



Queensland
Government

Biopsy (Image-Guided) Consent

Facility:

(Affix identification label here)

URN:

Family name:

Given name(s):

Address:

Date of birth:

Sex: ☐ M ☐ F ☐ I

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)
→ **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.

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

- ☐ Court order → ☐ Court order verified
☐ Legal guardian → ☐ Documentation verified
☐ Other person → ☐ Documentation verified

Name of parent/legal guardian/other person:

Relationship to child/young person:

B. Is an interpreter required?

- ☐ Yes ☐ No

If yes, the interpreter has:

- ☐ provided a sight translation of the informed consent form in person
☐ translated the informed consent form over the telephone

It is acknowledged that a verbal translation is usually a summary of the text on the form, rather than word-by-word translation.

Name of interpreter:

Interpreter code: Language:

C. Patient OR substitute decision-maker OR parent/legal guardian/other person confirms the following procedure(s)

I confirm that the referring doctor/clinician has explained that I have been referred for the following procedure:

Superficial biopsy: ☐ Yes ☐ No

Fine Needle Aspirate (FNA): ☐ Yes ☐ No

Core biopsy: ☐ Yes ☐ No

Site:

☐ Chest

☐ Liver

☐ Other (*specify*):

Name of referring doctor/clinician:

D. Risks specific to the patient in having a biopsy (image-guided)

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

E. Risks specific to the patient in *not* having a biopsy (image-guided)

(*Doctor/clinician to document specific risks in not having a biopsy (image-guided)*):

F. Alternative procedure options

(*Doctor/clinician to document alternative procedure not included in the patient information sheet*):



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G. Information for the doctor/clinician

The information in this consent form is not intended to be a substitute for direct communication between the doctor/clinician and the patient *OR* substitute decision-maker *OR* parent/legal guardian/other person.

I have explained to the patient *OR* substitute decision-maker *OR* parent/legal guardian/other person the contents of this form and am of the opinion that the information has been understood.

Name of doctor/clinician:

Designation:

Signature:

Date:

H. Patient *OR* substitute decision-maker *OR* parent/legal guardian/other person consent

I acknowledge that the doctor/clinician has explained:

- the 'Biopsy (Image-Guided)' patient information sheet
- the medical condition and proposed treatment, including the possibility of additional treatment
- 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 the procedure may involve a blood transfusion
- that tissues/blood may be removed and used for diagnosis/management of the condition
- that if a life-threatening event occurs during the procedure:
 - an adult patient will be treated based on documented discussions (e.g. AHD or ARP [Acute Resuscitation Plan])
 - a child/young person's health care will be provided in accordance with good clinical practice and in the best interests of the patient
- that a doctor/clinician other than the consultant/specialist may assist with/conduct the clinically appropriate procedure; this may include a doctor/clinician undergoing further training under supervision
- that if the doctor/clinician 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/clinician.

I understand I have the right to change my mind regarding consent at any time, including after signing this form (*this should be in consultation with the doctor/clinician*).

I/substitute decision-maker/parent/legal guardian/other person have received the following consent and patient information sheet(s):

- ☐ 'Biopsy (Image-Guided)'
- ☐ 'Ultrasound' (*Adult patient only*)
- ☐ 'Ultrasound' (*Child/young person patient only*)
- ☐ 'Computed Tomography (CT) Scan'
- ☐ 'About Your Anaesthetic' (*Adult patient only*)
- ☐ 'About Your Child's Anaesthetic' (*Child/young person patient only*)
- ☐ 'Blood and/or Manufactured Blood Products Transfusion (Full/Limited Consent)' (*Adult patient only*)
- ☐ 'Transfusion Consent: Fresh and/or Manufactured Blood Products (Full/Limited Consent)' (*Child/young person patient only*)

On the basis of the above statements,

1) I/substitute decision-maker/parent/legal guardian/other person consent to having a biopsy (image-guided).

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*).

2) Student examination/procedure for professional training purposes:

For the purpose of undertaking training, a clinical student(s) may observe medical examination(s) or procedure(s) and may also, subject to patient *OR* substitute decision-maker *OR* parent/legal guardian/other person consent, assist with/conduct an examination or procedure on a patient while the patient is under anaesthetic.

I/substitute decision-maker/parent/legal guardian/other person 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

Biopsy (Image-Guided)

Adult and Child/Young Person | Informed consent: patient information

A copy of this patient information sheet should be given to the patient or substitute decision-maker or parent/legal guardian/other person of a child or young person to read carefully and allow time to ask any questions about the procedure. The consent form and patient information sheet should be included in the patient's medical record.

