SESLHD PROCEDURE COVER SHEET

Health
South Eastern Sydney
Local Health District

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AUTHOR	Brent Rogers, SESLHD Radiation Safety Officer Erin McKay, RSO St. George Hospital
POSITION RESPONSIBLE FOR THE DOCUMENT	SESLHD Radiation Safety Officer SESLHD-RadiationSafetyOfficer@health.nsw.gov.au
FUNCTIONAL GROUP(S)	Radiation Safety
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SUMMARY	Procedure for the assessment of radiation dose and associated risk for research protocols requiring subjects to receive diagnostic tests or therapeutic procedures involving ionising radiation.

Radiation Exposure of Volunteers for Research Purposes

SESLHDPR/559

1. POLICY STATEMENT

South Eastern Sydney Local Health District (SESLHD) is committed, through a risk management approach, to protecting employees, contractors, students, volunteers, patients, members of the public and the environment from unnecessary exposure to radiation arising from systems and processes which use radiation apparatus and radioactive substances, whilst maintaining optimum diagnostic and therapeutic quality, therapeutic efficacy and patient care.

This document provides procedures necessary to ensure compliance in relation to the protection of persons undergoing radiological procedures as part of a research protocol.

2. BACKGROUND

Under the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) *Code for Radiation Protection in Medical Exposure* (C-5, Medical Code), no individual may receive a medical exposure as part of a program of research unless the exposure has been approved by a Human Research Ethics Committee (HREC) and a radiological medical practitioner has assumed responsibility. The medical exposure must be conducted in accordance with any conditions of the HREC approval including any dose constraints that may be specified and subject to applicable national or local regulations.

The ARPANSA RPS-8 Code of Practice - *Exposure of Humans to Ionizing Radiation for Research Purposes* (Research Code) is designed to ensure that researchers proposing to expose research participants to ionising radiation provide the participants and the HREC with information that allows consent to be properly considered by the research participants and approval considered by the HREC.

The Research Code applies to research involving humans who are exposed to radiation which is additional to that received as part of their normal clinical management. Thus, it applies to research involving healthy volunteers or patients and includes, but is not restricted to, research with diagnostic or therapeutic agents and procedures, including Phase I, II, III and IV clinical trials and novel procedures on selected groups of research participants.

Normal clinical management is defined as the typical or routine management of a patient with an identical condition that is not part of this research proposal. When considering what is 'normal clinical management' the following items need to be taken into account:

- the number of radiation procedures being performed
- the frequency or time interval between the radiation procedures
- the anatomical region being exposed to radiation, and
- whether the procedure will need to be modified to comply with the requirements of the research proposal.

3. RESPONSIBILITIES

3.1 The Researcher

The Researcher will:

- obtain, from their site's Radiation Safety Officer, an independent assessment or verification of the total effective dose and relevant organ doses for those radiological procedures that are performed specifically for the research protocol
- keep the radiation dose to research participants to the minimum level practicable and, where possible, select subjects who have not otherwise been exposed to radiation from research unless it can be demonstrated that dose constraints will be met when those other exposures are taken into account
- ensure that the selection of the participants is conducted according to the requirements of the Human Research Ethics Committee. 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 of the participants, their pregnancy status and whether the participant is breast-feeding. Refer to RPS-8 for details
- provide the research participant, or their parent or guardian, with sufficient written information about the purpose, methods, radiation dose, associated risks and any discomforts of the radiation exposure to enable the research participant, parent or guardian to give informed consent.

3.2 Medical Radiation Practitioner (MRP)

A Medical Radiation Practitioner will:

- compare the research protocol against standard care and confirm the assessment of procedures within their specialisation that are additional to that baseline, and
- assume responsibility for the safety and quality of diagnostic procedures within their area of specialisation that are performed as part of a research protocol.

3.3 Qualified Medical Physicist (QMP)

A Qualified Medical Physicist will:

- provide estimates of the equivalent dose distribution and effective dose for procedures within their area of specialisation using site-specific technical parameters.

3.4 Radiation Safety Officer (RSO)

The Radiation Safety Officer will:

- use the information provided by the Researcher, MRP and QMP to assess the expected total effective dose and organ doses which will be received by the research participant as a result of their participation in the research, along with the corresponding radiation risks

- where the dose constraints specified in RPS-8 are exceeded, obtain verification of the dose assessment by a second QMP who must be independent of the researcher
- draft a Radiation Safety Assessment Report describing the radiation dose and risk associated with the research and including language to be incorporated in the Patient Information and Consent Form.

