Saint Louis University Institutional Review Board
Ionizing Radiation Risk Informed Consent Template Language

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?

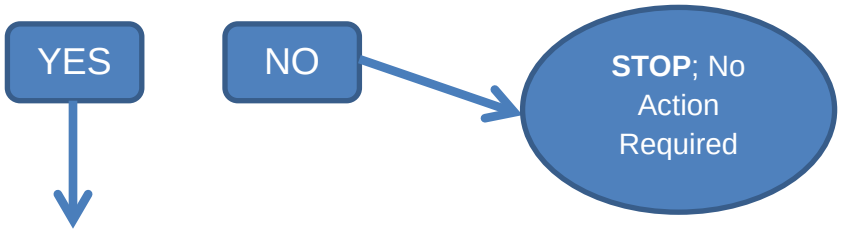
Example 1: A subject might require a chest x-ray in order to meet inclusion/exclusion criteria for the study: this chest x-ray is being done *solely* for research purposes; the subject would *not otherwise* be getting this chest x-ray, if not for participating in the research. This *is* research-related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

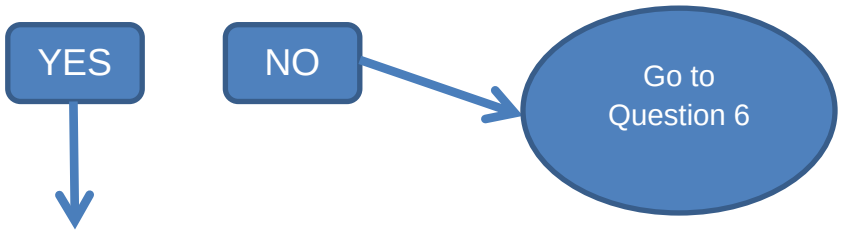
Example 3: A subject in a cancer trial receives an experimental (investigational, non-FDA approved) form of radiation therapy. This *is* research-related exposure to ionizing radiation. Answer "Yes" to Question 1.

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.

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

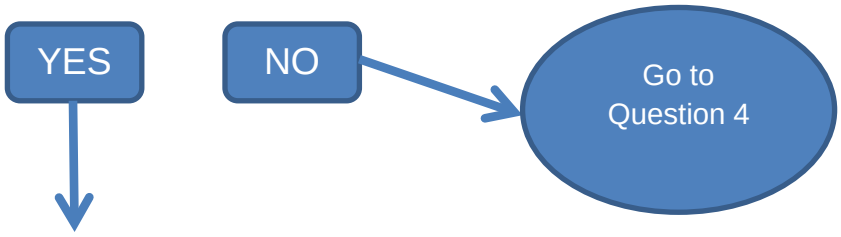


2. Does the study involve children (< 18 years of age)?



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?

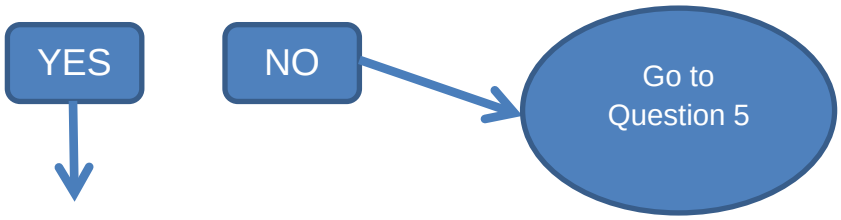


3.a. In section 4 of the study consent form ("What are the risks?"), insert the following language:

"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 very small."

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?



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

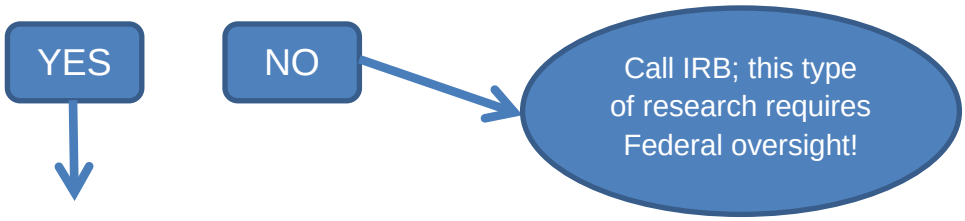
"In this study, you will be exposed to about 11-100 mrem of 'ionizing radiation,' such as x-rays. (A 'mrem' is how we measure radiation dose.) In comparison, one chest x-ray would give you 10-20 mrem. One airplane flight across the United States would give you 2-5 mrem. The natural radiation we are exposed to all the time—like from the sun—gives us about 300 mrem per year.

