

**UAB Department of Radiology Guidelines for Performing Examinations on Patients
Who are Pregnant or May be Pregnant
Revised August 27, 2009**

Some women who are pregnant or may be pregnant benefit from radiographic examinations. Because there are risks of radiation, and possibly MRI, to the fetus, evaluation and precautions must be taken to confirm the need for such examinations, to assess the risks and, sometimes, to secure informed consent before performing such examinations. These guidelines draw substantially from the “ACR Practice Guideline for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation” which should be reviewed for additional detail and numerous references. Note summary guidelines for convenient reference for technologists and for radiologists and radiology residents are included as Appendix I and II.

Topics Addressed in This Document

- 1. Procedures Requiring and Not Requiring Assessing Pregnancy Status**
- 2. Assessing Pregnancy Status**
- 3. Minors Who are or May be Pregnant**
- 4. Informed Consent**
- 5. Examination Technique and Documentation of Radiation Dose**
- 6. Counseling the Patient Not Known to be Pregnant at the Time of Exposure**
- 7. Performance of MRI and Administration of Gadolinium to the Pregnant Patient**
- 8. Risks of Radiation to a Fetus**
- 9. Risks of Intravenous Contrast Administration to a Fetus**
- 10. References and Recommended Reading**
- 11. Appendix I - Summarized Guidelines for Technologists Regarding Radiographic Procedures on a Patient Who is or May be Pregnant**
- 12. Appendix II - Summarized Guidelines for Radiologists and Radiology Residents Regarding Radiographic Procedures on a Pregnant Patient**
- 13. Appendix III – Risks of Radiation by Gestational Age**

Procedures Requiring and Not Requiring Assessing Pregnancy Status

No screening policy will guarantee 100% detection. The vast majority of routine diagnostic studies deliver less than 20 mGy to the uterus, and single-phase acquisition computed tomography (CT) of the abdomen including the pelvis usually delivers less than 35 mGy. Fluoroscopically guided interventional procedures in the pelvis might deliver doses above the teratogenic threshold (~100 mGy).

Because of the very low dose to a fetus for some examinations, no special precautions other than good collimation and radiographic technique need to be taken with the following examinations:

- Chest radiography

- Extremity radiography
- Head radiography
- Mammography
- Abdominal radiography (even if the pelvis is included)
- Other examinations that do not directly expose the pelvis

Tests that do not expose the pelvis to radiation administer only a negligible dose of radiation to the fetus. This includes helical chest CT or pulmonary arteriogram to evaluate for pulmonary embolism. However, the risks of radiation to the mother (particularly the breasts, which are particularly sensitive to radiation), and of intravenous contrast administration to the mother and fetus should be considered, although consent is not required for performing these tests in the pregnant woman. All other radiologic tests that directly expose the female pelvis to ionizing radiation and MRI require assessing pregnancy status. Even if the patient is pregnant, informed consent may not be required, depending on the level of risk. Tests requiring assessing pregnancy status include:

- Abdominal/pelvic CT
- Intravenous urogram (IVU)
- Fluoroscopy of the pelvis of unpredictable duration
- Interventional procedures including the pelvis
- Diagnostic angiography of the pelvis
- Hysterosalpingography
- MRI

A limited intravenous urogram has a similar radiation exposure to a low-dose CT of the abdomen and pelvis. Therefore, because of its superior anatomic depiction, CT is usually preferred over IVU. For the procedures listed above, which may deliver relatively high doses to a conceptus, a pregnancy test should be obtained within 72 hours prior to the procedure unless medical exigencies prevent it. While most patients will know their pregnancy status, additional assessment of the reproductive status prior to an examination will help decrease the likelihood of imaging patients with an unsuspected pregnancy.

