Research involving the measurement and/or analysis of radiation dose from imaging procedures should include a member of Florida Hospital medical physics or other person with demonstrated expertise related to radiation. This person should be listed as either a sub-investigator or consultant to the project. This recommendation holds even if all imaging performed for the protocol is standard of care.

The following represents IRB recommended language for the procedures and risks sections of consent forms for studies involving radiation.

Radiograph: Head (Head X-ray)
Procedure:
A radiograph is a picture of the body made using radiation. Prior to your radiograph you may be asked to remove jewelry and other objects that might interfere with the image. For a head radiograph examination 2 views are obtained. The first is called the anterior-posterior view, which means front to back projection. The second view is the lateral or side view.

Risks:
As a participant in this study you will receive radiation for research purposes that you would not receive if you were not part of this study. The typical effective radiation dose from a two view radiograph of the head is 0.04mSv. This is the same radiation dose you would receive from the natural background of the Earth in 5 days. The increased risk of disease from on head radiograph is minimal and may be non-existent; however, the effects of radiation add up over your lifetime with multiple scans.

Radiograph: Extremity (Extremity X-ray)
Procedure:
A radiograph is a picture of the body made using radiation. Prior to a radiograph you may be asked to remove clothing, jewelry, and other objects that might interfere with the image. If you are asked to remove clothing, you will be given a gown to wear. Often two pictures will be taken during the exam. Depending on the body part being x-rayed you will be asked to either stand or lie on a table and remain still while the picture is being taken.

Risks:
As a participant in this study you will receive radiation for research purposes that you would not receive if you were not part of this study. The typical effective radiation dose from an extremity radiograph is 0.01mSv. This is the same radiation dose you would receive from the natural background of the Earth in 30 hours. The increased risk of disease from one extremity radiograph is negligible and may be non-existent; however, the effects of radiation add up over your lifetime with multiple scans.

Radiograph: Chest (Chest X-ray)
Procedure:
A radiograph is a picture of the body made using radiation. Prior to a radiograph you may be asked to remove clothing, jewelry, and other objects that might interfere with the image. If you are asked to remove clothing, you will be given a gown to wear. Typically, two pictures of the chest are taken, one from the back and the other from the side of the body. During the exam you will be asked to stand with hands on

hips and hold your breath. Patients who cannot stand may be positioned lying down on a table. The chest x-ray examination is usually completed within 15 minutes.

Risks:
As a participant in this study, you will be exposed to radiation that you would not be exposed to if you were not a part of the study. The typical effective dose from a chest radiograph is 0.1 mSv. This is the same radiation dose you would receive from the natural background of the Earth in 12 days. The increased risk of disease from one chest radiograph is minimal and may be non-existent; however, the effects of radiation add up over your lifetime with multiple scans.

Radiograph: Abdomen (Abdominal X-ray)
Procedure:
A radiograph is a picture of the body made using radiation. Prior to a radiograph you may be asked to remove clothing, jewelry, and other objects that might interfere with the image. If you are asked to remove clothing, you will be given a gown to wear. You will be asked to lie on your back on a table and hold your breath during the procedure. You may also be asked to change position to the side or to stand up for additional pictures. The procedure takes less than 10 minutes on average.

Risks:
As a participant in this study, you will be exposed to radiation that you would not be exposed to if you were not a part of the study. The typical effective dose from a chest radiograph is 0.7 mSv. This is the same radiation dose you would receive from the natural background of the Earth in 3 months. The increased risk of disease from on abdominal radiograph is very low and may be non-existent; however, the effects of radiation add up over your lifetime with multiple scans.

Radiograph: Kidney, Ureter, Bladder (KUB X-ray)
Procedure:
A radiograph is a picture of the body made using radiation. Prior to a radiograph you may be asked to remove clothing, jewelry, and other objects that might interfere with the image. If you are asked to remove clothing, you will be given a gown to wear. During the exam you will be asked to lie on their back on a table and hold your breath. You may be asked to change position to the side or to stand up for additional pictures. The procedure takes less than 10 minutes on average.

