Queensland Government

Transjugular Intrahepatic Portosystemic Shunt (TIPS) Consent

Adult (18 years and over)

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?

☐ 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:

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/substitute decision-maker confirms the following procedure(s)

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

Transjugular Intrahepatic Portosystemic Shunt (TIPS): ☐ Yes ☐ No

Name of referring doctor/clinician:

D. Risks specific to the patient in having a Transjugular Intrahepatic Portosystemic Shunt (TIPS)

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

E. Risks specific to the patient in *not* having a Transjugular Intrahepatic Portosystemic Shunt (TIPS)

(Doctor/clinician to document specific risks in not having a Transjugular Intrahepatic Portosystemic Shunt [TIPS]):

F. Alternative procedure options

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

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/substitute decision-maker.

I have explained to the patient/substitute decision-maker the contents of this form and am of the opinion that the information has been understood.

Name of doctor/clinician:

Designation:

Signature: Date:

DO NOT WRITE IN THIS BINDING MARGIN

TIPS CONSENT

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H. Patient/substitute decision-maker consent

I acknowledge that the doctor/clinician has explained:

- the 'Transjugular Intrahepatic Portosystemic Shunt (TIPS)' 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, I will be treated based on documented discussions (e.g. AHD or ARP [Acute Resuscitation Plan])
- 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 have received the following consent and patient information sheet(s):

☐ 'Transjugular Intrahepatic Portosystemic Shunt (TIPS)'

☐ 'About Your Anaesthetic'

☐ 'Blood and/or Manufactured Blood Products Transfusion (Full/Limited Consent)'

On the basis of the above statements,

1) I/substitute decision-maker consent to having a Transjugular Intrahepatic Portosystemic Shunt (TIPS).

Name of patient/substitute decision-maker:

Signature: Date:

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/substitute decision-maker consent, assist with/conduct an examination or procedure on a patient while the patient is under anaesthetic.

I/substitute decision-maker 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

DO NOT WRITE IN THIS BINDING MARGIN

Transjugular Intrahepatic Portosystemic Shunt (TIPS)

Adult (18 years and over) | Informed consent: patient information

Queensland Government

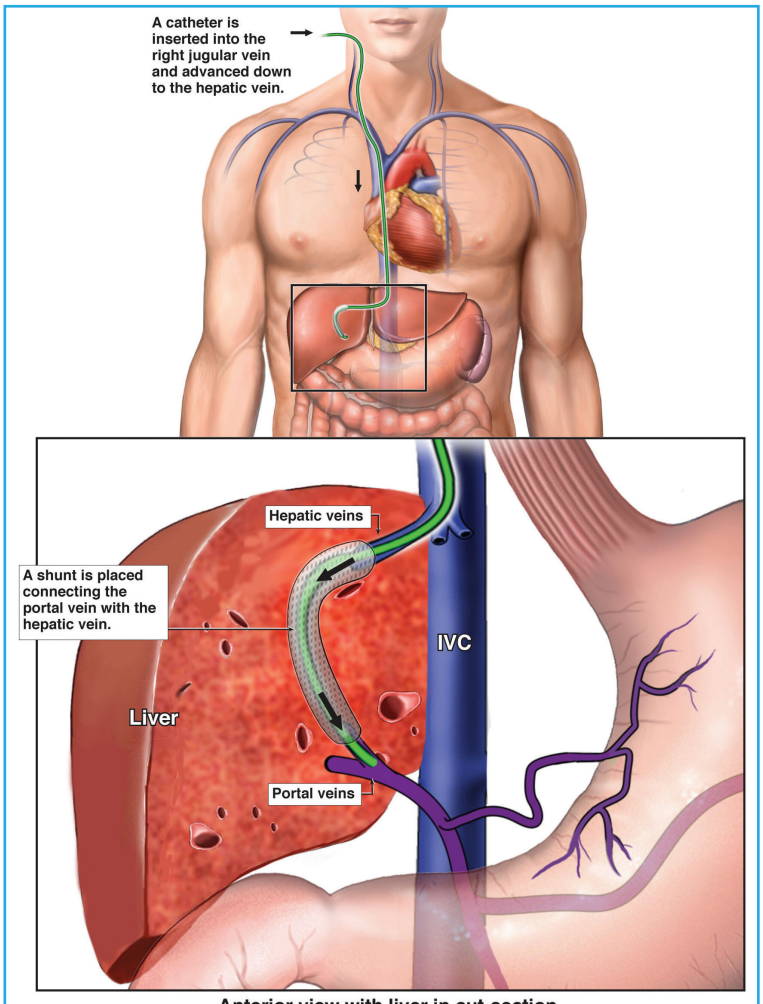
A copy of this patient information sheet should be given to the patient or substitute decision-maker to read carefully and allow time to ask any questions about the procedure. The consent form and patient information sheet should be included in the patient's medical record.

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

1. What is a Transjugular Intrahepatic Portosystemic Shunt (TIPS) and how will it help me?

A Transjugular Intrahepatic Portosystemic Shunt (TIPS) is the insertion of a device (commonly called a stent) to create a new connection between two blood vessels, the hepatic and portal veins, in your liver. This will reduce the pressure within your liver veins.