Assessing Pregnancy Status

Procedures for assessing pregnancy status of patients for whom radiographic examinations have been requested differ substantially between adults and minors. See the next section for a discussion of minors. Considerations include Alabama State law, HIPAA, medicolegal concerns and billing. If it is determined that a patient requires assessing pregnancy status prior to proceeding with an examination, the following procedures should be followed:

Patients who are in reproductive age (post menarche to menopause, e.g., age 12-50), should be asked the following questions and the answers should be documented:

1. What was the first day of your last complete menstrual period?
 Month ___ Day ___ Year ___

2. To the best of your knowledge, are you pregnant (or is there any possibility that you could be)?

Yes ___ No ___ Possibly/Not sure ___

Pregnancy test results:

Negative ___ Positive ___

If the answer to Question 1 is greater than 4 weeks OR the answer to Question 2 is Yes or Possibly/Not sure, a urine pregnancy test should be ordered if a test result from the past 72 hours is not available and if the examination is not emergent. If the patient is of childbearing age (12-50) and has altered mental status and there is a possibility of pregnancy, a urine pregnancy test should be obtained. The radiologist may be consulted to determine if this is appropriate. The date and results of a negative pregnancy test should be documented on a form entered either into the medical record or as a scanned image or form in the PACS archive.

For patients with a positive pregnancy test, except in the case of a life-saving emergency procedure, a radiologist should be informed prior to proceeding with an examination. The radiologist may then either discuss the case with the referring physician to determine if the radiographic examination can be deferred or modified or decide if an alternative examination should be performed. If the radiographic examination is performed, the appropriate protocol to minimize radiation to the fetus should be employed.

Minors Who are or May be Pregnant

Definitions of Minors in the State of Alabama:

- Minor: a person under the age of 19.
- Emancipated minor: a person under age 14, but who:
 - Is married or has been married previously,
 - Has had a child,
 - Is pregnant, or
 - Has graduated from high school.

A minor of the ages of 14-18 or an emancipated minor may provide consent for a medical procedure. For a minor or emancipated minor, the questions in the section above should not be asked in the presence of the parents. It is possible that a minor would be reluctant to answer such questions truthfully in the presence of a parent or guardian. Also, the minor has HIPAA rights that require you not to communicate the answers to these questions to the parents. Therefore, it is prudent to indicate to the parents before asking these questions that the patient (minor) will be taken into the scanner room and that the parents are to stay in an appropriate waiting area.

If a pregnancy test is needed as a result of answers to the above questions, consent to obtain that test is not needed and the test may be requested by the technologist, when stated in a protocol. However, the technologist should ask the attending radiologist,

resident or radiologist assistant if a test should be obtained. If a patient (minor or adult) indicates that their period began within the past four weeks AND the patient indicates that they are not or could not be pregnant, no pregnancy test should be requested, except at the specific direction of the responsible radiologist or radiology resident.

If the pregnancy test on a minor is positive, this information CANNOT be communicated to the parents without the patient's written consent, because of HIPAA regulations. If the pregnancy test is positive, informed consent is required to perform the test if there is more than negligible radiation to the embryo or fetus.

If obtaining consent for an examination from a minor who is pregnant, a parent or guardian AND the minor should be asked to sign the consent form, if both the parent or guardian is aware of the pregnancy or positive pregnancy test results. However, consent of either is adequate. See below for medicolegal considerations.

If obtaining consent from a minor who has a positive pregnancy test without the knowledge of the parent or guardian, consent should be obtained from the minor alone. However, it should be explained to the minor that a bill will be arriving at her home and that the parents may learn of the pregnancy from that.

If both the patient and the parent are involved in the consent process and there is a disagreement about consent between them, call Risk Management - Kimberly Winston - at 4-5387, or the on-call risk management person through paging. Legally, only the minor's consent is required, but a lawsuit might stem from such a disagreement. Because of the sensitive nature of pregnancy in minors, complete documentation should be placed in the radiology report or the medical record.

Informed Consent

Informed consent should be obtained prior to performing the following tests:

- Abdominal/pelvic CT
- Fluoroscopy of the pelvis of unpredictable duration
- Intravenous urography
- Interventional procedures including the pelvis
- Diagnostic angiography of the pelvis
- Hysterosalpingography
- MRI

When it is determined that informed consent is required because the patient is pregnant, such consent must be obtained by a radiologist or radiology resident who is familiar with the risks discussed in this document. It is not sufficient for a referring clinical attending or resident to obtain informed consent because they are unlikely to be familiar with the details of the risks of radiation, IV contrast administration and MRI to a fetus. The clinical service should be instructed specifically not to obtain informed consent.

