Title:	**Code of Practice for Exposure of Humans to Ionizing Radiation for Research Purposes**	
Department	Barwon Medical Imaging	PROCEDURE
Approved by	Director, Barwon Medical Imaging	

Purpose

The purpose of this document is to provide the following Code of Practice
This Code provides requirements which must be met for the exposure of humans to ionizing radiation for the purpose of research. This Code contains additional advice to that contained in the National Statement on Ethical Conduct in Research Involving Humans (NHMRC, 1999) which addresses the ethical principles and values which govern research involving humans.

Target Audience

Researchers
Medical Physicists
Human Research Ethics Committee
Responsible Person for the radioactive material, radiation apparatus, facility or premises

Definition

N/A

Procedure

Code of Practice Exposure of Humans to Ionizing Radiation for Research Purposes, Radiation Protection Series Number 8. ARPANSA, May 2005. Pages 1-7.

Content:

SCOPE

This 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, this Code 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. This Code does not apply to the use of radiation outside a research project even if it involves the use of a novel procedure.

This Code outlines the roles and responsibilities of the following:

- the researcher who proposes to undertake a project involving administration of ionizing radiation to research participants;
- the medical physicist verifying or assessing the total effective dose, organ doses and undertaking the radiation risk assessment;
- the Human Research Ethics Committee, constituted in accordance with the National Statement on Ethical Conduct in Research Involving Humans (NHMRC, 1999), which is an advisory body independent of the teams of researchers; and
- The Responsible Person for the radioactive material, radiation apparatus, facility or premises.
- Advice on radiation dose constraints for research participants is given in Section 3. The assessment of risk/benefit of research projects is given in Annex 1.

INTERPRETATION

In interpreting the provisions of the Code, the words *must* and *should* have particular meanings. The presence of the word must indicate that the requirement to which it refers is mandatory. The presence of the word should indicate a recommendation that is, a requirement that is to be applied as far as practicable in the interests of reducing risk.
Annexes to the Code provide information supplementary to the requirements embodied in the Code. Annexes provide material that will help in interpretation of the Code, and background information relevant to the development of the Code.

RESPONSIBILITIES

RESEARCHER

1. The researcher must obtain the approval of the Human Research Ethics Committee of the relevant institution for the research.
2. 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 following items;
   - **(a) Age of the research participants;**
     the research participants should, where practicable, be over 40 years of age, and preferably over 50; and exposure of children must only be permitted if the condition under study is related to the age of the participants and the information sought cannot be obtained using adult participants.
   - **(b) Pregnancy in the research participants;**
     pregnant women must be excluded except when conditions specific to this group are being investigated; in studies on pregnant women, the dose to the fetus must also be evaluated and advice provided to the Human Research Ethics Committee on the associated risks; where some participants are women of reproductive age, the possibility that a woman may be pregnant must be taken into account; and 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.
   - **(c) Research participants who are breastfeeding;**
     In the case of studies involving the administration of radioactive substances, research participants who are breastfeeding must be excluded unless conditions specific to this group are being investigated.
3. The researcher 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.
4. Where the research participant cannot give informed consent, including the case of a child, the researcher must provide the parent or guardian with sufficient written information about the purpose, methods, radiation dose, associated risks and any discomforts of the radiation exposure, and obtain the parent or guardians informed consent.
5. The researcher must:
   a) keep the radiation dose to research participants to the minimum level practicable; and
   b) whenever possible in the case of research involving the radiation exposure of healthy research participants, select persons who have not previously been or who are not currently exposed to radiation from research unless it can be demonstrated that the dose constraints in this Code will be met when those previous and current exposures are taken into account.
6. The researcher must obtain an independent assessment or verification by a medical physicist of:

(a) the total effective dose [1]and relevant organ doses for those radiological procedures that are performed specifically for the research protocol and which are additional to those received as a part of the research participants normal clinical management;
(b) whether these will exceed the dose constraints in Table 1; and
(c) the risks associated with the radiation exposure in accordance with Annex 1.

7. The researcher must prepare a submission to the Human Research Ethics Committee in accordance with its requirements. The submission must include the following information regarding radiation exposure:
   (a) the reasons why it is necessary to expose research participants to ionizing radiation for the purpose of the research;
   (b) the radiation dose assessment and risk assessment obtained in accordance with clause 2.1.6;
   (c) a statement confirming that the site at which the examination or procedure will be performed is actively involved in a relevant quality assurance program such as the programs of the Royal Australian and New Zealand College of Radiologists or of the Australian and New Zealand Association of Physicians in Nuclear Medicine;
   (d) the precautions to be taken to keep radiation exposure to a minimum;
   (e) the written information to be given to research participants relating to the doses and risks associated with the radiation exposure; and
   (f) for novel uses of radiation[2], the arrangements for a review of radiation doses actually received and the arrangements for retention of dose records.
8. 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.

MEDICAL PHYSICIST

The medical physicist must:
(a) independently verify the total effective dose and organ doses and radiation risk assessment which have been provided by the researcher; or
(b) 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; and
(c) where the dose constraints are exceeded, obtain verification of the dose assessment by a second medical physicist who must be independent of the researcher.

When undertaking the dose assessment or verification, the medical physicist must:
(a) assess only those radiological procedures which are performed specifically for the research protocol and which would not form part of the research participants normal clinical management; and
(b) take into account the technical specifications of the radiological procedures as detailed in the research protocol.

