Purpose

To describe procedures

- to be followed for research that involves the exposure of human participants to radiation,
- that comply with the National Code of Practice (RPS 8): Exposure of Humans to Ionizing Radiation for Research Purposes.

Target Audience

Barwon Health research personal who seek approval to undertake research involving the exposure of human participants to ionizing radiation.

Definitions

HREC: Human Research Ethics Committee
PICF: Participant Information and Consent Form
RAC: Radiation Advisory Committee
VSM: Victorian Specific Module

Procedure

Ionizing radiation that may be used in research includes:

- Diagnostic Radiographic procedures: (i.e. Plain film radiography, fluoroscopy, interventional radiography (angiography), dental cephalometry, CT examinations and DEXA scans or skeletal surveys).
- Nuclear Medicine procedures: (i.e. The *in vivo* application of unsealed radioactive sources for diagnosis or therapy purposes)
- Radiation Therapy procedures: (i.e. The use of ionizing radiation for therapy purposes)

Summary of requirements

For all research projects that involve exposing human volunteers to ionizing radiation, researchers **must** obtain:

- Independent advice from a medical physicist regarding the radiation dose to the participant, risk category & whether the Department of Health needs to be informed about the research project.
- A review of the research protocol by the radiation safety officer (RSO) and sign-off Section 4.10 of the VSM
- Review and approval of the radiation component of the research project by a Human Research Ethics Committee (HREC), in accordance with the Code of Practice *Exposure of Humans to Ionizing Radiation for Research Purposes* (RPS 8). Human Research Ethics Committee (HREC) is to review

<u>Standard of Care Doses</u>

If the project involves use of radiation that is additional to standard care and **does not** exceed the dose constraints (see Table 1 below), research cannot begin until

- the DoH is **notified** and acknowledgement of notification has been received by the Office for Research
- the HREC has reviewed and approved the application,

Dose Exceeds Standard of Care

If the project is additional to standard care and exceeds the dose constraints in the Code (see Table 1 below) and the participant receives no direct benefit, the research cannot commence until

- the research project is **approved** by the DoH Radiation Advisory Committee (RAC) (see http://www.health.vic.gov.au/radiation/forms.htm)

Dose constraints for participants in research

Table 1: Dose Constraints for Participants in Research[a] (taken from Table 1. RPS 8)

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

a The 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.

It should be noted that the ICRP released information on 21st April 2011 stating that the threshold for detectable lens opacities is now 500 mSv rather than 1000 mSv so it may be prudent to consider the threshold in the table above to be 50 mSv equivalent dose to the eye lens rather than 100 mSv.

How to obtain a medical physics report

It is the responsibility of the researcher to obtain an independent assessment or verification by a medical physicist.. Barwon Health has an accredited radiology medical physicist in Barwon Medical Imaging: Dr Alex Merchant amerchant@barwonhealth.org.au (03) 4215 0404.

Notification of currently approved medical physicists will be provided by the Department of Health by contacting the Radiation Safety Hotline at Phone: 1300 767 469 Fax: 1300 769 274 Email: radiation.safety@health.vic.gov.au

Researchers should contact the physicist directly either by e-mail or in hard copy, at least 7 days prior to the required date. The following documents must be provided:

1. A copy of the final research protocol;
2. A copy of the Participant Information and Consent Form (PICF);
3. A copy of the Victorian Specific Module (VSM) with Section 4 completed including:
   - Section 4.1: Is all the imaging standard of care? Apply the test statement: *If a participant was not enrolled in this clinical trial, would they still receive the same number of examinations involving the use of ionizing radiation at the specified intervals as stated in the research protocol?*
   - Section 4.2: How many participants will be from Barwon Health? What is the minimum age of participants? etc
   - Section 4.3: A summary of the type of ionizing radiation proposed to be used, with a detailed description of the radiation procedures involved and any special requirements as outlined in the research project;
   - An indication of whether each radiation procedure is to be performed at Barwon Health or at an external imaging provider. Also note clearly if the imaging involving radiation is part of standard clinical care **OR** additional to standard of care (note: imaging cannot be both standard and additional, some additional imaging may be standard care *if clinically indicated*). If an external imaging provider is used then a contact person should be provided who can answer questions of a technical nature on the equipment used for imaging or treatment.
   - The Barwon Health medical physicist can also arrange the services of a second medical physicist should it be required due to the dose constraint being exceeded.
   - Local policy is for the RSO to sign-off on all research involving radiation. Once completed the medical physics report and VSM Section 4 will be forwarded onto the RSO.

The Medical Physicist will provide you with the radiation dose for procedures additional to standard care, risk category, a statement of the radiation risks involved and a DOH approved radiation risk statement to be included in the Participant Information and Consent Form (PICF).

The medical physics report and completed Section 4 will be passed onto the Barwon Health Radiation Safety Officer for approval for all projects.

Fees for medical physics report

	Standard Care	*Additional*
Internal non-funded trials	no cost	no cost
External collaborative trials	no cost	$100
External funded trials	no cost	$350

Evaluation

Regular document revision and meeting of contributors (once annually).

Key Aligned Documents

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

Key Legislation, Acts & Standards

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Contributors

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Committee/s:	Members as per email	Radiation Safety Advisory Group (Ratification to occur at the next BH RSAG Meeting)	'out of session' email 21st October 2014