



Queensland  
Government

# Cardiac Biopsy Consent

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](http://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. Procedure details

I confirm that the referring doctor has informed me about the following procedure(s) and I consent to:

Cardiac biopsy:  Yes

Site/side of procedure/additional components:

## D. Risks specific to the patient in having a cardiac biopsy

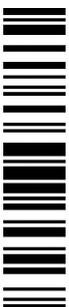
(Doctor to document additional risks not included in the patient information sheet)

## E. Risks specific to the patient in *not* having a cardiac biopsy

(Doctor to document specific risks in not having a cardiac biopsy)

DO NOT WRITE IN THIS BINDING MARGIN

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SW9638

CARDIAC BIOPSY CONSENT



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## F. Alternative procedure options

(Doctor to document alternative procedure not included in the patient information sheet)

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

- 'Cardiac Biopsy'
- 'About Your Anaesthetic' (*Adult patient only*)
- 'About Your Child's Anaesthetic' (*Child/young person patient only*)
- Other (*specify*):

On the basis of the above statements,

## I consent to having a cardiac biopsy.

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 this procedure (*not applicable if the child/young person is Gillick competent and signs this form*).

## H. Doctor confirms

I have explained to you the contents of this form and am of the opinion that the information has been understood.

Name of doctor:

Designation:

Signature:

Date:

## I. Clinical student involvement

For the purpose of undertaking training, a clinical student(s) may observe medical examination(s) or procedure(s) and may also, subject to my consent, assist with/conduct an examination or procedure on me/the patient while under sedation or anaesthetic.

I consent to a clinical student(s) undergoing training to:

- observe examination(s)/procedure(s):  Yes  No
- assist with examination(s)/procedure(s):  Yes  No
- conduct examination(s)/procedure(s):  Yes  No

*Note: you will also have the opportunity to say yes or no to student involvement, on the day of your procedure.*

*For further information please see [www.health.qld.gov.au/consent/students](http://www.health.qld.gov.au/consent/students)*

## G. Acknowledgment and consent

I acknowledge that the doctor has explained and I understand:

- the 'Cardiac Biopsy' patient information sheet
- the medical condition and proposed procedure, including the possibility of additional treatment
- this procedure requires sedation or general anaesthetic
- the specific risks and benefits of the procedure
- the prognosis and risks of not having the procedure
- alternative procedure options
- that there is no guarantee the procedure will improve the medical condition
- that tissues/blood may be removed and used for diagnosis/management of the condition
- that if an immediate life-threatening event happens during the procedure:
  - for an adult patient, health care will be provided based on their AHD (Advance Health Directive) or ARP (Acute Resuscitation Plan). If no AHD or ARP is in place, health care will be provided in accordance with good clinical practice and the *Guardianship and Administration Act 2000 (Qld)*
  - for a child/young person, health care will be provided in accordance with good clinical practice and in the best interests of the patient
- that a doctor other than the consultant/specialist may assist with/conduct the clinically appropriate procedure; this may include a doctor undergoing further training under supervision
- that if the doctor wishes to record video, audio or images during the procedure where the recording is not required as part of the treatment (e.g. for training or research purposes), I will be asked to sign a separate consent form. If I choose not to consent, it will not adversely affect my access, outcome or rights to medical treatment in any way.
- I was able to ask questions and raise concerns with the doctor.
- I understand I have the right to change my mind regarding consent at any time, including after signing this form.

# Cardiac Biopsy

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 a cardiac biopsy and how will it help me?

A cardiac biopsy is a procedure in which a doctor takes samples of heart tissue to help diagnose a cardiac condition. This may include but is not limited to:

- Cardiac transplant rejection, after a heart transplant.
- Cardiomyopathy – disease in which the heart muscle has become weakened, stretched or has another structural problem.
- Myocarditis – inflammation of the heart muscle, usually caused by an infection (viral or bacterial).
- Cardiac amyloidosis – disorder caused by the build-up of abnormal protein (amyloid) in the heart muscle.

The biopsy is taken via a small tube (catheter) inserted into the vein at the neck, groin or arm. The catheter is passed through the blood vessels to your heart. Samples are taken using a forceps-like device passed through the catheter. It is normal for the doctor to take 4–5 samples of tissue for analysis.

Iodinated contrast (also known as x-ray dye) may be required for this procedure.

