

<b>Title of Document:</b>	GUIDELINE FOR MRI EXPOSURE DURING PREGNANCY IN TRUST IMAGING DEPARTMENTS
<b>Directorate:</b>	RADIOLOGY DIRECTORATE

<b>Document type &amp; number:</b>	CG
<b>Approval committee:</b>	DIRECTORATE AND GOVERNANCE GROUP
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<b>Version number:</b>	V10
<b>Key amendments:</b>	<b>Date:</b>
Description changed to guideline instead of SOP	10.03.21
Signature requirement changed due to addition of prompts on ICE referral panel	10.03.21
Inclusion of 1.5T at KTC and some reformatting	05.02.24
<b>Individuals involved in developing / reviewing / amending this document: (titles only)</b>	
Countywide Modality Lead	
Clinical Lead for MRI	
MRI Site Leads	
<b>Key staff responsibilities</b>	<b>Post:</b>
Radiology Clinical Services Manager	Responsible for ensuring that the SOP is followed on all sites and CD
Appointed Superintendent Radiographer-in-charge	Responsible for the day to day implementation of the guideline
Radiologists / Radiographers	To comply with this guideline

Purpose of the Guideline:

The purpose of the guideline is to provide guidance for radiology staff on the referral of a patient for MRI examination during pregnancy.

This guideline is applicable to all MRI studies and will ensure risks and benefits have been fully explored by the referring clinician and discussed with the patient. To use this guideline, the patient must be able to provide informed consent.

This guideline is a mandatory, working document that describes the responsibilities of the staff and the process.

## **BACKGROUND**

Foetal safety of magnetic resonance imaging (MRI) during the first trimester of pregnancy or with gadolinium enhancement at any time of pregnancy is unknown.

Magnetic resonance imaging during pregnancy is generally thought to be safe for the foetus, especially in the second or third trimester. Concern has been expressed about the safety of MRI exposure in the first trimester, due to the heating of sensitive tissues by radiofrequency fields and exposure to the loud acoustic environment.

Clinicians need more data about the long-term safety for the child exposed to MRI in the first trimester of pregnancy or to gadolinium at any time during pregnancy.

There is no firm evidence in respect of the use of 1.5T or 3T scanner, therefore if a female requires scanning during pregnancy, WAHT radiology directorate has made the decision that a 1.5T scanner will be used to perform an exam in emergency circumstances according to this guideline. 1.5T scanners are in situ at ALEX, KTC and WRH.

When indicated, MRI's diagnostic accuracy is improved with gadolinium, an intravenous contrast medium; however, administration of gadolinium in pregnancy is discouraged because of possible teratogenicity in the first trimester during organogenesis. Additionally, gadolinium may cross the placenta in the second or third trimester, where it may be excreted by the foetal kidneys into the amniotic fluid and then recirculated by the foetus. Theoretically, persistence of dissociated-free gadolinium could cause nephrogenic systemic fibrosis (NSF) in the child. Although no cases of NSF have been reported, only one case series of gadolinium enhanced MRI in pregnancy has been published.

The findings of a population-based cohort study involving more than 1.4 million pregnancies were published in September 2016- **Association Between MRI Exposure During Pregnancy and Foetal and Childhood Outcomes** Joel G. Ray, MD, MSc, FRCPC; Marian J. Vermeulen, BScN, MHS; Aditya Bharatha, MD, FRCPC; Walter J. Montanera, MD, FRCPC; Alison L. Park, MSc)

