

## Procedure D

### **Procedure for making enquiries of individuals of childbearing potential to establish whether the individual is or may be Pregnant or breastfeeding**

All pre-examination pregnancy check forms are gender neutral inclusive and must be signed by the Operator and scanned onto PACS.

Compliance is audited through the Rolling IR(ME)R Audit Calendar.

#### **Objectives**

The aim of this procedure is to detail enquiries which must be made to individuals of childbearing potential to establish whether the individual is or may be pregnant or breastfeeding.

For the purpose of this procedure “childbearing age” should include the age range 11 to 55 years.

#### **Procedures**

In the first instance the Referring Clinician should check on the pregnancy status of the patient and indicate the result on the Radiology Referral. However, a further check must be made by an appropriately trained and entitled Operator when the patient attends for the examination, as pregnancy status may have changed since the Clinician completed the Referral.

Regulation 11(1)(f) states that a person must not carry out an exposure unless in the case of an individual of childbearing potential, the person has enquired whether that individual is pregnant or breastfeeding, if relevant. Regulation 11(3)(d)(i) requires the Practitioner to pay special attention when justifying an exposure for an individual where pregnancy cannot be excluded.

Making pregnancy or breastfeeding enquiries in advance of an exposure is an Operator task. The Operator undertaking the pregnancy enquiries must record the details onto the SET DOR Inclusive Pregnancy Status (IPS) Form (available on SharePoint). The appropriate information from the form must also be transferred onto the Examination page on PACS in the “LMP date” drop down box. The Operator undertaking this responsibility must record their details upon the Form. Ideally, the same Operator performing the exposure should make the pregnancy or breastfeeding enquiries.

However, if there are two Operators involved in the exposure (for example within CT), the person performing the pregnancy or breastfeeding enquiries should clearly communicate and cross check the individual’s pregnancy or breastfeeding status with the Operator undertaking the exposure, and

subsequently record their details within the Form, which must be scanned, verified and attached to the appropriate patient details on RIS/PACS. The Operator undertaking the exposure **remains responsible** and must satisfy themselves that the pregnancy or breastfeeding check has correctly occurred, as detailed in this procedure. The Operator undertaking the exposure must record their signature electronically on the on the PACS system within the “Performing Radiographer” box on the Examination page. The Operator undertaking the pregnancy enquiries must record the details from the Form onto the Examination page of PACS in the “LMP date” drop down box.

## **Pregnancy Enquiries**

Making pregnancy enquiries in advance of a medical exposure is an Operator task, however this does not disqualify the Referrer responsibility of providing sufficient medical data to enable the Practitioner to authorise and justify the exposure. The rationale for this procedure should be explained to the patient whilst ensuring privacy and confidentiality is afforded at all times. The Operator must explain the Radiation Safety questionnaire. If applicable the Operator should check the patient understands the procedure and the implication of their decision. Consideration must be given to patients who may lack capacity as identified by Fraser Competency.

Within SEHSCT enquiries will be made to individuals of child bearing potential (this shall include all patients of childbearing potential between the ages of 11 and 55 years of age) who are undergoing one of the following examinations:

- Individuals undergoing an exam where the primary beam may irradiate the pelvis,
- or individuals undergoing any Nuclear Medicine procedure involving radiopharmaceuticals

The Radiation Safety Questionnaire must be completed for all relevant individuals, as outlined above.

The PACS system within Northern Ireland is regionally standardised and as such must facilitate different pregnancy ‘LMP’ enquiries under IR(ME)R for each of the five appropriate Health and Social Care Trusts. The system therefore prompts Operators to enter information pertaining to pregnancy status on the “confirmation page” of RIS prior to beginning an exposure in the following circumstances:

- Patient aged between 11 and 55 years of age,
- receiving an ionising exposure to the pelvic area,
- or a Nuclear Medicine examination

Wherever practicable, pre attendance information (for example appointment letters or patient information leaflets) explaining the need for pregnancy

checking will be made available. Information shall also be made available within the Department in the form of displays, one of which is multi lingual highlighting the importance of disclosure of pregnancy and the potential risk to the foetus from exposure to ionising radiation.

