naista.		(Affix identification label hars)	1
Queensland	(Affix identification label here)		
Government	URN:		
0 1 1 1 1 (005)	Family	y name:	
Cerebrospinal Fluid (CSF)	Given	name(s):	<
Flow Study Consent		SS:	
Facility:	Date of	of birth: Sex: M F I	
A. Does the patient have capacity to provide		C. Patient <i>OR</i> substitute decision-maker <i>OR</i> parent/	ĺ
consent?		legal guardian/other person confirms the following	
Complete for ADULT patient only		procedure(s)	
☐ Yes → GO TO section B		I confirm that the referring doctor/clinician has explained that I have been referred for the following procedure:	
☐ No → COMPLETE section A		Cerebrospinal Fluid (CSF) flow study:	
You must adhere to the Advance Health Directive (AHD) or if there is no AHD, the consent obtained from a substi		Name of referring doctor/clinician:	
decision-maker in the following order: Category 1. Tribut			
appointed guardian; 2. Enduring Power of Attorney; or		D. Diele and Wie to the action to be in a	
3. Statutory Health Attorney. Name of substitute decision-maker:		D. Risks specific to the patient in having a Cerebrospinal Fluid (CSF) flow study	
ivame of substitute decision-maker:		(Doctor/clinician to document additional risks not included in	
Cata many of a photity to decision and a		the patient information sheet):	
Category of substitute decision-maker:			
Complete for CHILD/YOUNG PERSON patient only			
Yes Although the patient is a child/young person, the patien be capable of giving informed consent and having suffice maturity, understanding and intelligence to enable them fully understand the nature, consequences and risks of proposed procedure and the consequences of non-treating in 'Gillick competence' (Gillick v West Norfolk and Wisber Area Health Authority [1986] AC 112)	the tment		
→ GO TO section B		Pregnancy/breastfeeding questions for the patient	
No Parent/legal guardian/other person* with parental rights responsibilities to provide consent and complete this for → COMPLETE section A		If you are pregnant, this procedure would generally not be performed unless the benefits outweigh the risks of having the procedure.	CER
*Formal arrangements, such as parenting/custody orders, adoption, or other formally recognised carer/guardianship arrangements. Refer to th 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.	,	1. a) Are you pregnant?	EBRO
If applicable, source of decision-making authority (tick or	ne):	b) If required before the scan, do you agree to have a:	SP
☐ Court order → ○ Court order verified		Urine pregnancy test: Yes No	Ž
☐ Legal guardian → ☐ Documentation verified		Blood pregnancy test: Yes No	SPINAL
☐ Other person → ☐ Documentation verified		If you might be pregnant, further discussion with a doctor/ clinician will be provided to assist you in making an informed	
Name of parent/legal guardian/other person:		decision on continuing with the procedure.	FLUID
Deletion ship to shild/severy manager		2. Are you breastfeeding?	₽
Relationship to child/young person:		The doctor/clinician will review these answers and, if required,	
		obtain further advice from a doctor or another clinician regarding your pregnancy and/or breastfeeding status prior	(CSF)
B. Is an interpreter required?		to the scan.	$\overline{}$
☐ Yes ☐ No		E. Risks specific to the patient in <i>not</i> having a	먇
If yes, the interpreter has:		Cerebrospinal Fluid (CSF) flow study	FLOW
provided a sight translation of the informed consent form in person		(Doctor/clinician to document specific risks in not having a Cerebrospinal Fluid (CSF) flow study):	
translated the informed consent form over the telephone		(35.) non diady).	T
It is acknowledged that a verbal translation is usually a summary of the text on the form, rather than word-by-we translation.	ord		STUDY CONSENT
Name of interpreter:			0
			Ž
Interpreter code: Language:			SE/
			\Box

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	Queensland Government
CULT	Government

Cerebrospinal Fluid (CSF) **Flow Study Consent**

	(Affix identification	label ner	e)		
JRN:					
amily name:					
Given name(s):					
Address:					
Date of birth:		Sex:	M	F	

	1	
	Date	
F. Alternative procedure options		
(Doctor/clinician to document alternative procedure n included in the patient information sheet):	ot	
C Information for the destarialinisism		
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 <i>OR</i> substitute decision-maker <i>OR</i> parent/legal guardian/other person.		
I have explained to the patient <i>OR</i> substitute decision <i>OR</i> parent/legal guardian/other person the contents of form and am of the opinion that the information has bunderstood.	of this	
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 'Cerebrospinal Fluid (CSF) Flow Study' 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 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).

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

☐ 'Cerebrospinal Fluid (CS	SF) Flow Study
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- ☐ 'About Your Anaesthetic' (Adult patient only)
- 'About Your Child's Anaesthetic' (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 Cerebrospinal Fluid (CSF) flow study.

