for her husband, is adamant that the children should not be informed of their risk. Disclosing without consent is likely to irrevocably change relationships within the family. There is the possibility that adult children could be unduly distressed, that they may already have the onset of illness or could have a prodromal psychiatric illness. It is also possible that the mother may be refusing to disclose in order to conceal non-paternity.
- *What information could be given to the patient?* — In this case, reasonable efforts have been made to ensure that the patient's understanding is as thorough as possible. This included explaining the condition and the implications of disclosure using simple language. The neurologist then assessed the patient's ability to give informed consent. In this case the patient was severely impaired at presentation. When a person is judged as incompetent, reasonable efforts should be made to ensure that the person is, in fact, unable to understand this particular issue and its implications.

- *What information could be given to the **authorised representative**?* — As it has been determined that the patient lacks capacity to give informed consent, the wife as **authorised representative** should be given the necessary information and assistance regarding the disclosure to enable her to make an informed decision on the patient's behalf. Such information should include, for example, the likely threat to **genetic relatives** if they are not advised of their risk and therefore do not seek health advice, and the process for disclosure. It is important that the woman be asked to consider what her husband's wishes would have been. She could also be actively encouraged to seek further advice from a genetic counsellor.
- *Who might be involved in decision-making?* — The treating neurologist may elect to take this matter further by discussing with experienced colleagues whether or not to disclose in these circumstances. If there is **reasonable belief** that disclosure is **necessary** to **lessen** or prevent a **serious threat**, a decision may be taken to disclose without consent.
- *How might disclosure take place?* — In this case the couple's adult children could be contacted. Conditions such as Huntington disease are incurable and diagnosis can cause great anxiety. Before contacting the relatives, the **disclosing health practitioner** should be aware of interventions and actions that may help people who are dealing with the prodromal psychological consequences of being informed about the diagnosis, and of specific care for the relatives.

Scenario 5

This scenario describes a situation in which there is **reasonable belief** that disclosure is **necessary** to prevent harm to **genetic relatives** but difficulties arise in maintaining the **confidentiality** of the patient.

A GP in private practice in a country town diagnosed haemochromatosis in a male patient in his late thirties. As far as the man knew, no other member of his family had been diagnosed with haemochromatosis but his mother had severe arthritis. The GP explained the likelihood of the man's parents and younger brother carrying the mutated gene for the potentially serious condition. The patient did not want to contact family members himself because he did not want his identity revealed but agreed to the GP contacting them. However, at the following consultation the patient withdrew consent, saying that he didn't want to worry his family, and he declined to be referred to a clinical genetics service.

After a telephone consultation with a clinical geneticist in private practice in the city, the GP believed that there was a serious threat to the health of the man's relatives that could be lessened and that he should disclose. However, he was concerned about protecting the patient's identity. The GP prepared a letter on his letterhead for genetic relatives. He was able to obtain their contact details lawfully. He informed them that he had been advised that a member of the family had been diagnosed with a familial disorder. He explained that the serious nature of the condition provided exceptional circumstances in which they could be contacted without the consent of the patient concerned. He suggested that they attend their own GP or local health service, taking the letter with them.

Points for consideration

- *What factors support disclosure in these circumstances?* — Hereditary haemochromatosis increases the amount of iron that the body absorbs, with excess iron being deposited in multiple organs of the body. Excess iron stores can result in cirrhosis, diabetes, cardiomyopathy, pigmentation of the skin, and arthritis. The condition is fatal if not treated and early intervention can prevent organ damage before it occurs. The *GP* thus has *a* ***reasonable belief t****hat disclosure* to the man's parents or younger brother *is* ***necessary*** *to* ***lessen*** *or prevent a* ***serious threat*** *to* ***life, health or safety.***
- *What factors weigh against disclosure?* — As this is a common disorder, and easy to screen for by measuring iron levels in the blood, it may be detected in relatives anyway, removing the necessity for disclosure without consent. However, early detection is preferable as late diagnosis is associated with poorer outcomes.
- *What information could be given to the patient?* — In this case the patient has been provided with information about the condition and the benefits of informing **genetic relatives**. Disclosure to **genetic relatives** has also been discussed but the patient has withdrawn his consent.
- *Who might be involved in decision-making?* — The GP provided the patient with sufficient information to make a decision about disclosure. He also consulted a clinical geneticist about the likely threat to the patient's relatives.
- *How might disclosure take place?* — Disclosure is possible in this scenario because the GP has been able to obtain the contact details for the patient's relatives lawfully[12]. The approach taken considers the patient's **privacy**, the impact of the patient's diagnosis and the implications of this on **genetic relatives**. The GP should also notify the patient that disclosure to his relatives has taken place and that this was done in a way that reduced the likelihood of his identity and diagnosis being identifiable.

When consent is not given and disclosure does not take place

In the following scenarios no decision is reached as to whether disclosure without consent is permissible and the circumstances remain under review.

Scenario 6

This scenario describes a situation where the risk to **genetic relatives** is clear, with the potential for at least three people to benefit from the information. The scenario is provided as an illustration of how the nature of the situation and the potential for damage to relationships from non-consensual disclosure can complicate decision-making.

A patient was referred to a gastroenterologist. His father had had a familial form of colorectal cancer, familial adenomatous polyposis, and had died when the patient was 12 years old. The patient had been found to carry a mutation in the APC gene. The patient had already been given an explanation of the need to monitor people with this mutation and of the risks involved. This explanation was reinforced by the gastroenterologist, with discussion covering the importance of sharing the information with ***genetic relatives*** and the potential for disclosure to take place without consent in certain circumstances.

The patient refused to make contact with his estranged wife and their three sons. When the specialist suggested that she could contact them on his behalf, he said it was not his problem, that he did not know where they were and that he didn't want them to be contacted. However, the specialist realised that one of the sons (aged 13 years) had recently been referred to her complaining of abdominal pain. The gastroenterologist discussed the case with a senior colleague and also consulted a clinical geneticist.

