**Notification to the Reviewing HREC and/or site governance office: use of ionising radiation in a research project**

**Use this notification letter if:**

Ionising radiation exposure in a research project is **not** considered to be additional to standard of care for clinical management/care of the patient group at the site.

**Do not use this notification letter if:**

Ionising radiation exposure is **additional** to that received as standard of care for clinical management/care of the patient group at this site. Where radiation exposure is **additional** to standard of care, a full report from a Medical Physicist is required to be submitted to the reviewing HREC and/or site governance office. The Medical Physicist must be approved in the state/territory in which the site is located*.*

**OR**

The research project protocol does not include any exposure of participants to ionising radiation.

**Instructions**

1. The site Principal Investigator (PI) must complete the notification letter for this site
2. An independent clinical radiation expert, from the same discipline, must confirm the opinion of the PI
3. The Radiation Safety Officer must acknowledge recept of this form as notification that they have been advised of the research protocol indicates that the ionising radiation exposure schedule does not, in the opinion of the PI, exceed that required for the standard of care at this site
4. The PI must provide a copy of this signed letter to the HREC and/or site governance office as part of the ethics and/or site governance application.

Note: the reviewing HREC and/or site governance office may seek additional authoritative confirmation from the site’s Radiation Safety Officer (RSO).

**Schedule of x-ray imaging techniques associated with the research protocol**

|  |  |  |
| --- | --- | --- |
|  | **Type of Procedure and body region** | **Number Performed per year**\* |
|  | *Example: CT exam of chest* | *x 3* |
| **1** |  |  |
| **2** |  |  |
| **3** |  |  |
| **4** |  |  |

**Statement to HREC and/or Site Governance Office**

|  |  |
| --- | --- |
| **ACT Ref** |  |
| **Other Ref** |  |
| **Project Title** |  |

The purpose of this letter is to notify the reviewing HREC and/or site governance office that the ionising radiation exposure that is included in the protocol of the above named study, is in my clinical opinion, does **not** include radiological procedures which are performed specifically for the research protocol and which would not form part of the research participant’s normal clinical management at Canberra Hospital.

That is, if a participant was not enrolled in this study, they would 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.

**Certification by Principal Investigator**

I certify that the above information is correct. I have not consulted an appropriately certified medical physicist or the Radiation Safety Officer (RSO) at Canberra Hospital in relation to this protocol. I am of the clinical opinion that the 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.

I have provided this information to the Canberra Hospital Radiation Safety Officer who has acknowledged this correspondence.

|  |  |  |  |
| --- | --- | --- | --- |
| PI Name |  | | |
| PI Signature |  | Date |  |

**Certification by Independent Clinical Radiation Expert**

I have reviewed the research study protocol, including the schedule of x-ray imaging techniques (see appendix) and advise that the ionising radiation procedures are standard of care for the patient group at Canberra Hospital.

|  |  |  |  |
| --- | --- | --- | --- |
| Name |  | | |
| Signature |  | Date |  |

**Acknowledgement of Radiation Safety Officer**

I have been notified of the clinical opinion of the PI that that the ionising radiation procedures involved in this study as indicated in the appendix, are standard of care for the patient group at Canberra Hospital

|  |  |  |  |
| --- | --- | --- | --- |
| RSO Name |  | | |
| RSO Signature |  | Date |  |