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:

training to.		
 observe examination(s)/procedure(s) 	Yes	□No
assist with examination(s)/procedure(s)	Yes	□No
 conduct examination(s)/procedure(s) 	Yes	No

Cerebrospinal Fluid (CSF) Flow Study

Queensland Government

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 Cerebrospinal Fluid (CSF) flow study and how will it help me?

A Cerebrospinal Fluid (CSF) flow study is a procedure used to see the flow of CSF in and around your brain and spinal cord.

Nuclear medicine uses a small amount of a radioactive substance, also called a radioactive tracer, to see how organs or tissues are functioning at a cellular level.

The procedure begins with an injection of a radioactive tracer into the CSF around the spinal cord.



Image: Gamma camera. ID: 114784351. <u>www.shutterstock.com</u>

A gamma camera (scanner) is used to take images on the day of the injection and sometimes over several days after the injection. The gamma camera takes images of the radiation as it is emitted from the radioactive tracer that was injected into your CSF. This shows the flow of CSF in and around your brain and spinal cord.

Preparing for the procedure

The Nuclear Medicine department will give you instructions on how to prepare for the procedure.

Please tell the doctor/clinician if you are breastfeeding or pregnant or suspect that you may be pregnant. This procedure would generally not be performed if you are pregnant unless the benefits outweigh the risks of conducting the procedure.

Nuclear medicine staff will notify you beforehand if you are required to stop taking any blood-thinning medicines.

List or bring all your prescribed medicines, those medicines you buy over the counter, herbal remedies and supplements to show your doctor/nurse what you are taking.

The injection of the radioactive tracer will require the use of a local anaesthetic. Local anaesthetic is used to numb the area of your back where you will be injected. It is used to prevent or relieve pain, but will not put you to sleep.

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. A mild sedative may be required for adults or a general anaesthetic for a child/young person.

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 (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 CSF flow study

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

Local anaesthetic is injected into the soft tissues of your lower back at the planned injection site.

A thin needle is then placed into your lower back. Try not to move or cough while the needle is being inserted.

A radioactive tracer is injected into the fluid around the spinal cord and the needle is removed. A gamma camera will take pictures several times throughout the day and possibly over the next several days.

On occasion, the doctor/clinician may request a type of imaging called SPECT-CT. This is a 3D nuclear medicine image combined with a CT scan to assist clinicians with a more accurate interpretation of the study.

This usually takes 20–30 minutes, depending on the area to be scanned. No extra radiation is injected if a SPECT-CT is required, but additional radiation exposure will be received from the CT. You should remain as still as possible, as the slightest movement can blur the images.

At the end of the procedure, you will be monitored until it is safe to go home. Your doctor/clinician will let you know if you need to lie flat for a period of time to reduce the risk of a headache.

Take care when first standing as temporary leg weakness can occur.



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

- headache which may require medication and bed rest
- low blood pressure causing dizziness. Bed rest can help relieve this
- bleeding or bruising could occur
- 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 may require a further injection of anaesthetic, or a different method of anaesthesia
- nerve damage. Nerve damage is usually temporary and should get better over time.
 Permanent nerve damage is rare.

Uncommon risks and complications

- a severe headache which may require bed rest for several days. Sometimes other procedures are required to be done to relieve this headache
- vomiting may occur and require treatment with medication
- infection, this may require antibiotics and further treatment
- damage to surrounding structures such as blood vessels and muscles. This may require corrective surgery
- the procedure may not be possible due to medical and/or technical reasons.

Rare risks and complications

- an allergy to injected medications/ radioactive tracer may occur, requiring further treatment
- a stroke in the spinal cord that could result in spinal cord injury
- permanent nerve damage with possible paralysis
- seizures requiring medication and further treatment
- cardiac arrest due to local anaesthetic toxicity
- meningitis requiring antibiotics and other treatment
- death because of this procedure is very rare.

If serious complications occur, admission to hospital may be required.

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 CSF flow study?

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?

The Nuclear Medicine department will talk to you about what to expect after the procedure.

It is recommended that you avoid close contact with children or anyone pregnant, for at least 4 hours after the scan. The radioactive tracer that we use begins to disappear as soon as it is given. Most are undetectable within a day or two. Tracers do not impact your ability to drive, and you should not feel any different to how you felt on arrival for the scan. You will be informed if you are required to come back another day for more images.

If you no longer require your I.V. cannula, it will be removed.

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 experience:

- pain that is unrelieved by simple relievers
- continuous bleeding, swelling, redness or inflammation at the injection site

- fever
- other warning signs the doctor/clinician may have asked you to be aware of.



5. Who will be performing the procedure?

Nuclear medicine scientists/technologists, doctors and nurses make up a nuclear medicine 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 recognise that First Nations People's 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/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 Nuclear Medicine 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:

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