The consent form used should be the standard appropriate UAB Health System

institutional form for the site of the examination. This form should be placed in the medical record after completion. However, specific issues should be discussed with the person from whom informed consent is obtained. The information communicated must convey the benefits and risks posed by the procedure in language understandable to the layman.

Conveying information in a positive, rather than negative, format is useful in helping a patient understand an accurate perception of risk. Rather than saying that there is likelihood that her child could develop cancer later in life from radiation, the more appropriate message is that the cancer risk is small and that the likelihood the child will remain healthy with no adverse radiation effects is only slightly different from that of any other child.

Therefore, for most radiographic examinations, such as single-phase CT or standard radiography with direct exposure to the pelvis, the following elements should be communicated during the informed consent process. Note that this is summarized in Appendix II below for convenient reference:

- You and your unborn child will be exposed to X-rays.
- The risk to you is very small.
- The examination might slightly increase the possibility of cancer later in the unborn child's life, but the potential for a healthy life is very nearly the same as that of other children.
- The radiation from the examination does not add to risks for birth defects.
- Your physician has considered the risks associated with this examination and believes it is in your and your child's best interests to proceed.
- Alternative procedures or approaches should be discussed. However, it can be stated that the patient's doctor has considered other options and thinks that this test is the best for their situation.
- The patient and/or parent or guardian should be provided an opportunity to ask questions.

If an examination is planned that might administer a substantial radiation dose to the patient and/or fetus, the appropriate higher risks should be communicated. The radiographic report should include a statement regarding the informed consent process that was conducted. The following is a suggested "macro" that can also be downloaded from the voice recognition system, available in Dr. Berland's list as "consent pregnancy":

"Specific benefits and risks of the examination, appropriate for the patient's stage of pregnancy, were discussed with the [patient, patient's representative] along with possible alternatives and limitations of those alternatives. [(Include specific risks discussed here, if appropriate.)] The [patient, patient's representative] was given the opportunity to ask questions, verbalized understanding, and elected to proceed, expressing both verbal and written consent."

The physician obtaining consent may also wish to write additional details of what was

discussed directly on the consent form, such as the risks of ionizing radiation, MRI and/or intravenous contrast.

Examination Technique and Documentation of Radiation Dose

If it is determined that the examination cannot be deferred and that there is no alternative examination that does not use ionizing radiation, the examination may be modified to limit the radiation dose within reasonable parameters if such modification does not significantly compromise diagnostic examination quality. The following principles may be considered for CT examinations:

- The lowest reasonable kVp should be employed (e.g. 120 kVp rather than 140 kVp, if possible).
- The mAs may be reduced to approximately 2/3 of what would ordinarily be applied for a patient of this size.
- Automated dose reduction features should be used, if feasible.
- Multiphase examinations and repeat series should be avoided, if possible.

Because of the sensitive nature of irradiation of a fetus and the risks imposed by cumulative radiation dose from multiple examinations, radiation dose parameters should be recorded in the radiology report. It is sufficient to include the DLP values that are available from the CT operator's console or in the "tech comments" macro transferred from the Radiology Information System. An attempt should be made to determine if other radiographic examinations have been performed prior to the planned study and this should be included in the radiology report. A "macro" below with the title: "radiation factors" (separate from the informed consent macro) is available in the voice recognition system list of Dr. Berland's that includes the elements that may be included in the report:

"Reduced radiation factors were employed because of the patient's pregnancy."

Counseling the Patient Not Known to be Pregnant at the Time of Exposure

When a woman is discovered to be pregnant after having undergone an ionizing radiological procedure, counseling should be conducted to give her an assessment of risk. In the vast majority of circumstances, potential risks are very small and below the threshold for serious concern. As indicated in the informed consent process, an appropriate statement would be: "your child will have nearly the same chances of living a healthy life as any other child under similar medical circumstances because the actual risk that your child might develop cancer is very small."

