|  |
| --- |
| **Medical Physics Risk Assessment****Interventional, Diagnostic & Nuclear Medicine Procedures****Supporting Information****Use of Ionising Radiation in Research with Human Participants** |

Contents

[Before you begin 2](#_Toc176779634)

[Medical Physics requirements 2](#_Toc176779635)

[Glossary 3](#_Toc176779636)

[Definitions & Typical ionising radiation procedures encountered in research 3](#_Toc176779637)

[1.1 Research Project Details 4](#_Toc176779638)

[1.2 Contact Details for Further Information 4](#_Toc176779639)

[1.3 Certification By Principal Investigator *(or authorised representative)* 4](#_Toc176779640)

[1.4 Classification of Ionising Radiation Exposure Received by Participants 5](#_Toc176779641)

[1.5 Participants 5](#_Toc176779642)

[1.6 Procedures involving the use of ionising radiation 6](#_Toc176779643)

[1.7 Appendices 7](#_Toc176779644)

[1.7a Site Approval – Site completing Application 7](#_Toc176779645)

[1.7b Expected societal benefit (*for procedures identified to be in addition to standard care*) 8](#_Toc176779646)

Before you begin

In Victoria, the Department of Health (DoH) issues Radiation Management Licences. For sites carrying out research that involves exposure of humans to ionising radiation that is in addition to standard care, the Radiation Management Licence must include an authorisation for the “*procuring, arranging or conducting of research involving the irradiation of persons*”. Researchers are advised to refer to the following site: <https://www2.health.vic.gov.au/public-health/radiation>

A condition stipulated by DH on the Radiation Management Licence is that research involving the exposure of persons to ionising radiation is carried out in accordance with the ARPANSA Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes (2005). The Code can be downloaded from the following site[: https://www.arpansa.gov.au/regulation-and-licensing/regulatory-publications/radiation-protection-series/codes-and-standards/rps8](https://www.arpansa.gov.au/regulation-and-licensing/regulatory-publications/radiation-protection-series/codes-and-standards/rps8)

Medical Physics requirements

**For research involving ionising radiation procedures:**

* Sections 1.1 through to 1.6 of this form **MUST** be completed prior to submission to the medical physicist. The medical physicist will advise if Section 1.7 (a & b) requires completion and submission to the Ethics Committee in the Medical Physics Risk Assessment for this research proposal.
* This form has been developed to assist a medical physicist to generate a Medical Physics Risk Assessment. **Some sites will require this form to be submitted, along with supporting documents, with your ethics application. At other sites, this form can be submitted directly to the medical physicist who will be able to advise you which supporting documents you will need to complete. Please check your site requirements.**
* Please be advised that the Medical Physics Risk Assessment will be provided based on the information supplied by the researchers in this application. It is the responsibility of the researcher to provide as accurately as possible the following information:

1. The number and demographic of the participants to be included in the research at the site;

2. Median life expectancy of the participants to be included;

3. Identify all procedures involving the use of ionising radiation to be performed;

4. The type, number and frequency of studies to be performed;

5. The body region to be examined; and

6. Whether these procedures are considered to be in addition to standard care.

|  |  |
| --- | --- |
| Glossary |  |
|  |  |
| **ARPANSA** | *Australian Radiation Protection and Nuclear Safety Agency* |
|  |  |
| **Medical Physicist** | *A person qualified to perform radiation dosimetric calculations, measurements and monitoring and that has been approved by a regulatory authority to make estimates in a speciality relevant to the research project. A list of medical physicists approved by the Victorian Department of Health is available at* [*https://www.health.vic.gov.au/radiation/list-of-approved-medical-physicists*](https://www.health.vic.gov.au/radiation/list-of-approved-medical-physicists) |
|  |  |
| **Radiation Safety****Officer (RSO)** | *The responsible person at an institution for safety of radiation sources and the use of radiation at the institution.* |
|  |  |
| **Victorian Management Licence Authorisation** | *The site requires a management licence before conducting a radiation practice. The Management licence must be authorised to procure, arrange or conduct research involving irradiation of persons prior to any research being conducted at the site. Failure to hold the required management licence is a serious offence against the Radiation Act 2005.* |
|  |  |
| **Authorised Representative** | *Only persons identified by the director of the company that both authorises the person to lodge an application for a management licence (or act on their behalf) of the legal entity and nominates the person to be the contact in relation to the proposed radiation practice(s) can deal with the Department of Health in relation to management licensing matters. Further information is located at:*[*https://www.health.vic.gov.au/radiation/radiation-management-licences*](https://www.health.vic.gov.au/radiation/radiation-management-licences) |
|  |  |
| **Participant** | *A person taking part in a research project.* |
|  |  |
| **Volunteer** | *A participant that receives no benefit from radiation exposure incurred in the course of a research project and where such exposure does not form part of their standard clinical care.* |
|  |  |
| **PICF** | *Participant Information and Consent Form* |
|  |  |
| Definitions & Typical ionising radiation procedures encountered in research |
|  |  |
| **Standard Care Procedures** | *Standard Care Procedures are defined as:**If a participant was not enrolled in this clinical trial, would they still receive the identical type and number of exams involving the use of ionising radiation at the specified intervals as stated in the research protocol, taking in account:*1. *The body region being examined;*
2. *The modality (equipment) used being identical (ie. CT cf. Plain X-ray Equipment);*
3. *Frequency (or number) of the exams proposed.*