Risks:
As a participant in this study, you will be exposed to radiation that you would not be exposed to if you were not a part of the study. The typical effective dose from a KUB radiograph is 0.7 mSv. , This is the same radiation dose you would receive from the natural background of the Earth in 3 months. The increased risk of disease from on KUB radiograph is very low and may be non-existent; however, the effects of radiation add up over your lifetime with multiple scans.

Radiograph: Lumbar Spine (Lumbar Spine X-ray)
Procedure:
A radiograph is a picture of the body made using radiation. Prior to a radiograph you may be asked to remove clothing, jewelry, and other objects that might interfere with the image. If you are asked to remove clothing, you will be given a gown to wear. You will be asked to lie on a table in different positions and

hold your breath. Usually three to five pictures are taken. The procedure takes less than 10 minutes on average.

Risks:
As a participant in this study, you will be exposed to radiation that you would not be exposed to if you were not a part of the study. The typical effective dose from a lumbar spine radiograph is 1.8 mSv. This is the same radiation dose you would receive from the natural background of the Earth in 6 months. The increased risk of disease from on lumbar spine radiograph is very low and may be non-existent; however, the effects of radiation add up over your lifetime with multiple scans.

Barium Swallow (Upper GI)
Procedure:
A barium swallow exam uses x-rays to take a picture of the back of mouth, throat, and esophagus (a hollow tube of muscle extending from below the tongue to the stomach). Prior to your exam you may be asked to remove clothing, jewelry, and other objects that might interfere with the image. If you are asked to remove clothing, you will be given a gown to wear. You will be asked to drink a liquid (barium sulphate) that will make the esophagus more visible in the pictures. A series of x-ray pictures may also be taken to make a movie of your body (fluoroscopy)

Risks:
As a participant in this study you will receive radiation for research purposes that you would not receive if you were not part of this study. The typical effective radiation dose from a barium swallow exam is 1.5mSv. This is the same radiation dose you would receive from the natural background of the Earth in 6 months. The increased risk of disease from on barium swallow exam is very low and may be non-existent; however, the effects of radiation add up over your lifetime with multiple scans.
Another potential risk is aspiration of the barium sulphate (i.e., the liquid “going down the wrong pipe.” A patient may also be allergic to barium sulphate which may rarely cause bloating, constipation, cramping, nausea, abdominal pain, or wheezing.

Dual-energy X-ray Absorptiometry (DXA)
Procedure:
Dual-energy x-ray absorptiometry (DXA) uses x-rays to measure bone mineral density (BMD). This test most commonly measures the density of the hip and spine. During the procedure, you will be asked to lie on a padded table. The DXA bone density test is usually completed within 10 to 30 minutes.

Risk:
As a participant in this study, you will be exposed to radiation that you would not be exposed to if you were not a part of the study. Each DXA scan typically delivers 0.001mSv of effective dose. This is the same as radiation dose you would receive from the natural background of the Earth in 3 hours. The increased risk of disease from one DXA scan is negligible and may be non-existent; however, the effects of radiation add up over your lifetime with multiple scans.

MRI (without contrast)
Procedure:

MRI is a noninvasive medical imaging test which uses a powerful magnetic field to produce detailed pictures of your body. Prior to your exam you may be asked to remove clothing, jewelry, and other objects that might interfere with the image. If you are asked to remove clothing, you will be given a gown to wear. It is very important that you remove all magnetic objects and that you alert your doctor if you have any implants or other devices (e.g., pacemaker, artificial joint, etc.) During this procedure you will be asked to lie down on a table which will slide in and out of the MRI scanner. Depending on the body part being scanned you may be asked to hold your breath for short amounts of time. MRI scans usually take 30 to 50 minutes and you will be asked to wear earplugs or headphones as the machine is very loud when performing some sequences.

Risks:
MRI poses very little risk for the average patient. There is no ionizing radiation involved. Although the magnetic field has shown no long term deleterious effects, implanted metal devices can cause problems. Please alert the technologist or your doctor immediately if you have any implanted metal devices. Some patients with claustrophobia (fear of being in small spaces) may find the MRI machine uncomfortable. If you suffer from claustrophobia please inform the technologist or your study doctor.

