Queensland Government

Selective Internal Radiation Therapy (SIRT) 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:

Selective Internal Radiation Therapy (SIRT): ☐ Yes ☐ No

(Select ONE option only)

☐ Part 1 – Planning Hepatic Angiogram

OR

☐ Part 2 – Delivery of SIRT

Name of referring doctor/clinician:

D. Risks specific to the patient in having Selective Internal Radiation Therapy (SIRT)

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

E. Risks specific to the patient in *not* having Selective Internal Radiation Therapy (SIRT)

(Doctor/clinician to document specific risks in not having a Selective Internal Radiation Therapy [SIRT]):

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

SELECTIVE INTERNAL RADIATION THERAPY (SIRT) CONSENT

v1.00
Clinical content review: 2023
Clinical check: 09/2023
Published: 09/2023
SW9628

Queensland Government

Selective Internal Radiation Therapy (SIRT) Consent

Adult (18 years and over)

(Affix identification label here)

URN:

Family name:

Given name(s):

Address:

Date of birth: Sex: ☐ M ☐ F ☐ I

H. Patient/substitute decision-maker consent

I acknowledge that the doctor/clinician has explained:

- the 'Selective Internal Radiation Therapy (SIRT)' 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 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):

☐ 'Selective Internal Radiation Therapy (SIRT)'

☐ 'About Your Anaesthetic'

On the basis of the above statements,

1) I/substitute decision-maker consent to having a Selective Internal Radiation Therapy (SIRT).

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

Selective Internal Radiation Therapy (SIRT)

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 Selective Internal Radiation Therapy (SIRT) and how will it help me?

Selective Internal Radiation Therapy (SIRT), also known as Radioembolisation, combines the delivery of radiotherapy and an embolisation procedure to treat liver cancers or tumours.

The goal of SIRT is to reduce the size of the liver cancer. There are two ways in which SIRT does this:

1. Radiation therapy is directly delivered into the cancer to cause the destruction of cancer cells; and
2. The blood vessels supplying the cancer are blocked by a material called an embolic agent (beads).

This results in the radioactive material being trapped inside the tumour without exposing the entire body to its effects.

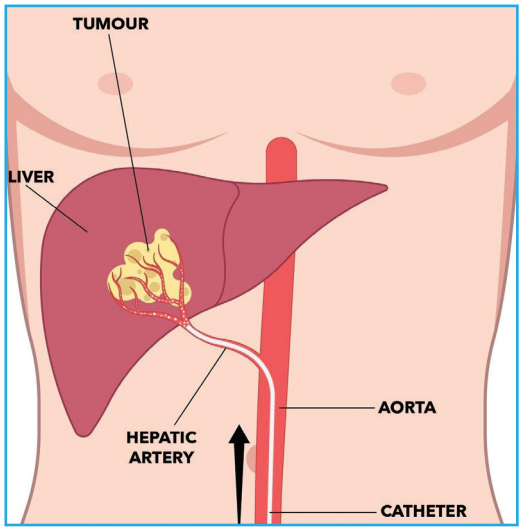

Image: Selective Internal Radiation Therapy (SIRT). ID: 2163416595 (adapted). www.shutterstock.com

There are 2 parts to a SIRT procedure; part 1 and part 2 can occur up to 2 weeks apart. Each part of the SIRT is done by placing a needle and a thin plastic tube (catheter) into an artery in your groin or your arm. This catheter allows the doctor/clinician to use iodinated contrast (also known as x-ray dye) during the procedure to help map your arteries and to locate and treat the tumour.

Part 1 is a planning angiogram, with an injection of a radioactive substance, followed by a scan to map your arteries. This is to help to calculate the dose of the embolic agent given in Part 2.

Part 2 is also an angiogram and the delivery of the radioactive embolic agent.

Preparing for the procedure

The Medical Imaging department will give you instructions on how to prepare for your 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.

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. If you have a drug or medication dependence, please tell your doctor/clinician.

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

There are 2 parts to the SIRT procedure.

Part 1: the planning angiogram and scan
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.

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

The skin in your groin or arm 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 in the puncture site area. Under ultrasound guidance, the doctor/clinician will place a special needle into the artery. Using iodinated contrast and x-ray images, the doctor/clinician will be able to guide a catheter up through the blood vessels to the liver. Once the catheter is in place the needle is removed.

