



information
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commission
new south wales

Use and disclosure of genetic information to a patient's genetic relatives: Guidelines for organisations in NSW

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Amendments to this publication have also been made where appropriate to reflect the March 2014 revision of the above Commonwealth Guidelines.

This publication takes effect when the *Health Legislation Amendment Act 2012* is proclaimed on 1 November 2014.

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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 are now aware of the genetic basis of a number of familial diseases and 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 2012, the New South Wales (NSW) Parliament passed the *Health Legislation Amendment Act 2012* (NSW) (Amending Act). Once commenced, the Amending Act will make amendments to include new Health Privacy Principles (HPP) 10(1)(c1) and 11(1)(c1) in the *Health Records and Information Privacy Act 2002* (NSW) (HRIP Act) to allow genetic information to be used or disclosed without consent for a secondary purpose other than for the purpose for which it was collected. HPP 10(1)(c1) will allow genetic information to be used by an organisation in circumstances where there is a reasonable belief that doing so would be necessary to lessen or prevent a serious threat to life, health or safety (whether or not the threat is imminent) of genetic relatives, and in accordance with guidelines issued by the NSW Privacy Commissioner, if any. HPP 11(1) (c1) will allow disclosure of genetic information to genetic relatives where there is a reasonable belief that disclosure is necessary to lessen or prevent a serious threat to life, health or safety of genetic relatives. This genetic information must also be disclosed in accordance with guidelines issued by the NSW Privacy Commissioner, if any.

The amendments to the HRIP Act provide 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 in appropriate circumstances.

[Breaches of the Guidelines may be pursued under the procedures for inquiries and investigations conducted by the NSW Privacy Commissioner.](#)

Purpose

The Guidelines specify the requirements that must be met by an organisation if they choose to **use or disclose genetic information without patient consent** under HPP 10(1)(c1) or 11(1)(c1). Use or disclosure of genetic information without consent must be in accordance with HPP 10 or 11 and these Guidelines. These Guidelines have been issued by the NSW Privacy Commissioner with the approval of the Minister for Health.

Application

These Guidelines apply to every organisation in NSW that is a health service provider or that collects, holds or uses genetic information in the course of providing health services to individuals (for example, medical specialists and general practitioners). The term **organisation** means public sector agencies, including public health organisations, or a private sector person.

A private sector person can be a natural person, body corporate, partnership or trust or any other unincorporated association or body, but does not include a small business operator within the meaning of the Commonwealth *Privacy Act 1988*, or an agency within the meaning of that Act (Section 4 of the HRIP Act).

Although small business operators are generally excluded, all health service providers are bound by the Guidelines irrespective of their size.

Organisations should take their own legal advice if they are in doubt about whether they are an organisation for the purposes of the HRIP Act, and these Guidelines.

Scope

As well as reflecting the amendments to the HRIP Act, 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 disclosure of **genetic information** to anyone other than the patient and genetic relatives, as this is outside the scope of HPP 10(1)(c1) and 11(1)(c1);
- situations in which consent to **use or disclose genetic information** to relatives has been given — in these cases, the provisions under HPP 10(1)(c1) and 11(1)(c1) are not applicable as HPP 10(1)(c1) and 11(1)(c1) are concerned with disclosure without consent.¹ However, the HPPs 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 HPP 10(1)(c1) and 11(1)(c1). The patient's consent to disclose his or her genetic information to a pregnant mother would be required if there was a serious threat to the unborn child;

¹ 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.

- 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 HRIP Act and the **duty of confidentiality** in health;
- genetic screening;
- **genetic information** that is stored in databases or registers maintained by the Commonwealth and other State or Territory agencies, as this is outside the scope of HPP 10(1)(c1) and 11(1)(c1); or
- the use of **genetic information** in human research (as discussed in Chapter 3.5 of the *National Statement on Ethical Conduct in Human Research*).

Structure of the guidelines

The guidance in this document is intended to satisfy the purpose of HPP 10(1)(c1) and 11(1)(c1). 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 HRIP Act introduced in the Amending Act (Chapter 1);
 - ethical considerations, including factors involved in understanding specific situations (Chapter 2); and
 - requirements for **use or disclosure** without consent in accordance with HPP 10(1)(c1) or 11(1)(c1) and good practice throughout the process of decision-making and, potentially, disclosure (Chapter 3); and
- 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 HPP 10(1)(c1) or 11(1)(c1) and act in accordance with the Guidelines. However, it should be noted that the scenarios are to assist **organisations** to comply with HPP 10(1)(c1) and 11(1)(c1) and the nine Guidelines. **Acting in accordance with the scenarios does not necessarily protect against a breach of the HPPs or a breach of the duty of confidentiality (common law)** (see Appendix 1).

The appendices provide:

- excerpts from the HRIP Act, including the HPPs (Appendix 1);
- sample materials that can be adapted for local use (Appendix 2); and
- answers to frequently asked questions (Appendix 3).

The Guidelines were adopted (with appropriate amendments) from the NHMRC's "*Use and disclosure of genetic information to a patient's genetic relatives under s95AA of the Privacy Act 1988 (Cth)*" to ensure consistency with the applicable Commonwealth standards. The Commonwealth Guidelines were approved by the Commonwealth Privacy Commissioner.

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 Health Privacy Principles 10(1)(c1) and 11(1)(c1). They should be read in conjunction with the full explanation; page references are provided in brackets.

For the purposes of Health Privacy Principles 10(1)(c1) and 11(1)(c1):

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 21-31; in particular pp 26-29)
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 15-20)
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 22-26)
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 25-26)
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 26-29)
Guideline 6	Where practicable, the identity of the patient should not be apparent or readily ascertainable in the course of inter-professional communication.	(p 26)
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.	(p 31)
Guideline 8	Disclosure of genetic information without consent should generally be limited to relatives no further removed than third-degree relatives.	(p 32)
Guideline 9	All stages of the process must be fully documented, including how the decision to use or disclose without consent was made.	(p 32)

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 HRIP 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

Authorised representative refers to the person authorised to act on behalf of a patient in relation to matters under the HRIP Act if the patient lacks capacity and means (as defined under section 8(1) of the HRIP Act):

- a) an attorney under an enduring power of attorney; or
- b) a guardian under the *Guardianship Act 1987* or a person responsible within the meaning of Part 5 of the *Guardianship Act*; or
- c) a person having parental responsibility if the individual is a child, or
- d) a person who is otherwise empowered under law to exercise any functions as an agent of or in the best interests of the individual.

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, sufficient knowledge of the patient's condition and its genetic basis and who has sought expert advice. This person may be a specialist or general practitioner as long as the 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 (e.g. 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 decisions 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 HRIP Act.

