

Title: Radiology – Pregnancy Verification	Procedure
Patient Age Group: <input type="checkbox"/> N/A <input type="checkbox"/> All Ages <input type="checkbox"/> Newborns <input checked="" type="checkbox"/> Pediatric <input checked="" type="checkbox"/> Adult	

DESCRIPTION/OVERVIEW

University of New Mexico Hospitals (UNMH) has established a uniform procedure to manage and document potentially pregnant patients and to manage patient consent for specific higher risk procedures that may require the use of substantial ionizing radiation or radioisotopes.

REFERENCES

- The American College of Radiology. (Amended 2014). *ACR-SPR Practice Parameter for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation* (Resolution 39).
- International Commission on Radiological Protection (2000). *Pregnancy and Medical Radiation*. Bethesda, Md: ICRP Publications 84; 1-43
- Bushberg, J. T., Seibert, J. A., Leidholdt Jr., E. M., & Boone, J. M. (2011). *The Essential Physics of Medical Imaging* (3rd ed., p. 1048). Philadelphia, PA: LWW.
- Wagner, L. K., Lester, R. G., & Saldana, L. R. (1997). *Exposure of the Pregnant Patient to Diagnostic Radiations: A Guide to Medical Management* (Second Edi., p. 259). Madison, WI: Medical Physics Pub Corp.

AREAS OF RESPONSIBILITY

Applies to the following Radiology Service areas using ionizing radiation sources (whether stationary or portable): Computed Tomography (CT), Nuclear Medicine (NM), Fluoroscopy (Fluoro), Mammography (MA), and X-ray within the UNM Hospitals.

Note: This procedure does not apply to emergent procedures, Interventional Radiology, patients undergoing diagnostic or therapeutic procedures in Radiation Oncology, or, patients undergoing therapeutic procedures in Nuclear Medicine for whom additional screening applies.

PROCEDURE

1. A preliminary discussion with the patient regarding pregnancy is the responsibility of the Licensed Independent Provider (LIP) in charge of the patient’s care.
2. All female patients aged 10 to 60 years must be screened for pregnancy by a licensed imaging specialist. Screening of female patients < 10 years should be performed with the parent, guardian, or LIP.
3. Chart 1 below outlines the process for pregnancy screening, notification of the referring LIP, and patient consent.

Chart 1

Pregnancy Status	Negligible Risk Exam (0)	Low Risk Exam (1)	High Risk Exam (2)
Not Pregnant	Document in Radnet & Shield as appropriate. No screening form.	Execute Pregnancy Screening form and scan into PACS	Execute Pregnancy Screening form and scan into PACS
Unknown	Document in	Order Pregnancy Test and proceed	Order Pregnancy Test and proceed

	Radnet & double shield as appropriate. No screening form.	based upon results	based upon results
Yes Pregnant	Document in Radnet & double shield as appropriate. No screening form.	Radiologist will notify ordering LIP to ensure exam is necessary at this time. If decision is made by LIP to proceed with the exam, patient will be consented using Low Risk Consent Form. If decision is made by LIP to delay, cancel exam.	Radiologist will notify ordering LIP to ensure exam is necessary at this time. If decision is made by LIP to go forward with the exam, patient will be consented using High Risk Consent Form. If decision is made by LIP to delay, cancel exam.

4. If the patient is having a Negligible Risk Exam (Level 0, Table 0):
 - 4.1. The patient's response regarding pregnancy should be documented in Radnet. *The Pregnancy Screening Form does not need to be filled out.*
 - 4.2. If the patient states she is not pregnant, proceed with the exam.
 - 4.3. If the pregnancy status is unknown or positive, the patient should be double-shielded for X-ray examinations. *No additional shielding is warranted for CT, fluoroscopy, and nuclear medicine examinations.*
5. If the patient is having a Level 1 or Level 2 exam (Tables 1 and 2):
 - 5.1 Under all circumstances, the imaging specialist ensures completion of the Pregnancy Screening Form and scans the form into PACS. A patient label must be placed on the form.
 - 5.2 If the patient states she is not pregnant, proceed with the exam.
 - 5.3 If the patient is unsure of pregnancy status, she should undergo a pregnancy test before proceeding with the examination. Radiology will place the urine pregnancy test order (PGU) using the Radiology Medical Director as the ordering provider.
 - 5.3.1. If the pregnancy test is negative, proceed with the examination.
 - 5.3.2. If the pregnancy test is positive, contact the Radiologist to notify ordering LIP to confirm that the exam is necessary at this time. If decision is made by LIP to proceed with the exam, the patient will be consented by the Radiologist using appropriate Pregnant Patient Consent form. If decision is made by LIP to delay, the patient will be informed of the decision and the rationale for such a decision by the Radiologist. The Imaging specialist will cancel the examination using the reason "Test not done per current protocol".
 - 5.4 If the patient refuses the pregnancy test, inform the Radiologist (attending or resident) who will contact the ordering LIP. Subsequent performance of the examination will be at the discretion of the LIP and Radiologist.
 - 5.4.1 If the decision is to continue with the test the appropriate Pregnant Patient Consent Form will be required.
 - 5.4.2 If the decision is made to cancel the exam, the Imaging specialist will cancel the examination using the reason "Test not done per current protocol"
7. A negative pregnancy test result for an outpatient is valid for seven days. A negative pregnancy result for an inpatient is valid for the length of the inpatient stay.
8. For Low Risk exams (Level 1, Table 1) or High Risk exams (Level 2, Table 2), the patient may elect additional counseling regarding the biological effects of radiation on fetal development. If elected, a Radiologist or Qualified Medical Physicist (QMP) will provide this counseling.
9. For all low risk and high risk exams, the imaging specialist is responsible for scanning the Pregnancy Screening and Patient Consent Forms into PACS.

