GUIDELINES FOR CONSENT TAKING IN PREGNANT OR POSSIBLY PREGNANT PATIENTS GOING FOR RADIOLOGICAL PROCEDURE

A) When to take consent

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 to take consent

i) The requesting doctor to be obtained on the day of request.

ii) The Radiology doctor on the day of the request.

iii) A medical officer may obtain the consent from the patient; however the form has to be counter-signed by the attending specialist.

C) How to take consent

i) The requesting doctor will explain more on the need and benefits of the procedure, available alternatives and how it will help in patient's subsequent management.

ii) The Radiology doctor will explain on the possible risks and complications towards patient and the fetus.

iii) For plain radiography, requesting medical officer shall take the consent after consulting their respective specialists.

iv) For special X-ray examinations, CT examinations and MRI examinations, the consent shall be taken by the requesting doctor and Radiology doctor accepting the case after consultation with the Specialists.

v) The consent shall be taken from patient herself. In the event she is not capable of doing so, consent may be taken from guardian / relative.

vi) If the procedure requires the injection of a contrast medium, the consent form for radiological procedures with contrast medium must be completed along with the checklist.

CONSENT – RADIOLOGICAL PROCEDURE FOR PREGNANT OR POSSIBLY PREGNANT LADY

PATIENT DETAILS

Name ……

IC No. ……

Address ……

Date ……

LMP ……

Ward /Clinic ……

Radiological procedure ……

This informed consent form applies only to eachradiological examination involving x-ray radiation or MRI.

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 doctor 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.

DECLARATION BY PATIENT / GUARDIAN / RELATIVE

I understand / agree that my doctor has explained the need this radiological examination and the possible risks of radiation to me and / or the pregnancy.

Signature ……

Print name ……

Date ……

IC No. ……

Relationship ……
(if patient not the person consenting)

DECLARATION BY ATTENDING / REQUESTING DOCTOR

I confirm that I have explained to the * patient / guardian / relative 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 ……

Date ……

Please STAMP here

DECLARATION BY THE RADIOLOGY DOCTOR / DOCTOR IN-CHARGE

I confirm that I have explained to the * patient / guardian / relative 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 ……

Print name ……

Please STAMP here

DECLARATION BY PATIENT / GUARDIAN / RELATIVE

I understand / agree that my doctor has explained the need this radiological examination and the possible risks of radiation to me and / or the pregnancy.

Signature ……

Print name ……

Date ……

IC No. ……

Relationship ……
(if patient not the person consenting)

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)
Conventional X-ray examination:		
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
Fluoroscopic examination:		
Barium meal (upper GI)	1.1	5.8
Barium enema	6.8	24
Computed Tomography:		
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