The arteries to the liver will be mapped out during the procedure to ensure that the SIRT treatment can be safely delivered to the liver and not to the surrounding structures such as the stomach or bowel.

In some cases, to safely direct the treating SIRT beads to the liver (in Part 2), small arteries may need to be permanently blocked using small metal coils. These coils stay in for life. When the catheter is in place the doctor/clinician can deliver the radioactive substance. Once the doctor/clinician has finished, they will remove the plastic tube and catheters and press on your puncture site to stop any bleeding.

You will then be moved to another area to have a scan to check the blood flow from your liver to your lungs. This scan provides information for the radiologist to calculate the dose required for your treatment and to assess where the SIRT beads might go when delivered in Part 2 of the SIRT procedure.

You will be required to lie flat during and after the procedure for up to 5 hours.

If the I.V. cannula is no longer required, it will be removed after you have recovered.

You will be sent home with your support person, or you may need to stay in hospital overnight.

Part 2: the angiogram and delivery of the radioactive embolic agent
An I.V. cannula will be inserted once again into a vein, usually in your hand or arm. This is for any medication or fluids required during the procedure, including sedation.

Routine observations will be taken before the start of the procedure.

The skin in your groin or arm area will be cleaned and a sterile drape will be applied to cover your body.

As in Part 1, the doctor/clinician will use local anaesthetic and ultrasound guidance to place a needle and catheter in the artery in your groin or arm. Iodinated contrast and x-rays are used to guide the catheter up through the blood vessels and into the liver. When the catheter is in place the doctor/clinician will deliver the SIRT beads to your liver cancer. Once the doctor/clinician has finished delivering the SIRT beads, they will remove the plastic tube and catheters and press on the puncture site to stop any bleeding.

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 up to 6 hours. Moving too soon after this procedure may cause bleeding at the puncture site.

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

You may eat and drink after your procedure unless otherwise advised.

The I.V. cannula will be removed after you have recovered, if it is no longer required.

Your doctor/clinician will discuss with you what level of activity is suitable after your procedure.

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 may occur. This is usually stopped by applying pressure and/or ice

- 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
- post- radiation and embolisation syndrome including fatigue, fevers, abdominal pain, nausea/vomiting and diarrhoea. Antibiotics and pain relievers will be required to treat this
- failure of local anaesthetic which may require a further injection of anaesthetic, or a different method of anaesthesia
- nerve damage, this is usually temporary and should get better over time. Permanent nerve damage is rare.

Uncommon risks and complications

- infection, requiring antibiotics and further treatment
- damage to surrounding structures such as blood vessels, organs and muscles, requiring further treatment.
- a blood clot or excessive bleeding from the puncture site. This may require other treatment and/or corrective surgery
- an allergy to injected medications, requiring further treatment
- the procedure may not be possible due to medical and/or technical reasons.

Rare risks and complications

- the passing of radioactive material to non-target organs causing potential damage
- incomplete blocking of the flow of blood. This may require further procedures
- infection and/or damage to the liver resulting in liver failure
- *(I.V. iodinated contrast only)* allergic reactions rarely occur, but when they do, they usually 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
- skin burns or damage to the area treated from exposure to x-ray radiation
- seizures and/or cardiac arrest due to local anaesthetic toxicity
- death because of this procedure is very rare.

If sedation is given, extra risks can 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

Contrast is removed from the blood by the kidneys through the urine. 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 the imaging used for 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. However, the potential risk is small compared to the expected benefit of this procedure[2].

What are the risks of not having SIRT?

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?

Most patients experience some post-embolisation syndrome symptoms which include fatigue, pain, nausea, vomiting and fever. It is due to the blood supply to the treated area being cut off.

You will be able to go home once your pain and nausea have settled, usually within 2 days. It is normal to have a fever for up to a week after the procedure. Loss of appetite and fatigue are common and may continue for 2 weeks or longer.

Your doctor/clinician will discuss with you the need to restrict your activities at home for up to 5 days. Follow these instructions carefully.

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

Once you leave hospital, go to your nearest Emergency department or GP (your local doctor) if you become unwell or have:

- a cool or cold limb
- uncontrolled pain and/or nausea
- continuous bleeding, swelling, redness or inflammation at the puncture site
- a 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?

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