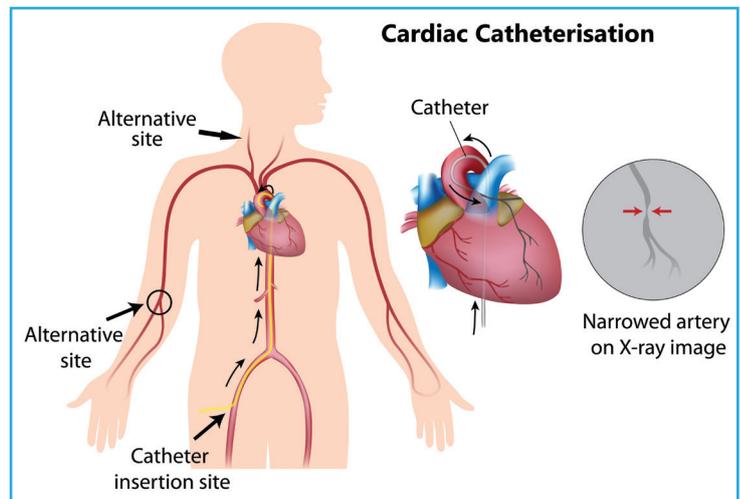


Image: Cardiac catheterisation.  
ID: 127004951. [www.shutterstock.com](http://www.shutterstock.com)

## Preparing for the procedure

The Cardiology department will give you instructions on how to prepare for the procedure. It is important to follow the instructions that are given to you. Your procedure might be delayed if you don't follow all the preparation steps.

Cardiology staff will notify you beforehand if you are required to stop taking any blood-thinning medication.

This procedure will require the use of a local anaesthetic and possibly a mild sedation. A child or young person may require a general anaesthetic. If you are having sedation or a general anaesthetic, and are being discharged on the same day, you cannot drive and you must have someone available to escort you home.

DO NOT WRITE IN THIS BINDING MARGIN

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Adult and Child/Young Person  
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Do not drink alcohol, smoke, vape or take recreational drugs for at least 24 hours before the procedure as these may alter the effects of the sedation anaesthetic.

Please tell the doctor if you:

- are breastfeeding or pregnant, or suspect that you may be pregnant
- have a drug or medication dependence.

## On the day of your procedure

- Nothing to eat or drink ('nil by mouth'): you will be told when to have your last meal and drink. Do NOT eat (including lollies), drink or chew gum after this time otherwise your procedure may be delayed or cancelled. This is to make sure your stomach is empty so that if you vomit, there will be nothing to go into your lungs.
- If you take medicines, most should be continued before a procedure and taken at the usual time, even on the day of the procedure, with a sip of water. There are some important exceptions:
  - your doctor will provide specific instructions about your medicines
  - take to the hospital all your prescribed medicines, those medicines you buy over the counter, herbal remedies and supplements. This may include and is not limited to blood-thinning medicines, the contraceptive pill, antidepressants and/or medicines for treating diabetes (e.g. insulin).
- If you feel unwell, telephone the Cardiology department for advice.
- Tell your doctor if you have:
  - health problems (e.g. diabetes, high blood pressure, infectious diseases, serious illnesses), including if undergoing regular treatment
  - had previous problems and/or known family problems with anaesthesia

- false teeth, caps, loose teeth or other dental problems
- allergies/intolerances of any type and their side effects.
- You will be required to change into a hospital gown and remove some of your jewellery. Your belongings will be kept in a safe location during the procedure.

## Sedation

Sedation is the use of medicines that help make you feel relaxed and drowsy for your procedure. You may remember some or little about what has happened. You may still be aware of your surroundings and should be able to follow simple instructions, such as holding your breath, when instructed by the doctor.

If you are booked for an anaesthetic or sedation, please read the information sheet *About Your Anaesthetic (for adults)* or *About Your Child's Anaesthetic (for child/young person)*. If you do not have one of these information sheets, please ask for one.

### **For a substitute decision-maker/parent/legal guardian/other person of a child/young person/adult without capacity to consent to having a cardiac biopsy**

To prepare the patient for this procedure and to ease their concerns, tell them what they can expect to happen during the procedure. This information sheet will assist you with this.

If the patient is having a general anaesthetic, you may be able to see them off to sleep. Once they are asleep, you will be asked to leave the procedure room and wait in the waiting area.

Other children are not allowed into the procedure room, and they must be supervised at all times by another parent/adult.

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## During the procedure

Before the procedure begins, an intravenous (I.V.) cannula (a small plastic tube) will be inserted into a vein, usually in your hand or arm. This is for medication or fluids required during the procedure, including sedation.