Genetic information

Genetic information refers to “health information” as described in section 6(d) of the HRIP Act. Genetic information is defined as: “other personal information that is genetic information about an individual arising from a health service provided to the individual in a form that is or could be predictive of the health (at any time) of the individual or of a genetic relative”.

Genetic relative

The term is defined as follows in the HRIP Act as: “a person who is related to an individual by blood, for example, a sibling, parent or descendant of the individual”.

In the context of these Guidelines, disclosure without consent is generally recommended to relatives no further removed than third-degree relatives,² as the process of **cascade contact** should facilitate access to information for the wider cross-section of a family³.

Lessen

The term “lessen”, as used in HPP 10(1)(c1) and 11(1)(c1) 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 HPP 10(1)(c1) and 11(1)(c1) will not apply.

² Third-degree relative has been chosen for practical reasons e.g. 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.

³ According to the United Kingdom’s NHS National Genetics and Genomics Education Centre, a third-degree relative is defined as “a first cousin, great-grandparent or great-grandchild. A third degree relative shares about one eighth of their genes with the person”. See <http://www.geneticseducation.nhs.uk/genetics-glossary/242-third-degree-relative>

Life, health or safety

The phrase “life, health or safety”, including as it is used in HPP 10(1)(c1) and 11(1)(c1), 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 HPP 10(1)(c1) and 11(1)(c1), 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

“Organisation” means a NSW public sector agency, including a public health organisation, or a private sector person.

Privacy

Privacy may refer to having a sense of personal freedom, having information about oneself used fairly and to be left alone. While there is no general legal right to privacy, legislative protection in NSW is provided through the operation of the *Privacy and Personal Information Protection Act 1998* (PIIP Act) governing the collection, retention, security, access to, alteration, use and disclosure of personal information by NSW public sector agencies. The HRIP Act affords further protection of individuals’ health information, applying to NSW public sector agencies, private health practitioners and businesses in NSW (eg. general practitioners, optometrists, dentists, private hospitals, insurance companies, airlines and medical centres).

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

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** (e.g. with the patient’s **genetic relatives**).

PART B: Summary and practical guide

What are these Guidelines for?

These Guidelines were developed in response to changes to the HRIP Act and to HPP 10(1)(c1) and HPP 11(1)(c1) that provide for disclosure of **genetic information** to **genetic relatives** without the consent of the patient in certain circumstances. The change that was introduced through the Health Privacy Principles:

- 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 **organisations** which include NSW public sector agencies, in particular public health organisations, and private sector persons; and
- does not apply to situations concerning **genetic information** that presents a **serious threat** to an unborn child. The patient's consent to disclose his or her genetic information to a pregnant mother would be required if there was a serious threat to the 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 HPP 10(1)(c1) and HPP 11(1)(c1). That test provides for use or disclosure when:

- an organisation reasonably believes that 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 case of **disclosure**, the recipient of the genetic information must be a genetic relative of the individual of whom the genetic information relates; and
- the use or disclosure is in accordance with guidelines, if any, issued by the NSW Privacy Commissioner.

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 HPPs (see Appendix 1) and **duty of confidentiality** are other considerations. The application of the Guidelines is considered in more detail below.

HPP 10(1)(c1) and HPP 11(1)(c1) **do 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 HPP 10(1)(c1) and HPP 11(1)(c1) 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 HPP 10(1)(c1) and HPP 11(1)(c1) and the nine Guidelines given here. Acting in accordance with the scenarios does not necessarily protect against a breach of the HPPs 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 21-31).**

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; and
- the probability that a **genetic relative** may also have the condition or be a carrier of the relevant mutation, and the modes of inheritance.

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 (e.g. whether the relatives can benefit from the information); and
- 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 p 28-29);
- 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 p 28-29);
- 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 28-29); and
- 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 are the ethical points that 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 15-20).**

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 22-26).**

In providing guidance on meeting the requirements of the HPPs, 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 22);

- advise that in certain circumstances, **use or disclosure** may be made without consent (see p 22);
- consider referring patients to a health practitioner with expertise in conveying relevant **genetic information** or consult such an expert (see p 22-23);
- consider arranging timely genetic counselling for patients or referring them to an organisation that provides genetic counselling (see p 22);
- 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 23);
- 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 23-24);
- 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 24); 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 15).

If consent is provided, the provisions under HPP 10(1)(c1) and HPP 11(1)(c1) 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 25-26).

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 26-29).

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 26).

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 25-29);
- 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 26);
- organise discussion of the case so that all involved have time to prepare and document the outcomes of these discussions (see p 26);
- identify another medical practitioner who is able to fulfil the role if unwilling to undertake the role of **authorising medical practitioner** (see p 20).

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 p 31).

Guideline 8 Disclosure of genetic information without consent should generally be limited to relatives no further removed than third-degree relatives (see p 32).

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 32).

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 HRIP Act, particularly HPPs 1-4.

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.