If a quantitative evaluation is requested, then it might be explained that compared to any other child in similar medical circumstances, the chances of being healthy are about or better than 99% of the chances that others have. (Note: this does not mean that the chances of being healthy are better than 99% since, for example, the risk for non-radiation related malformation is 3% or higher.)

Performance of MRI and Administration of Gadolinium to the Pregnant Patient

MRI is sometimes a reasonable alternative to CT in a patient who is or may be pregnant. There are no proven risks to a fetus from MRI. However, because energy is deposited in the tissues during MRI, even though this test does not involve ionizing radiation, informed consent should be obtained in all pregnant patients undergoing an MRI examination, even when no Gadolinium is given. Also, standard safety precautions (described in other guideline documents) should be taken to avoid injury related to the strong magnetic field.

Pregnant patients can be accepted to undergo MR scans at any stage of pregnancy if, in the determination of the attending radiologist and clinician ordering the examination, the risk–benefit ratio to the patient warrants that the study be performed. The radiologist should confer with the referring physician and document the following in the radiology report or the patient’s medical record:

- The information requested from the MR study cannot be acquired via nonionizing means (e.g., ultrasonography).
- The data are needed to potentially affect the care of the patient or fetus during the pregnancy.
- The referring physician does not feel it is prudent to wait until the patient is no longer pregnant to obtain these data.

If consent is being obtained for MRI without the use of intravenous Gadolinium, the following elements should be communicated during the informed consent process and documented in the report. Note that this is also summarized in Appendix II below for convenient reference:

- To date, there has been no indication that the use of clinical MR imaging during pregnancy has produced diseases or birth defects of the fetus. However, such effects are possible because the strong magnetic and radiofrequency waves may cause a small amount of heating of the fetus.
- They understand the potential risks and benefits of the MR procedure to be performed, are aware of the alternative diagnostic options available to them (if any), and wish to proceed.

Usually, an unenhanced MRI is adequate to answer the clinical question in a pregnant patient. However, in rare situations, Gadolinium (Gd) enhancement may be considered if the unenhanced MRI is not sufficient. Gadolinium is a class C drug and animal studies have shown that Gd enters the fetal blood stream by crossing the blood-placental barrier. When administered for diagnostic reasons, Gadolinium is bound as a chelate and is not toxic. However, it is known that some dissociation may occur, and as an unbound element, it may be toxic. There are no adequate studies to determine the toxicity to a fetus of administering Gd chelates to a pregnant mother. The following is quoted from ref. [5]: “The decision to administer a gadolinium-based MR contrast agent to pregnant patients should be accompanied by a well-documented and thoughtful risk–benefit analysis. This analysis should be able to defend a decision to administer the contrast agent based on overwhelming potential benefit to the patient or fetus outweighing the theoretic but potentially real risks of long term exposure of the developing fetus to free Gadolinium

ions.” The following are our guidelines for using Gadolinium in a pregnant patient:

- Administering Gadolinium to the pregnant woman should be avoided unless it is considered exceptionally important to patient management. Alternative imaging strategies such as ultrasound should be used whenever possible.
- When MRI is necessary, unenhanced MR should initially be performed. Only if the unenhanced MRI is indeterminate or inconclusive should using Gadolinium be considered. The decision to administer Gadolinium will be at the discretion of the Attending or Fellow radiologist on call.
- The dose of Gadolinium should be limited to 0.1 mmol/kg, if possible.
- When the decision to use Gadolinium is made, the referring obstetrician should enter a note in the chart that describes the clinical reason for its necessity and should discuss with the patient the potential risks of administering a class C drug.

Risks of Radiation to a Fetus

Stochastic Effects

Risks from radiation are defined as deterministic or stochastic. Stochastic effects are believed to be possible at any level of radiation exposure, with the likelihood increasing as dose increases. These can result from induced changes in single cells and can potentially result in neoplasia or in changes to reproductive genes. In contrast to deterministic effects, the severity of a stochastic effect does not increase as the radiation dose increases, but the probability of an effect does.