Points for consideration

- *What factors support* ***use or disclosure*** *in these circumstances?* — Because of the high risk and early onset of colon cancer (by age 40) in most individuals with an APC mutation, this situation represents a **serious threat** to the **life, health or safety** of **genetic relatives** that could be **lessened** by **use or disclosure**. Diagnosis before the development of cancer allows for preventive treatment eg colectomy during teenage years.
- *What factors weigh against* ***use or disclosure****?* — Although a **serious threat** to **genetic relatives** exists, and this could be **lessened** or prevented by **use or disclosure**, consent has not been given and the case must be reviewed by experts in the area. **Use or disclosure** has the potential to compromise the relationship between the patient and the gastroenterologist, and to further compromise the relationship between the patient and his family.
- *What information could be given to the patient?* — The patient has been given the information needed to understand the implications of the diagnosis for his **genetic relatives**. If he continues to withhold consent, discussion of the possible **use or disclosure** without consent should be initiated. This should cover the provision in legislation for non-consensual disclosure to **genetic relatives**, the basis of the belief that release of the information is **necessary** to **lessen** a **serious threat** and the fact that the information would not directly identify the patient or the condition. The practitioner's continued duty of care towards the patient and the continuing availability of genetic counselling for the patient should also be highlighted.
- *Who might be involved in decision-making about use or disclosure?* — The gastroenterologist could make a decision regarding **use or disclosure** in consultation with her senior colleague and the clinical geneticist (ensuring the identity of the patient is not apparent or readily ascertainable where practicable). In doing so she would be acting in accordance with these guidelines and thus with the law. She may also choose to seek advice from her medical defence **organisation**. If the gastroenterologist decides to **use or disclose** the information without consent, she should notify the patient of this decision.
- *How might disclosure take place?* — In general clinical practice, the medical practitioner in this scenario would most likely disclose to the mother, explain the risk and provide the opportunity for DNA testing of the adolescent. If the gastroenterologist makes a decision to disclose, she could contact the mother in writing advising her to make an appointment to discuss the familial disorder. The opportunity for genetic counselling and DNA testing could then be provided. **Cascade contact** (as outlined on p 33) could then be used to reach other **genetic relatives**. All communications with **genetic relatives** would need to be undertaken with consideration of the **privacy** of the patient and other relatives.

Scenario 7

This scenario describes a situation where there is a risk of psychological harm to **genetic relatives**. Further exploration of the situation would be required before non-consensual disclosure could proceed.

A 29 year-old man was found to have a balanced chromosome translocation during evaluation for his partner's history of recurrent miscarriages. When cells of people with balanced chromosomal rearrangement divide to create eggs or sperm for reproduction, some of the chromosomal material can be duplicated or missing. This leads to an unbalanced translocation, which often results in miscarriage or may result in a live-born child with major congenital malformations. The translocation diagnosed was considered to be unlikely to cause the man any medical problems but may have accounted for his partner's history of miscarriages. The man stated that there was no family history of children with major congenital malformations or disabilities.

Some of the man's relatives could carry the same balanced translocation, despite them being healthy. Disclosure of his genetic diagnosis could facilitate clarification of their risk of having miscarriages or may provide an explanation for miscarriages that have occurred. The man's sister was at risk of having the same translocation and potentially multiple miscarriages because of her carrier status. The man was provided with this information. He refused to advise her although she had recently miscarried and was known to be planning another pregnancy.

Points for consideration

- *What factors support disclosure in these circumstances?* — Miscarriage and especially repeated miscarriages may result in high psychological burden for a woman. Even though the sister's physical health is not under any **serious threat**, her circumstances mean that she is at high risk of psychological damage in the event of repeated miscarriage. Disclosure would allow her to choose to clarify her carrier status by genetic testing. She could be prepared for the likelihood of further miscarriages and access support and counselling services if necessary. This would apply to other close relatives, male or female. While it may be usual for the couple's chromosomes to be checked after three miscarriages, prior knowledge of the woman's carrier status would avoid the many months or even years of delayed fertility and the psychological and physical impact that multiple miscarriages may have.
- *What factors weigh against disclosure?* — Disclosure in this case may reinforce to the couple the man's perception that he is "responsible" for his partner's miscarriages. It may also affect relationships within the wider family.
- *What information should be given to the patient?* — The implications for the man's **genetic relatives** and benefits of notifying his sister have been explained. It would be worth exploring the man's response to his new diagnosis that probably accounts for his partner's continued miscarriages and the impact that the experience is having on their relationship.
- *Who might be involved in decision-making?* — The treating clinician should seek advice from other experts. Referral of the man for expert psychological counselling would also be advisable.

- *How might the disclosure take place?* — The man's initial response to the possibility of disclosure may reflect an acute reaction to the diagnosis. With support, information, and the passage of time, he may subsequently agree to disclosure. On the other hand, his response could represent difficulties in the family dynamics. In a situation where the patient continues to withhold consent and where there is **reasonable belief** that the threat to **genetic relatives** is of a serious nature and disclosure **necessary** to **lessen** the threat, informing the sister and other close relatives may be appropriate.

Scenario 8

This scenario describes a situation where the patient is a child and a parent decides not to give consent to disclosure. The diagnosis is such that there is the possibility that a number of the **genetic relatives** could experience a late onset degenerative neurological condition, and female **genetic relatives** could experience premature ovarian failure. However, further consideration is required to determine whether disclosure would be **necessary** to **lessen** or prevent a **serious threat**.

The autistic symptoms of a five-year-old boy combined with family history suggested to his paediatrician a diagnosis of Fragile X syndrome. The mother's father had shown Parkinsonian symptoms and an aunt had been unable to have children. On DNA testing of the boy, a mutation of the FMR1 gene diagnostic of Fragile X syndrome was identified; a premutation of the same gene was identified in his mother. Following discussion of the diagnosis, the woman decided not to share this ***genetic information*** with ***genetic relatives***. The woman had a number of siblings living in the same town.

The paediatrician sought advice from practitioners with appropriate expertise on the seriousness of the threat to the ***life, health or safety*** of ***genetic relatives***.