DEFINITIONS

Radiation: Energy emitted in the form of waves or particles. Radiation is emitted during the decay of radioisotopes or produced by x-ray generators.

Radioisotope: A radioactive species of an element often with the same chemical properties as non-radioactive species of the element.

mGy: One-thousandths of a Gray. The Gray (Gy) is the SI unit of absorbed dose. It is the amount of energy deposited by radiation per unit mass. 1 Gy = 1 J/kg = 100 rads.

SUMMARY OF CHANGES

Defined age range

Defined risk categories

Clarified pregnancy testing process/orders

Included an initial screening form for Level 1 and Level 2 Risk Exams

Included consents for Level 1 and Level 2 Risk Exams

Specified and charted work flow

Described communication to assess if Level 1 or Level 2 Exams should be performed while patient is pregnant

Replaces "Radiology – Pregnancy Verification", 7/2015.

DOCUMENT APPROVAL & TRACKING

Item	Contact	Date	Approval
Owner	Executive Director Radiology		
Consultant(s)	Rhonda Brown, BS RT (R), Meaghan Carey, DNP, RN, Greg Chambers, MS, DABR, Charlene Montoya, MBA, RT (R)(MR), Jane Potter, BFA, RT (R)(MR), Daniel Sandoval, MS, DABR, Reed Selwyn, PhD, DABR, Sarah Shortle, MBA, RT(R), Joanna Fair, MD, PhD		
Committee(s)	Clinical Operations PP&G Committee		Y
Medical Director	Steven Eberhardt, M.D.		Y
Official Approver	Erin Doles, Administrator		Y
Official Signature		Date: 11/12/2015	
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ATTACHMENTS

Attachment A – Table 0 – Level 0, Negligible Risk Exams & Table 1 – Level 1, Low Risk Exams

Attachment B – Table 2 – Level 2, High Risk Exams

Attachment C – Pregnancy Screening Form

Attachment D – Pregnant Patient Consent Form for Low Risk Imaging Procedures

Attachment E – Pregnant Patient Consent Form for Substantial Risk Imaging Procedures

Table 0 – Level 0, Negligible Risk Exams* (<5 mGy)	
Negligible Risk X-Ray Exams	Negligible Risk CT Exams
Upper Extremity	CT/CTA Head
Lower Extremity (excluding hip)	CT Facial Bones/Orbits/Temporal Bones
Skull	CT/CTA Neck
Mandible	CT/CTA Chest
C-Spine	CT C-Spine
T-Spine	CT T-Spine
Chest	CT/CTA Upper Extremity
Mammography (screening, diagnostic, and procedures)	CT/CTA Lower Extremity

*Note: This list is not all-inclusive but provides representative examples

Table 1 – Level 1, Low Risk Examinations (5-50 mGy)	
Examination	Protocol
Nuclear Medicine	
Bone Scan (High resolution bone PET)	F-18 NaF
Bone Scan (MDP)	Tc-99m MDP
Brain SPECT with or without CT	Tc-99m HMPAO (Ceretek), Tl-201 Chloride
Cardiac Perfusion (any protocol)	Tc-99m Sestamibi, Tl-201 Chloride
Cerebral Blood Flow (Brain Death)	Tc-99m DTPA
GI Bleed	Tc-99m Pertechnetate - Ultratag
Hemangioma	Tc-99m Pertechnetate - Ultratag
Hepatobiliary with CT	reinjection
Lung Ventilation (aerosol)	Tc-99m DTPA
MIBG	I-123 MIBG
MUGA	Tc-99m Pertechnetate - Ultratag
Octreoscan without or with CT	In-111 Octreoscan
Parathyroid Scan without or with CT	Tc-99m Sestamibi
PET (FDG) without or with CT	F-18 FDG
WBC Imaging without or with CT	Tc-99m HMPAO (Ceretek)
WBC Imaging with CT	In-111 Oxine
X-ray/Fluoroscopy	
L Spine	AP, Lateral, Spot, Rt. Oblique, Lt. Oblique, Flexion Extension
Pelvis	AP, judet views X2
Scoliosis Series	AP x 2, AP T-spine AP L-spine, Lat x2, Lat T-Spine or L-spine
Abdomen	AP and/or AP & Lateral
Hip	AP & Lateral
Fluoroscopy Exams	Barium Enemas, Cystograms. VCUG, Hysterosalpingogram, Defoecography, Small Bowel, G-Tube, J-Tube, Myelogram. Loop-o-gram, Pouch-o-gram
CT	
CT/CTA Abdomen	Any
CT/CTA Abdomen/Pelvis	Any
CT/CTA Chest/Abdomen/Pelvis	Any

