



**SULTAN AHMAD SHAH MEDICAL CENTRE @IIUM**

**CONSENT FORM**

**RADIOLOGICAL PROCEDURE WITH CONTRAST MEDIUM INJECTION**

Name : \_\_\_\_\_  
 RN : \_\_\_\_\_ NRIC/Passport 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 v):

	YES	NO
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		
f. Blood Urea: .....		
g. Serum Creatinine: .....		

Patients in Group a-c will need steroid premedication. Tab Prednisolone 50mg 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 reaction 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 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 emergency condition this may not prevent serious condition that may result in 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.



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**A) Patient Consent**

I, ..... NRIC/Passport No.: .....  
(Name of patient/husband/parents/guardian)

of .....  
(Address)

hereby consent to submit \*myself/my wife/ 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 / fingerprint: ..... Date: .....  
(Patient/Parents/Guardian)

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 official stamp:

Signature / Name:

..... Date: .....  
(Attending Doctor)

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

NRIC/Passport No. : .....



**SULTAN AHMAD SHAH MEDICAL CENTRE @IIUM**

**BORANG KEIZINAN**

**PROSEDUR RADIOLOGI YANG MEMERLUKAN SUNTIKAN KONTRAS MEDIA**

Nama : \_\_\_\_\_

RN : \_\_\_\_\_ No. Kad Pengenalan/Pasport: \_\_\_\_\_

Wad/Klinik: \_\_\_\_\_

**A) Prosedur**

Prosedur radiologi ..... memerlukan suntikan kontras media. Kontras media ini kebiasaannya disuntik ke dalam saluran darah menggunakan jarum suntikan yang kecil supaya organ-organ di dalam badan dapat dilihat dengan lebih jelas sekaligus membantu doktor dalam menentukan rawatan yang diperlukan.

**B) Kesesuaian untuk Suntikan Kontras Media**

Soalan-soalan berikut perlu dijawab untuk menentukan sama ada anda mempunyai risiko tindak balas terhadap kontras media. Sila tandakan (v) sekiranya anda berada dalam kategori seperti di bawah:-

- a. Sejarah tindak balas terhadap kontras media
- b. Sejarah alahan terhadap ubat-ubatan / makanan
- c. Asma / "Hay fever" / Resdung/ Rhinitis
- d. Penyakit buah pinggang
- e. Penyakit jantung
- f. Blood Urea:  
.....
- g. Serum Creatinine: .....

YA	TIDAK

Kategori **a-c** memerlukan pre-medikasi steroid. Tablet Prednisolone 50mg perlu diambil 12 jam sebelum prosedur dan 40mg diambil 2 jam sebelum prosedur (Dos dewasa yang dinyatakan, dos kanak kanak perlu dikira mengikut berat badan).

**C) Risiko dan Komplikasi Prosedur**

Terdapat risiko/ komplikasi apabila menggunakan suntikan kontras media termasuklah:

- a) Rasa kurang menyenangkan di lidah, rasa loya dan panas badan yang sepatutnya hilang setelah beberapa minit suntikan dilakukan.
- b) Reaksi sederhana seperti gatal-gatal, bersin, ruam badan, muntah dan kecederaan pada saluran darah/tisu badan ketika suntikan dilakukan (risiko kejadian <5% atau 5 daripada 100 pesakit).
- c) Risiko kemerosotan fungsi buah pinggang boleh terjadi terutama kepada pesakit yang telah mempunyai masalah kegagalan buah pinggang.
- d) Reaksi yang lebih serius seperti kesesakan pernafasan, renjatan dan sakit jantung amat jarang berlaku (risiko kejadian ~0.01% atau 1 dalam 10,000 pesakit).
- e) Doktor dan peralatan kecemasan sentiasa tersedia untuk memberikan rawatan segera. Walau bagaimanapun kematian boleh berlaku tetapi amat jarang sekali (risiko kejadian 0.0005% atau 1 dalam 200,000 pesakit).
- f) Nephrogenic systemic fibrosis, adalah penyakit yang memberi kesan kepada kulit,tisu, otot dan kadang-kadang sebahagian organ serta boleh menyebabkan pergerakan sendi menjadi sukar. Ini mungkin boleh berlaku kepada 1-7% pesakit yang mempunyai masalah kegagalan buah pinggang yang teruk atau kecederaan buah pinggang apabila menerima suntikan kontras media MRI yang berasaskan gadolinium
- g) Doktor telah mengambil kira risiko-risiko ini dan berpendapat bahawa faedah yang diperolehi daripada prosedur Radiologi ini mengatasi risiko yang mungkin diterima oleh pesakit.

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**BORANG KEIZINAN**

**PROSEDUR RADIOLOGI YANG MEMERLUKAN SUNTIKAN KONTRAS MEDIA**

**A) Keizinan Pesakit**

Saya, .....No. Kad Pengenalan/Pasport: .....  
(Nama pesakit/ Ibumama/ Penjaga)

beralamat .....  
(Address)

dengan ini memberi keizinan bagi \*diri /anak/ anak jagaan saya.....  
(Nama pesakit)

untuk menjalani prosedur radiologi.....  
(Nama prosedur)

Keadaan kesihatan \*saya/ anak/ anak jagaan saya dan keperluannya menjalani prosedur ini telah diterangkan

kepada saya oleh.....  
(Name Doktor yang merawat)

Tandatangan / Cap jari: ..... Tarikh: .....  
(Pesakit/Ibumama/Penjaga)

Saya mengesahkan bahawa penerangan telah diberikan kepada \*pesakit/ ibumama/ penjaga keperluan, kesan dan risiko prosedur radiologi ini kepada pesakit.

Tandatangan / Nama dan cop rasmi:

Tandatangan dan nama:

..... Tarikh: .....  
(Doktor yang merawat)

..... Tarikh: .....  
(Saksi / Penterjemah)

No. Kad Pengenalan/Pasport : .....