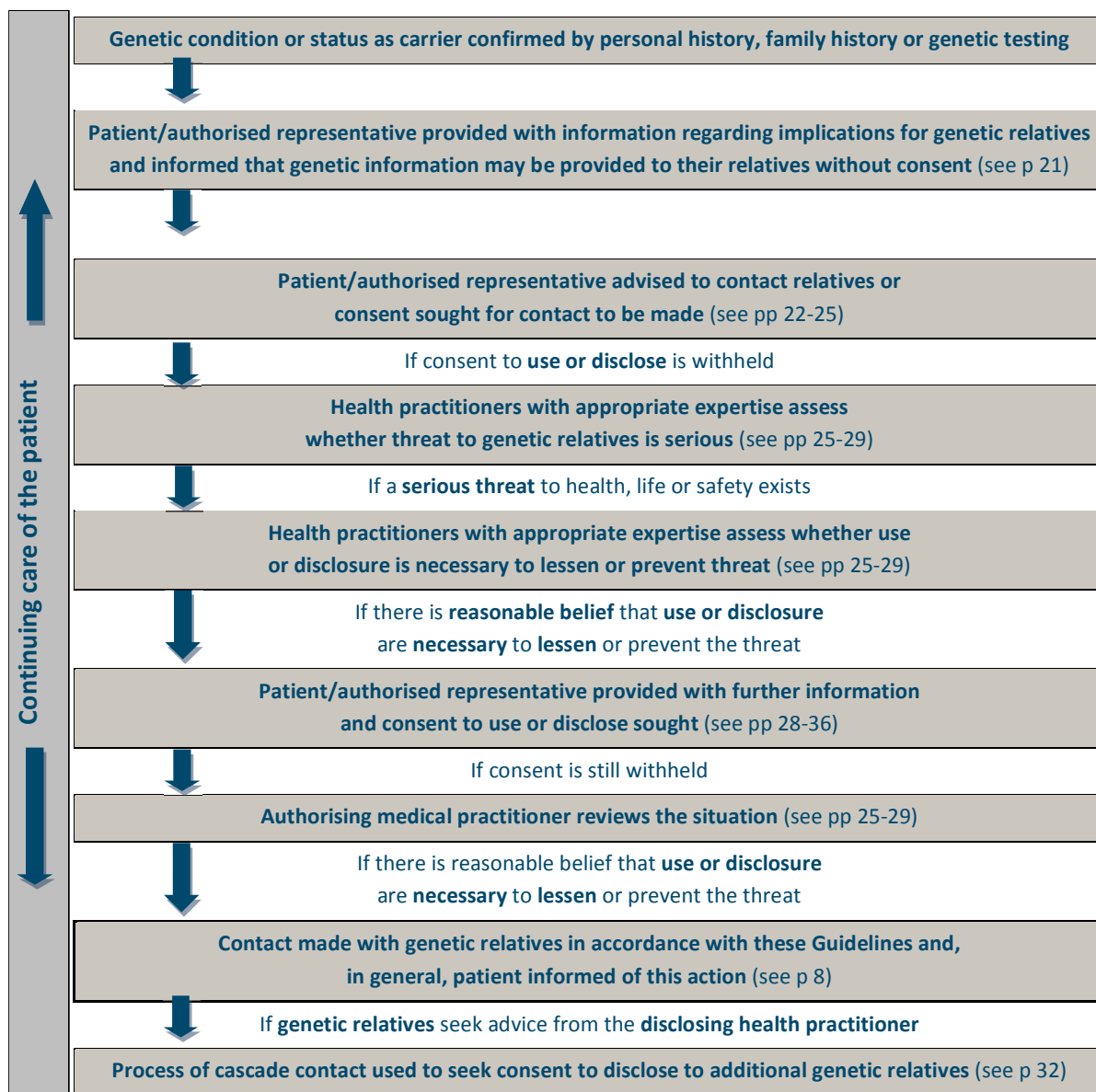
Key points for good practice are to:

- 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 28);
- 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 31);
- 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 31);
- consider using a step-by-step process of **cascade contact** if contemplating making contact beyond first-degree relatives (p 32); and

- 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 32).

A sample letter that may be used as a template for contact or as the starting point for **cascade contact** is included in Appendix 2.

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 (e.g. 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 page 2). 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 HPP 10(1) (c1) and HPP 11(1) (c1) are not applicable. The HPPs (see Appendix 1) 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:

- New South Wales privacy legislation (see Chapter 1);
- context for decision making (see Chapter 2); and
- practical considerations (see Chapter 3).

1. NEW SOUTH WALES PRIVACY LEGISLATION

In New South Wales, the privacy laws in operation are the PPIP Act and HRIP Act⁴.

The PPIP Act regulates the way in which all NSW public sector agencies collect, use, store and release personal information in order to maintain privacy of individuals. The PPIP Act contains a set of 'Information Protection Principles' (IPPs) which NSW public sector agencies must abide by and sets out the role of the NSW Privacy Commissioner. It also establishes methods for the enforcement of privacy and a complaints handling framework if an individual believes their personal information has been mishandled. The NSW Privacy Commissioner has the power to receive, investigate and conciliate complaints about privacy matters and may conduct inquiries and investigations if required.

Specifically for health information, the HRIP Act protects and enhances the privacy rights of individuals with respect to this highly sensitive information. The HRIP Act governs the use and disclosure of health information in both public and private sectors in NSW. This includes public and private hospitals, doctors and other health care organisations; or any other organisation that obtains any type of health information including (but not limited to) insurance companies, airlines, gymnasiums and universities.

The HRIP Act sets out legal obligations in the form of 15 HPPs, located in Schedule 1 of the HRIP Act, which concern the collection, storage, access and accuracy, use, disclosure, assigning identifiers, anonymity and transferrals and linkage of health records (see Appendix 1). These obligations are subject to a number of legal exemptions from these principles. With respect to health information, the NSW Privacy Commissioner has a number of functions. This includes, among a number of functions, promoting the adoption of, and monitoring compliance with, the HPPs; preparing, publishing and promoting guidelines relating to the protection of health information; and having the ability to receive, investigate and conciliate complaints regarding the handling of health information. The NSW Privacy Commissioner's functions can be found at section 58 of the HRIP Act.

⁴ Many private sector organisations may also be subject to the *Commonwealth Privacy Act 1988*

1.1 Information Protection Principles and Health Privacy Principles

The NSW privacy laws contain two sets of principles. The IPPs located in the PPIP Act, which apply to NSW public sector agencies, and the HPPs, contained in HRIP Act in regard to health information and applying to all public and private sector organisations.

The IPPs apply to how personal information is handled by NSW public sector agencies. Personal information refers to any information that relates to an identifiable person. The IPPs are legal obligations that NSW public sector agencies must comply with and cover the collection, storage, access, accuracy, use and disclosure of personal information. These legal obligations ensure that NSW public sector agencies are handling personal information responsibly, although lawful exemptions from the IPPs are available in particular circumstances. For example, a law enforcement agency is not required to comply if compliance by the agency would prejudice the agency's law enforcement functions.

The HPPs aim to protect health information through 15 principles imposed on organisations to ensure that health information is handled appropriately. Particularly relevant to these Guidelines are HPPs 10 and 11. Whilst organisations holding health information must not use the information for a purpose other than the purpose for which it was collected, HPP 10 provides for certain circumstances exempting organisations from the general requirements. This is also the case for disclosure of health information, where exemptions can be found in HPP 11.

An organisation may use or disclose health information for a purpose other than the purpose it was collected, in circumstances, for example, where:

- the patient consents;
- the secondary purpose is directly related to the primary purpose within the individual's reasonable expectations
- the information is disclosed to or used by a law enforcement agency ; and
- where any other exception applies.

1.2 Health Legislation Amendment Act 2012

The Amending Act was passed by New South Wales Parliament in 2012. The Amending Act amended the law regarding the protection of genetic information by establishing a framework in which such information can be used and disclosed to genetic relatives in certain circumstances.

Upon commencement of the Amending Act, the amendments will bring the HRIP Act in line with the Commonwealth's *Privacy Act 1988* regarding the use and disclose of genetic information.

Genetic information and genetic relative

The Amending Act defines "genetic information" as meaning health information of a type described in section 6 (d).

Once the amendments commence, the definition of genetic information in section 6(d) of the HRIP Act will be altered to "other personal information that is genetic information about an individual arising from a health service provided to the individual in the form that is or could be predictive of the health (at any time) of the individual or of a *genetic relative*".

