**Use of Ionising Radiation for Research Purposes**

Any research involving the exposure of humans to ionising radiation must follow the requirements of the Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes (2005) (ARPANSA Radiation Protection Series No. 8.

<https://www.arpansa.gov.au/regulation-and-licensing/regulatory-publications/radiation-protection-series/codes-and-standards/rps8>

An additional statement from ARPANSA containing important information about radiation assessments relating to clinical trials was released in February 2020:

<https://www.arpansa.gov.au/about-us/advisory-council-and-committees/radiation-health-committee/trials-statement>

A Radiation Safety Report is required in studies involving humans who are exposed to radiation which is in addition to that received as part of their normal clinical management.

A Radiation Safety Report is NOT required when the radiation administered is NOT in excess of standard of care. In these cases, **a Letter of Declaration** (refer page 2) must be provided by the PI/CPI stating that there are no radiation procedures conducted in the study that are not standard of care and it is the responsibility of the PI/CPI to ensure that this information is accurate. This letter must be signed by the PI/CPI.

Please note, either the Radiation Safety Report, or a Letter of Declaration from PI/CPI stating that all radiation exposure falls within the site’s standard of care must be submitted to the HREC for review and the Research Governance Officer prior to commencement of the study at a site.

A Radiation Safety Form (refer page 3) should be submitted with your HREC application where Radiation exposure will be in excess of Standard-of-Care. The HREC will obtain Specialist advice where warranted. The form must be submitted with a copy of the study protocol, patient information statement and consent form.

For further information, please contact the Ramsay Health Care National Research Unit on ph: (02) 9433 3854 or email the relevant HREC.

RHC.HREC@ramsayhealth.com.au

RamsayHREC.WA-SA@ramsayhealth.com.au

**SOC Declaration**

Ramsay Health Care HREC A

Ramsay Health Care WA|SA HREC

 (delete which not applicable)

c/o National Research Unit

Level 7, 7 Westbourne Street

St Leonards NSW 2065

Dear Committee,

**RE: Project Title**

**Application ID:**

The purpose of this letter is to notify the reviewing HREC that the ionising radiation that is included in the protocol of the above named study, is not additional to the current standard care to be provided for the potential participants at [INSERT NAME OF HOSPITAL(S)].

That is, if a participant was not enrolled in this study, they would still receive the identical number of exams involving the use of ionising radiation at the specified intervals as stated in the research protocol. In making this determination I have considered:

1. The body region being examined;
2. The modality being identical to that used as part of standard care;
3. Frequency or number of the exams proposed.

Declaration By Principal Investigator

I declare that the above information is correct and ionising radiation procedures are standard of care and therefore are outside of the scope of the ‘*Code of Practice - Exposure of Humans to Ionising Radiation for Research* (2005)’ published by ARPANSA.

|  |  |
| --- | --- |
| Signature of Principal Investigator |  |
| Principal Investigator’s name (Print) |  |
| Date |  |
| Principal Investigator’s Site |  |

# INTRODUCTION

For research trials, radiological procedures are deemed to be additional to standard of care if the radiation exposure is beyond that considered standard clinical care of the condition being treated and is requested specifically for the trial only. For example:

* Use of different modalities to perform imaging (i.e. CT instead of general X-ray).
* Increased frequency of radiological examinations being performed.
* Additional ionising radiation procedures to monitor adverse outcomes (e.g. heart conditions).
* Examinations being performed solely to exclude a volunteer’s participation in a clinical trial.
* Imaging of additional body regions.

Please note: If participants will be exposed to ionising radiation in addition to that for their normal clinical management then in accordance with ARPANSA RPS 8 *Code of Practice for Exposure of Humans to Ionizing Radiation for Research Purposes* (The Code), a radiation dose estimate and risk assessment by a medical physicist is required. If the dose from these procedures exceeds the levels in *The Code* then the proposal must be assessed by a second medical physicist independent of the study.

***For research trials that require use of radiation, this form must be completed and submitted for:***

1. ***New research studies in which participants will be exposed to ionising radiation from irradiating apparatus or radioactive substances which is additional to that received as standard of clinical care;***
2. ***Protocol amendment that results in a change to the participant’s radiation exposure where the radiation exposure is additional to that received as standard of clinical care.***

Please ensure that the documents listed below are submitted with this request form. The request will not be processed until all of the relevant documents are received:

1. Protocol
2. Imaging Manual
3. Participant Information Statement
4. Participant Consent Form
5. Medical Physicist radiation report from lead site\*

*\*This only applies to multicentre research where RHC is not the lead HREC. If the lead site is in VIC, please also submit the relevant section of the Victorian Specific Module (VSM).*

# INVESTIGATOR DETAILS

|  |
| --- |
| **CO-ORDINATING PRINCIPAL INVESTIGATOR / SITE PRINCIPAL INVESTIGATOR** |
| Name |  |
| Position(*Including Dept/Hospital)* |  |
| Phone |  |
| Email |  |
| **CONTACT PERSON** |
| Name |  |
| Position |  |
| Phone |  |
| Email |  |

