STANDARD OPERATING PROCEDURE (SOP)

TITLE: CONDUCTING RESEARCH WITH IONISING RADIATION

DO NOT USE THIS SOP IN PRINTED FORM WITHOUT FIRST CHECKING IT IS THE LATEST VERSION

Document ID:	SOP-RG-05
Version No:	2.0
Date Authorised:	Date of Approval
Effective Date:	17-Dec-2020
Review Date:	17-Dec-2023
Applicable Epworth Site/s:	All

Author:	Helen Christensen Research Quality Coordinator
Approved by:	Prof Nik Zeps Group Director Research and Development
Signature:	Nikolajs Zeps (Nov 17, 2020 15:48 GMT+11)
Date:	Nov 17, 2020

STANDARD OPERATING PROCEDURE (SOP)

TITLE: CONDUCTING RESEARCH WITH IONISING RADIATION

1. PURPOSE:

The purpose of this SOP is to provide guidance on preparing and submitting documentation to demonstrate compliance with the legislative and regulatory requirements for research involving ionising radiation at Epworth.

2. SCOPE:

All research conducted at Epworth where participation involves exposure to ionising radiation.

This SOP must be read in conjunction with SOP-RG-01: Research Governance.

3. APPLICABILITY:

This applies to all Epworth employees, non-employed staff and Visiting Medical Officers (VMOs) and to all relevant external persons and parties engaged in research activity at Epworth.

4. GLOSSARY OF TERMS:

Please refer to Epworth SOP Glossary of Terms (see *Related Documents*).

5. PROCEDURE:

The Principal Investigator (PI) is responsible for the research project conducted at Epworth and therefore must be familiar with all regulatory and institutional requirements as per the Research Policy[1] and Research Handbook[2]. The PI can delegate at his/her discretion certain trial duties to suitably qualified individuals (see also *SOP-TM-14 Delegation of Duties*). Delegation of trial activities must be recorded on the delegation log. The PI remains responsible for any delegated activity.

Any research involving the exposure of humans to ionising radiation for research purposes (including diagnosis, disease staging, therapy or follow-up) must comply with the *Radiation Protection Series Publication No. 8 - Code of Practice for the- Exposure of Humans to Ionizing Radiation for Research Purposes* (the Code of Practice)[3] set out by Australian Radiation & Nuclear Safety Agency (ARPANSA). The scope of the Code of Practice **only applies to research involving humans who are exposed to radiation which is additional to that received as part of their normal clinical management**. Examples of common ionising radiation procedures are provided in *APPENDIX A*.

5.1 Project Initiation, Development and Registration at Epworth

- The use of ionising radiation should be identified as early as possible. The PI is responsible for identifying the likely clinical setting and exposure required during the research.
- The documentation to be submitted for Human Research Ethics Committee (HREC) and Governance review and approval will depend on whether participation in the study involves exposure to ionising radiation above standard of care or not (as outlined in the following sections).

- The documentation to be provided to the reviewing HREC will also depend on whether the research is a multi-site study reviewed by a single central HREC under the National Mutual Acceptance arrangements. In these instances, the Coordinating Principal Investigator only need provide to the HREC the radiation risk assessment for the site with the highest assessed dose at the time [4]. Researchers must be guided at all times by the submission requirements of the reviewing HREC.
- As per SOP-RG-01 all research projects must be registered with the Research Development and Governance Unit (RDGU) prior to submitting studies for ethical review.

5.1.1 Where the research involves NO additional exposures to ionising radiation above standard of care

HRECs are required to consider the balance between the likely benefits and risks associated with radiation exposure **for the purpose of research**. Where a participant would receive the same number of examinations involving the use of the same ionising radiation modality at the same specified intervals in a study, this would not usually require further review by a HREC or Medical Physicist.

- Where this is the case the PI will be expected to confirm in writing that the exposure to ionising radiation is not above standard of care at this institution.
- This statement must be provided in accordance with the HREC submission requirements (and may not be required by the HREC for multi-site studies).
- Where not specifically stated by the HREC, the *HREC radiation notification letter template* (optional for Victorian HRECs) can be used to provide this confirmation.
- Research Governance submissions must be in line with SOP-RG-01.

