

## Disclosure of genetic information to at-risk relatives without a patient's consent

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<b>Applies to</b>	All THS staff
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### Part A – Guideline

#### I Guideline Statement

Where a patient refuses to notify his/her at-risk relatives of a genetic diagnosis which could result in serious and preventable harm to the life, health or safety of those relatives, staff may notify at-risk relatives without the patient's consent and against the patient's wishes, acting in strict accordance with the NHMRC guidelines (NHMRC, 2014).

#### Evidence Based Rationale

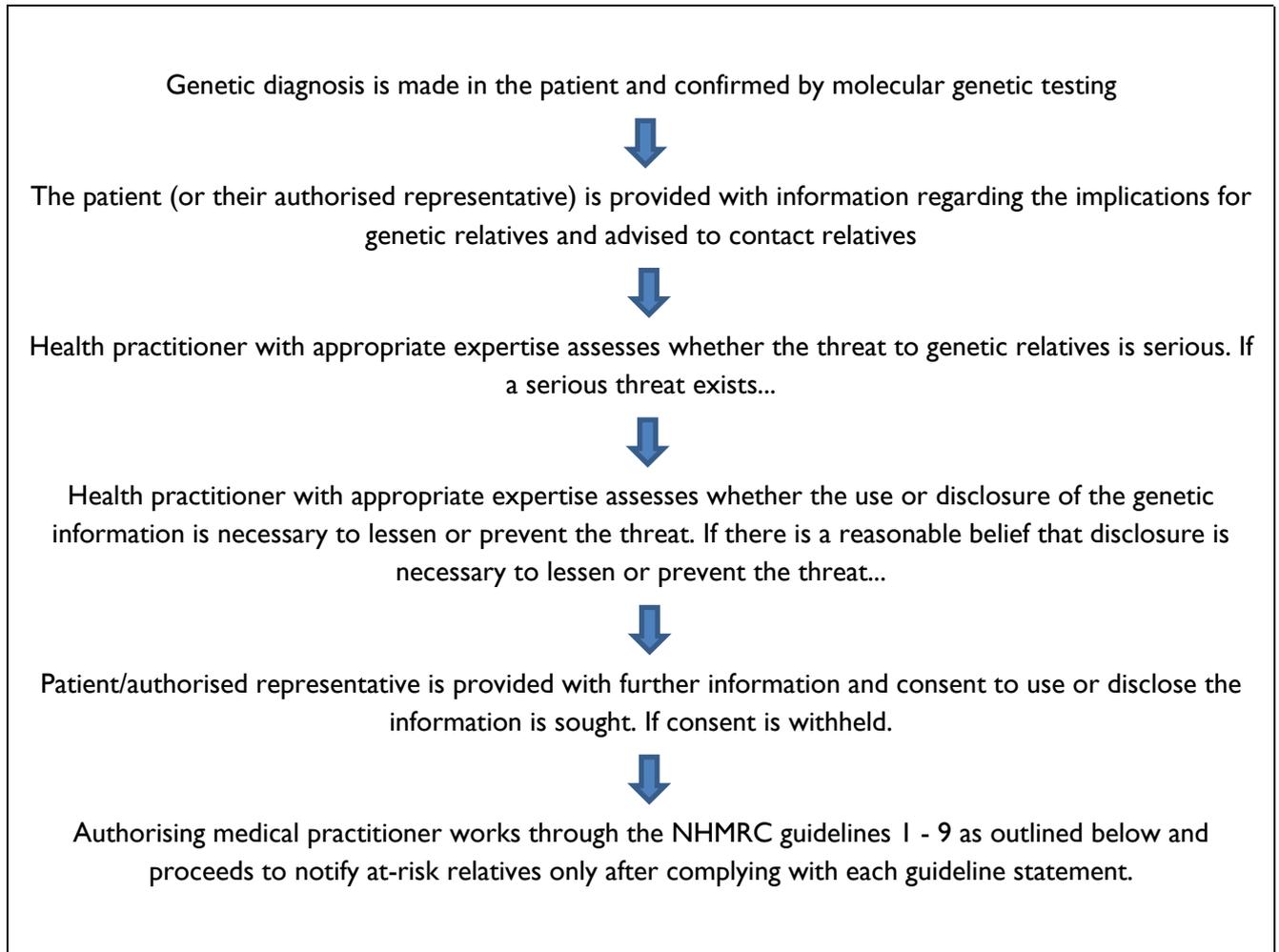
The *Privacy Legislation Amendment Act 2006 (Cth)*, to the *Privacy Act 1988 (Cth)* and more recently the *Privacy Amendment (Enhancing Privacy Protection) Act 2012 (Cth)* allow health practitioners to disclose patients' genetic information, whether or not they give consent, in circumstances where there is reasonable belief that doing so is necessary to lessen or prevent a serious threat to the life, health or safety of their genetic relatives, and regardless of whether that threat is imminent or not. *The Privacy Amendment Act (2012)* does not oblige disclosure but it, and the associated NHMRC guidelines entitled "*Use and Disclosure of Genetic Information to a Patient's Genetic Relatives under Section 95AA of the Privacy Act 1988 (Cth)*", (NHMRC, 2014; Attachment 1), specify the circumstances under which disclosure without consent is appropriate, the requirements and conditions which must be met before disclosure is made, and the manner in which disclosure should occur.

