**Notification to the Reviewing HREC:**

**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 normal clinical management/care at the site.

**AND**

The reviewing Human Research Ethics Committee (HREC) is in Victoria.

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

Ionising radiation exposure is additional to that received as normal clinical management/care. *In this situation, a full report from a Medical Physicist is required to be submitted to the reviewing HREC. The Medical Physicist must be approved in the state/territory in which the site is located.*

**OR**

The reviewing Human Research Ethics Committee (HREC) is **not** in Victoria.

**OR**

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

**Instructions:**

1. The site Principal Investigator (PI) should complete the notification letter for their site, and provide the signed letter to the Coordinating Principal Investigator (CPI) for inclusion in the ethics application.
2. On the Ethical Review Manager ([ERM](https://au.forms.ethicalreviewmanager.com/)) website, the CPI (or their delegate) must upload the PI letter(s) as a supporting document to the ethics application form, and submit electronically to the reviewing HREC.

# Note: the reviewing HREC may seek additional authoritative confirmation from the site’s Radiation Safety Officer (RSO).

[Date]

[Name of HREC Coordinator]

[Address]

[State] [Postcode]

Dear [Name of HREC Coordinator],

RE: [Title of Research Project]

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 [Name of Site].

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.

**Certification by Principal Investigator**

I certify that the above information is correct and that an appropriately certified medical physicist and the [Name of Site] Radiation Safety Officer (RSO) have not been consulted in relation to this protocol. 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.

Details of the site RSO are given below should you wish to seek further clarification for this research.

|  |  |
| --- | --- |
| Site Radiation Safety Officer (RSO) | |
| RSO name |  |
| Email |  |
| Phone |  |

|  |  |
| --- | --- |
| Site Principal Investigator (PI) | |
| Site name |  |
| PI name |  |
| PI signature |  | Date |  |