

## Use of Ionizing Radiation - Guidelines



### **GUIDELINES**

Please refer to these guidelines when answering each of the questions in the Use of Ionizing Radiation Form.

Research protocols need to follow the recommendations of:

- (ARPANSA) RPS 8. Code of Practice - Exposure of Humans to Ionizing Radiation for Research Purposes Radiation Protection Series Publication No. 8 (May 2005)

The Radiation Act 2005 and the Radiation Regulations 2007 control the use of ionizing radiation in Victoria. The responsible body in Victoria is the Radiation Safety Section (RSS) in the Department of Human Services (DHS).

Institutions carrying out research involving the exposure of human volunteers to ionizing radiation are required to be specifically licenced to do so.

The Principal Investigator must decide whether the radiation exposure of the research participant is either A or B and complete the relevant sections of the form.

A. \*Standard clinical care – complete sections 1 & 2 only

B. Additional to standard clinical care – complete all sections (1 - 9)

\*Standard clinical care is defined as the typical or routine management of the patient i.e. the number and type of radiological procedures that a patient would typically receive as part of the standard clinical care. When considering whether the management is 'standard clinical care' the following items need to be taken into account:

- The number of radiation procedures being performed;
- The frequency or time interval between the radiation procedures; and
- The body part region being exposed to radiation.

## **PROJECT DETAILS:**

HREC Application Reference Number - is allocated by the HREC Secretariat.

Name of the HREC reviewing the research project

Please state the full title of the research project.

### **Section 1                      Participants**

**(a)** Classification of radiation exposure re participants. Consideration of the radiation examinations and/or therapies being 'standard clinical care' or 'additional to standard clinical care' will determine whether sections 1 & 2 or all sections of the form are completed, respectively.

#### **(b)** Number of participants

As ionizing radiation has the potential for risk, restrict the number of participants to the minimum necessary for statistically meaningful results.

#### **(c)** Age of the research participants

Under normal circumstances, participants in medical research under the age of 18 would not be permitted to be exposed to ionizing radiation. However, if an Ethics Committee regards studies including minors are justified the following apply:

- The exposure should conform with the dose constraints given in *Table 1* of this guideline document;
- Should only be permitted if the condition under study is related to the age of the participants; or
- If the information sought cannot be obtained using adult participants; and
- Can be conducted only with the approval of those legally responsible, as minors are not in a position to give informed consent.

#### **(d)** Research participants who are pregnant

Pregnant women must be excluded except when conditions specific to this group are being investigated. In studies on pregnant women the dose must be evaluated for:

- the foetus; and
- the uterus where the dose is likely to exceed 0.1 mSv and the pregnancy status of the volunteer is uncertain.

Advice on these associated risks must be provided to the Human Research Ethics Committee.

The use of ionizing radiation regarding women of reproductive age should only apply when the information sought cannot be obtained by other means.

- The possibility that women of reproductive age may be pregnant must be taken into account.
- Premenopausal women whose radiation exposure exceeds 0.1mSv should have a biochemical pregnancy test to exclude pregnancy before the radiation exposure.

#### **(e)** Research participants who are breastfeeding

In studies involving the administration of radioactive substances, research participants who are breastfeeding must be excluded unless conditions specific to this group are being investigated.

#### **(f)** Research projects including babies, infants or foetuses

Usually, research projects involving irradiation of babies, infants or foetuses are not justified. Infants under the age of 1 year and foetuses should not be exposed to radiation for the purposes of medical research unless the appropriate health or medical authority, with the

permission of the parents or legal guardian, grants an approval in exceptional circumstances where the information sought is essential and cannot be obtained by other means. *For example, the condition under study is related to the age of the participants and the information sought cannot be obtained using adult participants.*

### **(g) Life expectancy of participants**

The radiation dose constraints that are applied to the research and the advice given in the participant information documentation depend on the life expectancy of the participants. The typical life expectancy of the participants should be quoted as either below or above 5 years.

## **Section 2                      Procedures involving the use of ionizing radiation**

**All** procedures involving ionizing radiation must be listed in the table. Include and identify procedures deemed to be 'standard care' and those procedures that are 'additional to standard care', being required purely because of the participant's inclusion in this research.

If you are unsure of the category (standard care or not) for a particular ionizing radiation procedure you should consult the Principal Investigator (if applicable), approved Medical Physicist, and/or the Department of Human Services – Radiation Safety Section.

## **Sections 3 to 5                Radiation Assessment & Categories of Risk & Dose**

Consult the Institution's Radiation Safety Officer (RSO)/Medical Physicist about the research protocol at the preparatory stage. If the RSO is not a Medical Physicist, then he/she must consult with a 'medical physicist' as defined in the Code.

In these sections you must list only the procedures involving the use of ionizing radiation that are additional to 'standard clinical care'. *Please note if you answered 'NO' to Section 1(a), then ALL the procedures listed will be additional to standard care.*

The Department of Human Services – Radiation Safety Section has compiled a list of **approved** Medical Physicists to perform radiation dosimetry assessments for research projects involving the exposure of human participants. To verify that a medical physicist is approved to perform the calculations contact the Radiation Safety Section, details can be found in the 'Useful Contacts' section of this document.

When requesting advice from the Radiation Safety Officer and the Medical Physicist include:

- the 'Use of Ionizing Radiation Form' (complete or partially complete)
- a copy of the research protocol; and
- proposed participant information and consent form;
- any relevant reference material relating to the procedure and/or radiation dose received by the participant.