Routine observations will be measured before and during the procedure, these may include cardiac rhythm, blood pressure, heart rate, respiratory (breathing) rate, and oxygen levels.

The skin over your neck, arm and/or groin will be cleaned and a sterile drape will be applied to cover your body. The doctor will use local anaesthetic to numb your skin and then make a small cut where the needle enters.

Using ultrasound as a guide the cardiologist (doctor) will insert a needle through the cut and into your vein.

If a biopsy is required from the left side of the heart, the femoral artery (groin) will be used.

You must remain as still as possible. At times, you may be asked to hold your breath.

The catheter will be inserted into the vein, and the needle removed. X-ray will be used to guide the catheter to the area of the heart for biopsy.

Once the catheter is in the heart, a long forceps-like device is then passed through the catheter to obtain the heart tissue sample. You will feel a few extra heartbeats, otherwise, this part of the procedure is painless.

It is not unusual for this step to be repeated up to 5 times.

After biopsy of the left side, iodinated contrast (x-ray dye) will be required to assess the heart under x-ray imaging.

At the end of the procedure, the catheter will be removed and pressure will be applied over the area where the catheter went into your skin (puncture site). A dressing will be applied to the site.

The biopsy tissue samples will be sent to Pathology for assessment.

After the procedure is complete, you will be transferred from the procedure room to a recovery area.

You may be required to rest in bed for up to 2 hours. Moving too soon after this procedure may cause bleeding at the puncture site.

Your observations and puncture site will be monitored regularly for swelling, oozing of blood and bruising.

If the I.V. cannula is no longer required, it will be removed.



## 2. What are the risks?

In recommending the procedure, the doctor believes that the benefits to you from having the procedure exceed the risks involved. There are risks and possible complications associated with the procedure which can occur with all patients – these are set out below.

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

### Common risks and complications

- minor bleeding and bruising at the puncture site
- abnormal heartbeat, lasting several seconds, and then settles by itself after the biopsy samples are taken
- mild pain or discomfort at the puncture site.

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## Uncommon risks and complications

- unable to get the catheter into the initial vein. The procedure may be changed to another site (e.g. the opposite leg, the neck or an arm)
- abnormal heart rhythm that continues for a long time. This may need a controlled electric shock to correct
- the carotid (in the neck) or femoral (in the groin) artery is accidentally punctured. This usually just requires pressure on the artery. In rare cases this may require surgery to repair
- bleeding at biopsy site
- bleeding is more common if you have been taking blood-thinning medicines, such as warfarin, aspirin, clopidogrel (Plavix, Iscover), prasugrel, dipyridamole (Persantin), ticagrelor (Brilinta), apixaban (Eliquis), dabigatran (Pradaxa), rivaroxaban (Xarelto) or complementary/alternative medicines, such as fish oil and turmeric
- unable to get any heart tissue samples. This may be due to scarring of the heart
- allergic reaction to injected medication, requiring further treatment
- the procedure may not be possible due to medical and/or technical reasons.

## Rare risks and complications

- (*iodinated contrast only*) allergic reactions rarely occur, but when they do, they occur within the first hour, with most happening in the first five minutes. Late reactions have been known to occur up to 1 week after the injection, but these delayed reactions are mild
- infection can occur, requiring antibiotics and further treatment
- a blood clot, this is treated with blood thinning medication
- air in the lung cavity. A chest tube may need to be put into the chest to drain the air

- a hole is accidentally made in the heart or the heart valve. This will need surgery to repair
- damage to the vein. This may need surgery to repair
- damage to the nerve in the leg
- air embolism. Oxygen may be given
- a stroke. This may cause long-term disability
- death because of this procedure is extremely rare.

## If a general anaesthetic or sedation is given, extra risks include:

- faintness or dizziness, especially when you start to move
- fall in blood pressure
- nausea and vomiting
- weakness
- heart and lung problems, such as a heart attack or pneumonia
- stroke resulting in brain damage.

## Iodinated contrast and risk to kidney function

Contrast is removed from the blood by the kidneys through the urine. It is easily removed from the body if you have normal kidney function. You may be asked to have a blood test to find out how well your kidneys are functioning.

In patients with severe renal impairment or acute kidney injury, careful weighing of the risk versus the benefit of giving iodinated contrast, needs to be undertaken.

However, severe renal impairment does not mean that iodinated contrast should not be given, if medically indicated<sup>1</sup>. Your treating doctor will discuss your specific circumstances with you.

