**Saint Louis University Institutional Review Board**

**Ionizing Radiation Risk Informed Consent Template Language**

1. **Does the Study Involve *Research-Related* Exposure to Ionizing Radiation?**

That is, will study subjects be exposed to *new or increased* levels of ionizing radiation to which they would not ordinarily be exposed if they were not in the study?

Example 1: A subject might require a chest x-ray in order to meet inclusion/exclusion criteria for the study: this chest x-ray is being done *solely* for research purposes; the subject would *not otherwise* be getting this chest x-ray, if not for participating in the research. This *is* research-related exposure to ionizing radiation. Answer “Yes” to Question 1.

Example 2: A subject in a cancer trial who is already getting large amounts of radiation from cancer treatment may require *additional* exposure to ionizing radiation *for research purposes only* (e.g., an additional CT scan during study follow-up that the subject would *not otherwise* receive, if not for participating in the research; that is, the scan is not standard of care for this subject). This *is* research-related exposure to ionizing radiation. Answer “Yes” to Question 1.

Example 3: A subject in a cancer trial receives an experimental (investigational, non-FDA approved) form of radiation therapy. This *is* research-related exposure to ionizing radiation. Answer “Yes” to Question 1.

Example 4: The results of existing, standard-of-care ionizing radiation tests may be used as research data, but the tests themselves are standard-of-care, and would have been done anyway, without the research. This is *not* research-related exposure to ionizing radiation. Answer “No” to Question 1.

# Determining Correct Ionizing Radiation Risk Language

**1. Does the study involve *research-related* exposure to ionizing radiation?**

NO

YES

**2. Does the study involve children (< 18 years of age)?**

YES

NO

**Questions 3 – 5 Pertain to Studies with Children (< 18 Years of Age)**

**3. Does this pediatric study involve *research-related* exposure to ≤ 10 mrem of ionizing radiation?**

NO

YES

**3.a.** In section 4 of the study consent form (“What are the risks?”), insert the following language:

*“In this study, you will be exposed to a small amount of ‘ionizing radiation’, such as x-rays. Studies have shown that getting a lot of radiation at one time or getting many small amounts over time may cause cancer. The risk of getting cancer from the radiation in this study is minimal.”*

## STOP

**[This is considered no more than minimal risk exposure for *children*]**

**4. Does this pediatric study involve *research-related* exposure to > 10 mrem, but ≤ 100 mrem, of ionizing radiation?**

YES

NO

**4.a.** In section 4 (“What are the risks?”) of the study consent form, insert language generated from the Duke website as specified below:

Duke Radiation Safety Committee IRB Protocol Radiation Risk Statements may be accessed at this link:

<https://vmw-oesoapps.duhs.duke.edu/radsafety/consents/irbcf_asp/default.asp>

1. Select “Pediatric Patients”
2. Leave all defaults in place except the following:
   1. For question (4) “Gender Predominance:” – Select “None”, “Female”, or “Male” depending on the gender predominance of the participants in the study.
   2. For question (8) “Include a Quantitative Expression of Radiation Dose (mSv):” – uncheck the box
3. Select the studies that will be done and the number of those studies from the appropriate drop-down lists. Enter only those studies which are research related. Do not enter studies that are standard of care.
4. Go to question (10) and select “Create Statement”.
5. The Duke site will generate risk language.
   1. Copy and paste only the risk language (not the worksheet) into section 4 (“What are the risks?”) of the study consent form.
   2. **Delete the following 2 sentences from the Duke language:**

“At such low radiation exposures, scientists disagree about the amount of risk. These estimates are very uncertain, and there may be no extra risk at all.”

## STOP

**[This is considered slightly more than minimal risk exposure for *children*]**

**5. Does this pediatric study involve *research-related* exposure to > 100 mrem of ionizing radiation *that could be beneficial to the subject therapeutically and/or diagnostically*?**

Regarding the potential for benefit, here are some examples: (a) If the therapy under study *is* radiation, then it has *potential* benefit to the research subject. (b) If the *research-related* radiation is used to guide treatment decision-making or could detect disease progression, then it has *potential* benefit to the subject. Neither of these conditions would apply to healthy subjects.

NO

YES

**5.a.** In section 4 (“What are the risks?”) of the study consent form, insert language generated from the Duke website as specified below:

Duke Radiation Safety Committee IRB Protocol Radiation Risk Statements may be accessed at this link:

<https://vmw-oesoapps.duhs.duke.edu/radsafety/consents/irbcf_asp/default.asp>

1. Select “Pediatric Patients”
2. Leave all defaults in place except the following:
   1. For question (4) “Gender Predominance:” – Select “None”, “Female”, or “Male” depending on the gender predominance of the participants in the study.
   2. For question (8) “Include a Quantitative Expression of Radiation Dose (mSv):” – uncheck the box
3. Select the studies that will be done and the number of those studies from the appropriate drop-down lists. Enter only those studies which are research related. Do not enter studies that are standard of care.
4. Go to question (10) and select “Create Statement”.
5. The Duke site will generate risk language.
   1. Copy and paste only the risk language (not the worksheet) into section 4 (“What are the risks?”) of the study consent form.
   2. **Delete the following 2 sentences from the Duke language:**

“At such low radiation exposures, scientists disagree about the amount of risk. These estimates are very uncertain, and there may be no extra risk at all.”