Data on stochastic risks to the fetus are not consistent. For exposure to a newborn child, the lifetime risk of developing cancer is estimated on an absolute scale to be 0.4% per 10 mGy (1 rad) dose to the baby. This likely also reflects the potential risk in-utero for the second and third trimesters and part of the first trimester, but the uncertainties in this estimate are considerable.

Deterministic Effects

Deterministic effects are dose related and are the result of cell damage, with the severity of the effects increasing with radiation dose. These effects are only seen above a baseline threshold dose representing a relatively large dose, and effects depend on the developmental stage of the fetus. Available data do not always allow for a clear identification of the value for that threshold or even the existence of a threshold dose in some cases. An example of a deterministic effect is radiation-induced malformations of a developing organ.

If the last complete menstrual period has occurred within the previous 4 weeks, diagnostic radiation represents no substantive risk to a conceptus. This conforms to statements previously put forth by the ICRP:

“Exposure of the embryo in the first 3 weeks following conception is not likely to result in deterministic or stochastic effects in the live-born child, despite the fact that the central nervous system and the heart are beginning to develop in the third week.”

*Summary of Suspected In-Utero Induced Deterministic Radiation Effects
(Also see Appendix for further discussion)*

Menstrual or Gestational age	Conception age	<50 mGy (<5 rad)	50-100 mGy (5 – 10 rad)	>100 mGy (>10 rad)
0-2 weeks (0-14 days)	Prior to conception	None	None	None
3 rd and 4 th weeks (15-28 days)	1 st -2 nd weeks (1 – 14 days)	None	Probably none	Possible spontaneous abortion
5 th -10 th weeks (29 – 70 days)	3 rd – 8 th weeks (15 – 56 days)	None	Potential effects are scientifically uncertain and likely too subtle to be clinically detectable.	Possible malformations increasing in likelihood as dose increases
11 th -17 th weeks (71- 119 days)	9 th – 15 th weeks (57 – 105 days)	None	Potential effects are scientifically uncertain and likely 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 th – 27 th weeks (120 – 189 days)	16 th – 25 th weeks (106 – 175 days)	None	None	IQ deficits not detectable at diagnostic doses

Risks of Intravenous Contrast Administration to a Fetus

The risks of Iodinated and Gadolinium-based contrast agents is more fully discussed in the Manual of Contrast Media from the American College of Radiology, Version 6, 2008. Please also see the section above addressing administration of Gadolinium. Throughout the remainder of this section are excerpts of the relevant text from the ACR document:

Diagnostic iodinated contrast media have been shown to cross the human placenta and enter the fetus when given in usual clinical doses. In-vivo tests in animals have shown no evidence of either mutagenic or teratogenic effects with lower osmolality contrast media. No adequate and well-controlled teratogenic studies of the effects of these media in pregnant women have been performed.

In conjunction with the existing ACR policy for the use of ionizing radiation in pregnant women, we recommend that all imaging facilities should have policies and procedures to attempt to identify pregnant patients prior to the performance of any examination involving ionizing radiation to determine the medical necessity for the administration of iodinated contrast media. If a patient is known to be pregnant, both the potential radiation risk and the potential added risks of contrast media should be considered before proceeding with the study. While it is not possible to conclude that iodinated contrast media present a definite risk to the fetus, there is insufficient evidence to conclude that they pose no risk.

Consequently, the Committee on Drugs and Contrast Media recommends the following:

- The radiologist should confer with the referring physician and document in the radiology report or the patient's medical record the following:
 - That the information requested cannot be acquired without contrast administration or via another image modality (e.g., ultrasonography).
 - That the information needed affects the care of the patient and fetus during the pregnancy.
 - That the referring physician is of the opinion that it is not prudent to wait to obtain this information until after the patient is no longer pregnant.
- It is recommended that pregnant patients undergoing a diagnostic imaging examination with ionizing radiation and iodinated contrast media provide informed consent to document that they understand the risk and benefits of the procedure to be performed and the alternative diagnostic options available to them (if any), and that they wish to proceed.
- Because free Iodide may suppress thyroid function in a fetus or neonate, some also recommend that a mother should not breast feed for at least 24 hours after administration of Iodinated contrast material and that thyroid function should be checked in the first week after birth for a fetus born after the mother has received contrast material.