The Amending Act defines “genetic relative” as “a person who is related to an individual by blood, for example, a sibling parent or descendant of the individual”. This definition will be inserted in section 4(1) of the HRIP Act once the amendments commence.

Changes to the Health Privacy Principles

The Amending Act introduces two exceptions to the general requirement that health information must not be used or disclosed for a purpose other than the purpose for which it was collected. The first exception in HPP 10(1)(c1) allows genetic information to be used by an organisation, without the consent of the individual, if it reasonably believes that using the individual’s genetic information is necessary to lessen or prevent a serious threat to the life, health or safety of a genetic relative, even if the threat is not imminent; and in accordance with guidelines issued by the NSW Privacy Commissioner, if any.

Similarly, the second exception located in HPP 11(1)(c1) allows genetic information to be disclosed by an organisation to a genetic relative of the individual, if it reasonably believes that disclosing genetic information to the genetic relative is necessary to lessen or prevent a serious threat to the life, health or safety of that genetic relative, even if the threat is not imminent and consent has not been given. It must also be in accordance with guidelines issued by the NSW Privacy Commissioner, if any.

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 (e.g. 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 free of clinical terms and reinforcing discussions with written and other relevant materials and services (e.g. video, websites, advice on relevant support groups, interpreters); and
- 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; and
- 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; and
- 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.

NSW Family and Community Services has produced a practical resource – *Working with Aboriginal people and communities* for all departmental and non-government organisation staff to improve cultural awareness and responsiveness to the needs of Aboriginal people and communities. Health practitioners may find this resource useful in understanding the cultural and historical factors that need to be acknowledged when interacting with Aboriginal people⁵.

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

⁵ Accessible at: http://www.community.nsw.gov.au/docswr/assets/main/documents/working_with_aboriginal.pdf

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 pre-symptomatic 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; and
- 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 (e.g. information compromising subsequent applications for life or disability insurance, potential impact on superannuation); or
- 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 3.2.3.

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.
- Possibility of causing anxiety, distress or other negative emotions in genetic relatives when receiving information about a possible genetic risk.
- **Genetic relatives** feeling that receiving unsolicited information about possible genetic risk is invasion of **privacy**.
- Perceived pressure on **genetic relatives** to undertake genetic assessment.
- Potential impact on insurances obtained, or that will be obtained, by genetic relatives as they have a duty to disclose to an insurer a possible genetic risk that may affect their insurability (eg. life insurance)

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 HPP 10(1)(c1) and HPP 11(1)(c1), the decision involves consideration of:

- the likely effect on the patient of breaching **confidentiality**; and
- 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 for 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 HPP 10(1)(c1) and HPP 11(1)(c1); and
- 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 HPPs (see Appendix 1) 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 HPP 10(1)(c1) and HPP 11(1)(c1) 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); and
- accurately documenting the process (see Section 3.4.4).

3.2 Discussing use of 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; and
- 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 HRIP 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 for the collection of personal information are set out in HPP 4 (see Appendix 1). It is therefore important to update patient information leaflets relating to the application of the HRIP Act to include possible **use or disclosure** of **genetic information** without consent. A sample patient privacy information leaflet is given in Appendix 2.

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 (e.g. 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; and
- 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 (e.g. 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 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 (e.g. 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 HRIP 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 person⁶ 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 page 36) 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 who lacks the capacity to consent, the HRIP Act requires the decision-making about sharing **genetic information** to fall with the authorised representative (e.g. parent or guardian).

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, although the responsibility for exercising the child or young person's rights rests with the parent or guardian.

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 (e.g. 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.

⁶ See definition on page 2.

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 page 40) describes a situation where the patient is a child and a parent decides not to give consent to disclosure.

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 HRIP 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 (e.g. 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**; and
- 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 HPPs;
- 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 (e.g. 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 (e.g. 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 (e.g. 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 page 38) 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; and
- the probability that a genetic relative may also have the condition or be a carrier of the relevant mutation.

Scenario 9 (see page 41) 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 page 39) 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 HRIP 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 of 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 (e.g. whether the relatives can benefit from the information); and
- if the disease is incurable, whether knowledge of the condition would allow specific management, treatment of distressing manifestations (e.g. 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 HRIP Act and these Guidelines may still be subject to the **duty of confidentiality** that exist outside the HRIP 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; and
- 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 2.

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 Information and Privacy Commission (see page 60 for further information).

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

Scenario 3 (see page 35) 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 HRIP Act, or may be an elective choice by the practitioner.

Non-disclosure when the guideline 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 fulfil 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 HRIP 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 (e.g. 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; and
- 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 HPPs 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 HRIP Act, particularly HPPs 1-4. 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 HRIP Act.

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 2). In some cases telephone contact may be suitable (e.g. 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 HRIP 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; and
- if possible, use a letterhead that does not identify the condition.

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 2.

Scenario 5 (see page 37) 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.

“Genetic relative” is defined as a person who is related by blood, for example, sibling, parent or descendant. Many genetic conditions involve more than the immediate family. A step-by-step process of **cascade contact** allows more **genetic relatives** to receive information about a genetic condition. 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. This process can provide access to **genetic information** for a wider cross-section of the family.

The sample letter in Appendix 2 can be used as the starting point for **cascade contact**.

Scenario 2 (see page 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 What information should be provided?

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; and
- 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**; and
- 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 HPP 10(1)(c1) and HPP 11(1)(c1) 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 HPP 10(1)(c1) and HPP 11(1)(c1) and the nine guidelines. Acting in accordance with the scenarios does not necessarily protect against a breach of the HPPs or a breach of confidence (common law).

When the patient chooses to contact relatives or provide consent

In the following scenarios the patient provides consent for relatives to be contacted. The process therefore falls beyond the scope of HPP 10(1)(c1) and HPP 11(1)(c1). 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 HPP 10(1)(c1) and HPP 11(1)(c1) 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 (e.g. Tamoxifen) can also be used to reduce risk and early detection methods (e.g. 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 (e.g. 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 one who is unable to meaningfully consider and make a decision, 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** that 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. 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 e.g. 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 page 32) 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 (e.g. 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, takes place

In the following scenario disclosure of **genetic information** is not permissible under HPP 11(1)(c1) but use of the **genetic information** within the **organisation** may be appropriate under HPP 10(1)(c1).