In this information sheet, the word 'you' means the patient unless a substitute decision-maker, parent, legal guardian or other person is providing consent on behalf of the patient, in which case the word 'you' means the substitute decision-maker, parent, legal guardian or other person when used in the context of the person providing consent to the procedure.



1. What is a biopsy (image-guided) and how will it help me?

A biopsy is the removal of a sample of tissue, cells or fluid from the body. The sample is sent to the Pathology department for testing.

A **superficial biopsy** means that the sample to be taken is close to the surface of the skin.

A **Fine Needle Aspirate (FNA)** involves inserting a thin needle into the tissue and taking a small sample for testing. An FNA is most often done on a swelling or a lump located just under the skin. Sometimes the procedure may need to be repeated, or a core biopsy may be needed.

A **core biopsy** involves the insertion of a larger needle to remove a solid specimen of tissue, known as a 'core'.

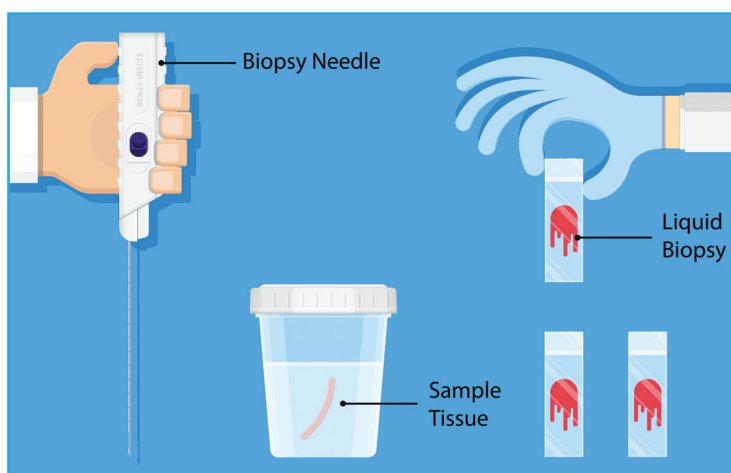


Image: Image shows the equipment used in a tissue biopsy.
ID: 1126114796. www.shutterstock.com

Biopsies performed in the Medical Imaging department are done with guidance from ultrasound or Computed Tomography (CT) images. For more information on these imaging methods, please read the *Ultrasound* or *Computed Tomography (CT) Scan* patient information sheet. If you do not have the relevant information sheet, please ask for one.

Preparing for the procedure

The Medical Imaging 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 of the preparation steps.

Medical imaging staff will notify you beforehand if you are required to stop taking any blood-thinning medicine. List or bring all your prescribed medicines, those medicines you buy over the counter, herbal remedies and supplements to show the doctor/clinician what you are taking.

This procedure will require the use of a local anaesthetic and possibly a mild sedation. If you received sedation and are being discharged on the same day, you cannot drive and you must have someone available to escort you home.

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 your doctor/clinician if you:

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

It is very important that you lie still for the procedure. Supporting straps, foam pads and light weights may be used to help support you.

Most biopsy procedures are performed using local anaesthetic. Some deep or core biopsies may require a mild sedative for adults or a general anaesthetic (for child/young persons).

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/clinician 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 Medical Imaging department for advice.
- Tell your doctor/clinician 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 may/will be required to change into a hospital gown and remove some of your jewellery.

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/clinician.

If you are booked for an anaesthetic, 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 parent/legal guardian/other person of a patient having a biopsy (image-guided)

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.

We welcome your help and support in preparing the patient for the procedure and in explaining why it's so important to lie still.

At the discretion of the procedure staff:

- a parent/adult (unless pregnant) may be invited into the procedure room to support the patient
- 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.

During the procedure

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

Images will be taken of the procedure site and your skin may be marked by a pen. The skin around the site will be cleaned and a sterile drape applied. Local anaesthetic will be injected to numb the skin at the biopsy site.

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

Using images as a guide, the doctor/clinician will insert the biopsy needle. Once the needle tip is in the correct location, a sample (biopsy) will be taken for testing. It is not unusual for this step to be repeated until the required number of samples have been taken. Sometimes you will hear a click as the sample is collected.

At the end of the procedure the needle is removed and a dressing will be applied to the biopsy site.



2. What are the risks?

In recommending the procedure, the doctor/clinician 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. There may also be additional risks and possible complications specific to your condition and circumstances which the doctor/clinician will discuss with you. If you have any further concerns, please ensure that you raise them with the doctor/clinician prior to giving consent to the procedure.