The medical physicist must prepare a written report, which includes:
(a) the assessed or verified expected total effective dose and relevant organ doses;
(b) a statement as to whether the dose constraints in Table 1 are likely to be exceeded;
(c) an assessment of the risks associated with the expected radiation exposure; and
(d) the proposed text on the radiation doses and risks to be included in the information provided to the research participants, consistent with Annex 2

[1] In radiation therapy research the effective dose is not an appropriate quantity for risk assessment.
[2] As defined in Annex 3.

HUMAN RESEARCH ETHICS COMMITTEE

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

The Human Research Ethics Committee should pay particular attention to:

(a) the estimates of expected radiation doses and associated risks, which must have been calculated or verified by a medical physicist;

(b) the dose estimates and radiation risk assessments and opinion of an independent medical physicist where the dose constraints are exceeded;

(c) the manner in which the radiation doses and risks are provided to the research participants in the information sheet;

(d) the justification for the radiation exposure particularly if the radiation dose exceeds the dose constraints in Table 1; and

(e) the measures to be taken during the project to assess the radiation doses actually received from novel uses of radiation where these may differ from the expected radiation doses and the arrangements for the retention of records of these doses.

THE RESPONSIBLE PERSON

The Responsible Person as defined in the glossary of this Code is responsible for establishing systems that ensure the overall observance of this Code and its implementation. In addition to the requirements of this Code, the Responsible Person is responsible for compliance with regulatory requirements for radioactive materials and radiation apparatus at the facility.

RADIATION DOSE CONSTRAINTS FOR PARTICIPANTS

The radiation doses to the research participants must be kept to the minimum level practicable and assessed or independently verified by a medical physicist. Wherever possible, the total effective doses and organ doses to adults and children should conform with the dose constraints as tabulated below. If these dose constraints are exceeded the Human Research Ethics Committee should give particular attention to the justification for the radiation exposure, and if necessary, seek further independent authoritative advice before approving the proposal. For comparison purposes the dose limits for occupational and public exposure see ARPANSA Radiation Protection Series F-1, *Fundamentals for Protection Against Ionising Radiation (2014)* http://www.arpansa.gov.au/Publications/Codes/rpsF-1.cfm

Participant Category		Dose Constraint[b]
Adults		
total effective dose	in any year	5 mSv[c]
	over 5 years	10 mSv
Total effective dose in adult with life expectancy less than five years	in any year	50 mSv
Equivalent dose to skin averaged over 1 cm^2	in any year	200 mSv[d]
Equivalent dose to any other organ or tissue	in any year	100 mSv[e]
Children and fetuses		
Total effective dose to age 18 years		5 mSv
- Subject to:		
• Effective dose from conception to birth; and		0.1 mSv
• Effective dose in any year from birth to 18 years		0.5 mSv
• Total equivalent dose to age 18 years to any organ or tissue		100 mSv

Table 1. Dose Constraints for Participants in Research

a. A dose constraint for research participants specifies a maximum dose with which it should be possible to comply in normal circumstances and it is intended to apply to radiation which is in addition to that received as part of normal clinical management.
   Dose constraints apply to diagnostic investigations not radiation therapy.
b. The dose constraint applies to the sum, over the relevant period, of doses received from external exposure and the 50-year committed dose (to age 70 years for children) from intakes over the same period.
c. When all the research participants are within the following specified age limits, the following total effective dose constraints apply:
   - for adult 60 years or more – in any year – 8 mSv and
   - for adult 70 years or more – in any year – 12 mSv.
d. Derived from Table 3.1 of ICRP85 – factor of 10 below the threshold of 2 Sv for early transient erythema.
e. Derived from Table 3.1 of ICRP85 – factor of 10 below the threshold of 1 Sv for detectable lens opacity.

Evaluation

Regular document revision and review of relevant RiskMan reports

Key Aligned Documents

BMI 4 Step Model for Correct Patient, Correct Site, Correct Procedure, PROMPT: Barwon Health \ Barwon Medical Imaging \ BMI

Hand Hygiene, PROMPT: Barwon Health \ Infectious Diseases \ Infection Prevention Services

Patient Identification Policy, PROMPT: Barwon Health \ Clinical Practice \ Clinical Practice

Radiation Management Plan Barwon Health, PROMPT: Barwon Health \ Barwon Medical Imaging \ BMI

Key Legislation, Acts & Standards

National safety and quality health service standards (2012, September). Retrieved April 30, 2015 from http://www.safetyandquality.gov.au/wp-content/uploads/2011/09/NSQHS-Standards-Sept-2012.pdf

Radiation Act 2005 (VIC) No. 62 of 2005 Version incorporating amendments as at 1 July 2014. Retrieved April 30, 2015 from http://www.austlii.edu.au/au/legis/vic/consol_act/ra2005103/

References

ARPANSA, (2008, May). Code of practice: Radiation protection in the medical applications of ionizing radiation. RPS.14. Retrieved April 30, 2015 from http://www.arpansa.gov.au/pubs/rps/rps14.pdf (includes Annex 1-6)

Commonwealth of Australia, (1999). National statement on ethical conduct in research involving humans. Retrieved April 30, 2015 from http://www.rtc.org.au/docs/NHMRC%20National%20Statement%20on%20Ethical%20Conduct%20in%20Research%20Involving%20Humans%201999.pdf

Contributors

	Name	Position	Service / Program
Lead Reviewer:	Philip Brough	Chief Radiographer	Barwon Medical Imaging
Contributors:	Alex Merchant	Radiology Medical Physicist	Barwon Health
Committee/s:	N/A		