Radiation Aspects Of Informed Consent Statements For Clinical Research Projects In Which Radiation Exposure Is For Research Purpose And Not For The Medical Benefit Of The Subject (Patients And Normals)

Basic Requirements

[NOTE: Your statement must accurately and completely reflect the sources of radiation exposure and the radiation doses to be received by subjects participating in your specific research project.]

1. Specify the source and amount of radiation by giving:
   a. The source or sources of radiation exposure, including x-ray exposure
   b. The dosage of any radionuclide in activity units (millicuries or equivalent units).
   c. The radiation dose(s) in rem, or the equivalent, to the organs and tissues that receive the higher dose(s). The use of radiation dose to the "whole body" is an important value only for certain radionuclides where the "whole body" or "total body" radiation dose is generally not an indicator of the overall potential radiation hazard or risk.

Typical wording:

"The radiation dose which you will receive as a result of participating in this study includes radiation from the administration of [# of millicuries] of [radiolabeled preparation] and/or [specify any research related radiological (x-ray) procedure required by the study]."

And

"Using the standard way of describing radiation dose, you will receive [# of rem to (greatest-dosed organ)], [# of rem to your (next highest organ)], and [# of rem to your (third highest organ)]."

2. State that this use of radiation was reviewed and approved by the UMB Radiation Safety Committee and, if applicable, the UMB Radioactive Drug Research Committee. Additionally, relate the radiation doses to the appropriate guideline or regulatory limit:
   a. The UMB Radiation Safety Guideline for Radiation Exposure to Research Subjects, both patients and normal subjects. This is 3 rem to any tissue within a 13 week period (quarter of year) and 5 rem annually.
   b. The FDA regulatory limits for exposure to research subjects from the use of "radioactive research drugs" that require approval by the UMB Radioactive Drug Research Committee. These limits are 3 rem per single administration or study and 5 rem per year to the whole body, blood forming organs, lens of the eye, and gonads; for other organs the limits are 5 rem per single administration or study and 15 rem annually.

Typical wording:

"The UMB HUSC of Radiation Safety Committee, a group of experts on radiation matters, has reviewed the use of radiation in this research study and has approved this use as being [choose the applicable statement from those below]

Within the UMB Radiation Safety Guidelines for research subjects of 3 rem to any tissue in a 13 week period and 5 rem in one year".

or

Within the FDA regulatory limits for the use of radioactive research drugs, which is, 3 rem per single administration or study and 5 rem per year to the whole body, blood forming organs, lens of the eye, and gonads; for other organs the limits are 5 rem per single administration or study and 15 rem annually".

[NOTE: The FDA limits are applicable only to the use of "radioactive research drugs" as defined in the FDA regulations. Unless your proposed study is subject to the review and approval of the UMB Radioactive Drug Research Committee, in addition to approval by the UMB HUSC of Radiation Safety Committee, you may not reference the FDA regulatory limits]

or

Above [or slightly above, if appropriate] the radiation doses usually permitted to research subjects at UMB, but the UMB HUSC of Radiation Safety Committee has approved this higher dose in view of the value of the scientific information to be obtained. The radiation dose usually permitted to research subjects at UMB is 3 rem to any tissue in a 13 week period, and 5 rem in one year".

3. Estimate the risks of the radiation doses in general terms and, as appropriate, relate the estimated risk to other types of risk.

Typical wording:

"The radiation dose you will receive is [choose the applicable statement from those below]

in the range of 0 to 300 mrem, which is equivalent to the level of natural background radiation that you would be exposed to each year living in this area of the country. Background radiation levels will vary from place to place, but this level of exposure has never been associated with any definite adverse effects".

or

in the range of 300 to 5000 mrem, which is equivalent to the exposure limit of 5,000 mrem or 5 rem per year that is established for radiation workers such as physicians and X-ray technologists who work with radiation and this level of exposure has never been associated with any definite adverse effects".

or

exceeds [or slightly exceeds, if appropriate] the radiation doses usually permitted to research subjects at the UMB, but the UMB Radiation Safety Committee has approved this higher dose. The radiation dose usually permitted to research subjects at UMB is 3 rem to any tissue in a 13-week period, and 5 rem in one year (5 rem is the limit of dose that may be received by an adult radiation worker)".

And, [if applicable]

> *"The potential long term risk from these radiation doses is uncertain, but these doses have never been associated with any definite adverse effects. Thus the risk to you, if any, is estimated to be slight."*

[NOTES: For extremely high radiation doses, these risk statements may not be correct, and should be modified to reflect actual estimated adverse effects.

Consent and assent statements are to be appropriately modified for pediatric subjects taking into account that dose guidelines are generally 1/10th of those for adults.]

4. State that the radiation exposure to be received by participation in this study is for research purposes and is not medically indicated for the benefit of the subject, unless the treatment is considered standard-of-care and the patient would be receiving it regardless of study participation.

Typical wording:

> *"Please be aware that this radiation exposure is necessary for this research study only and is not essential for your medical care".*

5. Ask the subject to inform you if they have participated in other studies involving radiation to ensure that the total dose from all studies is not excessive.

Typical wording:

> *"Please advise your doctor if you have participated in research studies at UMB or other institutions that involved the use of radiation so that it may be determined that the total radiation dose from all studies is not excessive. Examples of such studies include X-ray studies conducted in radiology departments, cardiac catheterizations, and fluoroscopy as well as nuclear medicine studies, e.g. technetium scans."*

FOR MORE INFORMATION OR CLARIFICATION, CONTACT THE UMB RADIATION SAFETY DIVISION at (410) 706-7055