This federal legislation applies to health practitioners working in the private sector. However, the disclosures it describes are permitted under Tasmanian Personal Information Protection Principle 2 (I)(d) of the *Personal Information Protection Act 2004 (Tas)* (the PIP Act) in circumstances where the personal information custodian reasonably believes that the use or disclosure is necessary to lessen or prevent a serious threat to an individual's life, health, safety or welfare, because genetic information is "health information" and "personal information" within the meaning of the PIP Act.

Advice from the Tasmanian Attorney General's office (2016), is that there is nothing preventing THS staff from acting in accordance with the NHMRC (NHMRC, 2014) guidelines when considering disclosure of genetic information without a patient's consent, and that doing so would not be a contravention of the PIP Act. This THS guideline document provides instruction and clarification on how to interpret the NHMRC guidelines within the THS context.

## 2 Process

Any disclosure must be conducted in accordance with this THS Protocol and the NMHRC Guidelines. The flow chart below, adapted from the NHMRC guidelines (NHMRC, 2014), is a step by step guide outlining the process by which a decision to disclose genetic information without a patient's consent can be made. As this is a summary only of some key matters, a medical practitioner considering making such a disclosure must first read the NHMRC guidelines which contain more detailed instructions and examples.



Below, each of the nine NHMRC guidelines statements is interpreted within the local THS context.

### 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.*

If the medical practitioner attending the patient is not certain of (a) how to interpret the genetic result in the patient (b) the seriousness of the genetic diagnosis in the patient, or (c) whether interventions exist which can lessen or prevent the threat to the life, health or safety of an at-risk relative, then the practitioner should seek advice from the Consultant Clinical Geneticist.

### 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.*

Medical practitioners need to be aware of family, cultural, ethnic, religious and spiritual beliefs which might impact on the patient's understanding of the risk to genetic relatives or their willingness to disclose information. It is essential that qualified interpreters, translated written resources, and culturally appropriate materials tailored to the individual needs of the patient are used when discussing the disclosure of genetic information. Involving a spiritual leader, pastoral care worker, Aboriginal liaison officer or patient advocate could be considered in circumstances where these issues are identified.

### **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.*

Disclosing genetic information without the consent of the patient should be a last resort. Patients should be offered assistance with the notification process – the medical practitioner should offer to mail a letter to relatives' addresses provided by the patient, or explore the involvement of other relatives who might assist with disclosure. Patients refusing to inform at-risk relatives may do so because they are still emotionally overwhelmed by their own genetic diagnosis or prognosis and should be given time to absorb this information before addressing issues concerning disclosure of information to at-risk relatives. Patients refusing to inform at-risk relatives may not understand the seriousness of the risk, or that steps can be taken to reduce the risk, or they may feel shame or guilt about their genetic diagnosis. They may fear stigmatisation or blame from their relatives. It should be made clear to the patient that the information can be shared with relatives without identifying the patient. Genetic counsellors have expertise in helping people to understand complicated genetic issues, and in managing issues such as shame, guilt and blame. The medical practitioner should involve an experienced genetic counsellor when a patient resists initial efforts to obtain consent to disclose information.

### **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.*

Even where the medical practitioner feels he/she has sufficient knowledge of the patient's condition and its genetic basis, he/she should seek the advice of the Consultant Clinical Geneticist to confirm his/her understanding of genetic test results.

### **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.*

Any intention to use or disclose genetic information without the consent of the patient should be discussed with the Consultant Clinical Geneticist before a decision is made. The Clinical Geneticist may seek the counsel of the THS legal advisor, the University of Tasmania Centre for Law and Genetics, or other relevant experts before proceeding.

### **Guideline 6:**

*Where practicable, the identity of the patient should not be apparent or readily ascertainable in the course of inter-professional communication.*

Requires no further interpretation

### **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.*

At-risk relatives should be notified that the genetic condition is present in their family, but the disclosing health practitioner should not disclose how or in whom the diagnosis was made.

#### **Guideline 8:**

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

If the health practitioner is uncertain how to interpret the degree of relatedness of an at-risk relative, or if the family structure is complicated or difficult to interpret, he/she should seek advice from the Consultant Clinical Geneticist.