References and Recommended Reading

1. ACR practice guideline for imaging pregnant or potentially pregnant adolescents and women with ionizing radiation.
2. Manual of Contrast Media from the American College of Radiology, Version 6, 2008.
3. McCollough CH, Schueler BA, Atwell TD, et al. Radiation exposure and pregnancy: when should we be concerned? Radiographics 2007;27:909-917; discussion 917-908.
4. Pahade JK, Litmanovich D, Pedrosa I, et al. Quality initiative: Imaging pregnant patients with suspected pulmonary embolism: what the radiologist needs to know. RadioGraphics 29:639-654, 2009.
5. Kanal E, Barkovich AJ, Bell C, et al. ACR guidance document for Safe MR practices: 2007. AJR 188:1447-1474, 2007

Policy approved by:

Lincoln L. Berland, M.D.
Vice-Chair for Quality Assurance and Patient Safety

Date

Reginald Munden, D.M.D., M.D.
Chairman, Department of Radiology

Date

William W. Andrews, PhD., M.D.
Director, Division of Maternal-Fetal Medicine

Date

Sheri M. Jenkins, M.D.
Assistant Professor, Maternal-Fetal Medicine

Date

Version: August 27, 2009

Appendix I
**Summarized Guidelines for Technologists Regarding Radiographic Procedures
on a Patient Who is or May be Pregnant**

All radiologic tests that directly expose the female pelvis to ionizing radiation and MRI require assessing pregnancy status. Even if the patient is pregnant, informed consent may not be required, depending on the level of risk. Tests requiring assessing pregnancy status include:

- Abdominal/pelvic CT
- Intravenous urography
- Fluoroscopy of the pelvis of unpredictable duration
- Interventional procedures including the pelvis
- Diagnostic angiography of the pelvis
- Hysterosalpingography
- MRI

Determine if a pregnancy test has been obtained in the past 72 hours. If not, patients who are in reproductive age (post menarche to menopause, e.g., age 12-50), should be asked the following questions and the answers should be documented:

1. What was the first day of your last complete menstrual period?

Month ___ Day ___ Year ___

2. To the best of your knowledge, are you pregnant (or is there any possibility that you could be)?

Yes ___ No ___ Possibly/Not sure ___

If answer to #1 is > 4 weeks OR the answer to #2 is Yes OR Possibly/Not sure, a urine pregnancy test should be ordered if a UCG from the past 72 hours is not available and if the examination is not emergent.

Appendix II

Summarized Guidelines for Radiologists and Radiology Residents Regarding Radiographic Procedures or MRI on a Pregnant Patient

Assessing Pregnancy Status

Determine if a pregnancy test has been obtained in the past 72 hours. If not, patients who are in reproductive age (post menarche to menopause, e.g., age 12-50), should be asked the following questions and the answers should be documented.

DO NOT ask these questions of a minor of consent age (14-18) or an emancipated minor with the parents present unless the minor provides permission:

1. What was the first day of your last complete menstrual period?

Month ___ Day ___ Year ___

2. To the best of your knowledge, are you pregnant (or is there any possibility that you could be)?

Yes ___ No ___ Possibly/Not sure ___

If answer to #1 is > 4 weeks OR the answer to #2 is Yes OR Possibly/Not sure, a urine pregnancy test should be ordered if a UCG from the past 72 hours is not available and if the examination is not emergent.

Determine who the consent should be obtained from. See the section “Minors Who are or May be Pregnant” in the “Guidelines for Performing Examinations on Patients Who are Pregnant or May be Pregnant”, which can be found at www.rad.uab.edu > Policies and Procedures. This is VERY IMPORTANT for HIPAA compliance.

DO NOT consent a minor of consent age (14-18) or an emancipated minor with the parents present until such a minor provides permission.

