Informed consent for genetic testing of tumour tissue

Patient details

I/the patient understand(s) the following information and conditions (**conditions of testing**):

1. The genetic testing of tumour tissue is voluntary and I/the patient can withdraw my/their consent for genetic testing of tumour tissue at any stage.

2. The genetic testing of tumour tissue is being undertaken to assist my/the patient's doctor with making decisions about cancer treatment.
   - testing provides information which may be used to change my/the patient's recommended treatment.
   - testing of blood or hair follicles is also undertaken at the same time, to assist in interpreting test results.

3. The testing will involve the collection of bone marrow / tissue /_____ *(Please circle/list).*

4. The testing will only report genetic changes that have been detected in the bone marrow / tumour tissue sample.

5. On occasion, a tissue sample may be sent to another laboratory, including outside of Queensland and Australia, for further testing or confirmation testing. The tissue sample(s) may be kept by that laboratory. A portion of the tissue sample may be stored in Queensland Health's Pathology Queensland laboratory and/or the second laboratory, for use as a control for the testing or for subsequent research. Scientists wanting to undertake research using my/the patient's tissue sample may need to obtain further consent from me/the patient.

6. Genetic test results will be held by Queensland Health and will be available to clinical staff, the testing laboratory and my/the patient's referring doctor. The genetic test results will not be disclosed to any third party without my/the patient's consent, or unless there is a legal requirement to do so.

7. The tissue sample is and remains the property of the laboratory. The tissue sample may be stored at the relevant laboratory but the laboratory cannot guarantee that the sample ~~it~~ will remain suitable for further testing.

8. I/the patient has/have been able to ask questions of the clinician prior to consenting to the genetic testing of my/the patient's tumour tissue.

Interpreter/cultural services

Is a language interpretation service required?
☐ Yes No

If yes, is a qualified Interpreter present?
☐ Yes No

Is a cultural support person required?
☐ Yes No

If yes, is a cultural support person present?
☐ Yes No

Statement of Interpreter

I have:
- ☐ provided a sight translation
- ☐ translated as per doctor/clinician explanation in:

_____
Language:
(state the patient's/substitute decision-maker's/parent/guardian language here)

of this consent form and assisted in the provision of any verbal and written information given to the patient/substitute decision-maker by the doctor/clinician.

_____
Name of patient:

_____
Language of patient/substitute decision-maker:

_____ _____
Name of Interpreter: Name of Interpreter service:

_____ _____
Signature of Interpreter Date

SECTION A: FOR ADULT PATIENT

I agree to the conditions of testing and I provide consent for the:

- □ genetic testing of my tumour tissue
- □ genetic testing of my blood/hair follicle/other tissue_____ *(Please circle/list).*

_____

Name of patient

_____ _____

Signature of patient **Date**

Statement of health practitioner obtaining consent

I have explained the potential and expected impacts (including risks, benefits and alternatives) of the requested genetic testing to the patient and answered the patient's questions relevant to the genetic testing.

Name (*Print*):_____ *Signature*: _____Date:____ /____/_____

Name of Supervising Consultant *(Print):*_____

SECTION B: CONSENT OF SUBSTITUTE DECISION MAKER FOR ADULT PATIENT

AUTHORITY AS SUBSTITUTE DECISION MAKER

Source of substitute decision-making authority

Does the patient have an Advance Health Directive (AHD) that is applicable to the procedure, treatment or investigation?

☐ **Yes** **No**

If yes, has the AHD been sighted and is a copy in the patient's medical record?

☐ **Yes (The AHD must be adhered to)** **No**

If no, then nominate the relevant authority below:

- ☐ Tribunal-appointed guardian
- ☐ Attorney(s) for health matters under an Enduring Power of Attorney or AHD
- ☐ Statutory Health Attorney
- ☐ If none of these, the Office of the Public Guardian must provide consent (ph: 1300 653 187).

CONSENT OF SUBSTITUTE DECISION MAKER

I agree to the conditions of testing and I provide consent for:

_____

Name of patient

To undergo:

- □ genetic testing of their tumour tissue
- □ genetic testing of their blood/hair follicle/other tissue_____ *(Please circle/list).*

_____

Name of substitute decision maker

_____ _____

Signature of substitute decision maker **Date**

Statement of health practitioner obtaining consent

I have explained the potential and expected impacts (including risks, benefits and alternatives) of the requested genetic testing to the patient's substitute decision maker and answered his/her questions relevant to the genetic testing.

Name (*Print*):_____ Signature: _____ Date:____ /____/_____

Name of Supervising Consultant *(Print):*_____

SECTION C: CHILD PATIENT: CHILD/YOUNG PERSON WHERE GILLICK COMPETENT

Although the patient is a child/young person, they may be capable of giving informed consent and having sufficient maturity, understanding and intelligence to enable them to fully understand the nature, consequences and risks of the proposed procedure/treatment and the consequences of non-treatment - 'Gillick competence' (*Gillick vs West Norfolk Area Health Authority* [1986] 1AC 112).

I agree to the conditions of testing and I provide consent for the:

- □ genetic testing of my tumour tissue
- □ genetic testing of my blood/hair follicle/other tissue_____ *(Please circle/list).*

_____ _____

Name of patient. **Date**

_____ _____

Signature of patient. **Date**

Statement of health practitioner obtaining consent

I have explained the potential and expected impacts (including risks, benefits and alternatives) of the requested genetic testing to the patient and answered his/her questions relevant to the genetic testing.

Name (*Print*):_____ Signature: _____ Date:____ /____/_____

Name of Supervising Consultant *(Print):*_____

SECTION D: CHILD PATIENT: CONSENT OF PARENT/GUARDIAN/OTHER PERSON

AUTHORITY AS PARENT/GUARDIAN/OTHER PERSON

If applicable, source of decision-making authority (tick one):

- ☐ Court order — Court order verified
- ☐ Legal guardian — Documentation verified
- ☐ Other person* — Documentation verified

*Formal arrangements such as parenting/custody orders, adoption, or other formally recognised carer/guardianship arrangements. Refer to the Queensland Health 'Guide to Informed Decision-making in Health Care' and local policy and procedures. Complete the source of decision-making authority as applicable below.

I am not aware of any legal or other reason that prevents me from providing unrestricted consent for this child/young person to undergo genetic testing.

_____

Name of parent/legal guardian/other person[1]

_____

Relationship to patient.

_____

CONSENT OF PARENT/LEGAL GUARDIAN/OTHER PERSON

I agree to the conditions of testing and I provide consent for:

_____

Name of patient.

To undergo:

- □ genetic testing of their tumour tissue
- □ genetic testing of their blood/hair follicle/other tissue_____ *(Please circle/list).*

_____

Name of Parent/guardian/other person

_____ _____

Signature of parent/legal guardian/other person **Date**

Statement of health practitioner obtaining consent

I have explained the potential and expected impacts (including risks, benefits and alternatives) of the requested genetic testing to the parent/guardian/other person and answered their questions relevant to the genetic testing.

Name (*Print*):_____ Signature: _____ Date:____/____/_____

Name of Supervising Consultant *(Print):*_____

[1] Other person with parental rights and responsibilities to provide consent