Notification to the reviewing HREC

# Use of ionising radiation in a clinical trial or health and medical research involving humans where radiation exposure is NOT considered to be additional to normal clinical management (care) at the particular 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 – fill out the letter below and send to the reviewing HREC.

[ ]  No – do not complete or send this letter as a full report from an approved (in the State in which the site is located) Medical Physicist assessment report is required.

# Instructions:

* This notification letter is to be completed by sites outside of Victoria where the reviewing HREC is located in Victoria and the Victorian Specific Module has not been completed.
* This letter is due by the Submission Closing Date/Cut Off Date as a supporting document for the NEAF submission.
* At each site the Principal Investigator is responsible for providing this letter to the reviewing HREC, via the CPI.
* The letter MUST be certified by the principal Investigator at the particular site.
* Please be advised that the reviewing HREC may seek additional authoritative confirmation from your site’s Radiation Safety Officer regarding your research submission.
* Applications which include any form of exposure of participants to ionising radiation in the study protocol, even if that exposure is part of standard care and/or the exposure is solely for the purposes of determining whether a participant can be included or needs to be excluded from a particular study, must be accompanied by this letter, completed by the site principal investigator.
* Delete these instructions before 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 |  |