Exposure of pregnant individuals to higher dose procedures may lead to fetal doses in excess of a few milligray and, at the highest doses, may result in a doubling of the childhood cancer risk compared to the natural rate. Consequently, such examinations should be avoided on pregnant individuals, if this can be achieved without serious detrimental effects to their health. The SEHSCT carries out the following high dose examinations;

- CT Abdomen and Pelvis
- CT Pelvis
- All other CT examinations including the pelvic area

Questions relating to the possibility of pregnancy may cause anxiety or embarrassment to the individual and anger or frustration to a parent, guardian or carer. This could lead to delays in diagnosis, which may cause additional emotional distress. Adequate information must therefore be available to ALL individuals prior to the exposure.

Individuals to be exposed should have time, opportunity and privacy, and feel safe to raise the possibility of pregnancy with either the Referrer, Practitioner or Operator where practicable. The Operator should be informed of any risk unless the patient has not consented to do so.

It is important that the person enquiring as to the possibility of pregnancy (usually the Operator) is adequately trained to do so and acts with sensitivity and compassion and without judgement. The individual should be given time to consider the information and think about their response.

### **Children and Young Persons (CYP)**

The Operator, before allowing confirmation of Radiation Safety Questionnaire details should verify with the clinician responsible for the person's care that the person has capacity under Fraser Competency. The Operator must record this on the patient's examination page on PACS. The legal age of consent to sexual activity in Northern Ireland is 16. Between the ages of 13 and 16, there are complex ethical, practical and contextual implications to be aware of when enquiring about sexual activity below the age of consent. Advice should be sought immediately from the local safeguarding team if factors such as coercion, sexual activity with a partner aged over 18 or abuse is suspected.

Establishing or excluding the possibility of pregnancy in Children and Young Persons (CYP) presents a number of challenges the Operator should be aware of:

- Children aged 12 years of age or younger are unable legally to give consent. An affirmative response to the question of pregnancy in individuals aged 12 years of age or younger must be reported and investigated under criminal law, in accordance with the SEHSCT Corporate Safeguarding Children Policy SETGen082020 (available on iConnect), where there are safeguarding concerns.
- If a child between the age of 11 and 16 confirms that they are sexually active, it is the operator's duty to inform the referrer, record the information on the appropriate Last Menstrual Period (LMP) form. In addition, the information must be recorded on the request notes on RIS and a "Safeguarding Children Record of Significant Information" form must be completed (available on SharePoint).
- The Referrer may not have considered the possibility of pregnancy and so may not have asked the patient prior to Referral.
- Onset of menarche varies and regular cycles may not be established for 2-3 years.
- The individual may not be able to reliably recall the first day of their Last Menstrual Period (LMP).
- The individual may be unaware that they are pregnant.
- They may be unwilling or afraid to answer truthfully in the company of their parent/guardian(s)
- They may be afraid of the legal consequences of engaging in under age sexual activity
- There may be religious or cultural consequences for a young unmarried individual admitting to the possibility of pregnancy
- The possibility of pregnancy in vulnerable individuals may indicate sexual abuse and therefore may be concealed

Guidance for pre-procedure checking of pregnancy for under 16s is available from the Royal College of Paediatrics and Child Health and includes a useful procedural flowchart. The Guidance is available on SharePoint.

### **Inclusive Pregnancy status guidance**

The SCoR has provided "Inclusive pregnancy status guidelines for ionising radiation: Diagnostic and therapeutic exposure", which is available on SharePoint. The SEHSCT has adopted an inclusive approach to pregnancy checking. All applicable patients, as outline the information above, will complete a SET DOR Radiation Safety Questionnaire.

The Referrer has a responsibility under regulation 10 (5) to supply the Practitioner with sufficient medical data relevant to the exposure to enable the Practitioner to decide whether there is sufficient net benefit. This generally includes the possibility of pregnancy. The exception to this may be when there is a need to protect the confidentiality of a person's transitional status due to threats or risk of personal harm for example. The individual must consent to this information being shared.

Where the Referrer, Practitioner and Operator are unaware of the possibility of pregnancy due to the individual being unidentified/undeclared as a trans male or are non-binary/gender non-conforming, or where the individual has not consented to the sharing of their gender identity, the individual has the sole responsibility for safeguarding the fetus. Providing the patient with adequate information relating to the risks and benefits associated with the radiation dose prior to the procedure gives the patient the opportunity to declare any possibility of pregnancy.

