

**MODULE FOUR:  
PROJECTS INVOLVING USE OF IONISING RADIATION –  
GUIDELINES**



**GUIDELINES**

These guidelines provide information and instructions on how to best answer the questions in the **Module Four: Projects Involving Use of Ionising Radiation**. Please refer to these guidelines when answering each of the questions in the application form.

The application forms and guidelines are modified and updated from time to time. Please go back to the website each time you make a new application, to ensure that you have the latest version of this Module.

It is important to include all essential information so that your application can be speedily assessed for approval. It is also important to give all information in clear, everyday English so that it can be easily understood by the members of HREC who may not have a science or health industry background. Clearly define all terminology and abbreviations.

Research protocols need to follow the recommendations of:

- Radiological Protection in Biomedical Research of the International Commission on Radiological Protection, 1992, Publication 62; and
- Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) RPS 1. Recommendations for Limiting Exposure to Ionizing Radiation (1995) and National Standard for Limiting Occupational Exposure to Ionising Radiation (republished 2002)
- (ARPANSA) RPS 8. Code of Practice - Exposure of Humans to Ionizing Radiation for Research Purposes Radiation Protection Series Publication No. 8 (May 2005)

Prior to its commencement, the research proposal may require approval from the local regulator. In Victoria, The Health Act 1958 and Health (Radiation Safety) Regulations 1994 control all uses of ionising radiation, and include a system requiring the licensing of operators of radiation equipment and radioactive sources, and the registration of irradiating apparatus and sealed radioactive sources.

There are specific licensing requirements related to research involving humans who are exposed to radiation which is additional to that received as part of their normal clinical management, either diagnostic or therapeutic, from the administration of ionising radiation.

With the Ionising Radiation Form, you must also include:

- Module One: Core Application Form; and
- Other modules that are relevant to your research project.

## **PROJECT DETAILS:**

### **Project Title, Principal Researcher and HREC number(s) (if known)**

Please state the full title of the research project, the name of the principal researcher and the HREC number, if one has been allocated for the research project.

Any person that voluntarily enrolls in a research project that:

- Results in them undergoing an examination that involves the use of ionising radiation which is additional to that typically received as part of their standard clinical care; or
- Is not specifically treating a disease or symptom

is by definition a **volunteer**.

This includes research involving volunteers and/or patients and includes, but is not restricted to, research with diagnostic/therapeutic agents and procedures, including Phase I, II, III and IV clinical trials and novel procedures on selected groups of research participants. It does not apply to the use of radiation outside a research project even if it involves the use of a novel procedure.

### **4.1 Identification of Participants**

Standard clinical care is defined as the typical or routine management of the patient with an identical condition that is not part of this clinical trial. 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.

#### **4.1(c) Number of participants**

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

#### **4.1(d) Age of the research participants**

The research participants should, where practicable, be over 40 years of age, and preferably over 50; and the exposure of children must only be permitted if the condition under study is related to the age of the participants and the information sought cannot be obtained using adult participants.

#### **4.1(e) Pregnancy in the research participants**

Pregnant women must be excluded except when conditions specific to this group are being investigated. In studies on pregnant women, the dose to the fetus must also be evaluated and advice provided to the Human Research Ethics Committee on the associated risks. Where some participants are women of reproductive age, the possibility that a woman may be pregnant must be taken into account; and where the pregnancy status is uncertain and the radiation dose to the uterus is likely to exceed 0.1 mSv, premenopausal women should have a biochemical pregnancy test to exclude pregnancy before the radiation exposure. Finally, the use of ionising radiation should only be undertaken when the information sought cannot be obtained by other means.

#### **Research participants who are breastfeeding**

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

#### 4.1(g) Life expectancy of research participants

The long-term risks from exposure to radiation are minimal in individuals who have a very short life expectancy, i.e. less than five years. Therefore, in such projects, the dose constraints, in accordance with the ARPANSA Code of Practice, can be higher (see Table 1 below). **N.B.:** In accordance with the Code, statements of risk in the participant information and consent form are inappropriate and are not required for research projects involving individuals with a life expectancy of less than five years.