MRI (with contrast)
Procedure:
MRI is a noninvasive medical imaging test which uses a powerful magnetic field to produce detailed pictures of your body. Prior to your exam you may be asked to remove clothing, jewelry, and other objects that might interfere with the image. If you are asked to remove clothing, you will be given a gown to wear. It is very important that you remove all magnetic objects and that you alert your doctor if you have any implants or other devices (e.g., pacemaker, artificial joint, etc.) During this procedure you will be asked to lie down on a table which will slide in and out of the MRI scanner. If contrast material (radiographic dye) is ordered by your physician, an IV will be inserted into your vein before the procedure. Depending on the body part being scanned you may be asked to hold your breath for short amounts of time. MRI scans usually takes 30 to 50 minutes and you will be asked to wear earplugs or headphones as the machine is very loud when performing some sequences.

Risks:
MRI poses very little risk for the average patient. There is no ionizing radiation involved. Although the magnetic field has shown no long term deleterious effects, implanted metal devices can cause problems. Please alert the technologist or your doctor immediately if you have any implanted metal devices. Some patients with claustrophobia (fear of being in small spaces) may find the MRI machine uncomfortable. If you suffer from claustrophobia please inform the technologist or your study doctor. Some patients may develop a reaction to the contrast material including headache, dizziness, nausea, reddening and pain around injection site, altered taste, itching, shaking, difficulty breathing, swelling, loss of consciousness, increased heart rate, trouble breathing, cardiac arrest (heart stops beating), and hot flashes. A very rare and serious complication called nephrogenic systemic fibrosis may also occur for patients with poor kidney function. Your kidney function will be assessed prior to the exam to minimize this risk.

Positron Emission Tomography (PET) with Fluorodeoxyglucose (FDG)
Procedure:

A Positron Emission Tomography (PET) scan is a nuclear medicine study used to examine the body for a variety of conditions. A radioactive liquid is injected into the body and pictures are taken to see how the liquid moves through the body. Prior to your exam you will be asked to fast (stop eating). You may be asked to remove clothing, jewelry, and other objects that might interfere with the image. If you are asked to remove clothing, you will be given a gown to wear. An intravenous catheter will then be placed in your arm or hand. Following the injection of radioisotope, you will be asked to sit in a quiet dark room and relax for about a half hour prior to the imaging portion of the study. You will then be asked to lie down on a table while the machine takes pictures.

Risks:
As a participant in this study, you will be exposed to radiation that you would not be exposed to if you were not a part of the study. Each PET scan typically delivers 10mSv of effective dose. This is the same as the radiation dose you would receive from the natural background of the Earth in about 3 years. The increased risk of disease from one PET scan is low and may be non-existent; however, the effects of radiation add up over your lifetime with multiple scans. Some patients with claustrophobia (fear of being in small spaces) may find the PET machine uncomfortable. If you suffer from claustrophobia please inform the technologist or your study doctor.

PET/CT with Fluorodeoxyglucose (FDG)
Procedure:
A Positron Emission Tomography (PET) scan is a nuclear medicine study used to examine the body for a variety of conditions. A radioactive liquid is injected into the body and pictures are taken to see how the liquid moves through the body. A CT scan is a set of pictures taken using radiation to look at specific organs or tissue. For this study you will have both a PET and CT study. Prior to your exam you will be asked to fast (stop eating). You may be asked to remove clothing, jewelry, and other objects that might interfere with the image. If you are asked to remove clothing, you will be given a gown to wear. An intravenous catheter will then be placed in your arm or hand. Using this catheter the radioactive liquid will be injected. Depending on your study, you may also have contrast material injected. Contrast material is similar to a dye and is used to make the images better. Following the injection, you will be asked to sit in a quiet dark room and relax for about a half hour prior to the imaging portion of the study. You will then be asked to lie down on a table while the machine takes pictures.