## **Process for Checking Pregnancy Status**

When an individual of childbearing potential attends for an examination they will be asked to complete a Radiation Safety Questionnaire:

### **“Are you, or might you be pregnant”?**

Depending on the individual’s response to this question, the individual can be assigned to one of the following groups:

1. Patient definitely or probably pregnant
2. No possibility of pregnancy
3. Pregnancy cannot be excluded

The following steps should be taken for each of these patient groups to prevent unnecessary exposure of a fetus where the risks may be of concern.

#### **1. Patient definitely or probably pregnant**

If pregnancy is established or likely, only proceed with low dose examinations if it has been justified by a Radiologist/referrer or Radiology Registrar. If, after review, a procedure is still considered to be justified and is undertaken, the fetal dose should be kept to the minimum consistent with the diagnostic purpose. A record of the patient’s pregnancy and subsequent review of justification and authorisation by the Practitioner must be recorded within the request notes of RIS. The patient must sign the “Diagnostic X-Ray Consent form for a Pregnant Patient” which must be scanned onto PACS.

#### **2. No possibility of pregnancy or where pregnancy cannot be excluded**

If the patient believes they are not pregnant, the Operator must still check the date of the patient’s last menstrual period (LMP) to ensure a robust checking system is in place, unless the patient is sterilised, pre-menstrual or post-menopausal for at least one year. The patient should be regarded as post-menopausal if the period has been absent for two years before the age of 50 and for one year after the age of 50 years. This is recorded in a drop-down menu in RIS.

If the patient falls into one of these three categories, the Operator must record the category and the patient must sign the SET DOR Inclusive Pregnancy Form, prior to proceeding with the examination.

All other patients (i.e. those who are not sterilized or pre-menstrual or post-menopausal for at least 1 year) who believe there is no possibility of pregnancy, or that pregnancy cannot be excluded will be managed in the following way:

For low dose procedures, the Operator shall apply the “28-day rule”, i.e. if the patient’s LMP date falls within 28 days, the examination may proceed. For further information, please refer to the Figure 1: Pregnancy Status Flowchart for Low Dose Examinations. The LMP date will be recorded on the SET DOR Radiation Safety Questionnaire and PACS by the Operator.

For high dose procedures, the Operator shall apply the “10-day rule”, i.e. if the patient’s LMP date falls within 10 days, the examination may proceed. For further information, please refer to the Figure 2: Pregnancy Status Flowchart for High Dose Examinations. The LMP date will be recorded on the SET DOR Radiation Safety Questionnaire and PACS by the Operator. If the Operator, Practitioner or Referrer wishes to offer the patient further advice with regards to the protection of the foetus during medical exposure to ionizing radiation, reference documentation may be accessed on the DOR SharePoint.

If the patient’s LMP date falls outside the “28day rule” for low dose examinations or the “10day rule” for high dose examinations, then the Operator must discuss which contraceptive method the patient has **effectively** implemented to protect against the risk of pregnancy.

Methods of contraception accepted by the SEHSCT include:

- Contraceptive Pill
- Abstinence
- Contraceptive Injection
- Contraceptive Implant
- Vasectomy Partner
- Contraceptive Coil
- Hysterectomy

The Operator will record the contraceptive method applied by the patient, where appropriate, on the SET Radiation Safety Questionnaire, and on PACS. If the patient has not effectively implemented one of the accepted methods listed above, then a pregnancy test must be carried out before the examination can proceed.

### **High Dose Procedures**

Patients requiring high dose procedures who are identified to be **outside the 10<sup>th</sup> day of the menstrual cycle** and cannot satisfy any of the above criteria should have

their examination deferred where clinical urgency permits. If the exam cannot be deferred due to the clinical urgency of the patient, only proceed with a high dose examination if: -

- Authorised and Justified by a Radiologist, Radiology Registrar
- For any other reason as listed on PACS as given by patient e.g. hysterectomy
- From day 28, a missed period and a recently obtained pregnancy blood or urine test is negative
- Pregnant patients only proceed with high dose examinations if it has been authorised and justified by a Radiologist/Surgeon or Radiology Registrar

### **Low Dose Procedures**

Patients requiring low dose procedures who are identified to be **outside the 28<sup>th</sup> day of the menstrual cycle** and cannot satisfy any of the above criteria to assist the Practitioner in the justification of the Referral. If it is more than 28 days since the first day of the LMP proceed with examination if: -

- Authorised and Justified by a Radiologist, Radiology Registrar
- For any other reason as listed on PACS as given by patient e.g. hysterectomy
- From day 28, a missed period and a recently obtained pregnancy blood or urine test is negative
- Pregnant patients; only proceed with low dose examinations if it has been justified by a Radiologist/referrer or Radiology Registrar. The patient must sign the “Diagnostic X-Ray Consent form for a Pregnant Patient” which must be scanned onto PACS.