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## Risks of radiation

The risks of radiation exposure from this procedure need to be compared to the risks of your condition not being treated. Exposure to radiation may cause a slight increase in the risk of cancer to you over your lifetime. However, the potential risk is small compared to the expected benefit of this procedure<sup>2</sup>.

## What are the risks of not having a cardiac biopsy?

There may be adverse consequences for your health if you choose not to have the proposed procedure. You and your doctor should discuss these.

If you choose not to have the procedure, 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 to have a procedure requires you to understand the options available. Your doctor will discuss any alternative procedure options and their risks or benefits with you, before signing the consent form.



## 4. What should I expect after the procedure?

Your healthcare team will talk to you about what to expect after your procedure and upon discharge from hospital.

The cardiologist (doctor) will send your biopsy samples to pathology after the procedure. The pathology report will be reviewed by the cardiologist and a report sent to your treating team. This may take up to 7 days.

You will receive the results from your treating team at your next follow-up appointment. Please make an appointment if you do not already have one.

Go to your nearest Emergency department or GP (your local doctor) if you become unwell or have:

- pain unrelieved by simple pain relievers or those prescribed for you
- bleeding, swelling, redness or inflammation at the puncture site
- a fever
- other warning signs the doctor may have asked you to be aware of.

If you had sedation or an anaesthetic, this will affect your judgement for about 24 hours. For your own safety:

- Do NOT drive any type of car, bike or other vehicle.
- Do NOT operate machinery including cooking equipment.
- Do NOT make important decisions or sign a legal document.
- Do NOT drink alcohol, smoke, vape or take recreational drugs. They may react with the anaesthetic medications.



## 5. Who will be performing the procedure?

Doctors, cardiac scientists, radiographers, sonographers, pharmacists, nurses, patient support officers and administration staff make up the cardiology team. All or some of these professionals may be involved in your journey.

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A doctor other than the consultant/specialist may assist with/conduct your procedure. This could include a registered doctor who is undergoing further training. All trainees are supervised according to relevant professional guidelines.

If you have any concerns about which doctor will be performing your procedure, please discuss this with the doctor.

## Clinical students

For the purpose of undertaking professional training in this teaching hospital, subject to your consent, a clinical student(s) may observe medical examination(s) or procedure(s). A clinical student may also, subject to your consent, assist with/conduct a clinically necessary examination or procedure on you while you are under the influence of anaesthetic.

You are under no obligation to agree to an examination(s) or a procedure(s) being observed or undertaken by a clinical student(s) for training purposes. If you choose not to consent, it will not adversely affect your access, outcome or rights to medical treatment in any way.

For more information on student care, please visit [www.health.qld.gov.au/consent/students](http://www.health.qld.gov.au/consent/students)



## 6. Where can I find support or more information?

Hospital care: before, during and after is available on the Queensland Health website [www.qld.gov.au/health/services/hospital-care/before-after](http://www.qld.gov.au/health/services/hospital-care/before-after) where you can read about your healthcare rights.

Queensland Health respects the privacy of patients and their families. To learn more about health records and personal information visit our website [www.health.qld.gov.au/system-governance/records-privacy/health-personal](http://www.health.qld.gov.au/system-governance/records-privacy/health-personal)

You can also see a list of blood-thinning medications at [www.health.qld.gov.au/consent/bloodthinner](http://www.health.qld.gov.au/consent/bloodthinner)

Further information about informed consent can be found on the Informed Consent website [www.health.qld.gov.au/consent](http://www.health.qld.gov.au/consent). Additional statewide consent forms and patient information sheets are also available here.

Staff are available to support patients' cultural and spiritual needs. If you would like cultural or spiritual support, please discuss this with your doctor.

Queensland Health recognises that First Nations Peoples' culture must be considered in the patient's clinical care to ensure their holistic health and individual needs are met.



## 7. Questions

Please ask the doctor if you do not understand any aspect of this patient information sheet or if you have any questions about your proposed procedure.

If you have further questions prior to your appointment, please contact the Cardiology department via the main switchboard of the facility where your procedure is booked.



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## 8. Contact us

**In an emergency, call Triple Zero (000).**

If it is not an emergency, but you have concerns, contact 13 HEALTH (13 43 25 84), 24 hours a day, 7 days a week.

References:

1. Use of Intravenous Iodinated Contrast Media in Patients with Kidney Disease: Consensus Statements from the American College of Radiology and the National Kidney Foundation.
2. Australian Radiation Protection and Nuclear Safety Agency (ARPANSA). Ionising radiation in our everyday environment, 2021. Available from [www.arpansa.gov.au](http://www.arpansa.gov.au)