### **Summary of Publication**

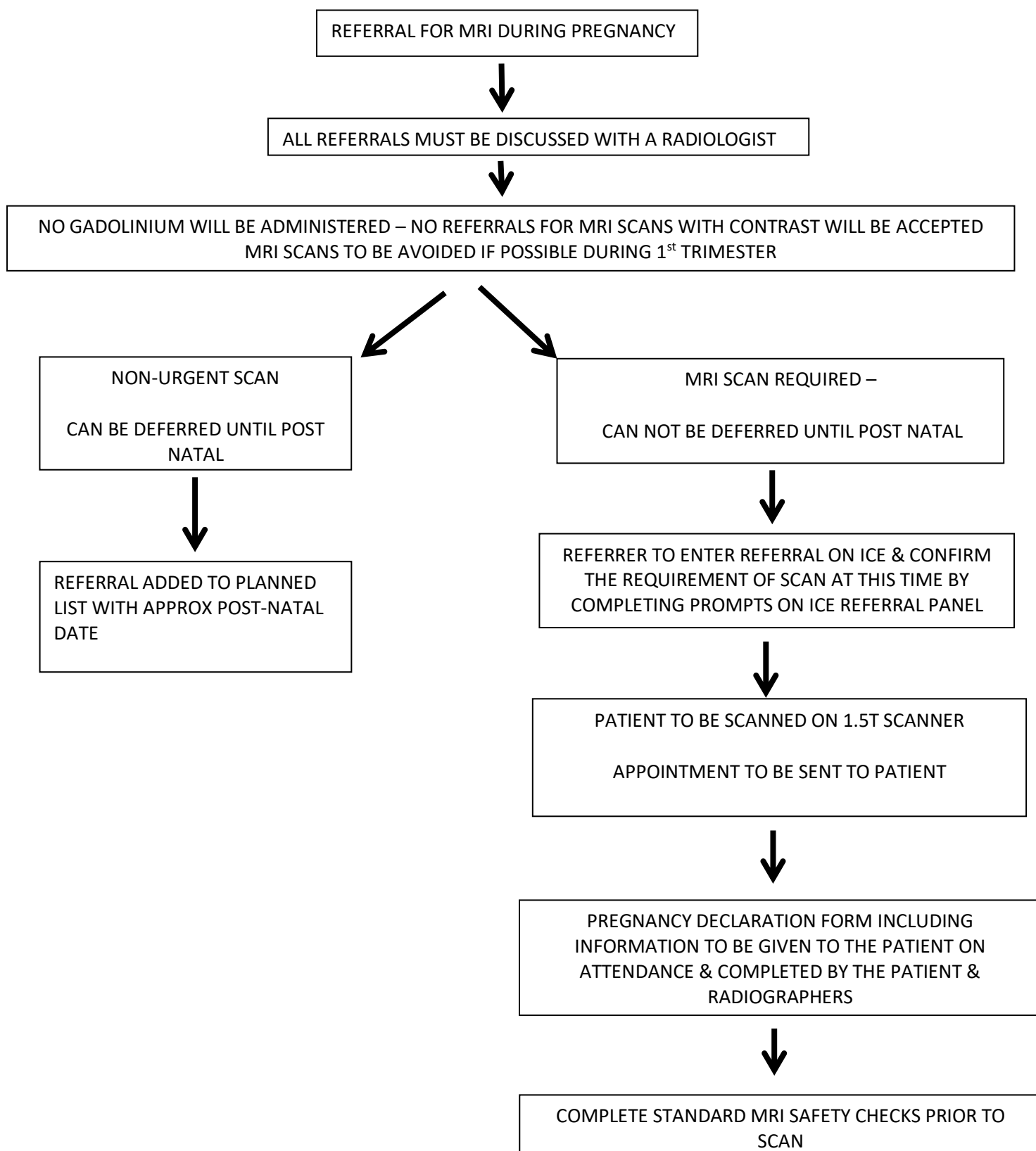
For first-trimester MRI exposure, the risk of stillbirth or neonatal death within 28 days of birth and any congenital anomaly, neoplasm, and hearing or vision loss was evaluated from birth to age 4 years. Exposure to MRI during the first trimester of pregnancy compared with non-exposure was not associated with increased risk of harm to the foetus or in early childhood.

**First-trimester MRI was not significantly associated with stillbirth or neonatal death, congenital anomaly, neoplasm, or hearing loss.**

Gadolinium MRI at any time during pregnancy was associated with an increased risk of a broad set of rheumatological, inflammatory, or infiltrative skin conditions and for stillbirth or neonatal death. The study may not have been able to detect rare adverse outcomes.

**Gadolinium-enhanced MRI was associated with a higher risk of stillbirth or neonatal death and a broad set of rheumatological, inflammatory, or infiltrative skin conditions.**

**Current recommendations are to forgo use of gadolinium enhanced MRI at any point during pregnancy, unless absolutely essential, and to carefully consider use of non-enhanced MRI in the first trimester**



**DIRECTORATE OF RADIOLOGY**

**MRI EXAMINATION FORM**

**Agreement for examination when the patient may be or is pregnant.**

**Patient name**.....

**Date of Birth**.....

**Address**.....

**CRIS number**.....

**Hospital/NHS number**.....

The referrer has reviewed the justification for this examination on this patient who is pregnant and requires an MRI examination at this time.

The referrer has confirmed the above on the ICE referral panel

MRI referral vetted by: ..... Consultant Radiologist

**Patient Information/ Declaration**

Your Doctor/Consultant has referred you for an MRI examination

By completing this form, you are confirming that you are pregnant or may be pregnant and that you understand any associated risks.

There is information available on the reverse of this form explaining the risks.

Your referrer has reviewed the need for this examination and considers that it should still be done even though you might be/are pregnant.

If you prefer not to have the examination, do not sign the form.

If you are willing to have this examination performed today, please sign this form.

**I may be or am pregnant**

**I understand that the risks to an unborn child if I have an MRI examination whilst pregnant as I have read and understood the information Sheet.**

**I agree to the examination being performed.**

Signature of Patient..... Date.....

Signature of Staff.....Print Name.....Date.....

## PATIENT INFORMATION

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*'Association Between MRI Exposure During Pregnancy and Foetal and Childhood Outcomes'*

*(Joel G. Ray, MD, MSc, FRCPC; Marian J. Vermeulen, BScN, MHSc; Aditya Bharatha, MD, FRCPC; Walter J. Montanera, MD, FRCPC; Alison L. Park, MSc)*

### Summary of Publication

For first-trimester MRI exposure, the risk of stillbirth or neonatal death within 28 days of birth and any congenital anomaly, neoplasm, and hearing or vision loss was evaluated from birth to age 4 years. Exposure to MRI during the first trimester of pregnancy compared with non-exposure was not associated with increased risk of harm to the foetus or in early childhood.

First-trimester MRI was not significantly associated with stillbirth or neonatal death, congenital anomaly, neoplasm, or hearing loss.

### REFERENCES:

*'Association Between MRI Exposure During Pregnancy and Foetal and Childhood Outcomes'* (JAMA September 6, 2016 Volume 316, Number 9 953 Joel G. Ray, MD, MSc, FRCPC; Marian J. Vermeulen, BScN, MHSc; Aditya Bharatha, MD, FRCPC; Walter J. Montanera, MD, FRCPC; Alison L. Park, MSc)