Points for consideration

- *What factors support disclosure in these circumstances?* — Fragile X syndrome is caused by a mutation of the FMR1 gene. When it occurs in a child, the mother usually carries a premutation of the gene. Males can also carry the premutation. Individuals with a premutation can experience early menopause and/or reduced fertility (women) and/or a late onset (over 50) degenerative neurological condition sometimes diagnosed as Parkinson's disease (FXTAS; more common in males). The diagnosis of Fragile X syndrome in the boy therefore has implications for a number of the woman's **genetic relatives**.
- *What factors weigh against disclosure?* The mother's lack of consent for disclosure is the main consideration in this case, as disclosure without consent is likely to affect family relationships and the doctor/patient relationship. The fact that the condition is not curable needs to be taken into account, although many of the symptoms can be treated.
- *What information could be given to the patient?* — The child in this case is very young and it is unlikely that he would play a role in discussion of the case. He is likely to have significant intellectual disability, and emotional and behavioural problems.
- *What information could be given to the **authorised representative**?* — Prior to DNA testing taking place, the mother of the child should have been given an explanation of the causes of Fragile X syndrome and the pattern of its inheritance, as well as an explanation of the significance of this diagnosis for **genetic relatives**, the need for them to be advised and the potential for them to be advised without her consent. She should also be aware that information allowing diagnosis in her relatives would prevent them having to undergo unnecessary interventions, some of which carry risk.

- *Who might be involved in decision-making?* — The seriousness of the threat to the **life, health or safety** of **genetic relatives** presented by the full mutation and the premutation would need to be considered by health practitioners with appropriate expertise (eg covering the areas of neurology and gynaecology as well as paediatrics and clinical genetics).
- *How might disclosure take place?* — It is possible that the paediatrician may identify another affected child in the family, thereby providing a second opportunity to notify the extended family and avoid invasive testing in other children in the family. If this does not occur, the paediatrician will need to make a decision about whether disclosure without consent is **necessary** to **lessen** or prevent a **serious threat** to the **life, health or safety** of **genetic relatives**.

When consent is not given and use but not disclosure of the information takes place

In the following scenario disclosure of **genetic information** is not permissible under NPP 2.1(ea) but use of the **genetic information** within the **organisation** may be appropriate.

Scenario 9

In this scenario the risk to **genetic relatives** is difficult to define and other measures (ie use rather than disclosure) are available to assess the risk to **genetic relatives** making disclosure without consent unnecessary.

A GP with considerable expertise in the management of diabetes diagnosed the condition in a middle-aged woman. The GP also treated most of the woman's immediate family, including her children and grandchildren. He explained the likelihood of other family members having a predisposition to the condition. The woman was adamant that no-one in her family should "know that she was sick or that there was a sickness in the family".

Points for consideration

- *What factors support disclosure in these circumstances?* —Diabetes is a common condition that can lead to a number of complications if left untreated. Early diagnosis and treatment can prevent many of these complications, and changes in lifestyle can delay onset of the condition.
- *What factors weigh against disclosure?* — The heritability of diabetes depends on multiple genes and their interactions with environmental factors, so the risks to **genetic relatives** are not clear. In addition, diabetes is easy to screen for during routine appointments, and is a common diagnosis. Given these factors, it is difficult to justify overriding the woman's refusal to consent to disclose.
- *What information could be given to the patient?* — The woman should be advised that although the risk to her **genetic relatives** is hard to define accurately, it would be preferable for them to know that they may be at increased risk so they can make lifestyle changes and have their glucose levels tested regularly.
- *Who might be involved in decision-making?* — In this case, the GP would not continue with consideration of disclosing **genetic information** without consent, as the risk to relatives is determined by a multitude of factors.
- *How might disclosure take place?* —Disclosure without consent would be inappropriate in this situation, as it would not lead to a **lessening** of the risk. As diabetes is a very prevalent disease, the condition is likely to be picked up by routine health screening. In dealing with other family members, the GP must ensure that his duty of confidentiality to the woman is not breached.

Abbreviations and acronyms

AHEC	Australian Health Ethics Committee
ALRC	Australian Law Reform Commission
Amendment Act	*Privacy Legislation Amendment Act 2006* (Cth)
ARC	Australian Research Council
AVCC	Australian Vice-Chancellors' Committee
GP	general practitioner
HGAC	Human Genetics Advisory Committee
NHMRC	National Health and Medical Research Council
NPP	National Privacy Principle
Privacy Act	*Privacy Act 1988* (Cth)

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Appendices

1 Working committee and terms of reference

Membership

Chair — Dr Sandra Hacker AO, HGAC

Ms Sharon Caris, AHEC

Dr Elizabeth McCusker
Neurologist
Westmead Hospital
Huntington Disease Service

Dr Graeme Suthers
Clinical geneticist
Deputy Head, South Australian Clinical Genetics Service

Dr Samantha Wake
Genetic Counsellor (FHGSA)
Genetic Health Services Victoria

Ex officio members

Professor Colin Thompson
Chair, Australian Health Ethics Committee, NHMRC

Professor Ron Trent
Chair, Human Genetics Advisory Committee, NHMRC

Observer

Office of the Privacy Commissioner

NHMRC support

Dr David Abbott

Ms Vesna Bencic

Ms Cheryl Cooke

Ms Vesna Cvjeticanin

Ms Jodie Francis

Dr Barbara Henderson-Smith

Ms Sharon Hill

Ms Cathy Mitchell

Ms Riki Porteous

Technical writers

Ms Elizabeth Hall & Ms Jenny Ramson, Ampersand Health Science Writing

Role

The role of the Section 95AA Guidelines Working Committee is to advise the technical writer about the content of the new guidelines, taking into account the requirements in the *Privacy Act 1988 (Cth)* (as amended 2006).

Line of reporting

The working committee was required to:

- regularly report on its progress to the steering committee, and seek endorsement of its activities
- through the steering committee, provide regular progress reports to the HGAC and AHEC
- through the Chairs of both Committees, report its progress to Council and the CEO on a regular basis.

2 Excerpts from the Privacy Act

95AA Guidelines for National Privacy Principles about genetic information

Overview

(1) This section allows the Commissioner to approve for the purposes of the National Privacy Principles (the ***NPPs***) guidelines that are issued by the National Health and Medical Research Council.

Approving guidelines for use and disclosure

(2) For the purposes of subparagraph 2.1(ea)(ii) of the NPPs, the Commissioner may, by legislative instrument, approve guidelines that relate to the use and disclosure of genetic information for the purposes of lessening or preventing a serious threat to the life, health or safety (whether or not the threat is imminent) of an individual who is a genetic relative of the individual to whom the genetic information relates.