*If the answer is yes to the above criteria then the ionising radiation procedures can be identified as being standard care procedures.* |
|  |  |
| **Bone Scan** | *A bone scan is a test that is performed by injecting an unsealed* [*radioactive*](http://www.wordiq.com/definition/Radioactive) *substance (radiolabeled substance) into a vein. This substance is preferentially absorbed by bone, particularly by areas of high bone activity. This is a scan performed in Nuclear Medicine.* |
|  |  |
| **CT** | *Computed Tomography: scans involving a 360-degree rotation of an X-ray beam and the computer generation of images. These scans allow for cross-sectional views of body organs and tissues.* |
|  |  |
| **DEXA or DXA** | *Dual Energy X-ray Absorptiometry (uses X-rays to provide a quantitative assessment of bone density).* |
|  |  |
| **Gated Blood Pool Scan (MUGA Scan)** | *Multiple Gated Acquisition Scan; A technique used to evaluate the heart's ability to respond to physical stress. Uses unsealed* [*radioactive*](http://www.wordiq.com/definition/Radioactive) *substances in the diagnosis. This is a scan performed in Nuclear Medicine.* |
|  |  |
| **Nuclear Medicine(Include Diagnostic & Therapy uses)** | *Nuclear medicine is the branch of* [*medicine*](http://www.wordiq.com/definition/Medicine) *that uses unsealed* [*radioactive*](http://www.wordiq.com/definition/Radioactive) *substances in diagnosis and therapy.* |
|  |  |
| **Positron Emission Tomography** (**PET)** | *Uses an injected unsealed* [*radioactive*](http://www.wordiq.com/definition/Radioactive) *substance to produce a three-dimensional image of functional processes in the body.* |
|  |  |
| **Skeletal Survey** | *Uses X-rays to image the body to review the skeleton.* |

|  |
| --- |
| 1.1 Research Project Details |
| **Site completing Application** |  |  |
| **Site Principal Investigator Name** |  |  |
| **Coordinating Principal Investigator Name** |  |  |
| **Project Title** |  |  |
| **Name of HREC Reviewing the Research Project** |  |  |
| **HREC Reference Number / Local Project Number** |  |  |
| **Duration of a volunteer’s participation in research *(average transit time of an individual through research) (years and months)*** | **Average** |  |  |  |
| **Maximum** |  |  |  |
|  | *(Years)* | *(Months)* |  |
|  |  |  |  |

|  |
| --- |
| 1.2 Contact Details for Further Information |
| **Name:** |  |  |
| **Telephone:** |  |  |
| **Email:** |  |  |
|  |  |

|  |
| --- |
| 1.3 Certification By Principal Investigator *(or authorised representative)* |
| I understand and acknowledge that:1. The information provided in this form is true and complete to the best of my knowledge.
2. The Medical Physicist may return this form if it is incomplete.
3. A copy of this form will be kept by the Medical Physicist for future reference and may be used by the Ethics Committee/Health Services Research Directorate/ Department of Health when discrepancies are identified.
 |
| **Principal Investigator Name** |  |
| **Signature of Principal Investigator** |  | **Date** |  |
|  |
|  |
|  |  |

|  |
| --- |
| 1.4 Classification of Ionising Radiation Exposure Received by Participants |
| If a participant was not enrolled in this clinical trial, would they still receive the same number of examinations involving the use of the same ionising radiation modality at the same specified intervals as outlined in the research protocol? | Choose an item. |  |
|  |  |

|  |
| --- |
| 1.5 Participants |
| **(a)** | Gender of participants? | Choose an item. |
|  |
| **(b)** | How many participants will be included in this research proposal at this site? |  |
|  |
| **(c)** | What is the minimum age of participants irradiated at this site?  |  |
|  |
| **(d)** | Will women who are pregnant or breastfeeding be irradiated in this research? | Choose an item. |
|  |
| **(e)** | Will babies, infants or fetuses be irradiated in this research? | Choose an item. |
|  |
| **(f)** | Is the median life expectancy of the participants less than five years? | Choose an item. |
|  | If Yes, state median life expectancy: |  |
|  |
| ***Note:****The radiation dose constraints that are applied to the research and advice given in the Participant Information and Consent Forms (PICFs) depend on the life expectancy of the participants. Consequently, it is extremely important that the median life expectancy of the volunteer cohort enrolled in this research proposal is accurately represented.* |

