

Purpose

To outline the requirements where research applications involve the use of ionising radiation.

Definitions

ARPANSA: Australian Radiation Protection and Nuclear Safety Agency.

Guidance

Bellberry Human Research Ethics Committees (HRECs) require that all applications that include the use of ionising radiation refer and adhere to the ARPANSA Code of Practice "Exposure of Humans to Ionising Radiation for Research Purposes" (RPS 8).

Researchers must ensure that all research involving irradiation of humans, (i.e., irradiation that would not have been received but through the research) is approved by the relevant state authority. Contact details for each state are in Annex 5 of ARPANSA RPS 8.

Bellberry HREC requirements

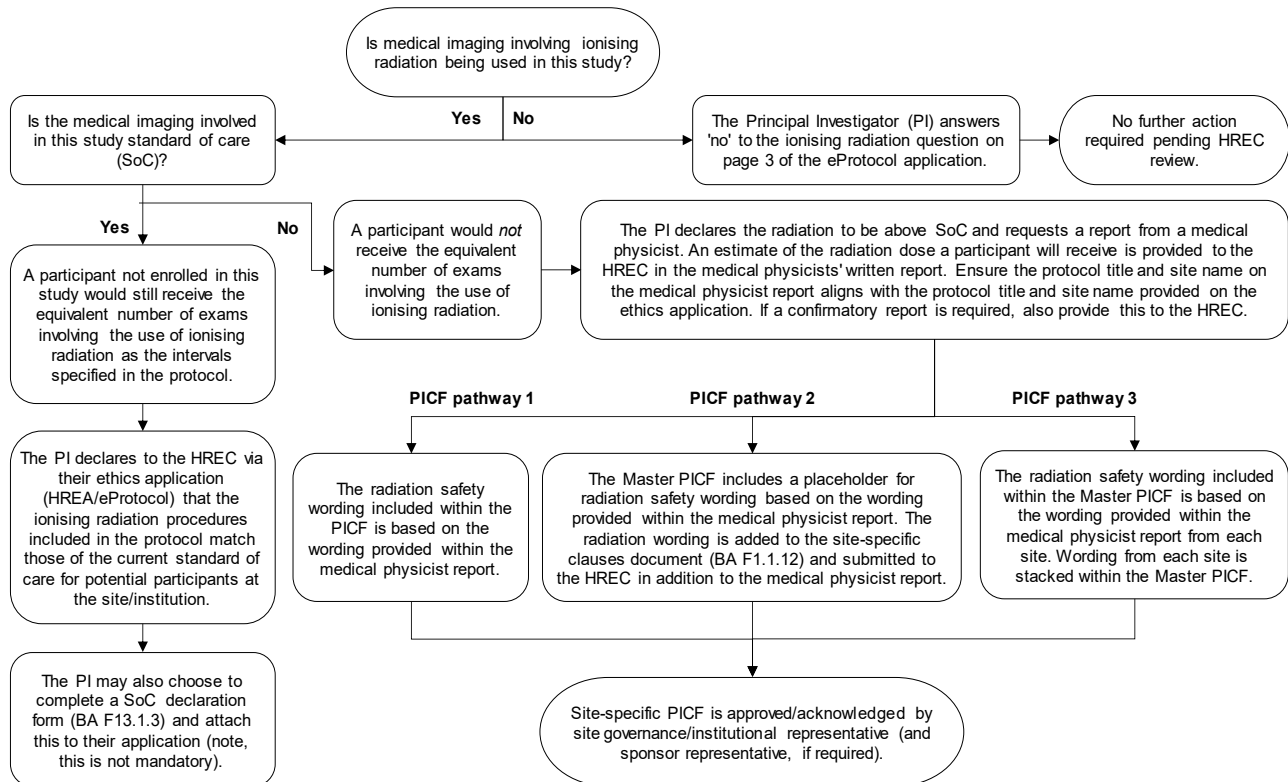
Bellberry HRECs require the following in relation to studies involving ionising radiation:

If the ionising radiation procedures included in the protocol match those of the current standard of care for potential participants at the site/institution, the principal investigator must declare this.

Where the ionising radiation exposure is in addition to that received as part of normal clinical management:

- An estimate of the radiation dose to be received by a participant (i.e. the effective dose and relevant organ doses), provided in a written report from a medical physicist.
- Identification of the site/institution.
- A Participant Information Sheet and Consent Form (PICF) that outlines:
 - The name of the imaging procedure(s) and how many procedures will be involved.
 - A statement declaring whether the type and number of imaging procedure(s) involved in the study are the same as or in addition to standard care.
 - Whether the exposure to radiation is a medically acceptable dose.
 - The purpose, methods, associated risks and any discomforts of the study and any radiation exposure.
 - An ionising radiation paragraph (please also see ARPANSA RPS 8).
 - Please note, consideration should be given to radiation risk statements where the estimated life expectancy of participants may be less than 5 years.
- Approval notification from the relevant state authority.

HREC REPORTING FLOWCHART



References

[ARPANSA Radiation Protection Series No.8](#)

[ARPANSA State and Territory Regulators](#)

BA F13.1.1 Ionising Radiation Standard Clauses

BA F13.1.3 Radiation Standard of Care Declaration Template