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
Amending Act	<i>Health Legislation Amendment Act 2012 (NSW)</i>
ARC	Australian Research Council
AVCC	Australian Vice-Chancellors' Committee
GP	general practitioner
HGAC	Human Genetics Advisory Committee
HPP	Health Privacy Principle
HRIP Act	<i>Health Records and Information Privacy Act 2002 (NSW)</i>
IPP	Information Protection Principle
NHMRC	National Health and Medical Research Council
PPIP Act	<i>Privacy and Personal Information Protection Act 1998 (NSW)</i>

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Appendices

1. HEALTH PRIVACY PRINCIPLES

Health Records and Information Privacy Act 2002 (NSW)

Schedule 1 Health Privacy Principles

1 Purposes of collection of health information

- (1) An organisation must not collect health information unless:
 - (a) the information is collected for a lawful purpose that is directly related to a function or activity of the organisation, and
 - (b) the collection of the information is reasonably necessary for that purpose.
- (2) An organisation must not collect health information by any unlawful means.

2 Information must be relevant, not excessive, accurate and not intrusive

An organisation that collects health information from an individual must take such steps as are reasonable in the circumstances (having regard to the purposes for which the information is collected) to ensure that:

- (a) the information collected is relevant to that purpose, is not excessive and is accurate, up to date and complete, and
- (b) the collection of the information does not intrude to an unreasonable extent on the personal affairs of the individual to whom the information relates.

3 Collection to be from individual concerned

- (1) An organisation must collect health information about an individual only from that individual, unless it is unreasonable or impracticable to do so.
- (2) Health information is to be collected in accordance with any guidelines issued by the NSW Privacy Commissioner for the purposes of this clause.

4 Individual to be made aware of certain matters

- (1) An organisation that collects health information about an individual from the individual must, at or before the time that it collects the information (or if that is not practicable, as soon as practicable after that time), take steps that are reasonable in the circumstances to ensure that the individual is aware of the following:
 - (a) the identity of the organisation and how to contact it,
 - (b) the fact that the individual is able to request access to the information,
 - (c) the purposes for which the information is collected,
 - (d) the persons to whom (or the types of persons to whom) the organisation usually discloses information of that kind,
 - (e) any law that requires the particular information to be collected,
 - (f) the main consequences (if any) for the individual if all or part of the information is not provided.

- (2) If an organisation collects health information about an individual from someone else, it must take any steps that are reasonable in the circumstances to ensure that the individual is generally aware of the matters listed in subclause (1) except to the extent that:
 - (a) making the individual aware of the matters would pose a serious threat to the life or health of any individual, or
 - (b) the collection is made in accordance with guidelines issued under subclause (3).
- (3) The NSW Privacy Commissioner may issue guidelines setting out circumstances in which an organisation is not required to comply with subclause (2).
- (4) An organisation is not required to comply with a requirement of this clause if:
 - (a) the individual to whom the information relates has expressly consented to the organisation not complying with it, or
 - (b) the organisation is lawfully authorised or required not to comply with it, or
 - (c) non-compliance is otherwise permitted (or is necessarily implied or reasonably contemplated) under an Act or any other law (including the [State Records Act 1998](#)), or
 - (d) compliance by the organisation would, in the circumstances, prejudice the interests of the individual to whom the information relates, or
 - (e) the information concerned is collected for law enforcement purposes, or
 - (f) the organisation is an investigative agency and compliance might detrimentally affect (or prevent the proper exercise of) its complaint handling functions or any of its investigative functions.
- (5) If the organisation reasonably believes that the individual is incapable of understanding the general nature of the matters listed in subclause (1), the organisation must take steps that are reasonable in the circumstances to ensure that any authorised representative of the individual is aware of those matters.
- (6) Subclause (4) (e) does not remove any protection provided by any other law in relation to the rights of accused persons or persons suspected of having committed an offence.
- (7) The exemption provided by subclause (4) (f) extends to any public sector agency, or public sector official, who is investigating or otherwise handling a complaint or other matter that could be referred or made to an investigative agency, or that has been referred from or made by an investigative agency.

5 Retention and security

- (1) An organisation that holds health information must ensure that:
 - (a) the information is kept for no longer than is necessary for the purposes for which the information may lawfully be used, and
 - (b) the information is disposed of securely and in accordance with any requirements for the retention and disposal of health information, and
 - (c) the information is protected, by taking such security safeguards as are reasonable in the circumstances, against loss, unauthorised access, use, modification or disclosure, and against all other misuse, and
 - (d) if it is necessary for the information to be given to a person in connection with the provision of a service to the organisation, everything reasonably within the power of the organisation is done to prevent unauthorised use or disclosure of the information.

Note. Division 2 (Retention of health information) of Part 4 contains provisions applicable to private sector persons in connection with the matters dealt with in this clause.

- (2) An organisation is not required to comply with a requirement of this clause if:
 - (a) the organisation is lawfully authorised or required not to comply with it, or
 - (b) non-compliance is otherwise permitted (or is necessarily implied or reasonably contemplated) under an Act or any other law (including the [State Records Act 1998](#)).
- (3) An investigative agency is not required to comply with subclause (1) (a).

6 Information about health information held by organisations

- (1) An organisation that holds health information must take such steps as are, in the circumstances, reasonable to enable any individual to ascertain:
 - (a) whether the organisation holds health information, and
 - (b) whether the organisation holds health information relating to that individual, and
 - (c) if the organisation holds health information relating to that individual:
 - i. the nature of that information, and
 - ii. the main purposes for which the information is used, and
 - iii. that person's entitlement to request access to the information.
- (2) An organisation is not required to comply with a provision of this clause if:
 - (a) the organisation is lawfully authorised or required not to comply with the provision concerned, or
 - (b) non-compliance is otherwise permitted (or is necessarily implied or reasonably contemplated) under an Act or any other law (including the [State Records Act 1998](#)).

7 Access to health information

- (1) An organisation that holds health information must, at the request of the individual to whom the information relates and without excessive delay or expense, provide the individual with access to the information.

Note. Division 3 (Access to health information) of Part 4 contains provisions applicable to private sector persons in connection with the matters dealt with in this clause.

Access to health information held by public sector agencies may also be available under the [Government Information \(Public Access\) Act 2009](#) or the [State Records Act 1998](#).

- (2) An organisation is not required to comply with a provision of this clause if:
 - (a) the organisation is lawfully authorised or required not to comply with the provision concerned, or
 - (b) non-compliance is otherwise permitted (or is necessarily implied or reasonably contemplated) under an Act or any other law (including the [State Records Act 1998](#)).

8 Amendment of health information

- (1) An organisation that holds health information must, at the request of the individual to whom the information relates, make appropriate amendments (whether by way of corrections, deletions or additions) to ensure that the health information:
 - (a) is accurate, and
 - (b) having regard to the purpose for which the information was collected (or is to be used) and to any purpose that is directly related to that purpose, is relevant, up to date, complete and not misleading.