The stent allows blood to bypass the liver and flow back to the heart. This reduces the pressure in the liver veins and protects the area from bleeding or the build-up of fluid within the abdomen (ascites).



Anterior view with liver in cut-section

Image: Catheter inserted in the right jugular vein down to the hepatic vein. Illustration Copyright © 2019 Nucleus Medical Media, All rights reserved. *www.nucleusmedicalmedia.com*

Preparing for the procedure

The Medical Imaging department will give 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 sedation, and in some cases, a general anaesthetic.

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

On the day of the 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 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 or sedation, please read the information sheet *About Your Anaesthetic.* If you do not have one of these information sheets, please ask for one.

During the procedure

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

Routine observations, for example blood pressure and heart rate, will be taken before the start of the procedure.

The skin on your neck area will be cleaned and a sterile drape will be applied to cover your body. The doctor/clinician will use local anaesthetic to numb the skin and then make a small cut where the needle enters.

Using ultrasound as a guide, the radiologist (doctor) will insert a needle through the cut and into your jugular vein. 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. Iodinated contrast (also known as x-ray dye) will be injected as x-ray images are taken.

In some instances, access cannot be safely obtained via the jugular vein. For these cases, the doctor/clinician may need to access the portal vein directly through the abdomen.

Once the catheter is in place, a long needle is then passed through the catheter and into the liver to make a tunnel between the portal and hepatic veins. A balloon catheter is then used to make the tunnel bigger before the stent is then inserted.

At the end of the procedure, the needle and 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 cover this.

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

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

You may be required to rest in bed for 2 to 4 hours. Moving too soon after this procedure may cause bleeding at the puncture site. You will need to keep your head raised.

Once your observations are stable, you will be transferred to a ward for an overnight stay.

You may eat and drink once you have fully recovered, unless otherwise advised.

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

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 puncture site
- bleeding or bruising at the puncture site
- bleeding 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
- abdominal pain. This may require treatment
- mild encephalopathy (brain intoxication) resulting in confusion. This is usually temporary and is treated with medication and a clinician-directed diet.

Uncommon risks and complications

- infection, requiring antibiotics and further treatment
- damage to surrounding structures such as blood vessels, organs and muscles, requiring further treatment
- excessive bleeding from the liver. This may require other treatment and/or corrective surgery
- an allergy to injected medications or contrast, requiring further treatment
- a fast or irregular heart beat. This usually resolves on its own but may need further treatment
- the stent may close or become blocked, requiring further treatment
- temporary epilation (hairloss) or skin damage, due to x-ray radiation
- the procedure may not be possible due to medical and/or technical reasons.

Rare risks and complications

- rupture of a blood vessel requiring other treatment and/or corrective surgery
- liver failure, requiring further treatment and/or the blocking of the stent
- *(I.V. 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. Note: Allergy to topical iodine and/or seafood does not imply an allergy to iodinated contrast. The reactions vary from:
  - mild: hives, sweating, sneezing, coughing, nausea
  - moderate: widespread hives, headache, facial swelling, vomiting, shortness of breath
  - severe: severe reactions are rare but include life-threatening heart palpitations, very low blood pressure, throat swelling, seizures and/or cardiac arrest
- seizures and/or cardiac arrest due to local anaesthetic toxicity
- skin burns or permanent epilation (hairloss) due to x-ray radiation
- severe encephalopathy (brain intoxication) resulting in permanent decreased conscious level, brain damage and/or death
- death because of this procedure is possible.

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.

Intravascular contrast and risk to kidney function

As contrast is not suitable for some people, you will be asked a series of questions before the contrast is given. The answers allow staff to identify any risk factors you may have.

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 iodinated contrast media administration needs to be undertaken. However, severe renal function impairment should not be regarded as an absolute contraindication to medically indicated iodinated contrast media administration[1].

When significant worsening of kidney function is seen, such as in kidney disease, there is often more than one factor causing stress to the kidneys such as certain medications, infection, dehydration or low blood pressure. To minimise stress to your kidneys your doctor/clinician may recommend you have extra fluid to ensure good hydration, stop some medications temporarily or have extra blood tests to monitor your kidney function around the time of your procedure.

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[2].

What are the risks of not having a TIPS?

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.

You will be given a Patient Implant Card (PIC) for your records with the specific details of any implanted devices used. This information may be helpful for safety for any future Magnetic Resonance Imaging (MRI) scans.

You will be able to go home when you feel better. This usually occurs in 1–2 days.

You may be required to have repeat ultrasounds after the procedure to confirm the stent is working properly.

Most people return to normal activities within 14 days.

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?

Doctors, radiographers, 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 journey.

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. Iodinated Contrast Media Guideline, V2.3 The Royal Australian and New Zealand College of Radiologists, March 2018. Available from www.ranzcr.com/college/document-library/ranzcr-iodinated-contrast-guidelines
2. Australian Radiation Protection and Nuclear Safety Agency (ARPANSA). Ionising radiation in our everyday environment, 2021. Available from www.arpansa.gov.au