## STOP

**[This is considered greater than minimal risk exposure for *children*]**

**Questions 6 – 9 Pertain to Studies with Adults (≥ 18 Years of Age)**

**6. Does this adult study involve *research-related* exposure to ≤ 100 mrem of ionizing radiation?**

NO

YES

**6.a.** In section 4 (“What are the risks?”) of the study consent form, insert the following language:

*“In this study, you will be exposed to a small amount of ‘ionizing radiation,’ such as x-rays. Studies have shown that getting a lot of radiation at one time or getting many small amounts over time may cause cancer. The risk of getting cancer from the radiation in this study is minimal.”*

## STOP

**[This is considered no more than minimal risk exposure for *adults*]**

**7. Does this adult study involve *research-related* exposure to > 100 mrem of ionizing radiation and not utilize PET/CT scans?**

NO

YES

**7.a.** In section 4 (“What are the risks?”) of the study consent form, insert language generated from the Duke website as specified below:

Duke Radiation Safety Committee IRB Protocol Radiation Risk Statements may be accessed at this link:

<https://vmw-oesoapps.duhs.duke.edu/radsafety/consents/irbcf_asp/default.asp>

1. Select “Adult Patients”

2. Leave all defaults in place except the following:

1. For question (4) “Gender Predominance:” – Select “None”, “Female”, or “Male” depending on the gender predominance of the participants in the study.
2. For question (7) “Include a Quantitative Expression of Radiation Dose (mSv):” – uncheck the box
3. For question (9) “Are the Radiation Exams in this Study Used for Follow-up of Cancer Treatment?” – Select “YES” or “NO” depending on whether the participants in the study have cancer.

3. Select the studies that will be done and the number of those studies from the appropriate drop-down lists. Enter only studies that are research related. Do not enter studies that are standard of care.

4. Go to question (10) and select “Create Statement”.

5. The Duke site will generate risk language.

1. Copy and paste only the risk language (not the worksheet) into section 4 (“What are the risks?”) of the study consent form.
2. **Delete the following 2 sentences from the Duke language:**

“At such low radiation exposures, scientists disagree about the amount of risk. These estimates are very uncertain, and there may be no extra risk at all.”

## STOP

**[This is considered greater than minimal risk exposure for *adults*]**

**8. Does this adult study involve *research-related* exposure to > 100 mrem of ionizing radiation AND utilize PET/CT scans?**

NO

YES

**8.a.** In section 4 (“What are the risks?”) of the study consent form, insert language generated from the Duke website as specified below:

Duke Radiation Safety Committee IRB Protocol Radiation Risk Statements may be accessed at this link:

<https://vmw-oesoapps.duhs.duke.edu/radsafety/consents/irbcf_asp/default.asp>

1. Select “Adult Patients”

2. Leave all defaults in place except the following:

1. For question (4) “Gender Predominance:” – Select “None”, “Female”, or “Male” depending on the gender predominance of the participants in the study.
2. For question (7) “Include a Quantitative Expression of Radiation Dose (mSv):” – uncheck the box
3. For question (9) “Are the Radiation Exams in this Study Used for Follow-up of Cancer Treatment?” – Select “YES” or “NO” depending on whether the participants in the study have cancer.

3. The PET/CT scanner at SLU Hospital results in lower exposure to patients compared to the values specified by the Duke website. Therefore, an equivalent number of chest x-rays will be used to simulate dose on the Duke website for the two most common PET/CT studies done at SLU Hospital (see below).

* 1. For each type of scan above enter the appropriate number of chest x-rays into the Duke website (or see the calculator in C. below).
     1. Each ***SLU Amyloid PET/CT scan*** is estimated to be 900 mrem (45 Duke chest x-rays).
     2. Each ***SLU FDG PET/CT scan*** is estimated to be 1,500 mrem (75 Duke chest x-rays).
  2. Select any other radiologic examinations that will be done from the appropriate drop down list and enter the number of those studies that will be done.
  3. Enter only studies that are research related. Do not enter studies that are standard of care.

4. Go to question (10) and select “Create Statement”.

5. The Duke site will generate risk language.

1. Copy and paste only the risk language (not the worksheet) into section 4 (“What are the risks?”) of the study consent form.
2. **Correct the types and numbers of scans specified by the Duke language** *(e.g., change “The tests or treatments you will have include 90 chest x-rays”. to “The tests or treatments you will have include 2 Amyloid PET/CT scans”.)*
3. **Delete the following 2 sentences from the Duke language:**

“At such low radiation exposures, scientists disagree about the amount of risk. These estimates are very uncertain, and there may be no extra risk at all.”

## STOP

**[This is considered greater than minimal risk exposure for *adults*]**

# Determining the Number of Chest X-Rays to Simulate PET/CT Scans at SLU Hospital

***Double-click*** on the spreadsheet embedded below to generate the number of chest x-rays to enter into the Duke website to simulate FDG PET/CT and/or Amyloid PET/CT scans done at SLU Hospital:



**Notes:** Dose from Amyloid PET/CT Scan (see package insert of drug): ~900 mrem

Dose from FDG PET/CT *at SLU Hospital*: ~1,500 mrem

**Alternative: *Right-click*** on the table. Hover cursor over “Worksheet Object” and select “Open” to open the table as an Excel spreadsheet to generate the number of chest x-rays to enter into the Duke website. Then save or print.