It is important to indicate that whilst the IR(ME)R regulations state that pregnancy status should be determined in relevant individuals of childbearing potential, where the uterus lies in or near the primary beam or for nuclear medicine procedures, all of the pregnancy tests that are currently available are only likely to detect hCG in urine at 14 days after conception (i.e. approximately 28 days since the last menstrual cycle) and in blood serum 7 days post conception (i.e. approximately 21 days since the last menstrual cycle).

### **Following all pregnancy/breast feeding enquiries**

The SET DOR Radiation Safety Questionnaire must be fully completed and signed by the patient and Operator prior to examination. The form must be scanned, verified and attached to the appropriate patient details on RIS/PACS.

The Operator must transcribe the appropriate pregnancy details from the SET DOR Radiation Safety Questionnaire onto the Examination page on PACS in the “LMP date” drop down box.

## **Emergency Situations**

In emergency/major trauma circumstances it may not be possible to determine pregnancy status. Treatment of the patient is the most important consideration, taking priority over possible risk to the fetus, however the Operator should ensure the dose to the uterus should be kept as low as reasonably practicable, consistent with the diagnostic purposes.

### **Emergency Situations where pregnancy is confirmed or when pregnancy cannot be excluded**

These situations may include:

1. Patients in an emergency situation who are aware and notify the Operator that they are pregnant
2. An unconscious patient in an emergency situation
3. Patients in an emergency situation who cannot confirm pregnancy status or their LMP date

If any of the above situations occur a review of the justification for the proposed examination with the relevant Practitioner (Radiologist) must occur. For out of hours CT this may be the Practitioner who justified the initial Referral, for example the Radiologist from the out-of-hours third party provider. For out of hours Plain Film X-ray the relevant Practitioner may be the Radiologist of the Day (ROD). The Practitioner must consider if an alternative imaging modality with non-ionising radiation will provide suitable information. If, after review, a procedure is still considered to be justified and is undertaken, the delivered dose should be optimized as far as reasonably possible. This may include giving consideration to reducing the number of views required, or modifying the technique to reduce the patient dose. Repeat exposures must be avoided.

A record of the patient's pregnancy status and subsequent review of justification by the Practitioner must be recorded within the request notes of RIS, and must include the name of the justifying Practitioner. Where it is practicable to do so, the Operator must inform the patient of the benefits and risks of the required examination.

## **The Unconscious Patient within a theatre setting**

The Operator must check the peri-operative care pathway for pregnancy status. The pathway can be located in the patient's notes. The Operator must then complete the Theatre Pre-Examination Radiation Safety Questionnaire.

In the event that a record of pregnancy status has not been documented on the peri-operative care pathway the examination must be justified and authorised by a Surgeon or a Radiologist. In theatre, for the unconscious or premed patient, the Operator undertaking the exposure will obtain the pregnancy status from the Surgeon/nurse in charge of theatre and document this on the SET DOR Radiation Safety Questionnaire within the Examination Page on PACS.

### **Other available options**

- Consider alternative imaging examination which does not use ionising radiation.
- If clinically acceptable, the patient may be offered an alternative appointment or the examination may be deferred.
- For SLNB procedures, authorisation and justification must be reviewed by the entitled Licensed Practitioner.
- the patient is unwilling to sign the Radiation Safety Questionnaire, do not proceed with the imaging examination. However, if possible, discuss with the referrer.

### **Patients requiring alternative method of pregnancy checking**

Patients requiring alternative method of pregnancy checking, including patient with sensory impairment, may be provided with written questions and materials to answer with, to verify their pregnancy status. The patients requiring alternative method of pregnancy checking Form should be used by the Operator to check the pregnancy status of such patients and is available on SharePoint). Staff must ensure appropriate materials are provided to assist the patient in completing the form, for example pens/pencils, clipboard etc. The Operator must ensure the patient has read and understood the information contained within the form before asking the patient to sign the pregnancy declaration. The Operator must then scan, attach and verify the form to the patient's details on RIS.