Risks:
As a participant in this study, you will be exposed to radiation that you would not be exposed to if you were not a part of the study. Each PET/CT scan typically delivers 25mSv of effective dose. This is the same as the radiation dose you would receive from the natural background of the Earth in about 8 years. The increased risk of disease from one PET/CT scan is moderate, but may be non-existent; however, the effects of radiation add up over your lifetime with multiple scans. Some patients with claustrophobia (fear of being in small spaces) may find the PET/CT machine uncomfortable. If you suffer from claustrophobia please inform the technologist or your study doctor.

Bone Scan
Procedure:

A bone scan is a nuclear medicine study that gives important information about your skeleton. A radioactive liquid is injected into the body and pictures are taken to see how the liquid moves through the body. After injection you will be asked to wait 20 minutes and then lie on a table for the pictures to be taken. You may be asked to remove clothing, jewelry, and other objects that might interfere with the image. If you are asked to remove clothing, you will be given a gown to wear. After the pictures are taken, you will be asked to wait or return 3-5 hours later for a second set of pictures.

Risks:
As a participant in this study, you will be exposed to radiation that you would not be exposed to if you were not a part of the study. Each bone scan typically delivers 4.5mSv of effective dose. This is the same as the radiation dose you would receive from the natural background of the Earth in about 1.5 years. The increased risk of disease from one bone scan is low and may be non-existent; however, the effects of radiation add up over your lifetime with multiple scans.

Computed Tomography: Head (CT Head, CAT Head) without contrast
Procedure:
A computed tomography (CT) scan is a series of pictures taken using radiation. Prior to the scan, you may be asked to remove clothing, jewelry, and other objects that might interfere with the image. If you are asked to remove clothing, you will be given a gown to wear. You will be asked to lie still on a table during the procedure which will take about 45 seconds.

Risks:
As a participant in this study, you will receive radiation for research purposes that you would not receive if you were not part of this study. Each CT of the head typically delivers 2mSv of effective dose. This is the same as the radiation dose you would receive from the natural background radiation of the Earth in 8 months. The increased risk of disease from one CT of the head is very low; however the effects of radiation add up over your lifetime and with multiple scans. Some patients with claustrophobia (fear of being in small spaces) may find the CT machine uncomfortable. If you suffer from claustrophobia please inform the technologist or your study doctor.

Computed Tomography: Head (CT Head, CAT Head) with contrast
Procedure:
A computed tomography (CT) scan is a series of pictures taken using radiation. Prior to the scan, you may be asked to remove clothing, jewelry, and other objects that might interfere with the image. If you are asked to remove clothing, you will be given a gown to wear. Contrast material will then be injected into you. Contrast material is like a liquid dye that improves the images. You will be asked to lie still on a table during the procedure which will take about 45 seconds.

Risks:
As a participant in this study, you will receive radiation for research purposes that you would not receive if you were not part of this study. Each CT of the head typically delivers 4mSv of effective dose. This is the same as the radiation dose you would receive from the natural background radiation of the Earth in 16 months. The increased risk of disease from one CT of the head is very low; however the effects of radiation add up over your lifetime and with multiple scans. Some patients with claustrophobia (fear of being in small spaces) may find the CT machine uncomfortable. If you suffer from claustrophobia please

inform the technologist or your study doctor. Some patients may develop a reaction to the contrast material including nausea, headaches, pain, changes in blood pressure, rash, hot flashes, diarrhea, numbness, cardiac arrest (heart stopping), renal failure, and seizures. Risks of some side effects are worse with poor kidney function so your kidney function will be assessed prior to the exam to minimize this risk.

Computed Tomography: Thorax (CT Chest; CAT Chest) without contrast
Procedure:
A computed tomography (CT) scan is a series of pictures taken using radiation. Prior to the scan, you may be asked to remove clothing, jewelry, and other objects that might interfere with the image. If you are asked to remove clothing, you will be given a gown to wear. During the scan you will be asked to lie still on a table and may be asked to hold your breath. The scan will take about 45 seconds.

Risks:
As a participant in this study, you will receive radiation for research purposes that you would not receive if you were not part of this study. Each CT of the chest typically delivers 7 mSv of effective dose. This is the same as the radiation dose you would receive from the natural background radiation of the Earth in about 2 years. The increased risk of disease from one CT of the chest is low; however, the effects of radiation add up over your lifetime and with multiple scans. Some patients with claustrophobia (fear of being in small spaces) may find the CT machine uncomfortable. If you suffer from claustrophobia please inform the technologist or your study doctor.

