Rhode Island Hospital
A Lifespan Partner

Consent for Imaging Studies Using Ionizing Radiation During Pregnancy

Dr. _____ is requesting the following imaging
referring physician
study _____ which uses radiation to
study to be performed
evaluate_____. Because you are pregnant, we
indication
would like you to understand what we know about the effects of the imaging study on you and your baby and need your consent before performing this exam. A patient information sheet that explains some of the risks from radiation in pregnancy is located on the back of this consent.

The following checked items apply:

☐ You and your baby will be exposed to low levels of radiation. This imaging study uses low doses of radiation and the risks from this test are much smaller than the normal risks of pregnancy. This examination might slightly increase the possibility of cancer later in my child's life, but the actual potential for a healthy life is very nearly the same as that of other children. The imaging study does not add to risks for birth defects. Birth defects occur in small numbers of pregnancies even without exposure to radiation.

☐ You will be given intravenous contrast during the scan. The FDA has not confirmed the safety of this contrast in pregnancy. Intravenous contrast can cross the human placenta and enter the fetus when given in usual clinical doses, but no well-controlled studies of the effects of this media have been performed in pregnant women. Tests in animals have shown no evidence of increased cancer or birth defects.

I understand this document and have had the opportunity to have my questions answered. I am aware that the practice of medicine is not an exact science and I acknowledge that no guarantees have been made to me regarding the outcome of this pregnancy. I agree to have the imaging study performed.

_____ _____
Patient's Name (printed) Patient's Signature

_____ _____
Patient's Agent or Representative (If patient unable to consent) Relationship to Patient

Date Signing:_____, 20_____ Time:_____A.M./P.M.

Physician's Acknowledgement
The undersigned confirms that informed consent, as described above, has been given by the patient. I have also discussed the possible need for contrast including the potential risks, benefits and consent was obtained.

_____
Referring Physician's Signature

☐ Emergent situation precluded obtaining written informed consent.

Emergency Rationale:_____
Please fax a copy of this form to Medical Physics at 444-4446, and place a copy in the patient's chart.

Rhode Island Hospital

Patient Information Sheet for Radiation Risks in Pregnancy

Your doctor has recommended that you have an imaging study to help in your care. Pregnant women may be concerned that radiation from these tests could harm the baby in some way. There is no specific amount of x-ray radiation that is totally free of adverse affects, so risks can never be said to be zero, however, in your case, the amounts of radiation used to make the pictures is very small. Common imaging studies use low doses of radiation and the risks from these studies are much smaller than the normal risks of pregnancy. The imaging study your doctor has ordered might slightly increase the possibility of cancer later in the child's life, but the actual potential for a healthy life is very nearly the same as that of other children. The imaging study does not increase the risk of birth defects.

Birth defects occur in 1 in 33 (3.0%) of all babies at birth, and cancer occurs in 1 or 2 in 1,000 children. Therefore a small percentage of all babies will have or will develop one of these problems whether the imaging study is performed or not. We can never guarantee that a baby will not have any of these problems. What we can say is that the chance of one of these problems occurring is not significantly increased by most of the examinations that we use for diagnosis. We would not recommend this study unless we felt that the information we will get from it is necessary to give you the best possible care.

Radiation Risks in Perspective

The millisievert (mSv) is the measurement used to assess the amount of radiation. Each year, people who live in New England are exposed to about 3 mSv of radiation from naturally occurring sources including radon and cosmic rays.

The following are the approximate radiation doses to the mother from common radiology examinations:

Chest X-ray	0.1 mSv
Mammogram	0.4 mSv
Head CT	2 mSv
Chest CT	10 mSv
Abdomen or Pelvis CT	10 mSv each

The largest dose of 10mSv may be taken to have a risk to the mother that is comparable to the risk of dying in an automobile accident when driving a distance of ~8,000 miles.

References:

1. ACR Practice Guidelines for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation- 2008 (Res. 26)
2. Cohen and Lee, "A Catalogue of Risks," Health Physics, vol. 36, June 1979
3. Centers for Disease Control and Prevention (CDC). Birth Defects: Frequently Asked Questions July 18,2007
4. American Cancer Society: Cancer Statistics 2008

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