A sign language interpreter can be booked to support communication for Deaf, Deafblind and Hard of Hearing patients through the Regional Interpreting Service provider "sign Language Interactions". Bookings can be made through: -

- online at <https://signlanguageinteractions.com/hscni/>
- via telephone to Sign Language Interactions on 0333 344 7712
- via email at [bookingsni@signlanguageinteractions.com](mailto:bookingsni@signlanguageinteractions.com)

Further information is available on the Equality and Human Rights i-connect pages, Interpreting and Translation Information.

The Operator must record details of the pregnancy checks on the Confirmation Page of RIS.

Patients with a visual impairment: a verbal explanation must be given to the patient and guidance to help sign the form. Consideration must be given to patients who may lack capacity as identified by Fraser Competency. If the operator has any concerns that a patient lacks capacity, the operator must not proceed with the examination and must discuss these concerns with the referring clinician, and or the consultant radiologist. The Operator must record this on the patient's examination page on RIS. Patients without capacity who are accompanied by a carer or comforter, the carer or comforter must sign the relevant SET DOR Radiation Safety Questionnaire. Patients without capacity who are unaccompanied, every effort should be made to establish that the patient is not pregnant. If there is any doubt do not proceed with the imaging examination but consult with the referrer or a Radiologist for authorisation and justification.

### **Speakers of other languages or patients with inadequate command of English**

If the patient is accompanied by an appropriate adult who can speak English, then the pregnancy status check may be carried out as detailed above with the accompanying adult:

If the patient is not accompanied by an adult who can speak English, the Operator should avail of the Trust's Accessing an interpreter for alternative language and sign language service. Further information is available on the Equality and Human Rights i-connect pages Interpreting and Translation Information

### **Nuclear Medicine**

It is the responsibility of the Operator who administers the Radiopharmaceutical within Nuclear Medicine, to make enquiries with all relevant patients of childbearing potential (11-55 years of age) with regards to whether the patient is breast-feeding or pregnant using the Assessment of Pregnancy and Breastfeeding low Dose procedures form. Nuclear Medicine patients of childbearing potential (11-55 years of age) who are breastfeeding must be managed in accordance with Procedure R.

The form must be fully completed, including details of both pregnancy status and breast feeding status, and signed by the patient and operator prior to examination and the form must be scanned, verified and attached to the appropriate patient details on RIS.

If a patient is known to be pregnant, this must be discussed with the licensed practitioner and the MPE.

Breast feeding patients will be discussed with the MPE on a patient to patient basis in order to fill in the breastfeeding form that we give to the patient, this has written instructions on what to do.

## **Fluoroscopy and interventional procedures where the primary beam directly irradiates the abdomen and pelvis Examinations including Hysterosalpingogram Examinations**

Individuals of child bearing potential, who are due to receive a fluoroscopy examination, where the primary beam may irradiate the pelvis, must be appointed in accordance with the relevant fluoroscopy Guideline/protocol, for example for the Guideline for undertaking Hysterosalpingograms in the DOR (available on SharePoint), due to the nature of the examination, the patient must be appointed within the first 10 days of their menstrual cycle, when conception is unlikely to have occurred. In certain circumstances the clinical urgency of the exam may require the exam to be undertaken outside the first 10 days of the patient's menstrual cycle, these situations include, but are not limited to; Red Flag Referrals, New Cancer Diagnosis and Emergency Situations.

For further information, please refer to the relevant Clinical Guideline/protocols (available on SharePoint).

### **Cardiac Cath Lab**

The Operator will undertake pre-procedure pregnancy enquires for examinations in the Cardiac Cath lab. The SET DOR Radiation Safety Questionnaire must be completed and scanned onto PACS. During Cardiac Cath Angiograms the Operator will document on the 'Cardiac Radiographer Timeout' on Encompass/Epic that the pregnancy check has been carried out.

Figure 1: Workflow for Carrying Out Pregnancy Enquiries Please follow the procedure below for **ALL** patients aged between **11- 55** years old undergoing ionising radiation-imaging examinations where the primary beam may irradiate the pelvis.

