

**Standard Operating Procedure for Consent Taking in Pregnant or Potentially Pregnant
Patient going for Radiological Procedure**

A) Radiological Procedures where consent is required

- i) All radiological examinations where ionizing radiation (x-ray) is used such as plain radiography, fluoroscopic examinations and CT examinations.
- ii) Magnetic Resonance Imaging examinations.

B) Who and how to take consent

- i) Consent is to be taken both by the requesting and radiology team using a designated consent form. The requesting team will explain more on the need and benefits of the procedure, available alternatives and how it will help in patient's subsequent management while Radiology team will emphasize more on the risk and complication towards patient and the fetus.
- ii) For plain radiography, requesting medical officer shall take the consent after consulting their respective specialists. The consent taking need to be witnessed by another medical personnel if necessary.
- iii) For special X-ray examinations, CT examinations and MRI examinations, the consent shall be taken by the Medical Officer requesting and Radiology Medical Officer accepting the case after consultation with the Specialists. The consent taking shall be witnessed by another medical personnel.
- iv) The consent shall be taken from patient herself. In the event she is not capable of doing so, consent may be taken from next-of kin.

C) Consent form

Attached.



**JABATAN RADIOLOGI
HOSPITAL SULTANAH AMINAH JOHOR BAHRU**

CONSENT - Radiological Procedure for Pregnant or Potentially Pregnant Lady

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

This informed consent form applies only to a single radiographic procedure, CT Scan or MRI examination. You are scheduled for a radiological procedure. You and your unborn child will be exposed to radiation / radiofrequency. The risks associated are very minimal. The X-radiation might slightly increase the possibility of cancer later in your child's life, but the actual potential healthy life is nearly the same as that of other children in circumstances similar to yours. The examination does not add to risks for birth defect.

There is also a risk of cancer induction in yourself but the risk is much lower than the risk to your baby. To date, there has been no indication that the use of clinical MR imaging during pregnancy has produced any deleterious effects. However, as noted by the U.S. Food and Drug Administration (FDA), the safety of MR imaging during pregnancy has not been proven. Your physician has considered the risk associated with this examination and believes it is in your and your child's best interest to proceed. Any doubts should be directed to the respective radiologist.

I, I/C 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)

The possible risks of the procedure to * me / my wife / my child and the pregnancy have been explained to me.

Signature or Thumbprint: Date:
 (Patient / Husband / Parents / Guardian)

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

Signature / Name and chop:

..... Date:
 (Attending Doctor)

Signature / Name:

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

I/C Number:

Signature / Name and chop:

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

Signature / Name:

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

I/C Number:

* delete whichever not applicable

Table 1: Summary of suspected In-utero Induced Deterministic Radiation effects

Menstrual or Gestational age (weeks)	< 50 mGy	50-100 mGy	> 100 mGy
0-2	None	None	None
3-4	None	Probably none	Possible spontaneous abortion
5-10	None	Potential effects are scientifically uncertain and probably too subtle to be clinically detectable	Possible malformations increasing in likelihood as dose increases
11-17	None	Potential effects are scientifically uncertain and probably too subtle to be clinically detectable	Increased risk of deficits in IQ or mental retardation that increase in frequency and severity with increasing dose
18-27	None	None	IQ deficits not detectable at diagnostic doses
>27	None	None	IQ deficits not detectable at diagnostic doses

Adapted from ACR Practice Guideline For Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation; ACR Practice Guideline 2014

Table 2 : Approximate foetal doses from common diagnostic procedures

Examination	Mean (mGy)	Maximum (mGy)
<u>Conventional X-ray examination:</u>		
Abdomen	1.4	4.2
Chest	<0.01	<0.01
Intravenous Urogram	1.7	10
Lumbar Spine	1.7	10
Pelvis	1.1	4
Skull	<0.01	<0.01
Thoracic spine	<0.01	<0.01
<u>Fluoroscopic examination:</u>		
Barium meal (upper GI)	1.1	5.8
Barium enema	6.8	24
<u>Computed Tomography:</u>		
Abdomen	8.0	49
Chest including CTPA	0.06	0.96
Head	<0.005	<0.005
Lumbar Spine	2.4	8.6
Pelvis	25	79

Adapted from Pregnancy and Medical Radiation; ICRP publication 84, Annals of the ICRP Vol 30, No 1 2000.