#### **Guideline 9:**

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

This information should be documented in the patient's digital medical record.

### **3 Definitions**

At-risk relative: A biological relative of the patient, who may have inherited the same genetic condition as the patient, who is no more distantly related to the patient than a first cousin.

### **4 Responsibilities**

#### **Consultant Clinical Geneticist**

- To make him/herself available to provide consultation and advice to medical practitioners within the THS who are considering making a disclosure of genetic information without a patient's consent.

### **5 References**

Privacy Act 1988 (Cth)

[http://www.austlii.edu.au/cgi-bin/viewdb/au/legis/cth/consol\\_act/pa1988108/](http://www.austlii.edu.au/cgi-bin/viewdb/au/legis/cth/consol_act/pa1988108/)

NHMRC (2014) Use and Disclosure of Genetic Information to a Patient's Genetic Relatives under Section 95AA of the Privacy Act 1988 (Cth) – Guidelines for Health Practitioners in the Private Sector. Available at: <https://www.nhmrc.gov.au/sites/default/files/documents/attachments/publications/Guidelines-approved-under-section-95AA.pdf>

### **6 Acknowledgements**

The Tasmanian Law Reform Institute

University of Tasmania Centre for Law and Genetics

### **7 Attachments**

- I NHMRC guidelines (2014)

<https://www.nhmrc.gov.au/about-us/publications/guidelines-approved-under-section-95aa-privacy-act-1988-cth>

## Part B - Quality Control

<b>Assess the Risk</b> to the patient/staff/community/organisation if this protocol/guideline is <b>not</b> implemented.	
1	Using the <a href="#">Risk Consequence</a> Table the <b>Degree of Severity</b> will be <b>Moderate</b>
2	Using the <a href="#">Risk Likelihood Table</a> the <b>Likelihood</b> will be <b>Rare</b>
3	Using the <a href="#">Risk Scoring Matrix</a> the <b>Risk Rating</b> will be <b>Low (1-3)</b>
<b>Implementation</b> of this policy document will be by <b>Inclusion in regular education programs</b> by Jo Burke, Manager Tasmanian Clinical Genetics Service It will be completed by <b>ongoing education at unit level</b> <b>New staff</b> will be advised of this directive by <b>Unit / Specialty specific orientation</b>	
<b>Specific staff training</b> required to support the protocol/guideline - <b>No specific training required</b>	
<b>Audits or other data collection</b> to monitor compliance are collated as previously assessed – <b>Low risk = informal monitoring (report non-compliance)</b> Audits and/or variances will be reported to the Genetic Services Clinical Advisory Group Compliance monitoring of this document will be the responsibility of Jo Burke, Manager Tasmanian Clinical Genetics Service	
<b>Replaces</b>	<a href="#">NEW</a>
<b>Overarching Policy</b>	<a href="#">NA</a> SDMS number: <a href="#">NA</a>

### Development and Consultation Record *(To be completed for all protocols or guidelines)*

Development / review authorised	Bruce Edwards	Group Manager, Cancer, Chronic Disease and Sub-Acute Care, THS-South	11 Apr 2019
Prepared by	Jo Burke	Manager Tasmanian Clinical Genetics Service	8 April 2019
Through Custodian	Dr Mathew Wallis	Clinical Director, Tasmanian Clinical Genetics Service	11 Apr 2019
Initial consultation with key stakeholders	<a href="#">Tasmanian Law Reform Institute</a> <a href="#">UTAS Centre for Law and Genetics</a> <a href="#">Dr Vanessa Goodwin</a> <a href="#">Bruce Patterson</a>	<a href="#">Tasmanian Attorney General</a> <a href="#">Executive Manager, Legislative Review &amp; Support DoH</a>	<a href="#">25 March 2019</a> <a href="#">13 Nov 2015</a> <a href="#">25 June 2019</a>
Final consult with staff affected <i>(If THS-Statewide, PC records on feedback sheet)</i>	<a href="#">THS Statewide Consultation Group</a>		<a href="#">17 May 2019</a>
Content confirmed - Delegated Authority*	<a href="#">Bruce Edwards</a>	Group Manager, Cancer, Chronic Disease and Sub-Acute Care, THS-South	<a href="#">10 May 2019</a>
Checked by PC team	<a href="#">Madonna Fahey</a>	THS Policy Team	<a href="#">11 July 2019</a>

### THS-Statewide Approval Record *(Delete table if local or regional document)*

Endorsed	THS Legal Compliance & Policy Committee		<a href="#">25 June 2019</a>
Uploaded to SDMS	<a href="#">Madonna Fahey</a>	<a href="#">Executive Support Officer, QPSS</a>	<a href="#">31 July 2019</a>

\*Delegated Authority – Executive Director, Director/Co-Director of Service, some Senior Managers (eg General Manager)