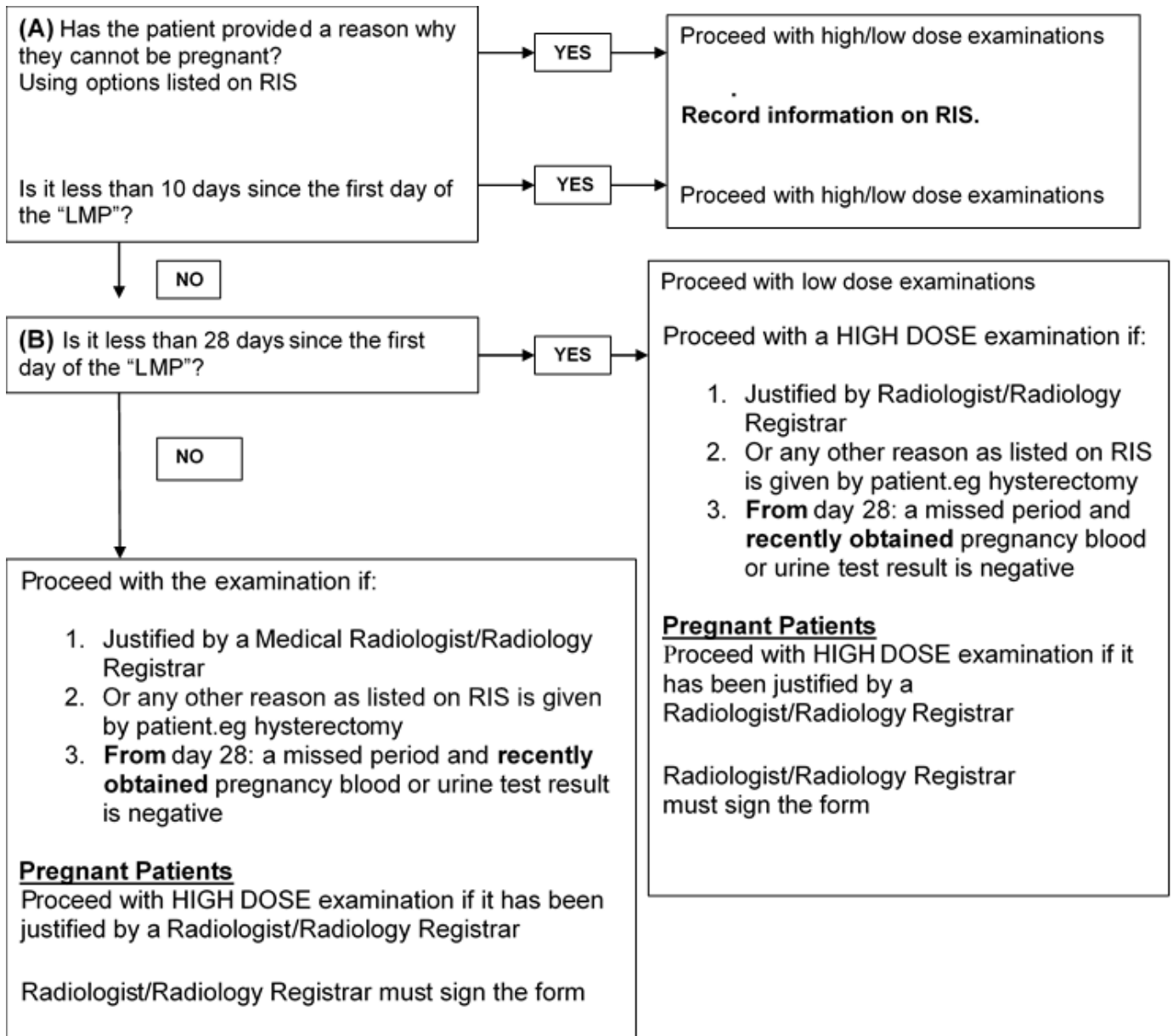
**High Dose** examinations are:

Any CT scans which expose the area between the diaphragm & symphysis pubis

All fluoroscopic and interventional procedures where the primary beam directly irradiates the abdomen and pelvis

**Low Dose** examinations are:

Any examinations that expose the area between the diaphragm & symphysis pubis



**Please note:** Authorisation must be demonstrated by signing or initialling the referral in a predetermined place or by entering an electronic password on RIS