The risk from radiation exposure is a very complex topic; however, when human subjects (either normal volunteers or patients) are exposed to radiation for research purposes (i.e. not for their normal medical care from which the patient derives a benefit), it is important to convey that risk in an understandable, but technically correct manner. In order to express the risk from radiation in a quantitative manner, the International Commission on Radiological Protection (ICRP) has established a dose metric called “effective dose.” The effective dose is a calculated value for the “typical” human anatomy and sensitivity. It should be understood that effective dose should not be used to express the risk to a specific individual since individuals have varying sensitivities to radiation and the actual effective doses can vary from one individual to another. Rather, the effective dose from various sources of radiation exposure can be compared to one another and also allow for a comparative estimate of radiation risk to the “average” individual or a group of individuals.

The IUMC/IUPUI Radiation Safety Committees have established “Dose Levels” and associated radiation risk wording to be included in Informed Consent Statements to express the risk subjects incur from the calculated, annual effective dose that human research subjects receive for research purposes. In order to select the appropriate “Dose Level” and subsequent radiation risk wording, the annual effective dose from the radiation used for research purposes must be calculated. This calculation is typically performed by a health physicist or medical physicist in the Office of Research Imaging (ORI) or the Radiation Safety Office (RSO); however, the following table may provide a reasonable estimate of what “Dose Level” should be used for various procedures involving radiation and/or radioactive materials:

<table>
<thead>
<tr>
<th>Dose Level 1</th>
<th>Multiple DXA scans, extremity x-rays, chest x-rays, skull x-rays; 1 to 3 x-rays of the abdomen, spine, or pelvis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dose Level 2</td>
<td>Fluoroscopic procedures (e.g. Upper/Lower GI, cardiac cath., interventional procedures, et.al.), 1 to 3 CT scans, 1 to 4 nuclear medicine scans, 1 to 3 PET/CT scans</td>
</tr>
<tr>
<td>Dose Level 3</td>
<td>Complicated fluoroscopy procedures, &gt;3 CT scans, &gt;3 PET/CT scans</td>
</tr>
<tr>
<td>Dose Level 4</td>
<td>Multiple CT scans (&gt;5)</td>
</tr>
</tbody>
</table>

Once the appropriate Dose Level is determined, the following paragraphs should be inserted into the Informed Consent Statement:

**Dose Level 1 – Annual effective dose \( \leq 3 \text{ millisieverts (mSv)} \) (300 millirem (mrem))**

“Your participation in this research study involves exposure to radiation in addition to what you may receive as part of your standard care. The benefit from the radiation you receive for your standard care typically outweighs the risk because it allows your doctor to provide appropriate medical care; however, the additional radiation “dose” you receive for research purposes may not benefit you personally.

Everyone is exposed to “background” radiation (e.g. radon gas in our homes, radiation from space, uranium in soil, etc.) and the radiation dose varies, depending upon where you live. Individuals who live in certain areas of the country may actually receive radiation doses that are higher than the average; however, individuals who live in those areas have not shown an increased risk of health effects (cancer and/or leukemia) above the average for the US population. The radiation dose you will receive in one
year from this study is less than the average annual “background” dose received by a member of the US population. We cannot say with absolute certainty that there is no risk from the radiation dose in this study. While there is no evidence that any risk exists for humans exposed to such low levels, it is assumed that the risks rise with lifetime accumulated dose from all sources of ionizing radiation, including the doses you receive from medical procedures and the environment. The calculated effective dose resulting from your participation in this study is available upon request.”

**Dose Level 2 – Annual effective dose >3 mSv (300 mrem), but ≤50 mSv (5,000 mrem)**

“Your participation in this research study involves exposure to radiation in addition to what you may receive as part of your standard care. The benefit from the radiation you receive for your standard care typically outweighs the risk because it allows your doctor to provide appropriate medical care; however, the additional radiation “dose” you receive for research purposes may not benefit you personally. Regulatory agencies have established annual radiation dose limits for both individuals who work with radiation (e.g. x-ray technologists, radiologists, etc.) and those participating in research studies. The additional radiation dose you will receive from participating in this study is less than either of those limits.

