

Standard Operating Procedure for Consent Taking in Patients going for Radiological Procedure Requiring Contrast Medium Injection

A) When to take consent ?

The consent is required if patient is going for a radiological procedure which requires injection of contrast medium (Intravenous Urography, Computed Tomography and Magnetic Resonance Imaging examinations).

B) Who and how to take consent ?

- i) Consent shall be taken by the doctor requesting the procedure and doctor in Department of Radiology.
- ii) For a patient who is going for a radiological examination that requires injection of contrast medium, he/she should be screened for any risk factors as stated in the consent form.
- iii) Both the requesting and radiology team shall be involved in the consent taking. The requesting doctor shall explain the patient's condition, the need of the investigation and how it is going to alter the management.
- iv) The radiology doctor shall explain on the procedure itself and the possible complications. A consent form has been designed (attached) for such purpose.
- v) Both the requesting doctor and radiology doctor shall sign the completed form witnessed by another medical personnel.
- vi) The radiology doctor shall sign the form after explaining to the patient in the witness of other medical personnel. He/she shall ensure that the patient authorizes his/her signature or thumbprint.
- vii) The consent shall be taken from patient himself/herself. In the event he/she is not capable of doing so, consent can be taken from next-of kin.

C) Consent form

Attached.



**JABATAN RADIOLOGI
HOSPITAL SULTANAH AMINAH JOHOR BAHRU**

CONSENT - Radiological Procedure with Contrast Medium Injection

Name : _____
 I/C No. : _____
 Ward / Clinic : _____

A) The Procedure

Your condition requires the radiological procedure which requires the injection of a contrast medium. The contrast medium is usually administered by injection into a vein through a small needle or cannula. This allows your organs to be seen more clearly and will help the doctor in your medical management.

B) Suitability for a Contrast Medium Injection

Please answer the following questions to assist us in deciding if you have a higher risk of adverse reactions to contrast media. Do you have any of the following conditions (please tick) :

- a. Previous history of reaction to contrast medium
- b. Definite history of allergy to medication / food
- c. Asthma / Hay fever / atopy / allergic sinusitis / rhinitis
- d. Renal disease
- e. Heart disease

YES	NO
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>

Patients in Group **a-c** will need steroid premedication. *Tab Prednisolone 40mg 12 hours and 2 hours before the procedure* (Adult doses quoted, children dose need to be adjusted according to ideal body weight).

C) Risks and Complications of the Procedure

There are some risks / complications, with use of intravascular contrast medium and may include:

- a) Metallic taste in the mouth, mild nausea and hot flush which should pass within a few minutes.
- b) Occasional mild reactions such as itchiness, sneezing, rashes/hives, vomiting and vein/ tissue injury secondary to contrast medium leaking outside vein. (chance of occurrence < 5% or 5 in 100 persons).
- c) Risk of worsening renal functions may occur especially in patient with pre existing condition of renal failure.
- d) Rarely, more serious reactions such as difficulty in breathing, shock, convulsions and cardiopulmonary arrest. (chance of occurrence ~0.01% or 1 in 10,000 persons).
- e) Doctors and emergency equipment are always readily available to treat any emergency condition or event that may arise from the contrast medium use. Despite prompt treatments administered during the emergency condition that may not prevent serious condition that may result death. This condition however may occur in extremely rare cases. (chance of occurrence about 0.0005% or 1 in 200,000 persons).
- f) Nephrogenic systemic fibrosis, a fibrosing disease that affects skin, subcutaneous tissues, muscles and occasionally other organs that can lead to contracture and joint immobility which may occur in 1-7% of patient who has severe acute or chronic kidney injury and receives gadolinium based MRI contrast medium.
- g) The doctor has considered these risks and believes that the benefits of obtaining the information from the radiological procedure far outweigh the risks.

D) Patient Consent

I, I/C No:
(Name of patient / parents / guardian)

of (Address)

hereby consent to submit * myself / my child (Name of patient)

to have the radiological procedure (Name of procedure)

* My / my child's medical condition and the needs to have the procedure have been explained to me by

.....
(Name of attending Doctor)

Signature or Thumbprint:
(Patient / Parents / Guardian)

Date:

The possible risks of the procedure have been explained to me by

.....
(Name of Radiology Medical Officer / Radiologist)

Signature or Thumbprint:
(Patient / Parents / Guardian)

Date:

I confirm that I have explained to the * patient / parents / guardian the needs, the effects and risks of the radiological examination to the patient. In my opinion, he/she understood the explanation.

Signature / Name and chop:

Signature / Name:

..... Date:
(Attending Doctor)

..... Date:
(Witness / Translator)

I/C No.:

Signature / Name and chop:

Signature / Name:

..... Date:
(Radiology Medical Officer / Radiologist)

..... Date:
(Witness / Translator)

I/C No.:

* delete whichever not applicable