POLICYI007 IONISING RADIATION

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PURPOSE

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

Bellberry HREC expects all applications that include the use of ionising radiation to refer and adhere to the Australian Radiation Protection and Nuclear Safety Agency's (ARPANSA's) Code of Practice "Exposure of Humans to Ionising Radiation for Research Purposes" (RPS No 8): https://www.arpansa.gov.au/regulation-and-licensing/regulatory-publications/radiation-protection-series/codes-and-standards/rps8

Researchers must ensure that all research involving irradiation of humans, (i.e. irradiation which would not have been received but for the purpose of the research) is approved by the relevant state authority as required.

Contact details for each state can be located In Annex 5 of RPS8.

Bellberry HRECs require the following:

1. Sufficient written information to the participant about the purpose, methods, radiation dose, associated risks and any discomforts of the radiation exposure. The Participant Information Sheet and Consent Form (PICF) should include the following:

   a. The name of the imaging procedure(s) and how many procedures are involved in the course of the study.
   b. A statement declaring whether the type and number of imaging procedure(s) involved in the course of the study are the same as or in addition to standard care and
   c. Whether the exposure to radiation is a medically acceptable dose.

2. 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 is required (i.e. the effective dose and relevant organ doses). This should be in the form of a written report from a medical physicist.

3. Approval notification from the relevant State authority, as required.

4. An ionising radiation paragraph in the PICF as outlined in the examples below (or in ARPANSA RPS8).

Examples of suitable wording for inclusion in the Participant Information Sheet:

EXAMPLE 1 – if the medical imaging used is the same as standard care:

This research study involves exposure to ionising radiation. You will have (insert number) x-rays, (insert number) CT scans, (insert number) MUGA scans of your (insert bodily location). These scans will expose you to a medically acceptable dose of radiation.

EXAMPLE 2 - to be included if extra, study specific medical imaging is undertaken:

This research study involves exposure to ionising radiation some of these procedures (name them and their number) are additional to those you would have received if you were not in this study.

As part of every day living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 to 3 millisieverts (mSv) each year. The effective dose from this study is about (insert number) mSv. ***(Insert paragraph 1, 2, 3, or 4 from below*)***

If there are no perceived benefits from participating then state this.

You will be given a certificate that states the radiation dose you have received from participating in this study. You should keep the certificate for five years and show it if you are recruited for any other research studies in that time.

If you would like to discuss your exposure to radiation with a radiation safety officer you may contact the radiation regulator in your state. See contact details at: https://www.arpansa.gov.au/regulation-and-licensing/regulatory-publications/radiation-protection-series/codes-and-standards/rps8

*** Choose one of the following paragraphs to be inserted above as indicated:**

1. *Effective doses less than 2 mSv*- At this dose level, no harmful effects of radiation have been demonstrated and the risk is negligible ***or***

2. *Effective doses between 2 and 20 mSv* - At this dose level, no harmful effects of radiation have been demonstrated and the risk is low. The dose from this study is comparable to that received from routine diagnostic medical x-ray and nuclear medicine procedures ***or***

3. *Effective doses between 20 and 50 mSv* – The dose from this study is comparable to that received from several computed tomography (CT) x-rays procedures. The benefits from the study should be weighed against the possible detrimental effects of radiation, including an increased risk of cancer.
In this particular study, the risk is moderate and the theoretically calculated risk of contracting fatal cancer in the future is considered acceptable.
The possible detrimental effects of radiation should be weighed against the benefits from the study which are (state benefits to the participant or to society*).*
If there are no perceived benefits from participating then state this. ***Or***

4. *Effective doses greater than 50 mSv* - This research study involves exposure to a significant amount of ionizing radiation. The benefits from the study should be weighed against the possible detrimental effects of radiation, including an increased risk of cancer. In this particular study, the risk is moderate and the calculated risk of such harm is about 1 in.... (Calculate using the ICRP risk coefficient for fatal cancer in the general population of 5 x 10^{-2} per Sv.

For studies in children or for persons over the age of 50, the risk of radiogenic cancer should be calculated using age- and sex-specific risk factors. The possible detrimental effects of radiation should be weighed against the benefits from the study which are (state benefits to the participant or to society).