- (2) If an organisation is not prepared to amend health information under subclause (1) in accordance with a request by the individual to whom the information relates, the organisation must, if so requested by the individual concerned, take such steps as are reasonable to attach to the information, in such a manner as is capable of being read with the information, any statement provided by that individual of the amendment sought.
- (3) If health information is amended in accordance with this clause, the individual to whom the information relates is entitled, if it is reasonably practicable, to have recipients of that information notified of the amendments made by the organisation.

Note. Division 4 (Amendment of health information) of Part 4 contains provisions applicable to private sector persons in connection with the matters dealt with in this clause.

Amendment of health information held by public sector agencies may also be able to be sought under the [Privacy and Personal Information Protection Act 1998](#).

- (4) An organisation is not required to comply with a provision of this clause if:
 - (a) the organisation is lawfully authorised or required not to comply with the provision concerned, or
 - (b) non-compliance is otherwise permitted (or is necessarily implied or reasonably contemplated) under an Act or any other law (including the [State Records Act 1998](#)).

9 Accuracy

An organisation that holds health information must not use the information without taking such steps as are reasonable in the circumstances to ensure that, having regard to the purpose for which the information is proposed to be used, the information is relevant, accurate, up to date, complete and not misleading.

10 Limits on use of health information

- (1) An organisation that holds health information must not use the information for a purpose (a **secondary purpose**) other than the purpose (the **primary purpose**) for which it was collected unless:
 - (a) **Consent**
the individual to whom the information relates has consented to the use of the information for that secondary purpose, or
 - (b) **Direct relation**
the secondary purpose is directly related to the primary purpose and the individual would reasonably expect the organisation to use the information for the secondary purpose, or

Note. For example, if information is collected in order to provide a health service to the individual, the use of the information to provide a further health service to the individual is a secondary purpose directly related to the primary purpose.

- (c) **Serious threat to health or welfare**
the use of the information for the secondary purpose is reasonably believed by the organisation to be necessary to lessen or prevent:
 - i. a serious and imminent threat to the life, health or safety of the individual or another person, or
 - ii. (ii) a serious threat to public health or public safety, or

(c1) Genetic information

the information is genetic information and the use of the information for the secondary purpose:

- i. is reasonably believed by the organisation to be necessary to lessen or prevent a serious threat to the life, health or safety (whether or not the threat is imminent) of a genetic relative of the individual to whom the genetic information relates, and
- ii. is in accordance with guidelines, if any, issued by the NSW Privacy Commissioner for the purposes of this paragraph, or

(d) Management of health services

the use of the information for the secondary purpose is reasonably necessary for the funding, management, planning or evaluation of health services and:

- i. either:
 - (A) that purpose cannot be served by the use of information that does not identify the individual or from which the individual's identity cannot reasonably be ascertained and it is impracticable for the organisation to seek the consent of the individual for the use, or
 - (B) reasonable steps are taken to de-identify the information, and
- ii. if the information is in a form that could reasonably be expected to identify individuals, the information is not published in a generally available publication, and
- iii. the use of the information is in accordance with guidelines, if any, issued by the NSW Privacy Commissioner for the purposes of this paragraph, or

(e) Training

the use of the information for the secondary purpose is reasonably necessary for the training of employees of the organisation or persons working with the organisation and:

- i. either:
 - (A) that purpose cannot be served by the use of information that does not identify the individual or from which the individual's identity cannot reasonably be ascertained and it is impracticable for the organisation to seek the consent of the individual for the use, or
 - (B) reasonable steps are taken to de-identify the information, and
- ii. if the information could reasonably be expected to identify individuals, the information is not published in a generally available publication, and
- iii. the use of the information is in accordance with guidelines, if any, issued by the NSW Privacy Commissioner for the purposes of this paragraph, or

(f) Research

the use of the information for the secondary purpose is reasonably necessary for research, or the compilation or analysis of statistics, in the public interest and:

- i. either:
 - (A) that purpose cannot be served by the use of information that does not identify the individual or from which the individual's identity cannot reasonably be ascertained and it is impracticable for the organisation to seek the consent of the individual for the use, or
 - (B) reasonable steps are taken to de-identify the information, and

- ii. if the information could reasonably be expected to identify individuals, the information is not published in a generally available publication, and
 - iii. the use of the information is in accordance with guidelines, if any, issued by the NSW Privacy Commissioner for the purposes of this paragraph, or
- (g) **Find missing person**
the use of the information for the secondary purpose is by a law enforcement agency (or such other person or organisation as may be prescribed by the regulations) for the purposes of ascertaining the whereabouts of an individual who has been reported to a police officer as a missing person, or
- (h) **Suspected unlawful activity, unsatisfactory professional conduct or breach of discipline**
the organisation:
- i. has reasonable grounds to suspect that:
 - (A) unlawful activity has been or may be engaged in, or
 - (B) a person has or may have engaged in conduct that may be unsatisfactory professional conduct or professional misconduct under the [Health Practitioner Regulation National Law \(NSW\)](#), or
 - (C) an employee of the organisation has or may have engaged in conduct that may be grounds for disciplinary action, and
 - ii. uses the health information as a necessary part of its investigation of the matter or in reporting its concerns to relevant persons or authorities, or
- (i) **Law enforcement**
the use of the information for the secondary purpose is reasonably necessary for the exercise of law enforcement functions by law enforcement agencies in circumstances where there are reasonable grounds to believe that an offence may have been, or may be, committed, or
- (j) **Investigative agencies**
the use of the information for the secondary purpose is reasonably necessary for the exercise of complaint handling functions or investigative functions by investigative agencies, or
- (k) **Prescribed circumstances**
the use of the information for the secondary purpose is in the circumstances prescribed by the regulations for the purposes of this paragraph.
- (2) An organisation is not required to comply with a provision of this clause if:
- (a) the organisation is lawfully authorised or required not to comply with the provision concerned, or
 - (b) non-compliance is otherwise permitted (or is necessarily implied or reasonably contemplated) under an Act or any other law (including the [State Records Act 1998](#)).
- (3) The Ombudsman's Office, Health Care Complaints Commission, Anti-Discrimination Board and Community Services Commission are not required to comply with a provision of this clause in relation to their complaint handling functions and their investigative, review and reporting functions.
- (4) Nothing in this clause prevents or restricts the disclosure of health information by a public sector agency:
- (a) to another public sector agency under the administration of the same Minister if the disclosure is for the purposes of informing that Minister about any matter within that administration, or

- (b) to any public sector agency under the administration of the Premier, if the disclosure is for the purposes of informing the Premier about any matter.
- (5) The exemption provided by subclause (1) (j) extends to any public sector agency, or public sector official, who is investigating or otherwise handling a complaint or other matter that could be referred or made to an investigative agency, or that has been referred from or made by an investigative agency.