Computed Tomography: Thorax (CT Chest; CAT Chest) with contrast
Procedure:
A computed tomography (CT) scan is a series of pictures taken using radiation. Prior to the scan, you may be asked to remove clothing, jewelry, and other objects that might interfere with the image. If you are asked to remove clothing, you will be given a gown to wear. Contrast material will then be injected into you. Contrast material is like a liquid dye that improves the images. During the scan you will be asked to lie still on a table and may be asked to hold your breath. The scan will take about 45 seconds.

Risks:
As a participant in this study, you will receive radiation for research purposes that you would not receive if you were not part of this study. Each CT of the chest typically delivers 14 mSv of effective dose. This is the same as the radiation dose you would receive from the natural background radiation of the Earth in about 5 years. The increased risk of disease from one CT of the chest is low; however the effects of radiation add up over your lifetime and with multiple scans. Some patients with claustrophobia (fear of being in small spaces) may find the CT machine uncomfortable. If you suffer from claustrophobia please inform the technologist or your study doctor. Some patients may develop a reaction to the contrast material including nausea, headaches, pain, changes in blood pressure, rash, hot flashes, diarrhea, numbness, cardiac arrest (heart stopping), renal failure, and seizures. Risks of some side effects are worse with poor kidney function so your kidney function will be assessed prior to the exam to minimize this risk.

Computed Tomography: Abdomen/Pelvis (CT Abdomen/Pelvis; CAT abdomen/Pelvis) without contrast

Procedure:
A computed tomography (CT) scan is a series of pictures taken using radiation. Prior to the scan, you may be asked to remove clothing, jewelry, and other objects that might interfere with the image. If you are asked to remove clothing, you will be given a gown to wear. During the scan you will be asked to lie still on a table and may be asked to hold your breath. The scan will take about 45 seconds.

Risks:
As a participant in this study, you will receive radiation for research purposes that you would not receive if you were not part of this study. Each CT of the abdomen and pelvis typically delivers 10 mSv of effective dose. This is the same as the radiation dose you would receive from the natural background radiation of the Earth in about 3 years. The increased risk of disease from one CT of the abdomen and pelvis is low; however the effects of radiation add up over your lifetime and with multiple scans. Some patients with claustrophobia (fear of being in small spaces) may find the CT machine uncomfortable. If you suffer from claustrophobia please inform the technologist or your study doctor.

Computed Tomography: Abdomen/Pelvis (CT Abdomen/Pelvis; CAT abdomen/Pelvis) with contrast
Procedure:
A computed tomography (CT) scan is a series of pictures taken using radiation. Prior to the scan, you may be asked to remove clothing, jewelry, and other objects that might interfere with the image. If you are asked to remove clothing, you will be given a gown to wear. Contrast material will then be injected into you. Contrast material is like a liquid dye that improves the images. During the scan you will be asked to lie still on a table and may be asked to hold your breath. The scan will take about 45 seconds.

Risks:
As a participant in this study, you will receive radiation for research purposes that you would not receive if you were not part of this study. Each CT of the abdomen and pelvis typically delivers 20 mSv of effective dose. This is the same as the radiation dose you would receive from the natural background radiation of the Earth in about 6 years. The increased risk of disease from one CT of the abdomen and pelvis is low; however the effects of radiation add up over your lifetime and with multiple scans. Some patients with claustrophobia (fear of being in small spaces) may find the CT machine uncomfortable. If you suffer from claustrophobia please inform the technologist or your study doctor. Some patients may develop a reaction to the contrast material including nausea, headaches, pain, changes in blood pressure, rash, hot flashes, diarrhea, numbness, cardiac arrest (heart stopping), renal failure, and seizures. Risks of some side effects are worse with poor kidney function so your kidney function will be assessed prior to the exam to minimize this risk.