Review by AAT

(3) Application may be made to the Administrative Appeals Tribunal for review of a decision of the Commissioner to refuse to approve guidelines.

Interpretation

SECTION 6 — INTERPRETATION

*"**health information**"* means:

(a) information or an opinion about:

(i) the health or a disability (at any time) of an individual; or

(ii) an individual's expressed wishes about the future provision of health services to him or her; or

(iii) a health service provided, or to be provided, to an individual;

that is also personal information; personal information; or

(b) other personal information collected to provide, or in providing, a health service; or

(c) other personal information about an individual collected in connection with the donation, or intended donation, by the individual of his or her body parts, organs or body substances; or

(d) genetic information about an individual in a form that is, or could be, predictive of the health of the individual or a genetic relative of the individual.

*"**health service**"* means:

(a) an activity performed in relation to an individual that is intended or claimed (expressly or otherwise) by the individual or the person performing it:
  (i) to assess, record, maintain or improve the individual's health; or
  (ii) to diagnose the individual illness or disability; or
  (iii) to treat the individual's illness or disability or suspected illness or disability; or

(b) the dispensing on prescription of a drug or medicinal preparation by a pharmacist.

SECTION 6C — ORGANISATIONS

What is an organisation?

(1) In this Act:

*"**organisation**"* means:

(a) an individual; or

(b) a body corporate; or

(c) a partnership; or

(d) any other unincorporated association; or business operator, a registered political party, an agency, a State or Territory authority or a prescribed instrumentality of a State or Territory.

Note: Regulations may prescribe an instrumentality by reference to one or more classes of instrumentality. See subsection 46(2) of the *Acts Interpretation Act 1901*.

Example: Regulations may prescribe an instrumentality of a State or Territory that is an incorporated company, society or association and therefore not a State or Territory authority.

Legal person treated as different organisations in different capacities

(2) A legal person can have a number of different capacities in which the person does things. In each of those capacities, the person is taken to be a different ***organisation***.

Example: In addition to his or her personal capacity, an individual may be the trustee of one or more trusts. In his or her personal capacity, he or she is one organisation. As trustee of each trust, he or she is a different organisation.

What is a State or Territory authority?

(3) In this Act:

State or Territory authority means:

(a) a State or Territory Minister; or

(b) a Department of State of a State or Territory; or

(c) a body (whether incorporated or not), or a tribunal, established or appointed for a public purpose by or under a law of a State or Territory, other than:
  (i) an incorporated company, society or association; or
  (ii) an association of employers or employees that is registered or recognised under a law of a State or Territory dealing with the resolution of industrial disputes; or

(d) a body established or appointed, otherwise than by or under a law of a State or Territory, by:

(i) a Governor of a State; or
(ii) the Australian Capital Territory Executive; or
(iii) the Administrator of the Northern Territory; or
(iv) the Administrator of Norfolk Island; or
(v) a State or Territory Minister; or
(vi) a person holding an executive office mentioned in section 12 of the Norfolk Island Act 1979; or

(e) a person holding or performing the duties of an office established by or under, or an appointment made under, a law of a State or Territory, other than the office of head of a State or Territory Department (however described); or

(f) a person holding or performing the duties of an appointment made, otherwise than under a law of a State or Territory, by:

(i) a Governor of a State; or
(ii) the Australian Capital Territory Executive; or
(iii) the Administrator of the Northern Territory; or
(iv) the Administrator of Norfolk Island; or
(v) a State or Territory Minister; or
(vi) a person holding an executive office mentioned in section 12 of the Norfolk Island Act 1979; or

(g) a State or Territory court.

Making regulations to stop instrumentalities being organisations

(4) Before the Governor-General makes regulations prescribing an instrumentality of a State or Territory for the purposes of the definition of ***organisation*** in subsection (1), the Minister must:

(a) be satisfied that the State or Territory has requested that the instrumentality be prescribed for those purposes; and

(b) consider:

(i) whether treating the instrumentality as an organisation for the purposes of this Act adversely affects the government of the State or Territory; and
(ii) the desirability of regulating under this Act the collection, holding, use, correction, disclosure and transfer of personal information by the instrumentality; and
(iii) whether the law of the State or Territory regulates the collection, holding, use, correction, disclosure and transfer of personal information by the instrumentality to a standard that is at least equivalent to the standard that would otherwise apply to the instrumentality under this Act; and

(c) consult the Commissioner about the matters mentioned in subparagraphs (b)(ii) and (iii).

State does not include Territory

(5) In this section:

State does not include the Australian Capital Territory or the Northern Territory (despite subsection 6(1)).

SECTION 6D — SMALL BUSINESS AND SMALL BUSINESS OPERATORS

What is a ***small business****?*

(1) A business is a ***small business*** at a time (the ***test time***) in a financial year (the ***current year***) if its annual turnover for the previous financial year is $3,000,000 or less.

Test for new business

(2) However, if there was no time in the previous financial year when the business was carried on, the business is a small business at the test time only if its annual turnover for the current year is $3,000,000 or less.

What is a ***small business operator****?*

(3) A ***small business operator*** is an individual, body corporate, partnership, unincorporated association or trust that:

(a) carries on one or more small businesses; and

(b) does not carry on a business that is not a small business.

Entities that are not small business operators

(4) However, an individual, body corporate, partnership, unincorporated association or trust is not a ***small business operator*** if he, she or it:

(a) carries on a business that has had an annual turnover of more than $3,000,000 for a financial year that has ended after the later of the following:

(i) the time he, she or it started to carry on the business;

(ii) the commencement of this section; or

(b) provides a health service to another individual and holds any health information except in an employee record; or

(c) discloses personal information about another individual to anyone else for a benefit, service or advantage; or

(d) provides a benefit, service or advantage to collect personal information about another individual from anyone else; or

(e) is a contracted service provider for a Commonwealth contract (whether or not a party to the contract).

Private affairs of small business operators who are individuals

(5) Subsection (4) does not prevent an individual from being a small business operator merely because he or she does something described in paragraph (4)(b), (c) or (d):

(a) otherwise than in the course of a business he or she carries on; and

(b) only for the purposes of, or in connection with, his or her personal, family or household affairs.