Common risks and complications

- minor pain, bruising and/or infection from the I.V. cannula
- pain or discomfort at the procedure site
- bleeding or bruising may occur at the procedure site

- bleeding or bruising is more common if you have been taking blood thinning medicines, such as warfarin, aspirin, clopidogrel (Plavix, Iscover, Coplavix), prasugrel (Effient), dipyridamole (Persantin or Asasantin), ticagrelor (Brilinta), apixaban (Eliquis), dabigatran (Pradaxa), rivaroxaban (Xarelto) or complementary/alternative medicines, such as fish oil and turmeric
- failure of local anaesthetic which may require a further injection of anaesthetic, or a different method of anaesthesia
- nerve damage, which is usually temporary and should get better over time
- *chest biopsies only:*
 - coughing up blood, small (teaspoon size) amounts. This usually resolves by itself
 - a small pneumothorax, which is a collection of air around the lining of the lungs. This usually goes away by itself, but sometimes may require further treatment, such as inserting a tube into your chest
- *liver biopsies only:*
 - right shoulder tip pain. This may require treatment
 - nausea and vomiting
 - faintness or dizziness, especially when you first move
 - muscle aches and pain.

Uncommon risks and complications

- the procedure may not be possible due to medical or technical reasons
- infection requiring antibiotics and further treatment
- damage to surrounding structures, such as blood vessels, organs and muscles, requiring further treatment
- excessive bleeding from the biopsy site. This may require other treatment and/or corrective surgery
- an allergy to injected medication, requiring further treatment
- the biopsy procedure may not obtain enough tissue or cells for testing and it may need to be repeated at a later date
- *chest biopsies only:*
 - a large pneumothorax, which is a collection of air around the lining of the lungs. This usually may require further treatment, such as inserting a tube into your chest

- *liver biopsies only:*
 - peritonitis (inflammation of the lining of the abdomen). This may require further treatment or surgery
 - internal bleeding. This may settle without treatment but may require a blood transfusion and/or surgery
 - injury or puncture of an organ near your liver, such as the right lung, gallbladder or bowel. This may need further treatment or surgery
 - heart problems. You will need to stop any blood thinning medicines prior to the biopsy. This increases your risk of clots, heart attack or stroke during the time you are not taking these medications
 - blood clots in the leg (deep vein thrombosis [DVT]) with pain and swelling. Rarely a clot may break off a DVT and move to the lungs.

Rare risks and complications

- *chest biopsies only:*
 - an air bubble enters the blood stream from the lung. This can travel to the heart causing a heart attack or the brain causing a stroke
- *liver biopsies only:*
 - ‘dead arm’ type feeling in any nerve, due to your position during the procedure. This is usually temporary and rarely permanent
- seizures and/or cardiac arrest due to local anaesthetic toxicity
- death because of a biopsy procedure is very rare.

If 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 heart attack or pneumonia
- stroke resulting in brain damage.

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 procedure¹.

What are the risks of not having a biopsy (image-guided)?

There may be adverse consequences for your health if you choose not to have the proposed procedure. Please discuss these with the referring doctor/clinician.

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. Please contact the doctor/clinician to discuss.



3. Are there alternatives?

Making the decision to have a procedure requires you to understand the options available. Please discuss any alternative procedure options with your doctor/clinician 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, and what level of activity is suitable after your procedure.

The recovery time varies depending on the biopsy site and if sedation was given. This can take from 30 minutes to 6 hours.

For chest biopsies, you may have a chest x-ray 2 to 4 hours after the procedure. This is to make sure that you do not have an air leak around your lungs.

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

The radiologist (doctor) will review the final images after the procedure and send a report to your treating team.

You will receive the results of the examination 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
- continuous bleeding, swelling, redness or inflammation at the puncture site
- coughing up blood which does not stop or increases in volume
- fever
- other warning signs the doctor/clinician may have asked you to be aware of.

If you had sedation, 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?

Radiographers, doctors, nuclear medicine technologists, sonographers, nurses, and medical imaging assistants make up the medical imaging team. All or some of these professionals may be involved in your procedure.

A doctor/clinician other than the consultant/specialist may assist with/conduct the clinically appropriate procedure. This could include a doctor/clinician undergoing further training, however all trainees are supervised according to relevant professional guidelines.

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

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

You are under no obligation to consent to an examination(s) or a procedure(s) being 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.



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 where you can read about your healthcare rights.

You can also see a list of blood thinning medications at 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. 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/clinician.

Queensland Health recognises that Aboriginal and Torres Strait Islander patients will experience the best clinical care when their culture is included during shared decision-making.

7. Questions

Please ask the doctor/clinician 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 Medical Imaging department via the main switchboard of the facility where your procedure is booked.

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. Australian Radiation Protection and Nuclear Safety Agency (ARPANSA). Ionising radiation in our everyday environment, 2021. Available from www.arpansa.gov.au