3.5 Human Research Ethics Committee (HREC)

The Human Research Ethics Committee will:

- when assessing research proposals involving ionizing radiation, consider the balance between the likely benefits and risks associated with any radiation exposure including consideration of the advice provided in Annex 1 of RPS-8 and approve or reject the research proposal accordingly
- when dose constraints are exceeded, give particular attention to the justification for the radiation exposure, and if necessary, seek further independent authoritative advice before approving the proposal.

4. PROCEDURE

4.1 Obtaining a Dose Assessment

The researcher must complete a Radiation Research Assessment Request (SESLHD Form F014) and forward it to their site's RSO, together with a copy of the research protocol and the Master Patient Information Statement, for a radiation dosimetry and risk assessment.

The RSO will review the research proposal and determine which procedures in the protocol require a radiation dose assessment to be performed, then forward this information to one or more appropriately specialised QMPs.

The QMP(s) will perform the dose calculations for each procedure in their speciality, based on current, local technical parameters and protocols, then return the results of these calculations to the RSO.

The RSO will assess the expected total effective dose and organ doses which will be received by the research participant as a result of their participation in the research, along with the corresponding radiation risks, then compile these results into a standard Radiation Dose Assessment Report which will be returned to the researcher. This report will include:

- the assessed or verified expected total effective dose and relevant organ doses
- a statement as to whether the dose constraints of RPS-8 are likely to be exceeded
- an assessment of the risks associated with the expected radiation exposure, and
- the proposed text on the radiation doses and risks to be included in the information provided to the research participants.

If any dose constraints are exceeded, the RSO will seek confirmation of the dose assessments from an independent QMP prior to completing the report.

4.2 Patient Information and Consent Form

The local Patient Information and Consent form (PICF) must contain language describing the additional radiation dose associated with the research protocol, along with any estimate of risk provided by the RSO. The required language will be included in the RSO's Radiation Dose Assessment Report.

The researcher must advise the research participant to retain the information about the procedure, including the radiation dose, for at least five years in the case of an adult or, in the case of a child, to age 18 or for five years (whichever is the longer period), so that it can be provided to researchers in any future research project involving exposure to ionizing radiation.

4.3 HREC Submission

The researcher must prepare a submission to the HREC including the following information regarding radiation exposure:

- a copy of the application form which will give:
  - the reasons why it is necessary to expose research participants to ionizing radiation for the purpose of the research (Section 11 of the Form)
  - the precautions to be taken to keep radiation exposure to a minimum (Section 12 of the Form)
  - 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; (Section 9 of the Form)
  - for novel uses of radiation, the arrangements for a review of radiation doses actually received and the arrangements for retention of dose records (Section 19 of the Form)
- the Radiation Dose Assessment Report obtained from the RSO
- the local Patient Information and Consent Form to be given to research participants, which must include the prescribed language provided by the RSO describing the radiation doses and risks associated with the radiation exposure.

4.4 Novel Uses of Radiation

In most research, the estimate of the radiation exposure of the research participant determined by the RSO 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 HREC.

The procedures to be used for estimating these radiation doses must be written up or reviewed by an appropriately specialised QMP and then submitted to the HREC along with the other documents described herein.

5. DOCUMENTATION

- Radiation Research Study Request

6. AUDIT

The following records should be available for audit:

- Radiation Dose Assessment Reports for all research protocols involving radiological procedures.

7. REFERENCES

[1] ARPANSA RPS C-5 (2019) Code for Radiation Protection in Medical Exposure

[2] ARPANSA RPS-8 (2005) Code of Practice - Exposure of Humans to Ionizing Radiation for Research Purposes

8. VERSION AND APPROVAL HISTORY

Date	Version	Version and approval notes
July 2010	draft	Richard Smart, Area Radiation Safety Officer in conjunction with the Area Radiation Safety Committee
February 2011	0	Approved by Combined Clinical Council
December 2015	1	Periodic Review
October 2016	1	Updates endorsed by Executive Sponsor
December 2019	2	Updates endorsed by Executive Sponsor
1 May 2024	3.0	Major review. Approved at SESLHD Clinical and Quality Council.