Chest x-rays and background radiation have not been found to harm most healthy people. The main potential risk from radiation exposure is cancer. The risk of getting cancer from radiation depends on how much radiation you are exposed to. It is difficult to calculate an exact risk of cancer from the low amounts of radiation used in this study, but the extra risk will be no more than about 1 in 5,000. In comparison, the risk of anyone getting cancer over the first 20 years of life is just over 1 in 300."

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.



5.a. In section 4 ("What are the risks?") of the study consent form, insert the following language:

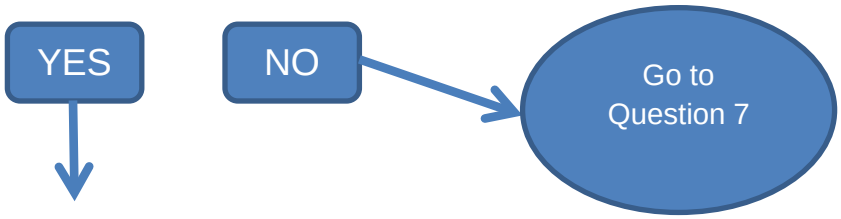
"In this study, you will be exposed to more than 100 mrem of 'ionizing radiation,' such as x-rays. (A 'mrem' is how we measure radiation dose.) In comparison, one regular chest x-ray would give you 10-20 mrem. One airplane flight across the United States would give you 2-5 mrem. The natural radiation we are exposed to all the time—like from the sun—gives us about 300 mrem each year.

Chest x-rays and background radiation have not been found to harm most healthy adults. The main potential risk from exposure to radiation is cancer. It is difficult to calculate an exact risk of cancer from the amount of radiation used in this study, but the extra risk will be at least around 1 in 5,000. As the amount of radiation increases, so does the potential risk of cancer. For example, the extra risk of cancer from exposure to more than 500 mrem would be at least around 5 in 5,000. In comparison, 2 in 5 people will get cancer at some point during their lifetime, and 1 of those 5 will die from the cancer."

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?

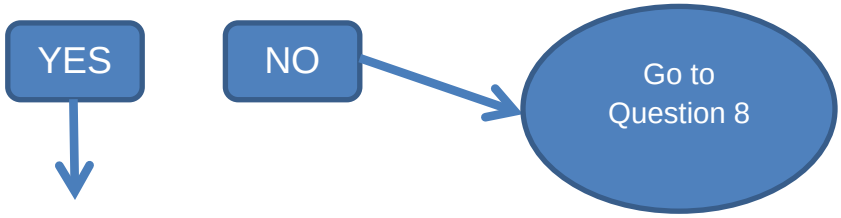


6.a. In section 4 ("What are the risks?") of the study consent form, insert the following language:

"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 very small."

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

7. Does this adult study involve *research-related* exposure to > 100 mrem, but ≤ 500 mrem, of ionizing radiation?



7.a. In section 4 ("What are the risks?") of the study consent form, insert the following language:

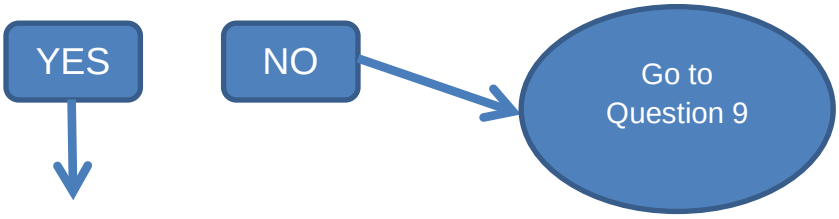
"In this study, you will be exposed to about 101-500 mrem of 'ionizing radiation,' such as x-rays. (A 'mrem' is how we measure radiation dose.) In comparison, one chest x-ray would give you 10-20 mrem. One airplane flight across the United States would give you 2-5 mrem. The natural radiation we are exposed to all the time—like from the sun—gives us about 300 mrem per year.