Non-business affairs of other small business operators

(6) Subsection (4) does not prevent a body corporate, partnership, unincorporated association or trust from being a small business operator merely because it does something described in paragraph (4)(b), (c) or (d) otherwise than in the course of a business it carries on.

Disclosure compelled or made with consent

(7) Paragraph (4)(c) does not prevent an individual, body corporate, partnership, unincorporated association or trust from being a small business operator only because he, she or it discloses personal information about another individual:

(a) with the consent of the other individual; or

(b) as required or authorised by or under legislation.

Collection with consent or under legislation

(8) Paragraph (4)(d) does not prevent an individual, body corporate, partnership, unincorporated association or trust from being a small business operator only because he, she or it:

(a) collects personal information about another individual from someone else:

(i) with the consent of the other individual; or

(ii) as required or authorised by or under legislation; and

(b) provides a benefit, service or advantage to be allowed to collect the information.

Related bodies corporate

(9) Despite subsection (3), a body corporate is not a small business operator if it is related to a body corporate that carries on a business that is not a small business.

National Privacy Principles

NPP 1 — COLLECTION

1.1 An organisation must not collect personal information unless the information is necessary for one or more of its functions or activities.

1.2 An organisation must collect personal information only by lawful and fair means and not in an unreasonably intrusive way.

1.3 At or before the time (or, if that is not practicable, as soon as practicable after) an organisation collects personal information about an individual from the individual, the organisation must take reasonable steps to ensure that the individual is aware of:

(a) the identity of the organisation and how to contact it; and

(b) the fact that he or she is able to gain access to the information; and

(c) the purposes for which the information is collected; and

(d) the organisations (or the types of organisations) to which the organisation usually discloses information of that kind; and

(e) any law that requires the particular information to be collected; and

(f) the main consequences (if any) for the individual if all or part of the information is not provided.

1.4 If it is reasonable and practicable to do so, an organisation must collect personal information about an individual only from that individual.

1.5 If an organisation collects personal information about an individual from someone else, it must take reasonable steps to ensure that the individual is or has been made aware of the matters listed in subclause 1.3 except to the extent that making the individual aware of the matters would pose a serious threat to the life or health of any individual.

NPP 2 — USE AND DISCLOSURE

2.1 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:

(a) both of the following apply:

(i) the secondary purpose is related to the primary purpose of collection and, if the personal information is sensitive information, directly related to the primary purpose of collection;

(ii) the individual would reasonably expect the organisation to use or disclose the information for the secondary purpose; or

(b) the individual has consented to the use or disclosure; or

(c) if the information is not sensitive information and the use of the information is for the secondary purpose of direct marketing:

(i) it is impracticable for the organisation to seek the individual's consent before that particular use; and

(ii) the organisation will not charge the individual for giving effect to a request by the individual to the organisation not to receive direct marketing communications; and

(iii) the individual has not made a request to the organisation not to receive direct marketing communications; and

(iv) in each direct marketing communication with the individual, the organisation draws to the individual's attention, or prominently displays a notice, that he or she may express a wish not to receive any further direct marketing communications; and

(v) each written direct marketing communication by the organisation with the individual (up to and including the communication that involves the use) sets out the organisation's business address and telephone number and, if the communication with the individual is made by fax, telex or other electronic means, a number or address at which the organisation can be directly contacted electronically; or

(d) if the information is health information and the use or disclosure is necessary for research, or the compilation or analysis of statistics, relevant to public health or public safety:

(i) it is impracticable for the organisation to seek the individual's consent before the use or disclosure; and

(ii) the use or disclosure is conducted in accordance with guidelines approved by the Commissioner under section 95A for the purposes of this subparagraph; and

(iii) n the case of disclosure the organisation reasonably believes that the recipient of the health information will not disclose the health information, or personal information derived from the health information; or

(e) the organisation reasonably believes that the use or disclosure is necessary to lessen or prevent:

(i) a serious and imminent threat to an individual's life, health or safety; or

(ii) a serious threat to public health or public safety; or

(ea) if the information is genetic information and the organisation has obtained the genetic information in the course of providing a health service to the individual:

(i) the organisation reasonably believes that the use or disclosure is necessary to lessen or prevent a serious threat to the life, health or safety (whether or not the threat is imminent) of an individual who is a genetic relative of the individual to whom the genetic information relates; and

(ii) the use or disclosure is conducted in accordance with guidelines approved by the Commissioner under section 95AA for the purposes of this subparagraph; and

(iii) in the case of disclosure-the recipient of the genetic information is a genetic relative of the individual; or

(f) the organisation has reason to suspect that unlawful activity has been, is being or may be engaged in, and uses or discloses the personal information as a necessary part of its investigation of the matter or in reporting its concerns to relevant persons or authorities; or

(g) the use or disclosure is required or authorised by or under law; or

(h) the organisation reasonably believes that the use or disclosure is reasonably necessary for one or more of the following by or on behalf of an enforcement body:

(i) the prevention, detection, investigation, prosecution or punishment of criminal offences, breaches of a law imposing a penalty or sanction or breaches of a prescribed law;
(ii) the enforcement of laws relating to the confiscation of the proceeds of crime;
(iii) the protection of the public revenue;
(iv) the prevention, detection, investigation or remedying of seriously improper conduct or prescribed conduct;
(v) the preparation for, or conduct of, proceedings before any court or tribunal, or implementation of the orders of a court or tribunal.

Note 1: It is not intended to deter organisations from lawfully co-operating with agencies performing law enforcement functions in the performance of their functions.

Note 2: Subclause 2.1 does not override any existing legal obligations not to disclose personal information. Nothing in subclause 2.1 requires an organisation to disclose personal information; an organisation is always entitled not to disclose personal information in the absence of a legal obligation to disclose it.

Note 3: An organisation is also subject to the requirements of National Privacy Principle 9 if it transfers personal information to a person in a foreign country.

2.2 If an organisation uses or discloses personal information under paragraph 2.1(h), it must make a written note of the use or disclosure.

2.3 Subclause 2.1 operates in relation to personal information that an organisation that is a body corporate has collected from a related body corporate as if the organisations primary purpose of collection of the information were the primary purpose for which the related body corporate collected the information.