CT Perfusion of the Brain (CT Perfusion):
Procedure:
A perfusion computed tomography (CT) scan of the brain is a specially designed study how blood flows in your brain using pictures created with radiation. Prior to the scan, you may be asked to remove clothing, jewelry, and other objects that might interfere with the image. If you are asked to remove clothing, you will be given a gown to wear. Contrast material will then be injected into you. Contrast material is like a liquid dye that improves the images. During the scan, you will be asked to lie still on a table. The procedure will take about 45 seconds.

Risks:
As a participant in this study, you will receive radiation for research purposes that you would not receive if you were not part of this study. Each CT perfusion scan of the head typically delivers 4mSv of effective dose. This is the same radiation dose you would receive from the natural background of the Earth in 16 months. The increased risk of disease from one perfusion scan is low and may be non-existent; however the effects of radiation add up over your lifetime and with multiple scans. Some patients with claustrophobia (fear of being in small spaces) may find the CT machine uncomfortable. If you suffer from claustrophobia please inform the technologist or your study doctor.Some patients may develop a reaction to the contrast material including nausea, headaches, pain, changes in blood pressure, rash, hot flashes, diarrhea, numbness, cardiac arrest (heart stopping), renal failure, and seizures. Risks of some side effects are worse with poor kidney function so your kidney function will be assessed prior to the exam to minimize this risk.

CT Angiography (CTA)
Procedure:
A computed tomography (CT) angiography scan is a series of x-ray pictures that are used to examine the blood vessels. Prior to the scan, you may be asked to remove clothing, jewelry, and other objects that might interfere with the image. If you are asked to remove clothing, you will be given a gown to wear. Next you will be injected with contrast material. Contrast material is like a dye that improves the picture quality. During the procedure, you will be asked to lie still on a table and may be asked to hold your breath. The CT scan typically takes less than one minute.

Risks:
As a participant in this study, you will receive radiation for research purposes that you would not receive if you were not part of this study. Each CT angiography scan typically delivers 12mSv of effective dose. This is the same radiation dose you would receive from the natural background of the Earth in 4 years. The increased risk of disease from one angiography scan is low and may be non-existent; however the effects of radiation add up over your lifetime and with multiple scans. Some patients with claustrophobia (fear of being in small spaces) may find the CT machine uncomfortable. If you suffer from claustrophobia please inform the technologist or your study doctor. Some patients may develop a reaction to the contrast material including nausea, headaches, pain, changes in blood pressure, rash, hot flashes, diarrhea, numbness, cardiac arrest (heart stopping), renal failure, and seizures. Risks of some side effects are worse with poor kidney function so your kidney function will be assessed prior to the exam to minimize this risk.

Mammogram
Procedure:
A mammogram consists of 2 x-ray pictures of the breast. Prior to the scan, you may be asked to remove clothing, jewelry, and other objects that might interfere with the image. If you are asked to remove clothing, you will be given a gown to wear. For the procedure you will be asked to sit while and place your breast on a small table for pictures. You may experience some discomfort as your breast is compressed by two plates into a position for the procedure. Depending on the position, you will be asked to look a specific direction and hold your breath during the scan.

Risk:

As a participant in this study, you will receive radiation for research purposes that you would not receive if you were not part of this study. Each mammographic scan typically delivers 0.4mSv of effective dose. This is the same radiation dose you would receive from the natural background of the Earth in 6 weeks. The increased risk of disease from mammographic scan is low and may be non-existent; however the effects of radiation add up over your lifetime and with multiple scans.

Digital Breast Tomosynthesis (DBT)

Procedure:

A digital breast tomosynthesis consists of several x-ray pictures of the breast. Prior to the scan, you may be asked to remove clothing, jewelry, and other objects that might interfere with the image. If you are asked to remove clothing, you will be given a gown to wear. For the procedure you will be asked to sit while and place your breast on a small table for pictures. You may experience some discomfort as your breast is compressed by two plates into a position for the procedure.

Risk:

As a participant in this study you will receive radiation for research purposes that you would not receive if you were not part of this study. Each digital tomosynthesis exam for one breast typically delivers 1.0 mSv of effective dose. This is the same radiation you would receive from the natural background of the earth in approximately 4 months. The increased risk of disease from one mammogram is 1:70,000.