11 Limits on disclosure of health information

(1) An organisation that holds health information must not disclose the information for a purpose (a **secondary purpose**) other than the purpose (the **primary purpose**) for which it was collected unless:

(a) **Consent**

the individual to whom the information relates has consented to the disclosure of the information for that secondary purpose, or

(b) **Direct relation**

the secondary purpose is directly related to the primary purpose and the individual would reasonably expect the organisation to disclose the information for the secondary purpose, or

Note. For example, if information is collected in order to provide a health service to the individual, the disclosure of the information to provide a further health service to the individual is a secondary purpose directly related to the primary purpose.

(c) **Serious threat to health or welfare**

the disclosure of the information for the secondary purpose is reasonably believed by the organisation to be necessary to lessen or prevent:

- i. a serious and imminent threat to the life, health or safety of the individual or another person, or
- ii. a serious threat to public health or public safety, or

(c1) **Genetic information**

the information is genetic information and the disclosure of the information for the secondary purpose:

- i. is to a genetic relative of the individual to whom the genetic information relates, and
- ii. is reasonably believed by the organisation to be necessary to lessen or prevent a serious threat to the life, health or safety (whether or not the threat is imminent) of a genetic relative of the individual to whom the genetic information relates, and
- iii. is in accordance with guidelines, if any, issued by the NSW Privacy Commissioner for the purposes of this paragraph, or

(d) **Management of health services**

the disclosure of the information for the secondary purpose is reasonably necessary for the funding, management, planning or evaluation of health services and:

- i. either:
 - (A) that purpose cannot be served by the disclosure of information that does not identify the individual or from which the individual's identity cannot reasonably be ascertained and it is impracticable for the organisation to seek the consent of the individual for the disclosure, or
 - (B) reasonable steps are taken to de-identify the information, and

- ii. if the information could reasonably be expected to identify individuals, the information is not published in a generally available publication, and
- iii. the disclosure of the information is in accordance with guidelines, if any, issued by the NSW Privacy Commissioner for the purposes of this paragraph, or

(e) Training

the disclosure of the information for the secondary purpose is reasonably necessary for the training of employees of the organisation or persons working with the organisation and:

- i. either:
 - (A) that purpose cannot be served by the disclosure of information that does not identify the individual or from which the individual's identity cannot reasonably be ascertained and it is impracticable for the organisation to seek the consent of the individual for the disclosure, or
 - (B) reasonable steps are taken to de-identify the information, and
- ii. if the information could reasonably be expected to identify the individual, the information is not made publicly available, and
- iii. the disclosure of the information is in accordance with guidelines, if any, issued by the NSW Privacy Commissioner for the purposes of this paragraph, or

(f) Research

the disclosure of the information for the secondary purpose is reasonably necessary for research, or the compilation or analysis of statistics, in the public interest and:

- i. either:
 - (A) that purpose cannot be served by the disclosure of information that does not identify the individual or from which the individual's identity cannot reasonably be ascertained and it is impracticable for the organisation to seek the consent of the individual for the disclosure, or
 - (B) reasonable steps are taken to de-identify the information, and
- ii. the disclosure will not be published in a form that identifies particular individuals or from which an individual's identity can reasonably be ascertained, and
- iii. the disclosure of the information is in accordance with guidelines, if any, issued by the NSW Privacy Commissioner for the purposes of this paragraph, or

(g) Compassionate reasons

the disclosure of the information for the secondary purpose is to provide the information to an immediate family member of the individual for compassionate reasons and:

- i. the disclosure is limited to the extent reasonable for those compassionate reasons, and
- ii. the individual is incapable of giving consent to the disclosure of the information, and
- iii. the disclosure is not contrary to any wish expressed by the individual (and not withdrawn) of which the organisation was aware or could make itself aware by taking reasonable steps, and
- iv. if the immediate family member is under the age of 18 years, the organisation reasonably believes that the family member has sufficient maturity in the circumstances to receive the information, or

(h) **Find missing person**

the disclosure of the information for the secondary purpose is to a law enforcement agency (or such other person or organisation as may be prescribed by the regulations) for the purposes of ascertaining the whereabouts of an individual who has been reported to a police officer as a missing person, or

(i) **Suspected unlawful activity, unsatisfactory professional conduct or breach of discipline**

the organisation:

i. has reasonable grounds to suspect that:

(A) unlawful activity has been or may be engaged in, or

(B) a person has or may have engaged in conduct that may be unsatisfactory professional conduct or professional misconduct under the [Health Practitioner Regulation National Law \(NSW\)](#), or

(C) an employee of the organisation has or may have engaged in conduct that may be grounds for disciplinary action, and

ii. discloses the health information as a necessary part of its investigation of the matter or in reporting its concerns to relevant persons or authorities, or

(j) **Law enforcement**

the disclosure of the information for the secondary purpose is reasonably necessary for the exercise of law enforcement functions by law enforcement agencies in circumstances where there are reasonable grounds to believe that an offence may have been, or may be, committed, or

(k) **Investigative agencies**

the disclosure of the information for the secondary purpose is reasonably necessary for the exercise of complaint handling functions or investigative functions by investigative agencies, or

(l) **Prescribed circumstances**

the disclosure of the information for the secondary purpose is in the circumstances prescribed by the regulations for the purposes of this paragraph.

(2) An organisation is not required to comply with a provision of this clause if:

(a) the organisation is lawfully authorised or required not to comply with the provision concerned, or

(b) non-compliance is otherwise permitted (or is necessarily implied or reasonably contemplated) under an Act or any other law (including the [State Records Act 1998](#)), or

(c) the organisation is an investigative agency disclosing information to another investigative agency.

(3) The Ombudsman's Office, Health Care Complaints Commission, Anti-Discrimination Board and Community Services Commission are not required to comply with a provision of this clause in relation to their complaint handling functions and their investigative, review and reporting functions.

(4) Nothing in this clause prevents or restricts the disclosure of health information by a public sector agency:

(a) to another public sector agency under the administration of the same Minister if the disclosure is for the purposes of informing that Minister about any matter within that administration, or

(b) to any public sector agency under the administration of the Premier, if the disclosure is for the purposes of informing the Premier about any matter.

- (5) If health information is disclosed in accordance with subclause (1), the person, body or organisation to whom it was disclosed must not use or disclose the information for a purpose other than the purpose for which the information was given to it.
- (6) The exemptions provided by subclauses (1) (k) and (2) extend to any public sector agency, or public sector official, who is investigating or otherwise handling a complaint or other matter that could be referred or made to an investigative agency, or that has been referred from or made by an investigative agency.