2.4 Despite subclause 2.1, an organisation that provides a health service to an individual may disclose health information about the individual to a person who is responsible for the individual if:

(a) the individual:

(i) is physically or legally incapable of giving consent to the disclosure; or
(ii) physically cannot communicate consent to the disclosure; and

(b) a natural person (the ***carer***) providing the health service for the organisation is satisfied that either:

(i) the disclosure is necessary to provide appropriate care or treatment of the individual; or
(ii) the disclosure is made for compassionate reasons; and

(c) the disclosure is not contrary to any wish:

(i) expressed by the individual before the individual became unable to give or communicate consent; and
(ii) of which the carer is aware, or of which the carer could reasonably be expected to be aware; and

(d) the disclosure is limited to the extent reasonable and necessary for a purpose mentioned in paragraph (b).

2.5 For the purposes of subclause 2.4, a person is responsible for an individual if the person is:

(a) a parent of the individual; or

(b) a child or sibling of the individual and at least 18 years old; or

(c) a spouse or de facto spouse of the individual; or

(d) a relative of the individual, at least 18 years old and a member of the individual's household; or

(e) a guardian of the individual; or

(f) exercising an enduring power of attorney granted by the individual that is exercisable in relation to decisions about the individual's health; or

(g) a person who has an intimate personal relationship with the individual; or

(h) a person nominated by the individual to be contacted in case of emergency.

2.6 In subclause 2.5:

child of an individual includes an adopted child, a step-child and a foster-child, of the individual.

parent of an individual includes a step-parent, adoptive parent and a foster-parent, of the individual.

relative of an individual means a grandparent, grandchild, uncle, aunt, nephew or niece, of the individual.

sibling of an individual includes a half-brother, half-sister, adoptive brother, adoptive sister, step-brother, step-sister, foster-brother and foster-sister, of the individual.

NPP 3 — DATA QUALITY

An organisation must take reasonable steps to make sure that the personal information it collects, uses or discloses is accurate, complete and up-to-date.

NPP 4 — DATA SECURITY

4.1 An organisation must take reasonable steps to protect the personal information it holds from misuse and loss and from unauthorised access, modification or disclosure.

4.2 An organisation must take reasonable steps to destroy or permanently de-identify personal information if it is no longer needed for any purpose for which the information may be used or disclosed under National Privacy Principle 2.

NPP 5 — OPENNESS

5.1 An organisation must set out in a document clearly expressed policies on its management of personal information. The organisation must make the document available to anyone who asks for it.

5.2 On request by a person, an organisation must take reasonable steps to let the person know, generally, what sort of personal information it holds, for what purposes, and how it collects, holds, uses and discloses that information.

NPP 6 — ACCESS AND CORRECTION

6.1 If an organisation holds personal information about an individual, it must provide the individual with access to the information on request by the individual, except to the extent that:

(a) in the case of personal information other than health information—providing access would pose a serious and imminent threat to the life or health of any individual; or

(b) in the case of health information—providing access would pose a serious threat to the life or health of any individual; or

(c) providing access would have an unreasonable impact upon the privacy of other individuals; or

(d) the request for access is frivolous or vexatious; or

(e) the information relates to existing or anticipated legal proceedings between the organisation and the individual, and the information would not be accessible by the process of discovery in those proceedings; or

(f) providing access would reveal the intentions of the organisation in relation to negotiations with the individual in such a way as to prejudice those negotiations; or

(g) providing access would be unlawful; or

(h) denying access is required or authorised by or under law; or

(i) providing access would be likely to prejudice an investigation of possible unlawful activity; or

(j) providing access would be likely to prejudice:

(i) the prevention, detection, investigation, prosecution or punishment of criminal offences, breaches of a law imposing a penalty or sanction or breaches of a prescribed law; or

(ii) the enforcement of laws relating to the confiscation of the proceeds of crime; or

(iii) the protection of the public revenue; or

(iv) the prevention, detection, investigation or remedying of seriously improper conduct or prescribed conduct; or

(v) the preparation for, or conduct of, proceedings before any court or tribunal, or implementation of its orders; by or on behalf of an enforcement body; or

(k) an enforcement body performing a lawful security function asks the organisation not to provide access to the information on the basis that providing access would be likely to cause damage to the security of Australia.

6.2 However, where providing access would reveal evaluative information generated within the organisation in connection with a commercially sensitive decision-making process, the organisation may give the individual an explanation for the commercially sensitive decision rather than direct access to the information.

Note: An organisation breaches subclause 6.1 if it relies on subclause 6.2 to give an individual an explanation for a commercially sensitive decision in circumstances where subclause 6.2 does not apply.

6.3 If the organisation is not required to provide the individual with access to the information because of one or more of paragraphs 6.1(a) to (k) (inclusive), the organisation must, if reasonable, consider whether the use of mutually agreed intermediaries would allow sufficient access to meet the needs of both parties.

6.4 If an organisation charges for providing access to personal information, those charges:

(a) must not be excessive; and

(b) must not apply to lodging a request for access.

6.5 If an organisation holds personal information about an individual and the individual is able to establish that the information is not accurate, complete and up-to-date, the organisation must take reasonable steps to correct the information so that it is accurate, complete and up-to-date.

6.6 If the individual and the organisation disagree about whether the information is accurate, complete and up-to-date, and the individual asks the organisation to associate with the information a statement claiming that the information is not accurate, complete or up-to-date, the organisation must take reasonable steps to do so.

6.7 An organisation must provide reasons for denial of access or a refusal to correct personal information.

NPP 7 — IDENTIFIERS

7.1 An organisation must not adopt as its own identifier of an individual an identifier of the individual that has been assigned by:

(a) an agency; or

(b) an agent of an agency acting in its capacity as agent; or

(c) a contracted service provider for a Commonwealth contract acting in its capacity as contracted service provider for that contract.

7.1a However, subclause 7.1 does not apply to the adoption by a prescribed organisation of a prescribed identifier in prescribed circumstances.

Note: There are prerequisites that must be satisfied before those matters are prescribed: see subsection 100(2).

7.2 An organisation must not use or disclose an identifier assigned to an individual by an agency, or by an agent or contracted service provider mentioned in subclause 7.1, unless:

(a) the use or disclosure is necessary for the organisation to fulfil its obligations to the agency; or

(b) one or more of paragraphs 2.1(e) to 2.1(h) (inclusive) apply to the use or disclosure; or

(c) the use or disclosure is by a prescribed organisation of a prescribed identifier in prescribed circumstances.