# STUDY DETAILS

|  |  |
| --- | --- |
| Title |  |
| Protocol # (if applicable) |  |
| Protocol Version |  | Protocol Date |  |

|  |  |  |
| --- | --- | --- |
| Is this a study of a ‘novel use’ of radiation?(e.g. new radiopharmaceutical or new type of radiological imaging device) | Yes ☐ | No ☐ |
| If *Yes*, please attach a statement of explanation |
| Is this study part of a multi-centre trial? | Yes ☐ | No ☐ |
| If *Yes*, please:1. List the other Australian participating centres or attach a list
 |  |
| 1. Indicate the Lead HREC
 |  |

# PROCEDURE DETAILS

|  |
| --- |
| Please explain why it is necessary to expose the research participants to ionising radiation in this research study? |
|  |

**Please list all procedures involving exposure to ionizing radiation including those deemed to be standard of care. Add extra rows if required.**

| **Procedure****(e.g. X-ray, CT)** | **Site/Department where procedure will be performed** | **Timepoint****(e.g. Screening, Cycle 2 etc)** | **Deemed to be** **(please mark one only)** |
| --- | --- | --- | --- |
| **Standard of care** | **Additional to standard of care** |
|  |  |  | ☐ | ☐ |
|  |  |  | ☐ | ☐ |
|  |  |  | ☐ | ☐ |
|  |  |  | ☐ | ☐ |
|  |  |  | ☐ | ☐ |
|  |  |  | ☐ | ☐ |
|  |  |  | ☐ | ☐ |
|  |  |  | ☐ | ☐ |
|  |  |  | ☐ | ☐ |

**Practices where procedures will be performed (if there is more than one practice then make copies of this table)**

|  |  |
| --- | --- |
| Hospital/Department |  |
| Licence number (if outside RHC) |  |  Date of Expiry: |  |
| Please list the precautions to be taken to ensure that the radiation exposure is kept to a minimum: |
|  |

# PARTICIPANT INFORMATION

|  |  |
| --- | --- |
| Total numbers of participants at site |  |
| Gender |  |
| Age range |  |
| What is the estimated five-year survival rate for participants in this trial who receive only standard treatment? |  |
| Life expectancy reference |  |
| Will women who are pregnant or breastfeeding be exposed to irradiation in this research? | Yes ☐ | No ☐ |
| *If yes then please justify* |
| Will babies, infants or foetuses be exposed to irradiation in this research?  | Yes ☐ | No ☐ |
| *If yes then please justify* |
| Will any participants of the study be under the age of 18 years?  | Yes ☐ | No ☐ |
| *If yes then please justify* |

# ATTACHMENTS CHECKLIST

|  |  |  |
| --- | --- | --- |
| Protocol | Yes ☐ |  |
| Imaging Manual | Yes ☐ | NA ☐ |
| Participant Information Statement | Yes ☐ |  |
| Consent Form | Yes ☐ |  |
| Radiation Report from lead site (if not RHC) | Yes ☐ | NA ☐ |

# CERTIFICATION

This form must be signed by the Coordinating Principal Investigator or Site Principal Investigator.

|  |  |
| --- | --- |
| NAME (BLOCK LETTERS) |  |
| Signature |  |
| Date |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| STUDY DETAILS – OFFICE USE

|  |  |
| --- | --- |
| Title |  |
| REGGS Application ID  |  |

 |
| **Dose Constraints for Participants in Research** |
| **Adults** | **DosimetricQuantity** | **Constraint** | **Met/ Exceeded/Not Applicable** |
| * **all 18 years+**
 | Total Effective Dose | 5mSv in any year10mSv over 5 years |  |
| * **all 60 years+**
 | Total Effective Dose | 8mSv in any year |  |
| * **all 70 years+**
 | Total Effective Dose | 12mSv in any year |  |
| * **life expectancy <5 years**
 | Total Effective Dose | 50mSv in any year |  |
| * **Skin(Averaged over 1cm2)**
 | Equivalent Dose | 200mSv in any year |  |
| * **any other organ or tissue (including lens of eye)**
 | Equivalent Dose | 100mSv in any year |  |
| **Children and fetuses** | **DosimetricQuantity** | **Constraint** | **Met/ Exceeded/Not Applicable** |
| * **Conception to birth**
 | Total Effective Dose | 0.1mSv in utero |  |
| * **Birth to 18 years**
 | Total Effective Dose | 0.5mSv in any year5mSv to 18 years |  |
| * **Any organ or tissue**
 | Equivalent Dose | 100mSv to 18 years |  |
| **Recommendations to Researcher and Ethics Review Committee** | **Yes/No** |
| Pregnancy test is required in women of reproductive capacity prior to exposure, because dose to the uterus is likely to exceed 0.1mSv. |  |
| Records should be kept and doses actually received should be reviewed because this is a novel use of radiation. |  |
| RSO signature |  |
| Date |  |