Chest x-rays and background radiation have not been found to harm most healthy adults. The main potential risk from exposure to radiation is cancer. The risk of getting cancer from radiation depends on how much radiation you are exposed to. It is difficult to calculate an exact risk of cancer from the amount of radiation used in this study, but the extra risk will be no more than about 1 in 2,000. In comparison, 2 in 5 people will get cancer at some point during their lifetime, and 1 of those 5 will die from the cancer."

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

8. Does this adult study involve *research-related* exposure to > 500 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.



8.a. For exposures >500mrem- </= 2,000 mrem, insert the following language in section 4 ("What are the risks?") of the study consent form. For >2000 mrem, see 8b, below.

"In this study, you will be exposed to more than 500 mrem of 'ionizing radiation,' such as x-rays. (A 'mrem' is how we measure radiation dose.) In comparison, one chest x-ray would give you 10-20 mrem. One airplane flight across the United States would give you 2-5 mrem. The natural radiation we are exposed to all the time—like from the sun—gives us about 300 mrem per year.

Chest x-rays and background radiation have not been found to harm most healthy adults. The main potential risk from exposure to radiation is cancer. It is difficult to calculate an exact risk of cancer from the amount of radiation used in this study, but the extra risk will be at least around 1 in 2,000. As the amount of radiation increases, so does the potential risk of cancer. For example, the extra risk of cancer from exposure to more than 1,500 mrem would be at least around 3 in 2,000. In comparison, 2 in 5 people will get cancer at some point during their lifetime, and 1 of those 5 will die from the cancer."

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

8b. For exposures >2,000 mrem insert the following language in section 4 ("What are the risks?) of the study consent form.

For the consent risk language for this level of exposure, go the the Duke radiation exposure calculator: https://vmw-oesoapps.duhs.duke.edu/radsafety/consents/irbcf_asp/default.asp.

Enter the radiological procedures that will be part of this study that are not standard of care, and then have the site generate a risk statement. Note: choose whether your study involves subjects with or without cancer. Some minor editing of the Duke language will be required to make it study and site specific (see highlighted portions of the following EXAMPLE).

EXAMPLE: If you take part in this research, you will have one or more medical imaging studies which use radiation. The tests or treatments you will have include four abdominal CT scans. The radiation dose from this research is about XXX mrem. (EDIT NOTE: SLU prefers to list exposures in mrems. Convert the millisievert figure generated by the Duke website to mrem by multiplying by 100 (e.g., 31 millisieverts = 3,100 mrem). To give you an idea about how much radiation you will get, we will make a comparison with an every-day situation. Everyone receives

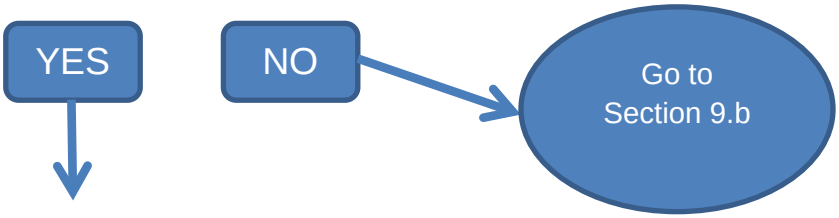
a small amount of unavoidable radiation each year. Some of this radiation comes from space and some from naturally-occurring radioactive forms of water and minerals. This research gives your body the equivalent of about 10 extra years' worth of this natural radiation. The radiation dose we have discussed is what you will receive from this study only, and does not include any exposure you may have received or will receive from other tests.

A possible health problem seen with radiation exposure is the development of a second cancer later in life. This extra cancer risk is higher at younger ages and for girls and women. The extra lifetime risk of dying of a fatal cancer due to the radiation exposure from this research may range from about one in 1,000 to about one in 400. At such low radiation exposures, scientists disagree about the amount of risk. (EDIT NOTE: remove the following line, since prior line describes that there is some disagreement as to levels of risk. “These estimates are very uncertain, and there may be no extra risk at all.”)

We can compare this possible extra cancer risk to other risks (over a lifetime) that everyone is subject to in everyday life. For example, the chances of a person dying of cancer with no extra radiation exposure are about one in 4. The chances of dying in a car crash are about one in 82, and the chances of being killed by a car while crossing the street are about one in 730.

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

9. Does this adult study involve (no benefit) *research-related* exposure to > 500 mrem, but ≤ 2,000 mrem, of ionizing radiation?