Note: There are prerequisites that must be satisfied before the matters mentioned in paragraph (c) are prescribed: see subsections 100(2) and (3).

7.3 In this clause:

identifier includes a number assigned by an organisation to an individual to identify uniquely the individual for the purposes of the organisation's operations. However, an individual's name or ABN (as defined in the A New Tax System (Australian Business Number) Act 1999) is not an *identifier*.

NPP 8 — ANONYMITY

Wherever it is lawful and practicable, individuals must have the option of not identifying themselves when entering transactions with an organisation.

NPP 9 — TRANSBORDER DATA FLOWS

An organisation in Australia or an external Territory may transfer personal information about an individual to someone (other than the organisation or the individual) who is in a foreign country only if:

(a) the organisation reasonably believes that the recipient of the information is subject to a law, binding scheme or contract which effectively upholds principles for fair handling of the information that are substantially similar to the National Privacy Principles; or

(b) the individual consents to the transfer; or

(c) the transfer is necessary for the performance of a contract between the individual and the organisation, or for the implementation of pre-contractual measures taken in response to the individual's request; or

(d) the transfer is necessary for the conclusion or performance of a contract concluded in the interest of the individual between the organisation and a third party; or

(e) all of the following apply:
  (i) the transfer is for the benefit of the individual;
  (ii) it is impracticable to obtain the consent of the individual to that transfer;
  (iii) if it were practicable to obtain such consent, the individual would be likely to give it; or

(f) the organisation has taken reasonable steps to ensure that the information which it has transferred will not be held, used or disclosed by the recipient of the information inconsistently with the National Privacy Principles.

NPP 10 — SENSITIVE INFORMATION

10.1 An organisation must not collect sensitive information about an individual unless:

(a) the individual has consented; or

(b) the collection is required by law; or

(c) the collection is necessary to prevent or lessen a serious and imminent threat to the life or health of any individual, where the individual whom the information concerns:
  (i) is physically or legally incapable of giving consent to the collection; or
  (ii) physically cannot communicate consent to the collection; or

(d) if the information is collected in the course of the activities of a non-profit organisation—the following conditions are satisfied:
  (i) the information relates solely to the members of the organisation or to individuals who have regular contact with it in connection with its activities;
  (ii) at or before the time of collecting the information, the organisation undertakes to the individual whom the information concerns that the organisation will not disclose the information without the individual's consent; or

(e) the collection is necessary for the establishment, exercise or defence of a legal or equitable claim.

10.2 Despite subclause 10.1, an organisation may collect health information about an individual if:

(a) the information is necessary to provide a health service to the individual; and

(b) the information is collected:
  (i) as required or authorised by or under law (other than this Act); or
  (ii) in accordance with rules established by competent health or medical bodies that deal with obligations of professional confidentiality which bind the organisation.

10.3 Despite subclause 10.1, an organisation may collect health information about an individual if:

(a) the collection is necessary for any of the following purposes:
  (i) research relevant to public health or public safety;
  (ii) the compilation or analysis of statistics relevant to public health or public safety;
  (iii) the management, funding or monitoring of a health service; and

(b) that purpose cannot be served by the collection of information that does not identify the individual or from which the individual's identity cannot reasonably be ascertained; and

(c) it is impracticable for the organisation to seek the individual's consent to the collection; and

(d) the information is collected:

(i) as required by law (other than this Act); or

(ii) in accordance with rules established by competent health or medical bodies that deal with obligations of professional confidentiality which bind the organisation; or

(iii) in accordance with guidelines approved by the Commissioner under section 95A for the purposes of this subparagraph.

10.4 If an organisation collects health information about an individual in accordance with subclause 10.3, the organisation must take reasonable steps to permanently de-identify the information before the organisation discloses it.

10.5 In this clause:

non-profit organisation means a non-profit organisation that has only racial, ethnic, political, religious, philosophical, professional, trade, or trade union aims.

3 Sample materials

Sample Points for inclusion in a privacy leaflet

The following paragraphs related to the disclosure of genetic information could be included in privacy leaflets of health organisations in the private sector.

Privacy leaflet

This leaflet is about privacy, your personal information and our organisation.

Your personal information is protected by law

Our organisation handles your personal information, including your health information, in accordance with the *Privacy Act 1988* (Cth). The Privacy Act has rules about how your personal information is handled, including how it is given to others. There are special rules for health information. Generally, information about you and your health, such as test results and diagnoses, is confidential and will not be given to anyone else without your consent.

Disclosing personal information without consent

Sometimes, in special circumstances, your personal information must be given to someone else even if you do not consent. For example:

- a court may issue a subpoena requiring that we release this information to assist in resolving an investigation or a court case

  or

- you might be diagnosed with a condition, such as a serious infection, that is an immediate threat to other members of the community.

In circumstances like this, we are required by law to release personal information about you. In such a situation, we will continue to provide you with ongoing care.

It may be important to share personal information with relatives

There is another situation in which personal information about you may be given to others.

People can develop a familial disease. A familial disease is one that can be inherited from one or both parents. Other people in your family may be affected, or this may be the first time that this disease has been diagnosed in your family. Being told that you have a familial disease is clearly very important for you as the affected person. This diagnosis is also very important for your genetic relatives because they may develop the disease in the future.

If you are diagnosed with a familial disease, we may recommend that you tell your relatives so that they can take action to reduce the risk, severity, or impact of the disease to themselves and their families.

Most people are willing to do this because it helps their relatives.

The law may allow your doctor to give some information to relatives

Sometimes, a patient may, for some reason, not want to tell relatives about the diagnosis, even though treatment and other help and support are available.

When this happens, privacy laws allow a doctor to inform genetic relatives that there is a genetic condition in the family without the patient's consent for this disclosure. This can only happen if the particular disease poses a serious threat to relatives and the information will be effective and necessary to prevent or lessen harm. The relatives would not be told what the genetic disease is or who in the family was found to have the disease. They would be advised to seek advice from a doctor.

If we decide to give information to your relatives, we will again advise you about the privacy law that allows this disclosure. Your ongoing care will not be affected by your decision.

