



**Queensland
Government**

Consent to use Unapproved Product

Facility:

(Affix identification label here)

URN:

Family name:

Given name(s):

Address:

Date of birth:

Sex: M F I

This consent form and patient information sheet uses the words 'I/you/your/me/my' to mean the patient or another person who is providing consent on behalf of the patient.

A. Does the patient have capacity to provide consent?

Complete for ADULT patient only

Yes → **GO TO** section B

No → **COMPLETE** section A

You must adhere to the Advance Health Directive (AHD), or if there is no AHD, the consent obtained from a substitute decision-maker in the following order: Category 1. Tribunal-appointed guardian; 2. Enduring Power of Attorney; or 3. Statutory Health Attorney.

Name of substitute decision-maker:

Category of substitute decision-maker:

Complete for CHILD/YOUNG PERSON patient only

Yes Although the patient is a child/young person, the patient 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 and the consequences of non-treatment – 'Gillick competence' (*Gillick v West Norfolk and Wisbech Area Health Authority* [1986] AC 112). See the 'Guide to Informed Decision-making in Health Care' www.health.qld.gov.au/consent/clinician-resources/guide-to-informed-decision-making-in-healthcare for further information.

→ **GO TO** section B

No Parent/legal guardian/other person* with parental rights and responsibilities to provide consent and complete this form.

→ **COMPLETE** section A

*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.

Name of parent/legal guardian/other person:

Relationship to child/young person:

B. Is an interpreter required?

Yes No

If yes, the interpreter has translated:
 in person over the telephone

A verbal translation is a summary of the form.

Name of interpreter:

National Accreditation Authority for Translators and Interpreters (NAATI) code:

Language:

C. Unapproved product details

I confirm that the doctor/clinician has informed me about the unapproved product and I consent to the unapproved product being used for my procedure:

Yes

(Name of unapproved product)

Additional information:

D. Risks specific to the patient associated with using the unapproved product

(Doctor/clinician to document additional risks not included in the patient information sheet)

E. Risks specific to the patient associated with not using the unapproved product

(Doctor/clinician to document specific risks in not having the unapproved product)

F. Alternative treatment options

(Doctor/clinician to document alternative treatment not included in the patient information sheet)

DO NOT WRITE IN THIS BINDING MARGIN

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SW9644

UNAPPROVED PRODUCT CONSENT



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G. Acknowledgment and consent

I acknowledge that the doctor/clinician has explained and I understand:

- that an unapproved product is being used i.e. it is not currently approved (registered or listed) for the intended use in Australia
- the reason the unapproved product is being used, including alternative treatment options
- the 'Unapproved product' patient information sheet
- the specific risks and benefits of using the unapproved product
- the prognosis and risks of not having the unapproved product
- alternative product and treatment options
- that there is no guarantee the unapproved product will improve the medical condition
- that a doctor/clinician other than the consultant/specialist may assist with the use of the clinically appropriate unapproved product; this may include a doctor/clinician undergoing further training under supervision
- I was able to ask questions and raise any concerns about the use of the unapproved product with the doctor/clinician
- I understand I have the right to change my mind regarding consent at any time, including after signing this form.

I have received the following consent and patient information sheet(s):

'Unapproved Product'

Other (specify):

On the basis of the above statements,

I consent to the use of the unapproved product.

Name of patient/substitute decision-maker/parent/legal guardian/other person:

Signature:

Date:

If the patient is a child/young person:

I am not aware of any legal or other reason that prevents me from providing unrestricted consent for this child/young person for the unapproved product (*not applicable if the child/young person is Gillick competent and signs this form*).

H. Doctor/clinician confirms

- The unapproved product has been authorised by the Australian Therapeutic Goods Administration (TGA) for use in the circumstances of your medical condition.
- I have explained to you the contents of this form and am of the opinion that the information has been understood.

Name of doctor/clinician:

Designation:

Signature:

Date:

Unapproved Product

Adult and Child/Young Person
Informed consent: patient information

(Affix identification label here)

URN:

Family name:

Given name(s):

Address:

Date of birth:

Sex: M F I

This patient information sheet has been given to you to read carefully and allow time to ask your doctor any questions about this procedure. Your doctor will include the consent form and a copy of this patient information sheet in your medical record.

This patient information sheet uses the words 'I/you/your/me/my' to mean the patient or another person who is providing consent on behalf of the patient.



1. What is the unapproved product and how will it help me/the patient?

Additional information about the unapproved product

The unapproved product being used in this procedure is a highly specialised piece of healthcare equipment. Typically, products or devices used in surgery and other medical treatment by Queensland Health are already approved for use by the Therapeutic Goods Administration (TGA) and are listed on the Australian Register of Therapeutic Goods (ARTG).

Sometimes, there may be critical shortages in Australia of a specialised product or device that has TGA approval. A doctor/clinician may recommend accessing a similar specialised product or device that does not have TGA approval (e.g. supplied from overseas).

In circumstances such as these, where patients require access to a product(s) that are not approved by the TGA, a medical practitioner may be granted special authority by the TGA, to access a specified unapproved therapeutic good for specific patients with a particular medical condition. This occurs through the Special Access Scheme (for an individual patient) or the Authorised Prescriber Scheme (for a class of persons/procedures) (refer to [Unapproved therapeutic goods | Therapeutic Goods Administration \(TGA\)](#)). The TGA monitors all products accessed via these schemes.

Unapproved Product

Adult and Child/Young Person
Informed consent: patient information

(Affix identification label here)

URN:

Family name:

Given name(s):

Address:

Date of birth:

Sex: M F I



2. What are the risks?

In recommending the unapproved product, the doctor/clinician is of the opinion that the benefits to you from using the unapproved product outweigh the identified risks involved. These risks will be written on the consent form.

There are risks with possible complications associated with the unapproved product which can occur with all patients - these are set out below.

Your doctor/clinician will discuss any additional risks, specific to your individual condition and circumstances, with you. These additional risks will be written on the consent form before you sign it.

Common risks and complications

Uncommon risks and complications

Rare risks and complications

What are the risks of not having the unapproved product?

There may be adverse consequences for your health if you choose not to consent for the proposed unapproved product to be used. These risks will be written on the consent form. You and your doctor/clinician should discuss these.

If you choose not to consent for the unapproved product you will not be required to sign a consent form.

If you have signed a consent form, you have the right to change your mind at any time prior to the procedure.



3. Are there alternatives?

Making the decision for the unapproved product to be used requires you to understand the options available. Your doctor/clinician will discuss any alternative options and their risks or benefits with you, and these will be written on the consent form, before signing the form.



4. Questions

Please ask the doctor/clinician if you do not understand any aspect of this patient information sheet or if you have any questions.