



Joshua L. Weintraub, MD FSIR  
Chair  
Joint Radiation Safety Committee

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Dear Colleagues:

RE: IRB Consent Form Language for Radiation Risk for All Studies Using Ionizing Radiation

New disclosure language relating to ionizing radiation risk to be used in IRB consent forms was distributed to the research community on October 9, 2017. Having received some comments on the language, the JRSC has revised the language to read as follows:

*The procedures involving radiation in this research study will expose you to a small amount (XX mSv) of radiation in addition to the amount that you might receive from your normal medical care. There may be an increase in the chances of your developing cancer many years after this study. The additional risk from this research study is less than X%. At this very low level, scientists are uncertain as to the actual risk from research and there may be no risk at all.*

If you believe including the reference to “(XX mSv)” in the consent form is inappropriate for the population of subjects in a study and the total radiation exposure in the study is less than 1 mSv, you may leave the mSv reference out of the consent form.

For calculating the additional risk X% value, I would suggest using the X Ray Risk Calculator at <http://www.xrayrisk.com/calculator/calculator-normal-studies.php>

The X% value can be calculated using a range of subjects of different age groups. For studies using both male and female adults, we recommend using the range from an 18 year old female to a 60 year old male, with adjustments made if there is an age or gender restriction in the study population. For minors, we recommend using the range from a 5 year old female to a 15 year old male, again with adjustments made if there is an age or gender restriction in the study population.

You should add the following language for studies where a tissue reaction is possible (e.g., fluoroscopy):

*In addition, the procedures involving radiation in this research study (e.g., fluoroscopy): may add to the radiation that you might receive from concurrent standard of care procedures. This might increase the possibility of [Note to researchers: pick applicable injury or injuries][skin injury] [hair loss] [cataracts]. Note to researchers: add additional sentence(s) depending on the risk(s) chosen.] [Skin injuries seldom occur and are usually limited to a small area of reddening. They rarely result in an ulcer.] [If hair loss occurs, it is usually temporary, but could be permanent.] [Cataracts occur rarely after many years of exposure of the eyes to large doses of radiation.]*

Please do not hesitate to reach out to me if you have any questions or concerns.

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