Do you have any questions?

We would be pleased to give you further information and to answer any questions you may have. Please contact us.

Statement of acknowledgement

In signing this form, I confirm that:

I (patient/authorised representative) have discussed the diagnosis of …….....

..... with my doctor, and

- understand that this condition is inherited and that my genetic relatives are at increased risk of developing this serious condition
- have been advised to disclose this information to my genetic family
- have been allowed time to discuss and ask questions about disclosing this information, and have been offered the opportunity to seek another medical opinion and genetic counselling
- give consent to have information regarding this diagnosis disclosed by my doctor to my genetic relatives.

OR

I (patient/authorised representative) **do not** give consent to have information regarding the diagnosis of a genetic disorder in my family disclosed by my doctor to my genetic relatives. I understand that disclosure without my consent may be allowed under federal privacy legislation, and that my identity would not be disclosed under this provision.

- I understand that any decision I make will not affect the care provided to me by my doctor.

	Name	Signature	Date
Patient	.....	.....	.....
or Authorised representative	.....	.....	.....
Doctor	.....	.....	.....

Form letter to relative

It is suggested that this letter be marked "private and confidential".

Dear…….....

Recently a genetic (blood) relative of yours was diagnosed with an inherited condition. This may mean that you and your genetic relatives (brothers and sisters and your children and other relatives) could also inherit this condition. Perhaps you are already aware of an inherited disease in the family.

While we want to respect your relative's right to privacy, the condition has been judged to be serious enough for you to be contacted. In certain circumstances, the *Privacy Act 1988* (Cth) allows for this information to be passed to genetic relatives like yourself.

This letter is not intended to create distress. Many inherited conditions can be treated and any symptoms lessened.

This letter does not give you any details of this disease, but allows you to decide for yourself whether you wish to have more information. If you do, I would be pleased to provide you with more details. Any information you give me will be treated confidentially. Please note that I cannot give you any information about other family members.

If you choose to make an inquiry, you are not committed to do anything more than receive more detailed information. Genetic testing can be done for some inherited conditions but that would only take place after allowing time to consider the full implications for you, at your request and with your consent.

Please take this letter to your GP if you would like him or her to make contact with me on your behalf. Or you may want to call the contact number listed below to arrange a meeting. Other genetic relatives may also wish to attend, or they can make individual appointments.

Appointments can be organised for discussions with suitable specialists and/or a genetic counsellor. If you live in remote or rural Australia, your GP or health worker is best placed to contact experts to advise and assist, and offer counselling if you would like more information.

It is important for us to know that you have received this letter. Even though you may not want to act on this information, **please acknowledge receipt** by telephoning the number below or returning the enclosed acknowledgement slip in the stamped addressed envelope provided.

I urge you to take this matter seriously as this information could be very important for the health of you and your close relatives.

Yours sincerely

Disclosing Health Practitioner

4 Further information

What is the role of the OPC?

The Office of the Privacy Commissioner (OPC) is an independent statutory office established under the *Privacy Act 1988* (Cth). The Privacy Commissioner has responsibilities under the Privacy Act and other federal legislation to regulate the way these agencies and organisations collect, use, store (to ensure accuracy and security of data records) and disclose people's personal information. The Privacy Commissioner investigates complaints from the public about the misuse of their personal information by agencies and organisations covered by the Privacy Act. More detailed information is available at www.privacy.gov.au.

Do these Guidelines apply to health practitioners in the public sector?

These Guidelines only apply to health service providers in the *private* sector.

Do these Guidelines apply to research settings?

These Guidelines do not apply to research settings. The use of genetic information in human research is discussed in Chapter 3.5 of the *National Statement on Ethical Conduct in Human Research*.

Do these Guidelines apply to all genetics services?

These Guidelines apply to private genetics services but not those in the public sector.

What happens if the patient with the genetic disorder is deceased?

Currently the Privacy Act applies to living persons only. However, genetic information about a deceased person may be subject to legal duties of confidentiality. As well, information about a deceased person may have implications for the confidentiality and privacy of living genetic relatives and advice from a medical defence organisation should therefore be obtained.

The Royal College of Physicians of London publication, *Consent and Confidentiality in Genetic Practice. Guidance on Genetic Testing and Sharing Genetic information* (2006), provides a detailed discussion of this issue.

Where can further advice on providing information and support to patients be obtained?

The NHMRC guidelines on communicating with and providing information to patients (NHMRC 2004a; 2004b) are available at http://www.nhmrc.gov.au.

Where can further advice on genetics and genetic conditions be obtained?

The Centre for Genetics Education develops resources specifically for health professionals. These include the *Australasian Genetics Resource Book,* which provides information on and access to support groups for genetic conditions and genetics services across Australia and New Zealand. Order forms are available at www.genetics.com.au/publications/healthprof.html

The Genetic File is a GP resource available at: www.mcri.edu.au/GF/pages/GeneticsFile.asp

Support groups include the Association of Genetic Support of Australasia (www.agsa-geneticsupport.org.au).

Where can legal advice be obtained by health practitioners?

Healthcare indemnity providers are generally available to provide medico-legal advice to members on a 24-hour 7-day basis.

Where can further advice on cultural issues be obtained?

The NHMRC publications *Cultural Competency in Health: a Guide for Policy, Partnerships and Participation, Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research* and *Keeping Research on Track: a guide for Aboriginal and Torres Strait Islander peoples about health research ethics* provide advice on cultural competency in health organisations. The guides are available at www.nhmrc.gov.au.

What happens if a patient is unhappy with the medical practitioner's decision to use or disclose their genetic information without consent?

If an individual thinks a health service provider has interfered with their privacy, they can complain to the Office of the Privacy Commissioner. In most cases, the Commissioner will not investigate the complaint unless the individual has first tried to resolve the complaint with the health service provider.

If the individual and the provider cannot resolve the complaint between themselves, the Office of the Privacy Commissioner conciliates the complaint. As a last resort, the Commissioner can make a formal determination. The Privacy Commissioner can also investigate an act or practice that may be a breach of privacy even if there is no complaint.

Further information on the Office of the Privacy Commissioner's complaint handling process is available at: http://www.privacy.gov.au/privacy_rights/complaints/index.html#decision