Notification to the reviewing HREC:

use of ionising radiation in a research project

# Use this notification if ionising radiation exposure in a clinical trial or health and medical research involving humans is NOT considered to be additional to normal clinical management/care at the participating site.

Would the participant have received radiation exposure equivalent to that received in this research as part of their current normal clinical management/care?

[ ]  Yes – complete letter below and submit to the reviewing HREC.

[ ]  No – do not complete. A Radiation Dose and risk Assessment from a Medical Physicist (in the State in which the site is located) is required.

# Instructions:

* 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.

* Please be advised that the reviewing HREC may seek additional authoritative confirmation from your site’s Radiation Safety Officer regarding your research submission.

Date

[Name of HREC Coordinator/Executive Officer]

[Address]

[Address]

[State] [Postcode]

Dear [Name, HREC Coordinator]

RE: [HREC NUMBER]

[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.*

|  |  |
| --- | --- |
| RSO’s name: |  |
| Contact Details (email) |  |
| Contact Details (phone) |  |

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