

Guidance Note # 17

Special Categories of Research: Research Involving Radiation Exposure

(Note: this Guidance Note is in Draft Form, May 2012)

Article 17.1: Research Involving Radiation Exposure

UBC's REBs make case-by-case judgements about the merits of research in light of the risks posed. As radiation exposure escalates, expectations of risk minimization and prospect of direct benefit will proportionally escalate. This guidance focuses on improving communication with research participants about radiation risk.

When using radiation or radioactive materials in human subjects, the study should be designed to use minimum radiation doses following prevailing medical radiation exposure guidance, and those that are as low as reasonably achievable (the "ALARA" principle).

Radiation exposure includes the dose from all radionuclide procedures and all diagnostic radiology procedures related to the research study, together with doses from other research studies in which the participant may be participating or has participated in previously. Repeated use of the same volunteers for different projects involving radiation exposure is discouraged. Similarly, it may be inappropriate to involve subjects with substantial prior radiation exposure. UBC's REBs understand that the risk of exposure to radiation is cumulative over a lifetime.

While radiation is categorized by the FDA as a known carcinogen, considerations pertaining to informing participants of radiation risks need to be tailored to the particular circumstances of the study population. For example, communication of risk to cancer patients who may be participating in studies that involve exposure to radiation would be quite different than communication of risk to adults without cancer. Similarly, risks to adults over 50 are somewhat lower, and risks to children are higher, due to their heightened sensitivity.

Article 17.2: Assessment/ Categorization of Radiation Risk

UBC's REBs base their understanding of the risks of radiation on the European Commission document noted below.

“Radiation protection 99, Guidance on Medical Exposures in Medical and Biomedical Research, 1998”

http://ec.europa.eu/energy/nuclear/radioprotection/publication/doc/099_en.pdf

The European Guidance describes the following primary categories of radiation risk:

Category 1: Effective doses less than 0.1 mSv (adults)

This category involves a risk (total detriment from the radiation exposure for normal subjects of less than one in a million.

Category 2a: Effective dose range 0.1 – 1 mSv (adults)

This category involves risks of the order of one in a hundred thousand.

Category 2b: Effective dose range 1 – 10 mSv (adults)

This category involves risks to the irradiated individual of the order of one in ten thousand.

Category 3: Effective doses greater than >10 mSv (adults)

Here the risks to the irradiated individual are estimated at greater than one in a thousand.

The risks referenced in the categories, are “lifetime risk of death [from cancer] due to hematologic or solid organ malignancy”.

The categories noted apply to healthy adults (those without cancer) under 50 years of age. The dose figures may be increased by a factor of 5 – 10 for individuals over 50. In the event that approval is being sought for research on children, the corresponding dose figures should be reduced by a factor of 2 or 3.

Article 17.3: Informing / Disclosing risks of radiation to research subjects

UBC’s REBs (with the exception of the BC Cancer REB) recommend that the following principles be adhered to in all study-related communications about the risk of radiation exposure:

1. State the effective dose (or dose range) in mSv.

The conversion factor between the mSv and Radiation Equivalent Man (REM) units is
 $10\text{mSv}=1\text{ rem}$.

2. Describe the exposure in terms of common life events, such as:

Chest radiograph	0.02 mSv ¹
Natural Background radiation	2.4 mSv / year ²

A guide to the exposure associated with various other procedures is available at http://www.radiologyinfo.org/en/safety/index.cfm?pg=sfty_xray#3

3. Describe the risk in absolute based on the categories and age adjustments in section 20.1.2. and disclose that the risk being referred to is “your lifetime risk of dying from cancer”.

For example, the additional risk of fatal cancer from a single 20 mSv exposure in a person <50 years old is 1 in 1000 or 0.1%.

4. Mention the time horizon over which the risk occurs. For example, “If it were to occur, it could take many years or decades for you to develop cancer related to this study.”

The latent period for cancer induction is estimated to be 6 to 10 years for blood borne cancers (leukemia, lymphoma) and 10 to 25 years for solid organ cancers.

5. Disclose to research subjects that the risk from all sources of radiation is cumulative over a lifetime.

Investigators requiring assistance in estimating the levels of risk or the practical equivalents should speak with the Radiation Protection Officer of their institution. Researchers conducting studies with participants who have cancer should consult with the BC Cancer REB concerning the need to include any specific information pertaining to radiation risks in their proposed studies.

Article 17.4: Positron-Emitting Radiopharmaceuticals (PERs)

Researchers conducting studies utilizing positron-emitting radiopharmaceuticals should consult with the 2006 interim compliance policy and guidance documents found at:

¹ The Royal College of Radiologists. Making the best use of clinical radiology services: referral guidelines. London: The Royal College of Radiologists, 2007, page 17, Table 2.

² Mettler FA, Bhargavan M, Faulkner K, Gilley DB, Gray JE, Ibbott GS, Lipoti JA, Mahesh M, McCrohan JL, Stabin MG, Thomadsen BR, Yoshizumi TT. Radiologic and nuclear medicine studies in the United States and worldwide: Frequency, radiation dose and comparison with other radiation sources – 1950 – 2007.

http://www.hc-sc.gc.ca/dhp-mps/brgtherap/applic-demande/guides/radiopharm/research_per_recherche_prep-eng.php

http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/drugs-drogues/pol_0053_tc-tm-eng.php

References

Health Canada:

http://www.hc-sc.gc.ca/dhp-mps/compli-conform/clini-pract-prat/docs/gui_68_tc-tm-eng.php

Health Canada:

[“Factors considered in the assessment of risks involved in the use of positron emitting radiopharmaceuticals in basic research involving humans”](#)

FDA:

<http://www.fda.gov/Drugs/ScienceResearch/ResearchAreas/Oncology/ucm196484.htm#dose>

International Commission on Radiological Protection)[§ 361.1(b)(3)(iv)].

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?fr=361.1>

Medical Internal Radiation Dose Committee of the Society of Nuclear Medicine

<http://www.snm.org/index.cfm?PageID=1372>

The European Commission document *“Radiation protection 99, Guidance on Medical Exposures in Medical and Biomedical Research, 1998”*

http://ec.europa.eu/energy/nuclear/radioprotection/publication/doc/099_en.pdf

Radiology Info: A guide to the exposure associated with various other procedures is available at

http://www.radiologyinfo.org/en/safety/index.cfm?pg=sfty_xray#3