5.1.2 Where the research includes exposures IN ADDITION to standard of care

- Where a study is identified as involving exposure to ionising radiation above standard of care the PI must ensure a Medical Physics Risk Assessment Report is obtained. This must be provided by an approved medical physicist as listed on the Victorian *Department of Health and Human Services (DHHS) list of Approved Medical Physicists*[5].
- The Medical Physicist report should be specific to the site where the radiation exposure is occurring in accordance with Annex 3 of the Code. This particularly applies to CT and fluoroscopic units as exposure between sites may vary substantially with the technique factors used.
- The PI must ensure a completed *Medical Physics Risk Assessment: Interventional, Diagnostic & Nuclear Medicine Procedures – Supporting Information Form (MPRAF)*, protocol and current draft version of the PICF are provided to the Medical Physicist for review.

- The Medical Physicist will provide a report which includes:
  - a radiation dose and risk assessment for imaging that is above standard of care;
  - recommended wording for the PICF; and
  - instructions for completion of the MPRAF Appendices (Section 1.7) where applicable.
- The PI must ensure the MPRAF Appendices are completed as instructed by the Medical Physicist.
  - MPRAF Section 1.7a must be completed by the Epworth Authorised Licence Representative (see *APPENDIX B* for Epworth details)
  - MPRAF Section 1.7b must be completed by the Authorised Representative(s) of each 3rd party provider where applicable (see *APPENDIX C* for examples)
  - MPRAF Section 1.7c (justification for why it is necessary to expose research participants to additional ionising radiation for research purposes) must be completed by the PI where the exposure is above standard of care
- The completed MPRAF and Medical Physicist Report must be provided to the HREC for review and approval where required (i.e. for multi-centre studies, the site with the highest assessed dose at the time may only be required).
- Where the study is single site (to be conducted at Epworth only) the PICF reviewed by the HREC must include the updated radiation risk wording recommended by the Medical Physicist. The HREC approval should list/confirm these documents were reviewed.
- With reference to SOP-RG-01 the final Research Governance submission must include:
  - the completed MPRAF and Medical Physicist report;
  - HREC approval letter with the radiation risk category included (in accordance with the Code of Practice); and
  - The site specific PICF with the recommended radiation risk wording.
- Additional supporting documentation such as the MPRAF and Medical physicist report reviewed and acknowledged by the reviewing HREC (i.e. with the highest assessed dose) may be requested to support the local governance review process if required.
- Where the radiation exposure exceeds dose constraints, the RDGU will provide written notification to the DHHS in accordance with their requirements[6]. This notification will take place within 14 days after Research Governance Authorisation is granted for the study.

- Where applicable the RDGU will provide copies of the DHHS Notification to the Epworth Authorised Representative and Principal Investigator.
- The Research Quality Coordinator (RQC) will maintain a central Register of Research involving the Use of Ionising Radiation.

5.2 Post-Approval Changes to the research protocol

- Where a research protocol has been approved previously, subsequent protocol revisions should include review of changes to the exposure type, frequency and provider. If the revisions include changes to these points, the MPRAF should be revised, and the Medical physicist consulted regarding the requirement for further review.
- For single site studies where there is an update to the MPRAF and/or Medical Physicist Report that results in an increase in the assessed radiation risk category further review and approval by the HREC will be required
- For multi-site studies where there is an update to the MPRAF and/or Medical Physicist Report that results in a radiation risk assessment higher than that specified in the HREC approval letter further review and approval by the HREC will be required.
- Any updates to the MPRAF and/or Medical Physicist report must be submitted to the RDGU in line with the SOP-RG-01 Research Governance.
- The RQC will update any changes on the central Register of Research involving the Use of Ionising Radiation and notify the DHHS if necessary.

All documentation pertaining to the above must be filed in the investigator site file and available for review on request by the RDGU.

6. REFERENCES AND RELATED DOCUMENTS:

The Epworth Research Policy, handbook, SOPs and supporting forms and templates can be found on the *Epworth Resources for Researchers* webpage.

1. Epworth Research Policy
2. Epworth Research Handbook
3. ARPANSA, 2005. *Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes, Radiation Protection Series Publication No. 8*
4. ARPANSA, 2020. *Statement on ethical review for multi-centre trials*
5. Department of Health and Human Services. *List of approved medical physicists*.
6. Department of Health and Human Services. *Research involving irradiation of people*.

6.1 Related Forms and Templates

- *HREC radiation notification letter template*
- MPRAF: Medical Physics Risk Assessment Interventional, Diagnostic & Nuclear Medicine Procedures Supporting Information Form
- *DHHS Notification of a research project where the dose constraints will be exceeded*
- SOP-RG-01-FORM-02 Researcher Declaration

6.2 Related SOPs

- SOP-Glossary-of-Terms
- SOP-RG-01 Research Governance

7. VERSION CONTROL

Document History	
Version	**Summary of Changes**
1.0	N/A First Issue
2.0	SOP updated throughout in response to release of ARPANSA *Statement on ethical review for multi-centre trials* (2020).