It is recommended that the following items be included when acquiring informed consent for a radiologic procedure:

- You and your unborn child will be exposed to X-rays.
- The risk to you is very small.
- The examination might slightly increase the possibility of cancer later in the unborn child’s life, but the potential for a healthy life is very nearly the same as that of other children.
- The radiation from the examination does not add to risks for birth defects.
- Your physician has considered the risks associated with this examination and believes it is in your and your child’s best interests to proceed.
- Alternative procedures or approaches should be discussed. However, it can be stated that the patient’s doctor has considered other options and thinks that this test is the best for their situation.
- As with any informed consent process, the patient and/or parent or guardian should be provided an opportunity to ask questions.

Pregnant patients can be accepted to undergo MR scans at any stage of pregnancy if, in the determination of the attending radiologist and clinician ordering the examination, the risk–benefit ratio to the patient warrants that the study be performed. The radiologist should confer with the referring physician and document the following in the radiology report or the patient’s medical record:

- The information requested from the MR study cannot be acquired via nonionizing means (e.g., ultrasonography).
- The data are needed to potentially affect the care of the patient or fetus during the pregnancy.
- The referring physician does not feel it is prudent to wait until the patient is no longer pregnant to obtain these data.

If consent is being obtained for MRI without the use of intravenous Gadolinium, the following elements should be communicated during the informed consent process and documented in the report:

- To date, there has been no indication that the use of clinical MR imaging during pregnancy has produced diseases or birth defects of the fetus. However, such effects are possible because the strong magnetic and radiofrequency waves may cause a small amount of heating of the fetus.
- They understand the potential risks and benefits of the MR procedure to be performed, are aware of the alternative diagnostic options available to them (if any), and wish to proceed.

Appendix III

Risks of Radiation by Gestational Age

1. The weeks prior to conception

During the preconception interval from last menstruation to just prior to conception, the ovum is potentially susceptible to the genetic effects of radiation, a stochastic effect. While heritable effects have been demonstrated in experiments involving large doses of radiation to populations of mice and insects, the results of these investigations demonstrate that the likelihood of inducing a harmful effect from a dose of radiation typical of that from imaging is so small as to be undetectable in human populations. In fact no statistically significant heritable genetic effects have ever been observed in a human population, not even in those exposed to atomic-bomb radiation (mean dose approximately 200 mGy) or to radiation received in radiation accidents or as a result of medical radiation treatment. Any potential adverse effect to human progeny resulting from irradiation during this preconception interval is therefore unlikely and has not been documented at levels of imaging examinations.

2. Conception to implantation and preorganogenesis

For about 2 weeks after conception, the only established deterministic effect of radiation is induced abortion. Much of the experimental data to assess this effect has involved rodents. While doses of 1,000 mGy (1 Gy) or more result in a high rate of lethality, the likelihood of inducing this effect at doses of less than 50 mGy (0.05 Gy) (i.e., at doses in the upper range of imaging radiological examinations) is unlikely and not distinguishable from zero. Reported data for animal experiments suggest that the risk of embryonic loss at this stage increases incrementally between 0.5% and 1% per 10 mGy. Surviving conceptuses develop normally. If any potential for observable teratological effects in surviving embryos exists, they have not been observed at doses typical of any imaging examination. Because of this “all-or-none” phenomenon, this stage of gestation is sometimes called the period of the “all-or-none effect.”

3. Organogenesis

The period of organogenesis is one in which there is increased radiosensitivity to potential teratogenic effects of ionizing radiation. These are deterministic effects and therefore do not occur unless the dose to the embryo exceeds the threshold necessary to induce the effect. Organogenesis occurs after implantation and throughout the remainder of gestation but can be divided into 4 distinct intervals with different vulnerabilities.

a. Embryonic stage or major organogenesis (~15 to 56 days after conception)

In the embryonic stage, beginning near the end of the second postconception week and extending through the eighth week postconception (about 4-10 weeks menstrual age), major organogenesis occurs. This period is subject to radiation-mediated malformation of most organs and to generalized growth retardation, believed to result from cell depletion. The threshold for major effects during this period is about 100-200 mGy. At doses in the

vicinity of the threshold dose, the likelihood of observing an induced effect is relatively small. The type of vulnerability depends on the timing between radiation delivery and the developmental stage of differentiated and differentiating cells. The likelihood of inducing an effect and its severity increase as dose increases beyond the threshold.

