SESLHD PROCEDURE COVER SHEET

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KEY TERMS	Radiation safety; ionising radiation; x-rays; radiology; medical imaging; radiotherapy; research; HREC
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.

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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

Research protocols need to follow the requirements of the ARPANSA Code of Practice - Exposure of Humans to Ionizing Radiation for Research Purposes (ARPANSA Radiation Protection Series Publication No. 8 (May 2005)). This Code of Practice is designed to ensure that researchers proposing to expose research participants to ionising radiation provide the participants and the Human Research Ethics Committee (HREC) with information that allows consent to be properly considered by the research participants and approval considered by the HREC.

This Code of Practice 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 and/or patients and includes, but is not restricted to, research with diagnostic/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:

- must 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 RPS8 for details.

- must provide the research participant with sufficient written information about the purpose, methods, radiation dose, associated risks and any discomforts of the radiation exposure to enable the research participant to give informed consent.
- must 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.

3.2 The Radiation Safety Officer (RSO) or Medical Physicist:

- must independently verify the total effective dose and organ doses and radiation risk assessment which have been provided by the researcher
- must 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 and the corresponding radiation risks
- must, where the dose constraints specified in RPS-8 are exceeded, obtain verification of the dose assessment by a second medical physicist who must be independent of the researcher.

3.3 The Human Research Ethics Committee:

- when assessing research proposals involving ionizing radiation, should 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.

4. PROCEDURE

4.1 Procedure to be followed by the Researcher

The researcher must complete Form F014 and forward it to the Sector RSO, together with a copy of the research protocol and Patient Information Statement, for a radiation dosimetry and risk assessment.

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 and risk assessment obtained from the RSO
- the written information to be given to research participants relating to the doses and risks associated with the radiation exposure.

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.

4.2 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.

5. DOCUMENTATION

- Radiation Research Study Request Form (F014)

6. AUDIT

The following records should be available for audit:

- Research radiation dosimetry reports for all research involving radiological procedures.

7. REFERENCES

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

8. REVISION AND APPROVAL HISTORY

Date	Revision No.	Author and Approval
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