SOP RSC 2.1 Radiation Exposure of Research Participant or Participants

Version and Date of Issue: V6 October 2025
Written by: Radiation Safety Committee
Review due date: October 2028

BACKGROUND

Research protocols must comply with the ARPANSA Code of Practice - Exposure of Humans to Ionizing Radiation for Research Purposes (RPS8). This Code of Practice is designed to ensure that researchers proposing to expose research participants to ionising radiation provide the participants, the Charles Sturt University (CSU) Human Research Ethics Committee (HREC) and the CSU Radiation Safety Committee (RSC) with information that allows consent to be properly considered by the research participants and approval considered by the CSU HREC and the CSU RSC.

This Code of Practice applies to research involving healthy participants who are exposed to radiation which is additional to that received as part of any normal clinical management. Thus, it applies to, but is not restricted to, research with diagnostic/therapeutic agents and procedures, including Phase I, II, III and IV clinical trials and novel procedures.

Normal clinical management with regards to radiation is defined as typical or routine radiation management or investigation of a patient.

Knowledge of normal clinical management with regards to radiation is important to proposal preparation because:

(a) a proposal might be a modification of normal clinical management with regards to radiation; or

(b) the patient will be exposed during the research to additional radiation due to their normal clinical management.

RESPONSIBILITIES

The Principal Investigator

The researcher must:

- ensure that the selection of the participants is conducted according to the requirements of RPS8, the HREC and the RSC.
- provide information regarding normal clinical management to the HREC, the RSC and the independent assessor (medical physicist). This information on normal clinical management will include:
    - the number of radiation procedures being performed;
    - the frequency or time interval between the radiation procedures; and
    - the anatomical region being exposed to radiation;
- obtain an independent assessment or verification by a medical physicist of the total effective dose and relevant organ doses for those radiological procedures that are performed specifically for the research protocol.
- ensure that the research participant is provided with sufficient written information in a language that is comprehensible to the patient about the purpose, methods, radiation dose, associated

risks, and any discomforts of the radiation exposure to enable the research participant to give informed consent.

- ensure that for novel uses of radiation, the actual doses received are calculated or measured.

  Note: Due to the long latent period associated with certain carcinogenic effects of radiation and the possibility of genetic effects, special consideration must be given to the age, pregnancy status and whether the participant is breast-feeding. Refer to RPS8 for details.

The Radiation Safety Committee or Medical Physicist

The RSC or medical physicist must:

(a) independently verify the total effective dose, organ doses and radiation risk assessment which have been provided by the principal investigator; or

(b) assess the expected total effective dose and organ doses which will be received by the research participant because of their participation in the research and the corresponding radiation risks; and

(c) where the dose constraints specified in RPS8 are exceeded, obtain verification of the dose assessment by a second medical physicist who must be independent of the researcher.

The Human Research Ethics Committee and the Radiation Safety Committee

When assessing research proposals involving ionising radiation the Human Research Ethics Committee and the Radiation Safety Committee should work closely together and consider the balance between the likely benefits and risks associated with any radiation exposure including consideration of the advice provided in Annex 1 of RPS8.

PROCEDURE

Procedure to be Followed by the Principal Investigator

The Principal Investigator must:

(a) complete and submit both HREC and RSC applications.

(b) ensure that the patients are given a written description of the procedure and the dose and dose frequency that they received.

(c) advise the patient over the age of 13 to retain the written description of the procedure and the dose and dose frequency that they received for at least five years or, in the case of the being 13 years old or younger, to keep the records at least to the age of 18. This will enable the patient to provide to researchers or medical practitioners with this information if required.

(d) ensure that there is a measure or calculation of the actual doses received by the patient when the procedure includes novel uses of radiation and report these in accordance with their project approval to the CSU RSC.

The information on the forms will include:

(a) the reasons why it is necessary to expose research participants to ionizing radiation;

(b) the precautions to be taken to keep radiation exposure to a minimum;

(c) a statement confirming that the site(s) at which the examination or procedure will be performed is actively involved in a relevant quality assurance program (see Radiation Management Plan Section 13);

(d) for novel uses of radiation, the arrangements for a review and reporting to the RSC of radiation doses actually received and the arrangements for retention of dose records;

(e) the radiation dose assessment and risk assessment obtained from the RSO or medical physicist;

(f) the written information to be given to research participants relating to the doses and risks associated with the radiation exposure.

Novel Uses of Radiation

In most research, the estimate of the radiation exposure of the research participant determined by the medical physicist will be close to the actual exposure received during the research project. This will not necessarily be the case for novel uses of radiation. This type of research will include, for example, the initial use of a new radiopharmaceutical or the initial use of a new radiology imaging device. The dose estimations available to the HREC may have been calculated based on the results of animal experiments or derived using anthropomorphic phantoms. In these circumstances, it is essential that the actual doses received are calculated or measured and should be included in any reports on the project which are prepared by the researcher for the RSC and Ethics Committee.

DOCUMENTATION

RISK ASSESSMENT
INFORMED CONSENT
DOSE ASSESSMENT REPORT – NOVEL APPLICATIONS

AUDIT

Every 2 years

REFERENCES

Code of Practice - Exposure of Humans to Ionizing Radiation for Research Purposes (ARPANSA Radiation Protection Series Publication No. 8 (May 2005))

REVISION & APPROVAL HISTORY

Date	Revision No.	Author and Approval
Dec 2014	Version 1	William Bartolo, Bartolo Safety Management Service
May 2016	Version 2	William Bartolo, Bartolo Safety Management Service
Dec 2016	Version 3	Radiation Safety Committee, Charles Sturt University
Jan 2017	Version 4	William Bartolo, Bartolo Safety Management Service and Radiation Safety Committee, Charles Sturt University
Nov 2022	Version 5	Radiation Safety Committee, Charles Sturt University
Oct 2025	Version 6	Dr Praneel Titheradge; Radiation Safety Committee, Charles Sturt University