12 Identifiers

- (1) An organisation may only assign identifiers to individuals if the assignment of identifiers is reasonably necessary to enable the organisation to carry out any of its functions efficiently.
- (2) Subject to subclause (4), a private sector person may only adopt as its own identifier of an individual an identifier of an individual that has been assigned by a public sector agency (or by an agent of, or contractor to, a public sector agency acting in its capacity as agent or contractor) if:
 - (a) the individual has consented to the adoption of the same identifier, or
 - (b) the use or disclosure of the identifier is required or authorised by or under law.
- (3) Subject to subclause (4), a private sector person may only use or disclose an identifier assigned to an individual by a public sector agency (or by an agent of, or contractor to, a public sector agency acting in its capacity as agent or contractor) if:
 - (a) the use or disclosure is required for the purpose for which it was assigned or for a secondary purpose referred to in one or more paragraphs of HPP 10 (1) (c)–(k) or 11 (1) (c)–(l), or
 - (b) the individual has consented to the use or disclosure, or
 - (c) the disclosure is to the public sector agency that assigned the identifier to enable the public sector agency to identify the individual for its own purposes.
- (4) If the use or disclosure of an identifier assigned to an individual by a public sector agency is necessary for a private sector person to fulfil its obligations to, or the requirements of, the public sector agency, a private sector person may either:
 - (a) adopt as its own identifier of an individual an identifier of the individual that has been assigned by the public sector agency, or
 - (b) use or disclose an identifier of the individual that has been assigned by the public sector agency.

13 Anonymity

Wherever it is lawful and practicable, individuals must be given the opportunity to not identify themselves when entering into transactions with or receiving health services from an organisation.

14 Transborder data flows and data flows to Commonwealth agencies

An organisation must not transfer health information about an individual to any person or body who is in a jurisdiction outside New South Wales or to a Commonwealth agency unless:

- (1) the organisation reasonably believes that the recipient of the information is subject to a law, binding scheme or contract that effectively upholds principles for fair handling of the information that are substantially similar to the Health Privacy Principles, or
- (2) the individual consents to the transfer, or
- (3) 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

- (4) 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
- (5) 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
- (6) the transfer is reasonably believed by the organisation to be necessary to lessen or prevent:
 - i. a serious and imminent threat to the life, health or safety of the individual or another person, or
 - ii. a serious threat to public health or public safety, or
- (7) the organisation has taken reasonable steps to ensure that the information that it has transferred will not be held, used or disclosed by the recipient of the information inconsistently with the Health Privacy Principles, or
- (8) the transfer is permitted or required by an Act (including an Act of the Commonwealth) or any other law.

15 Linkage of health records

- (1) An organisation must not:
 - (a) include health information about an individual in a health records linkage system unless the individual has expressly consented to the information being so included, or
 - (b) disclose an identifier of an individual to any person if the purpose of the disclosure is to include health information about the individual in a health records linkage system, unless the individual has expressly consented to the identifier being disclosed for that purpose.
- (2) An organisation is not required to comply with a provision of this clause if:
 - (a) the organisation is lawfully authorised or required not to comply with the provision concerned, or
 - (b) non-compliance is otherwise permitted (or is necessarily implied or reasonably contemplated) under an Act or any other law (including the [State Records Act 1998](#)), or
 - (c) the inclusion of the health information about the individual in the health records information system (including an inclusion for which an identifier of the individual is to be disclosed) is a use of the information that complies with HPP 10 (1) (f) or a disclosure of the information that complies with HPP 11 (1) (f).
- (3) In this clause:

health record means an ongoing record of health care for an individual.

health records linkage system means a computerised system that is designed to link health records for an individual held by different organisations for the purpose of facilitating access to health records, and includes a system or class of systems prescribed by the regulations as being a health records linkage system, but does not include a system or class of systems prescribed by the regulations as not being a health records linkage system.

disclose an identifier of an individual to any person if the purpose of the disclosure is to include health information about the individual in a health records linkage system, unless the individual has expressly consented to the identifier being disclosed for that purpose.

2. 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 *Health Records and Information Privacy Act 2002 (NSW)*. The *Health Records and Information Privacy Act 2002 (NSW)* 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 the NSW 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.

PATIENT OR AUTHORISED REPRESENTATIVE

Name:

Signature:

DOCTOR

Name:

Signature:

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 *Health Records and Information Privacy Act 2002 (NSW)* 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

3. FURTHER INFORMATION

What is the role of the IPC?

The Information and Privacy Commission (IPC) is an independent statutory authority that administers New South Wales' legislation dealing with privacy and access to government information. The NSW Privacy Commissioner is responsible for resolving complaints, protecting and enhancing the privacy rights of the NSW community and ensuring that privacy principles in the PPIP Act and HRIP Act. More detailed information is available at www.ipc.nsw.gov.au.

Who do these Guidelines apply to?

These Guidelines apply to all organisations that are a health service provider or that collects, holds or uses genetic information. This includes NSW public sector agencies, including public health organisations, and private sector persons, eg. medical specialists and general practitioners.

Do these Guidelines apply to research settings?

These Guidelines do not apply to research settings.

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

Currently the HRIP Act applies to personal information about an individual who has been dead for less than 30 years. 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.

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 NSW Health provides fact sheets, resources and information for health professionals and their patients including contact details for genetics services and support groups across Australia and New Zealand. The resources are available at www.genetics.edu.au.

EviQ, the NSW Cancer Institute's online resource provides health professionals with current, evidence based, point of care Cancer Genetics information. The information is available at www.eviq.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 an organisation has interfered with their privacy, the individual can:

- 1 Request an internal review if the complaint is against a NSW public sector agency.

If the complainant is dissatisfied with the outcome of the internal review, they can apply to the NSW Civil and Administrative Tribunal (NCAT) for a review of the NSW public sector agency's decision and seek an enforceable decision.

- 2 Lodge a complaint with the NSW Privacy Commissioner if the complaint is against a private sector provider.

If the NSW Privacy Commissioner thinks it is appropriate, and if both parties agree, the NSW Privacy Commissioner will endeavour to resolve the matter by conciliation. Choosing conciliation as the option for a complaint means the matter ends with the conciliation process (ie. no further appeal mechanisms is available).

Alternatively, the NSW Privacy Commissioner may investigate the matter further and issue a non-binding written report to both parties, stating the NSW Privacy Commissioner's findings or recommendations. If the individual is still not satisfied with the process, they can request the NSW Civil and Administrative Tribunal (NCAT) to conduct a review of their complaint within 28 days of receiving the report of the NSW Privacy Commissioner (or a later date if the NSW Privacy Commissioner's report sets a later date).

Further information on the Information and Privacy Commission's complaint handling process is available at: http://www.ipc.nsw.gov.au/privacy/ipc_complaints/privacy_complaints.html