9.a. In section 4 ("What are the risks?") of the study consent form, insert the following language:

"This research study involves exposure to about 501-2,000 mrem of 'ionizing radiation,' such as x-rays, from one or more procedures that are not for your medical care and are for research purposes only. (A 'mrem' is how we measure radiation dose.) In comparison, one chest x-ray would give you 10-20 mrem. One airplane flight across the United States would give you 2-5 mrem. The natural radiation we are exposed to all the time—like from the sun—gives us about 300 mrem per year.

Chest x-rays and background radiation have not been found to harm most healthy adults. The main potential risk from exposure to radiation is cancer. The risk of developing cancer from radiation may occur 5-10 years after the exposure, but also may not happen until decades later. As the amount of radiation increases, so does the potential risk of cancer. It is difficult to calculate an exact risk of cancer from the amount of radiation used in this study, but the extra risk will be no more than about 1 in 500. In comparison, 2 in 5 people will get cancer at some point during their lifetime, and 1 of those 5 will die from the cancer. However, the risk of getting cancer and the risk of dying from any cause are fairly low in young people and increase progressively as we get older, as shown in the table below:

At age:	**The risk of getting cancer over the next 10 years is:**	**The risk of dying from cancer over the next 10 years is:**	**The risk of dying from any cause over the next 10 years is:**
20 years	1 in 200	1 in 400	1 in 111
40 years	3 in 100	3 in 200	3 in 111
60 years	13 in 100	13 in 200	13 in 104

You should discuss all of the information in this section with the study investigator, and ask questions to clarify anything you do not understand. Be sure to tell the study investigator about any other research you have been in where you had ionizing radiation, and also whether you are exposed to radiation in other ways like on your job or as part of your medical care."

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

9.b. In section 4 ("What are the risks?") of the study consent form, insert the following language **(note that this language requires you to calculate the cancer risk and the cancer death risk and insert them in paragraph 2; see the formulas at the bottom of the page)**:

"This research study involves exposure to > 2,000 mrem of 'ionizing radiation,' such as x-rays, from one or more procedures that are not for your medical care and are for research purposes only. (A 'mrem' is how we measure radiation dose.) In comparison, one chest x-ray would give you 10-20 mrem. One airplane flight across the United States would give you 2-5 mrem. The natural radiation we are exposed to all the time—like from the sun—gives us about 300 mrem per year.

Chest x-rays and background radiation have not been found to harm most healthy adults. The main potential risk from exposure to radiation is cancer. The risk of developing cancer from radiation may occur 5-10 years after the exposure, but also may not happen until decades later. As the amount of radiation increases, so does the potential risk of cancer. It is difficult to calculate an exact risk of cancer from the amount of radiation used in this study, but the extra risk is thought to be about *X* in *XXX* people, and the estimated risk of dying from that cancer is about *X* in *XXX* people. In comparison, 2 in 5 people will get cancer at some point during their lifetime, and 1 of those 5 will die from the cancer. However, the risk of getting cancer and the risk of dying from any cause are fairly low in young people and increase progressively as we get older, as shown in the table below:

At age:	**The risk of getting cancer over the next 10 years is:**	**The risk of dying from cancer over the next 10 years is:**	**The risk of dying from any cause over the next 10 years is:**
20 years	1 in 200	1 in 400	1 in 111
40 years	3 in 100	3 in 200	3 in 111
60 years	13 in 100	13 in 200	13 in 104

You should discuss all of the information in this section with the study investigator, and ask questions to clarify anything you do not understand. Be sure to tell the study investigator about any other research you have been in where you had ionizing radiation, and also whether you are exposed to radiation in other ways like on your job or as part of your medical care."

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

Use these formulas to calculate the values needed for the second paragraph above*:
(a) Cancer risk = 1 / ((mrem/100)*.0001)
(b) Risk of dying from cancer = ½ the cancer risk

Example: 5,000 mrem exposure: 1/((5,000/100)*.0001) = 1 in 200, half of that is 1 in 400.
(a) Cancer risk = "about 1 in 200 people"; first number should always be a whole number for ease of interpretation
(b) Cancer death risk = "about 1 in 400 people"; first number should always be a whole number for ease of interpretation

* Click to use the SLU IRB Radiation Risk Calculator for computations.