The Medical Physicist will be able to assist you with the radiation dose, risk category, inclusion of a statement of the radiation risks involved and how this risk compares with everyday risks in the participant information and consent form. The Medical Physicist will also advise which procedures do, and do not, involve ionizing radiation.

**Note:** The Medical Physicist must **complete Section 3 "Radiation Assessment"** and **sign the Certification.**

To help the HREC make an informed decision as to whether the radiation dose to the participant is justified and whether the research should be approved, the Medical Physicist will:

- make an assessment of the radiation dose;
- determine the relevant category of risk;
- produce the recommended statement outlining the risks associated with radiation exposure to be included in the participant information and consent form; and
- advise on the appropriate approvals required, for example, licence approvals from the State or Territory Regulators.

**Note:** The radiation doses to the research participants must be kept to the minimum level practicable. Wherever possible, the total effective doses and organ doses to adults and children should conform with dose constraints tabulated below. If these dose constraints are exceeded the Human Research Ethics Committee should give particular attention to the justification for the radiation exposure, and if necessary, seek further independent authoritative advice before approving the proposal.

**When the radiation dose exceeds the dose constraints, an independent second Medical Physicist must verify the initial dosimetry assessment, and express approval must be gained from the Radiation Safety Section, DHS.** A second medical physics assessment will need to be arranged by the Medical Physicist.

Table 1: Dose Constraints for Participants in Research<sup>a</sup>

Participant Category	Dose Constraint <sup>b</sup>
<b>Adults</b>	
Total effective dose	- in any year - over 5 years 5 mSv <sup>c</sup> 10 mSv
Total effective dose in adult with life expectancy less than five years	- in any year 50 mSv
Equivalent dose to skin averaged over 1 cm <sup>2</sup>	- in any year 200 mSv <sup>d</sup>
Equivalent dose to any other organ or tissue	- in any year 100 mSv <sup>e</sup>
<b>Children and fetuses</b>	
Total effective dose to age 18 years, - Subject to:	5 mSv
• Effective dose from conception to birth; and	0.1 mSv
• Effective dose in any year from birth to 18 years.	0.5 mSv
Total equivalent dose to age 18 years to any organ or tissue	100 mSv

<sup>a</sup> A dose constraint for research participants specifies a maximum dose to comply in normal circumstances and intended to apply to radiation which is in addition to that received as part of normal clinical management. Dose constraints apply to diagnostic investigations not radiation therapy.

- <sup>b</sup> *The dose constraint applies to the sum, over the relevant period, of doses received from external exposure and the 50-year committed dose (to age 70 years for children) from intakes over the same period.*
- <sup>c</sup> *When all the research participants are within the following specified age limits, the following total effective dose constraints apply:*
- *for adults 60 years or more – in any year – 8 mSv and*
  - *for adults 70 years or more – in any year – 12 mSv.*
- <sup>d</sup> *Derived from Table 3.1 of ICRP85 – factor of 10 below the threshold of 2 Sv for early transient erythema.*
- <sup>e</sup> *Derived from Table 3.1 of ICRP85 – factor of 10 below the threshold of 1 Sv for detectable lens opacity.*

## **Section 6 Expected Societal Benefit**

The risk categories for stochastic effects in adults<sup>1</sup>, differing by an order of magnitude from each other and associated information are given below:

### **Category I (risk less than 1 in 100,000)**

The dose range for this project category is less than 0.2 mSv, which is the dose delivered by natural background radiation in a few weeks. It is considerably less than the variations in annual dose from natural background radiation to persons living in different locations, and the risk level is considered minimal. The level of benefit needed as the basis for approval of research with doses in this category will be minor and will include those investigations expected only to increase knowledge.

### **Category II**

The dose range for this category includes the annual doses received by essentially all radiation workers in the course of their employment and the annual doses received by members of the public from the totality of naturally occurring sources to which they are exposed, apart from some of the doses from radon where the radon contribution to the annual doses is somewhat higher.

**Category IIa (risk less than 1 in 10,000)** represents a very low level of risk. The dose range of 0.2 to 2 mSv covers the allowable annual dose to the public from controlled sources. To justify risks in this category the benefit will probably be related to increases in knowledge leading to health benefit.

**Category IIb (risk less than 1 in 1,000)** represents a low level of risk. The dose range of 2 to 20 mSv covers the annual doses received by most radiation workers in the course of their employment, and most diagnostic radiological procedures. To justify the risks a moderate benefit will be needed. The benefit will be more directly aimed at the diagnosis, cure or prevention of disease.

### **Category III (risk greater than 1 in 1,000)**

The dose range for this category is tens of mSv or more, which is greater than the annual dose limit of 20 mSv for occupational exposure and is comparable to that received from several CT procedures together. To justify research involving doses or risks in this category, the benefit will have to be substantial and usually directly related to the saving of life or the prevention or mitigation of serious disease.

---

<sup>1</sup> See RPS 8 Annex 1



<http://www.health.vic.gov.au/ethics/>

ARPANSA

Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes

<http://www.arpansa.gov.au/Publications/codes/rps8.cfm>

ARPANSA

Recommendations for Limiting Exposure to Ionizing Radiation (Printed 1995 - Republished 2002) National Standard for Limiting Occupational Exposure to Ionizing Radiation (Printed 1995 - Republished 2002)

<http://www.arpansa.gov.au/pubs/rps/rps1.pdf>

Radiological Protection in Biomedical Research of the International Commission on Radiological Protection, 1992, Publication 62.