|  |
| --- |
| 1.6 Procedures involving the use of ionising radiation |
| List **all** procedures involving ionising radiation in your project. Include and identify procedures deemed to be ‘standard care’ and those procedures that are ‘additional to standard care’ and are required because of the participant’s inclusion in the research. *Add rows if required.* |
| **(a)** Detail the **type**, **number** and **frequency** of ionising investigations |
|  | **Site: Imaging Location** | **Type of Exam** | **Number Performed**\* | **Frequency** (weeks/days) | **Deemed to be:***(please mark one column per investigation only)* |
|  |  |  |  |  | **All exams are Standard Care** | **All exams are Additional to Standard Care** |
|  | *Example: Springfield Hospital* | *Example: CT exam of chest* *Nuclear Medicine Bone Scan Nuclear Medicine Therapy* | *x 3* | *Every 8 weeks* |[x] [ ]
| **1** |  |  |  |  |[ ] [ ]
| **2** |  |  |  |  |[ ] [ ]
| **3** |  |  |  |  |[ ] [ ]
| **4** |  |  |  |  |[ ] [ ]
| **5** |  |  |  |  |[ ] [ ]
| **6** |  |  |  |  |[ ] [ ]
| **7** |  |  |  |  |[ ] [ ]
| **8** |  |  |  |  |[ ] [ ]
| **(b)** Additional Comments (if necessary) |
|  |
| \* Where the exact number of examinations is not known, please indicate the anticipated average and maximum number likely to be performed over the duration of the research. Indicate “(Avg)” & “(Max)” next to value stated.\*\*Where a type of examination includes both standard of care and additional examinations due to the required frequency, please list these on separate rows in the table. The total number of additional examinations a participant may undergo as a result of participation in the study must be clearly identified. |
|  |
| **(c)** For any of the above procedures is there a trial specific imaging protocol involved? |   |
| *If yes, please include imaging protocols with this submission.* |

|  |
| --- |
| **(d)** For remote “third party” imaging locations (listed above) please include the details of a contact person that would be directly involved with patient imaging at each site: |
| **Site** | **Contact Name** | **Telephone** | **Email** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

|  |
| --- |
| 1.7 Appendices |
| *The Medical Physicist in their report will advise if this Section requires to be submitted with the ethics/governance application.* |
| 1.7a Site Approval – Site completing Application |
|  |
| The completed approval section should be included as part of the Ethics Submission with the Medical Physics Risk Assessment. A copy of the Medical Physics Risk Assessment should be provided to the representative of the Radiation Management Licence Holder to enable final site sign-off to occur (for example, this may be the site’s RSO).The institution must hold a Radiation Management Licence that authorises research involving the exposure of humans to ionising radiation before a specific project can be undertaken.The representative of the Radiation Management Licence Holder will be able to advise you if the:1. Organisation already holds a Radiation Management Licence that is authorised for research;
2. Radiation source(s) are appropriately licensed for use; and
3. Operators are appropriately authorised to use the equipment.
 |
|  |
| **Certification by the representative of the Radiation Management Licence Holder** I confirm that I am authorised to sign-off on behalf of the Organisation in relation to the Radiation Management Licence issued by the Victorian Department of Health (DoH).I confirm that the authorisation to conduct research involving irradiation of persons is held by the Organisation. The ionising apparatus to be used as part of this research is appropriately licensed for use and the operators are appropriately authorised to use the equipment.I have reviewed the information and agree it should be submitted for review by the relevant Human Research Ethics Committee.The proposal meets the scope of the ‘Code of Practice - Exposure of Humans to Ionising Radiation for Research (2005)’. |
|  |
| **Radiation Management Licence Number:** |  |
| **Radiation Management Licence Holder’s Name:** |  |
| **Representative Name:** |  |
| **Signature of Representative:** |  | **Date:** |  |
|  |
|  |
| **Position held within the Organisation:** |  |
|  |

|  |
| --- |
| **1.7 Appendices** |
| *The Medical Physicist in their report will advise if this Section requires to be submitted with the ethics/governance application.* |
| 1.7b Expected societal benefit (*for procedures identified to be in addition to standard care*) |
|  |
| Please justify the reasons why it is necessary to expose research participants to additional ionising radiation for the purpose of the research. That is:1. Why are the additional ionising radiation procedures above standard care required in this research?
2. How will these additional ionising radiation procedures aid either the individual (participant) or the proposed research?

**Additional justification will be required if the study involves pregnant or breastfeeding women; participants under the age of 18 years (including babies, infants or fetuses). 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**Depending on the amount of additional radiation dose and therefore the category (*Refer to the Medical Physics Risk Assessment*), the level of justification associated with the risks from these exposures that must be provided / demonstrated should be commensurate with the following:**Category I**: Minor with the expectation that the information obtained will increase knowledge;**Category IIa:** Related to increases in knowledge leading to health benefit.**Category IIb:** A moderate benefit directly aimed at the diagnosis, cure or prevention of disease.**Category III:** Be substantial and usually directly related to the saving of life or the prevention or mitigation of serious disease. |
|  |
| *Note:**The Code of Practice states:*1. *The researcher must prepare a submission to the Human Research Ethics Committee in accordance with its requirements. The submission must include the following information regarding radiation exposure:*
	1. *The reasons why it is necessary to expose research participants to ionizing radiation for the purpose of the research;*
2. *The Human Research Ethics Committee should pay particular attention to:*
3. *The justification for the radiation exposure particularly if the radiation dose exceeds the dose constraints.*
 |
|  |
|  |  |  |