A finding of small head circumference, without cognitive effects, has also been reported in atomic-bomb survivors exposed during the organogenesis stage of intrauterine life. There was no discernible threshold for this effect. The mechanism for such an effect is unclear. The finding has been interpreted as a result of generalized growth retardation. For doses in the range of that which might be delivered from a diagnostic examination (less than 0.1 Gy), the effect, if it truly exists, is subtle, only identified under statistical analysis of physical characteristics in a study population, and the children act and behave normally.

b. Early fetal stage

In the early fetal stage, after the eighth and through the 15th week postconception (after the 10th and through the 17th weeks menstrual age or approximately days 56-105 postconception), the central nervous system (CNS) is very radiosensitive, due to the high neuronal mitotic rate and organized neuronal migration occurring during this time. Radiation-induced CNS effects, particularly mental retardation (defined as inability to care for oneself or to make simple calculations or conversation), are among the most frequently identified teratogenic effects associated with intrauterine radiation exposure and are most likely to occur during this stage of development. A threshold dose for mental retardation has been estimated, using the Japanese DS86 radiation data, at 60-310 mGy. The broad range of the threshold estimate is a consequence of the very small sample size at this radiation level. Further, this threshold range is determined on the basis of one model for statistical analysis, and other higher thresholds are predicted by other models. The lowest clinically documented dose to produce severe mental retardation is 610 mGy. Thus, the putative threshold is an extrapolation from data observed at higher doses. The absolute risk of mental retardation is estimated at 44% for 1000 mGy exposure. The threshold range for CNS effects is significantly higher than the range of doses delivered from single well-managed imaging examinations (i.e., less than 50 mGy).

Dose-dependent radiation-mediated deficits in Intelligence Quotient (IQ) have also been observed when irradiation occurs in this interval. No effects on IQ have been observed below 100 mGy. Beyond the dose of 100 mGy, the decline in IQ is estimated at 25-29 points per 1,000 mGy.

During the fetal period, radiation exposure is also associated with growth retardation, which tends to persist beyond birth into adulthood only when doses are well beyond those normally delivered by imaging radiological examinations.

c. Midfetal stage

Beginning with the 16th and extending through the 25th week postconception, the risk for

mental retardation remains, but is less pronounced than in the earlier 8-15 week stage. It is estimated that the threshold dose for severe mental retardation is approximately 250-280 mGy. The decline in IQ is also less than for the early fetal stage. Beyond the dose of 100 mGy, the decline is estimated at 13-25 points per 1,000 mGy. The threshold dose during this period for other types of malformation is about 1,000 mGy.

d. Late fetal stage

After the 25th postconception week of pregnancy, exceptionally high doses of radiation are required to induce deterministic effects. For this stage of development the risks associated with medical imaging are stochastic risks, principally the potential for induced neoplasia. These are discussed below.

D. Risk of Cancer Induced by Imaging Procedures Using Ionizing Radiation

The relative risk of cancer development secondary to in-utero exposure has been debated in the scientific literature for years. From studies on the offspring of mothers who received diagnostic pelvic radiation during pregnancy, there appears to be an increased risk of childhood leukemia with exposures as low as 10 mGy, although firmly establishing cause and effect has proven to be difficult. The findings in offspring of Japanese atomic bomb survivors are not consistent with the case-control studies of medical in-utero irradiation. After an exposure of 10 mGy to a newborn, the lifetime risk of developing childhood malignancy, particularly leukemia, might increase from a background rate of about 0.2%-0.3% to about 0.3%-0.7%, where the estimate varies depending on the methods used to assess the risk from statistical data. The lifetime risk of developing radiation-induced cancer from in-utero exposure has been estimated to be similar, but the uncertainties in the estimate are so great that it is only possible to say that doses on the order of 10 mGy are associated with a discernable increase the risk of childhood cancer. The relationship of vulnerability to gestational age is additionally uncertain, but, within the uncertainties in the estimates of risk, it is assessed to be relatively constant from the beginning of major organogenesis to term.