CONSENT GUIDANCE

Risk information is based on radiation dose.

Case 1 (Low Dose) - CXR, Mammography, Extremity, Lung scan
Case 2 (Moderate Dose) CT, Angiography, PET scan, Bone scan
Case 3 (Significant Dose) Therapy, Multiple CT
Case 4 (Fluoroscopy)

- **Case 1**
  
  This research study involves exposure to radiation from a **(name procedure)**. This (these) procedure(s) is (are) routinely used for medical purposes. This radiation dose **(is/is not)** necessary for your medical care and **(will/will not)** occur only as a result of your participation in this study. The radiation dose that you will receive is equal to or less than the natural environmental radiation the average person receives in the United States annually. The principal risk associated with a radiation dose is the possibility of developing a radiation-induced cancer later in life. The risk from radiation exposure of this magnitude is considered to be negligible when compared to everyday risks.

- **Case 2**
  
  This research study involves exposure to radiation from a **(name procedure)**. This (these) procedure(s) is (are) routinely used for medical purposes. This radiation dose **(is/is not)** necessary for your medical care and **(will/will not)** occur only as a result of your participation in this study. The radiation dose that you will receive is equal to or less than the annual radiation exposure limit allowed for persons who are occupationally exposed to radiation (for example, x-ray technologist, radiologist). The principal risk associated with a radiation dose is the possibility of developing a radiation-induced cancer later in life. The risk for radiation-induced cancer from this study is minimal. The risk from radiation exposure of this magnitude is considered to be comparable to other everyday risks.

- **Case 3**
  
  This research study involves exposure to radiation from a **(name procedure)**. This (these) procedure(s) is (are) routinely used for medical purposes. This radiation dose **(is/is not)** necessary for your medical care and **(will/will not)** occur only as a result of your participation in this study. The radiation dose that you will receive for each scan is equal to or less than the annual radiation exposure limit allowed for persons who are occupationally exposed to radiation (for example, x-ray technologist, radiologist). The principal risk associated with a radiation dose is the possibility of developing a radiation-induced cancer later in life. Although the risk from radiation is cumulative it is not expected to adversely affect your condition or treatment. The risk from radiation exposure of this magnitude is considered to be comparable to other everyday risks.

- **Case 4**
  
  Same as “Case 2” **Plus**:
  
  You will receive radiation exposure from the fluoroscope that produces pictures of your internal organs. Your soft tissue and bones will receive a radiation exposure, but the highest radiation exposure will be to your skin. Very high skin exposures can cause reddening of the skin, blistering and even ulceration. Sometimes this will be delayed for weeks or months after exposure. If you should experience skin discomfort in the area that was pictured, report this to the study doctor or your personal physician.

Revised 111209
PCI PROCEDURE RISKS/BENEFITS
Radiation Exposure
The heart catheterization procedure you are scheduled to have involves exposure to radiation. This procedure is routinely used to visualize blockages in your arteries. This radiation dose is necessary for your medical care even if you do not participate in this study. If you decide to participate in this study, you will not receive any additional radiation exposure other than what you will already receive from your heart catheterization.

The radiation dose that you will receive is equal to or less than the annual radiation exposure limit minimal risk associated with a radiation dose is the possibility of developing a radiation – induced cancer later in life. The risk for radiation-induced cancer from the heart catheterization procedure is minimal. The risk from radiation exposure of this magnitude is considered to be comparable to other everyday risks.

You will receive radiation exposure from the fluoroscope that produces pictures of your internal organs. Your soft tissue and bones will receive a radiation exposure, but the highest radiation exposure will be to your skin. Very high skin exposure can cause reddening of the skin, blistering and even ulceration. Sometimes this will be delayed for weeks or months after exposure. If you should experience skin discomfort in the area that was pictured, report this to your cardiologist or your personal physician.