#### 4.2-4.4 Radiation Assessment & Categories of Risk & Dose

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

In these sections you must list all procedures involving the use of ionising radiation. Please identify which procedures are equivalent to 'standard clinical care' and which are additional to 'standard clinical care'. Please note if you answered '**NO**' to question 4.1(a), then **ALL** the procedures listed will be additional to standard care.

The Department of Human Services – Radiation Safety Program has compiled a list of Medical Physicists approved to perform radiation dosimetry assessments for research projects involving the exposure of human volunteers. You should verify that the medical physicist is approved to perform the calculations. If you are unsure of the medical physicist's status the contact details for the Radiation Safety Program can be found in the 'Useful Contacts' section of this document.

When making an application to the Radiation Safety Officer/Medical Physicist, include a copy of the research protocol and proposed participant information and consent form. Other information that can be useful to provide to the Radiation Safety Officer/Medical Physicist is to identify the ionising radiation procedures that are additional to that of standard care of the patient, the age, gender and pregnancy status of the volunteers. Hence, it is advisable that you attempt to complete as much as possible of Module Four prior to meeting with the Radiation Safety Officer/Medical Physicist.

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 ionising radiation.

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 the radiation exposure to be included in the participant information and consent form; and
- Usually 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 the dose constraints as 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.

**Finally, when the radiation dose exceeds the dose constraints, an**

**independent second Medical Physicist must verify the initial dosimetry assessment.** This second opinion 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 with which it should be possible to comply in normal circumstances and it is 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.

#### 4.5 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.

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

#### **4.6 Participant Information Risk Statements**

- **Communication Of The Risk To The Research Participant**

The main risk from low levels of ionising radiation is the induction of cancer some time in the future. It is particularly important that information about this risk and other risks are communicated in a manner that will be understood by the research participant. It is recommended that a consistent approach be used by researchers for the 'lay language' description of risk.

The researchers must ensure that the participant is provided with sufficient written information about the purpose, methods, radiation dose, associated risks and any discomforts of the radiation exposure to enable the research participant to give informed consent. The ARPANSA Code of Practice includes numerous model statements that can be incorporated into the participant information and consent form. Each version is applicable to the level of exposure indicated, and is in keeping with the risk categories described above. In addition, as the long-term risks from radiation exposure are minimal in patients who have a very short life expectancy, these statements of risk may be inappropriate and are not required for research studies involving such patients.

Finally, the Regulatory Authority may also have their requirements with respect to the inclusion of appropriate risk communication statement. Consequently it is recommended that you consult your Radiation Safety Officer/Medical Physicist regarding the inclusion of an appropriate risk communication statement.

#### **4.7 Regulatory Authorisations**

Prior to commencement of any research project that exposes volunteers to ionising radiation, the research project must have HREC approval. The Department of Human Services – Radiation Safety Program must be notified so that a licence may be issued or the project added to an already existing licence. The Radiation Safety Officer/Medical Physicist will be able to advise you whether the facility already possesses a licence and the process required to have the research project approved by the Regulatory Authority. In addition, the Radiation Safety Officer/Medical Physicist will be able to advise you whether the ionising apparatus is appropriately registered for use and operators of the equipment are appropriately authorised to use the equipment.

**Once a research project is identified as including volunteers that are receiving a radiation exposure additional to that received as part of standard care, the research projects cannot commence until the specific research project is listed on the Institution's licence issued by the Department of Human Services – Radiation Safety Program.**

## Useful Contacts

- Your Institution's Human Research Ethics Committee
- Your Institution's Radiation Safety Officer/Medical Physicist
- Department of Human Services  
Radiation Safety Program  
50 Lonsdale St  
**MELBOURNE VICTORIA 3000**  
Phone: 1300 767 469  
Facsimile: 1300 769 274  
Email: radiation.safety@dhs.vic.gov.au

## Useful Links

DHS - Radiation Safety Program

<http://www.health.vic.gov.au/environment/radiation/index.htm>

DHS - Human Research Ethics Committee (The Common Application Form)

[http://www.health.vic.gov.au/ethics/application/common\\_app\\_form.htm](http://www.health.vic.gov.au/ethics/application/common_app_form.htm)

ARPANSA

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

<http://www.arpansa.gov.au/rps8.htm>

ARPANSA

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

and

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

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