Table 2 – Level 2, High Risk Examinations (>50 mGy)		
Examination	Protocol	Estimated Whole Body Fetal Dose (mGy) > 50 mGy?
Nuclear Medicine		
Brain SPECT without or with CT	Tc-99m ECD (Neurolite)	yes
Cerebral Blood Flow (Brain Death)	Tc-99m Pertechnetate	No, but > 50 mGy to the fetal thyroid if developed
Gallium Scan without or with CT	Ga-67 Citrate	yes
Meckel's Scan	Tc-99m Pertechnetate	No, but > 50 mGy to the fetal thyroid if developed
Thyroid Cancer Imaging	I-123 NaI or I-131 NaI	No, but > 50 mGy to the fetal thyroid if developed
Thyroid Scan and/or Scan	Tc-99m Pertechnetate, I-123 or I-131	No, but > 50 mGy to the fetal thyroid if developed
CT or IR Examinations		
CT Lumbar Spine	Any	yes
CT/CTA Pelvis	Any	yes
Interventional Radiography	Any	Variable



Pregnancy Screening Form

For Level 1/Level 2 Exams

Patient Label

Date: ____ / ____ / ____

For women ages 10-60:

Are you pregnant or could you be pregnant? Circle one:

YES NO MAYBE

Patient/guardian signature: _____

Instructions to UNMH staff:

If the patient answers “maybe” a pregnancy test is required.

Type: urine serum

Results (circle one): Negative Positive Date _____

(Valid for 7 days or entire inpatient stay)

*If positive, notify the radiologist

Transcribing Imaging Specialist initials: _____

Dose to the Fetus is less than 50 mGy

Pregnant Patient Consent for Low Risk Imaging Procedures

You are scheduled for an imaging test with radiology or nuclear medicine. During this test, you and your unborn child will be exposed to a small amount of radiation. Radiation can be harmful.

The examination does **not** increase the chance for birth defects or miscarriage. But it might be a little more likely that your child could have cancer later in life. This chance is very small.

Your test is: _____

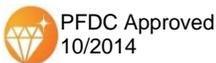
You have the right to not have this test. **But your doctor feels that this test has more benefit than risk for you and your child.**

By signing below, you are saying that:

- Your doctor has explained the benefits of this test.
- You understand what this form says about the very small chance of cancer your child may have because of this test.
- All of your questions have been answered.
- You understand that no guarantees are being made about the outcome of your pregnancy.
- You agree to have this test.

Patient Signature	Patient Name (print)	Date/Time
Witness Signature	Witness Name (print)	Date/Time
Radiologist Signature	Radiologist Name (print)	Date/Time
Interpreter Signature	Interpreter Name (print)	Date/Time

Patient Label





Dose to the Fetus is greater than 50 mGy

Pregnant Patient Consent for High Risk Imaging Procedures

You are scheduled for an imaging test with radiology or nuclear medicine. During this test, you and your unborn child will be exposed to radiation. Radiation can be harmful.

The risk to you is small. You have a higher chance of miscarriage during the first 3 months of pregnancy.

Your child also has a small chance of having:

- ~ birth defects
- ~ lower IQ or mental retardation
- ~ a higher risk of cancer later in life.

Your test is: _____

You have the right to not have this test. **But your doctor feels that the test has more benefit than risk for you and your child.**

By signing below, you are saying that:

- Your doctor has explained the benefits of this test.
- You understand what this form says about the risks this test.
- All of your questions have been answered.
- You understand that no guarantees are being made about the outcome of your pregnancy.
- You agree to have this test.

_____	_____	_____
Patient Signature	Patient Name (print)	Date/Time
_____	_____	_____
Witness Signature	Witness Name (print)	Date/Time
_____	_____	_____
Radiologist Signature	Radiologist Name (print)	Date/Time
_____	_____	_____
Interpreter Signature	Interpreter Name (print)	Date/Time



Patient Label