Radiation has been shown to cause cancer and/or leukemia from doses that are significantly higher than the additional annual radiation dose you will receive by participating in this study. According to the Health Physics Society (an international organization that specializes in radiation protection), the increased risk of health effects (i.e. cancer and/or leukemia) from radiation doses of this amount is either too small to be observed or nonexistent in a normal population. While there is no evidence that any risk exists for humans exposed to such low levels, it is assumed that the risks rise with lifetime accumulated dose from all sources of ionizing radiation, including the doses you receive from medical procedures and the environment. You should also be aware that everyone’s sensitivity to radiation is not the same and some diseases (e.g. genetic diseases, diseases affecting DNA repair, and immune diseases such as HIV) may make you more sensitive to the effects and consequences of the radiation exposure than the normal population. Finally, you should know that even if there is an increased risk of an effect, it could be 5 to 20 years before any effect would actually occur. Thus, you may want to factor in your age, overall health, and the number of medical radiation procedures that you’ve had when determining if this risk is acceptable to you. The calculated effective dose resulting from your participation in this study is available upon request.”

**Dose Level 3 – Annual effective dose > 50 mSv (5,000 mrem) but ≤100 mSv (10,000 mrem)**

“Your participation in this research study involves exposure to radiation in addition to what you may receive as part of your standard care. The benefit from the radiation you receive for your standard care typically outweighs the risk because it allows your doctor to provide appropriate medical care; however, the additional radiation “dose” you receive for research purposes may not benefit you personally. Regulatory agencies have established annual radiation dose limits for individuals who work with radiation (e.g. x-ray technologists, radiologists, etc.). If you decide to participate in this research study, the radiation dose you receive will be above the annual limit for radiation workers, but no more than 2 times that limit.

Radiation has been shown to cause cancer and/or leukemia from doses that are higher than the additional annual radiation dose you will receive by participating in this study. According to the Health Physics Society (an international organization that specializes in radiation protection), the increased risk of health effects from the additional annual radiation exposures in the range of those you will receive while
participating in this research study is either too small to be observed or nonexistent in the normal population. While there is no evidence that any risk exists for humans exposed to this amount, it is assumed that the risks rise with lifetime accumulated dose from all sources of ionizing radiation, including the doses you receive from medical procedures and the environment. You should also be aware that everyone’s sensitivity to radiation is not the same and some diseases (e.g. genetic diseases, diseases affecting DNA repair, and immune diseases such as HIV) may make you more sensitive to the effects and consequences of the radiation exposure than the normal population. Finally, you should know that even if there is an increased risk of an effect, it could be 5 to 20 years before any effect would actually occur. Thus, you may want to factor in your age, overall health, and the number of medical radiation procedures that you’ve had when determining if this risk is acceptable to you. The calculated effective dose resulting from your participation in this study is available upon request.”

**Dose Level 4 – Annual Effective Dose >100 mSv (10,000 mrem) but ≤150 mSv (15,000 mrem)**

“Your participation in this research study involves exposure to radiation in addition to what you may receive as part of your standard care. The benefit from the radiation you receive for your standard care typically outweighs the risk because it allows your doctor to provide appropriate medical care; however, the additional radiation “dose” you receive for research purposes may not benefit you personally. Regulatory agencies have established annual radiation dose limits for individuals who work with radiation (e.g. x-ray technologists, radiologists, etc.). If you decide to participate in this research study, the annual radiation dose you receive will be between two and three times that limit.

Radiation has been shown to cause an increase in cancer and/or leukemia incidence from doses that are similar to the annual radiation dose you will receive by participating in this study. You should also be aware that everyone’s sensitivity to radiation is not the same and some diseases (e.g. genetic diseases, diseases affecting DNA repair, and immune diseases such as HIV) may make you more sensitive to the effects and consequences of the radiation exposure than the normal population. Finally, you should know that even if there is an increased risk of an effect, it could be 5 to 20 years before any effect would actually occur. Thus, you may want to factor in your age, overall health, and the number of medical radiation procedures that you’ve had when determining if this risk is acceptable to you. The calculated effective dose resulting from your participation in this study is available upon request.”

**If the annual effective dose exceeds 150 mSv (15,000 mrem), the Radiation Safety Office should be consulted for appropriate radiation risk wording.**