Informed consent for paired tumour / germline gene testing

Patient details. (Please print or attach Patient ID Label.)

Patient Surname:_____ Patient First Name:_____

UR Prefix:_____ UR No.:_____ Hospital:_____

Date of Birth: _____/_____/_____ (dd/mm/yyyy)

Gender:_____ (M/F)

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

1. The paired tumour/germline gene testing is voluntary and I/the patient can withdraw my/their consent for paired tumour/germline gene testing at any time

2. The genetic testing of tumour tissue / bone marrow is 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 can sometimes yield results which indicate a family predisposition to cancer.

3. Testing of blood or hair follicles is also undertaken at the same time, to assist in interpreting test results.
   - The testing may identify inheritable gene faults (mutations) associated with a family predisposition to cancer which may:
     - be unexpected
     - have implications for myself/the patient and other family members
     - have benefits for myself/the patient or my/the patient's family in reducing or managing future cancer risks.
   - If the testing fails to identify an inheritable gene mutation, this does not exclude a family predisposition to cancer.
   - Inheritable gene mutations need to be confirmed on a second, independently collected, DNA sample, which will require my/the patient's separate consent.

4. The test result will be held by Queensland Health and will be available to clinical staff, the testing and reporting 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 Tissue and DNA samples are and remain the property of the laboratory.

5. The tissue sample may be stored at the relevant laboratory, but the laboratory cannot guarantee that the sample will remain suitable for further testing or use.

6. I/the patient has/ have been given, and have/has read and understood, the Patient Information Sheet titled: 'Paired tumour/germline DNA testing in patients with cancer'.

7. I/the patient have/has been able to ask questions of the clinician prior to consenting to the paired tumour/germline testing.

8. Genomic test results are based on current knowledge, which may change in the future.

9. I/the patient have/has agreed to the retaining or storing of the genomic data and related health information in hard copy or digitally in the testing or reporting laboratory.

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 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:

☐ Gene testing of my tumour tissue

☐ Gene testing of my blood/hair follicle/other tissue_____ *(Please circle/list)*

☐ Be advised of the detection of any clinically actionable heritable gene mutations associated with a familial predisposition to cancer

☐ The results being used for further testing, in order to identify whether the results may be of benefit to my blood relatives and spouse/partner.

- If the results are unable to be returned to me due to death/other factors, they may be made known to:

  _____

_____
Name of patient

_____ _____
Signature of patient **Date**

Statement of health professional 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 B: CONSENT OF SUBSTITUTE DECISION MAKER FOR ADULT PATIENT (page 1 of 2)

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 the patients' tumour tissue

☐ Genetic testing of the patient's blood/hair follicle/other tissue_____ *(Please circle/list).*

☐ Be advised of the detection of any clinically actionable heritable gene mutations associated with a familial predisposition to cancer

☐ The results being used for further testing, in order to identify whether the results may be of benefit to the patient's blood relatives and spouse/partner.

SECTION B: CONSENT OF SUBSTITUTE DECISION MAKER FOR ADULT PATIENT (page 2 of 2)

_____

Name of substitute decision maker

_____ _____

Signature of substitute decision maker **Date**

Statement of health professional 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:

- ☐ Genetic testing of my tumour tissue
- ☐ Genetic testing of my blood/hair follicle/other tissue_____ *(Please circle/list)*
- ☐ Myself to be advised of the detection of any clinically actionable heritable gene mutations associated with a familial predisposition to cancer
- ☐ My tissue samples being used for further testing in order to identify whether the results may be of benefit to my blood relatives
- ☐ The results to be made known to _____if they are unable to be returned to me due to death or other factors,

_____

Name of patient

_____ _____

Signature of patient **Date**

Statement of health professional 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 the patient's tumour tissue
- ☐ Genetic testing of the patient's blood/hair follicle/other tissue_____ *(Please circle/list)*
- ☐ I also wish to be advised of the detection of any clinically actionable heritable gene mutations associated with a familial predisposition to cancer
- ☐ The tissue samples being used for further testing, in order to identify whether the results may be of benefit of the patient's blood relatives

_____

Name of Parent/guardian/other person

_____ _____

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

Statement of health professional obtaining consent

I have explained the potential and expected impacts (including risks, benefits and alternatives) of the requested genetic testing to the patient/substitute decision maker/parent/guardian/other 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