The Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes (2005) (ARPANSA Radiation Protection Series No. 8) sets out the requirements that apply to research protocols. This includes the requirement for an independent radiation dosimetry and risk assessment report. This assessment can be requested by completing a Radiation Safety Request Form. This Guideline provides instructions on how to complete a Radiation Safety Request Form.

The Code of Practice is designed to ensure that researchers proposing to expose research participants to ionizing 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 to be considered by the HREC.

The 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, this Code of Practice 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.

When completing sections 5, 6 and 7 of the Form, please list all procedures that will be performed, and then separately identify which (if any) of these procedures form part of the participant’s normal clinical management and which are being performed specifically for this research proposal.

The Radiation Study Request Form must be submitted to the Radiation & Laser Safety Officer for assessment even if all of the procedures to be performed are considered to be part of the participant's normal clinical management. The form must be signed in section 10 by the appropriate radiation licence holder (eg the Director of Radiology).

Diagnostic studies requiring the use of ionising radiation should only be performed when the information required cannot be obtained by other procedures. The justification for the use of ionising radiation in this research protocol must be provided in Section 11 of the form.

Even when the use of ionising radiation is justified, the researcher must keep the radiation dose to research participants to the minimum level practicable and, due to the long latent period associated with the carcinogenic effects of radiation, must where practicable, restrict research participants to those over the age of 40 years. If younger adults or children need to be studied please justify their inclusion in sections 14 and/or 15.

Normally women who are pregnant or who are breast feeding must be excluded from participating in the research. If women in these categories are to be recruited, their inclusion must be justified in sections 16 or 17. Where the pregnancy status is uncertain and the radiation dose to the uterus is likely to exceed 0.1 mSv, premenopausal women should have a biochemical pregnancy test to exclude pregnancy before the radiation exposure.
Based on the information in the Application Form and the study protocol, the RSO will provide a dosimetry report which includes the total effective dose and the relevant organ doses and a risk assessment in accordance with the Code of Practice. If the RSO is also an investigator for a particular research protocol, the dosimetry report will be prepared by another medical physicist who is independent of the researcher. The risk assessment needs to take into account the life expectancy of the research participants. If this is less than 5 years (section 18) please provide supporting evidence. It will often only be necessary to identify the appropriate section of the study protocol.

**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.

**Responsibilities of the Researcher**

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

(a) a copy of this application form which will give:
   i. the reasons why it is necessary to expose research participants to ionizing radiation for the purpose of the research (Section 11 of the Form)
   ii. the precautions to be taken to keep radiation exposure to a minimum (Section 12 of the Form)
   iii. 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)
   iv. 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)

(b) the radiation dose assessment and risk assessment obtained from the RSO;

(c) 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.