

**GUIDELINES FOR ETHICS APPROVAL OF RESEARCH PROTOCOLS**  
**INVOLVING HUMAN EXPOSURE TO IONIZING RADIATION**

**1.0 The Hazards and Risks of Ionizing Radiation**

While radiation risks are among the more controllable hazards in research and should not be viewed in a different light from other hazards, the risks of low doses of radiation are not precisely known. The major risk, however, is development of cancer. Risks may be different for Participants with different resistance to cancer - perhaps by 10 or more times. In general there are no means to identify those who may be at higher risk. Typical risks of cancer induction for the whole body are 100 cases per rem per million irradiated, and for specific high risk tissues (thyroid, breast) 50 cases per rem to the tissue per million irradiated (International Commission on Radiology Protection (ICRP), Healing Arts Radiation Protection) (HARP). Risks of death are 50% less than the risks of development of a malignancy.

**2.0 The Research Protocol**

In preparing a research protocol which involves the exposure of human Participants to ionizing radiation, the investigator must include in addition to the standard information required the following:

1. A statement of the exact examinations to be carried out (site, number of views, number of exams, radio-pharmaceutical agent, administered activity, facility, personnel).
2. A statement regarding the radiation dose equivalent to specially sensitive organs (thyroid, breast, bone marrow). The dose should also be given in terms of the effective whole body dose equivalent to both the Participants and to the investigators.
3. A discussion of dose - what efforts will be made to minimize the patient dose, particularly to sensitive organs; how the dose relates to the risks normally associated with working in an office or in the retail trade (ICRP 27, ICRP 45).
4. Justification of the use of especially sensitive groups if they are involved in the study, e.g. children, women of child bearing potential, fetuses and discussion of the kind of protection to be available to them.
5. References as to the origin of all data, radiation doses and estimates of risk.

The applicant is referred to the HARP Guidelines (1987) issued by the Ministry of Health, Ontario and to ICRP Publications 27 and 45. Doses should be equated to a risk factor (i.e.  $25 \times 10^{-6}$ ) and comparisons of risk should be with those relating to "safe" industries.

**UWO – HSREB GUIDELINES (January 2003)**  
**GUIDELINE 2-G-003 (formerly APPENDIX 2)**

**3.0 The Letter of Information**

In regard to the specific concerns associated with studies involving radiation, the investigator is asked to include the following:

A description of the risks from radiation together with the other risks of the research. The nature of the potential risks should be clearly explained along with the procedure to be followed. Since the numbers and units of radiation dose mean little to a lay person, the risk may be compared with other everyday risks that Participants may face in their normal lives, such as risks associated with working in offices ( Ref: ICRP # 27 and ICRP # 45, 1985) and to limits for workers exposed routinely to radiation with attempts to approximate the increased risk for cancer development. Comparison with medical x-ray procedures, such as chest x-rays, are inappropriate since the dose and risks from these may vary widely from one x-ray facility to another. The comparison with a chest x-ray may also play upon the belief that it is not associated with any risk because it is such a common procedure. In the discussion of risks, increased risk to special groups (e.g. pregnant women) should be highlighted.

**EXAMPLES**

Description of cumulative effect:

Although the risk of cancer increases with exposure to x-rays, this is less likely to occur in an older person because of the length of time required for radiation to exert this effect.