APPENDIX A: Examples of Medical Ionisation Radiation Procedures

Procedure	Common Abbreviation(s)	Comments
X-ray Computed Tomography	CT	
Planar X-Ray	X-Ray / General X-ray	
Dual Energy X-ray Absorptiometry / Bone Densitometry	DEXA / DXA	
Gated Blood Pool Scan	MUGA	
Skeletal Survey		
Dental Cone Beam CT	OPG	
Mammography		
Dual Subtraction Angiography	DSA	
EOS		A weight bearing anterior-posterior and lateral X-ray obtained simultaneously.
Fluoroscopy		
Nuclear Medicine	NM	Any diagnostic or therapeutic procedure involving use of an unsealed radioisotope typically labelled to a pharmaceutical
Positron Emission Tomography	PET / PET-CT	Note that PET scans may also include at least one CT scan
Single Photon Emission Computed Tomography	SPECT /SPECT-CT	Note that SPECT scans may also include at least one CT scan
Bone Scan		
Radiation Therapy	RT/ EBRT /IMRT / SBRT / SABR / SRS	External beam radiation therapy delivered by a medical linear accelerator or Cobalt-60 source (e.g. GammaKnife)
Computed Tomography Planning/Simulation	CT-Sim	CT scan specifically for the purpose of radiation therapy treatment planning
Cone Beam CT Image Guided Radiation Therapy	IGRT / CBCT	Imaging performed during radiation therapy treatment
kV X-ray Image Guided Radiation Therapy	IGRT / kV Imaging	Imaging performed during radiation therapy treatment
Brachytherapy	HDR / LDR	Radiation therapy delivered by internal placement of sealed radiation sources

Note this list is not exhaustive and is provided as an example only.

APPENDIX B: Epworth Radiation Management Licence Details

Epworth Foundation radiation management licence number: **300042097**

Richmond licence representative:

Name	Meagan Suter
Position	Senior Nuclear Medicine Technologist / Radiation Safety Officer Epworth Medical Imaging
Contact Phone	0412758706
Contact Email	MSuter@emi.net.au

Geelong licence representative:

Name	John Laughlin
Position	Chief Medical Imaging Technologist / Radiation Safety Officer Epworth Medical Imaging
Contact Phone	0408 320 720
Contact Email	JLaughlin@emi.net.au

APPENDIX C: Examples of who needs to sign the MPRA

In Victoria, entities carrying out research that involves exposure of humans to ionising radiation that is **in addition to standard care**, must hold a Radiation Management Licence that includes an authorisation for the "*procuring, arranging or conducting of research involving the irradiation of persons*". Epworth's Radiation Management Licence includes this authorisation. **Note that this applies even if the actual application of ionising radiation will be conducted by another entity under their own Licence. In this case, where Epworth is still conducting the research i.e. managing the research, acting as a "Sponsor" or facilitating investigator lead studies, Epworth is still specifying the use of ionising radiation as part of the research and the Licence requirements apply.**

Example 1:

Bridge Road Imaging is intended to be the provider of medical imaging procedures for a clinical trial conducted by an Epworth HealthCare researcher.

Example 2:

Radiation Oncology Centres (i.e. ICON Cancer Care) located in the Epworth Medical Centre will provide radiation therapy treatments as part of a clinical trial conducted by an Epworth HealthCare researcher.

In the case of both Example 1 & 2, the requirements of the protocol apply to the Epworth researcher if the exposures will be in addition to standard of care. In that case the licence and practice details of each provider must be recorded in the Medical Physics Risk Assessment - Section 1.7b in additional to Section 1.0 – 1.7a. If the research requires additional to standard of care procedures from both Bridge Rd Imaging and Radiation Oncology Centres, then the details of both providers should be added to the form.

Example 3:

Epworth Medical Imaging is intended to be the provider of medical imaging procedures for a clinical trial conducted by an Epworth HealthCare researcher, for imaging in addition to standard of care.

Epworth Medical Imaging (EMI) operates under the Epworth Foundation radiation management licence and so only Section 1.0 - 1.7a of the Medical Physics Risk Assessment will need to be completed. Note however that if multiple EMI sites will be involved e.g. EMI-Richmond and EMI-Freemasons, then each site should be listed in 1.6(a).

Example 4:

EMI is contracted to provide medical imaging procedures for a clinical trial conducted by a non-Epworth researcher. This imaging is in addition to standard of care.

In this case, EMI medical imaging would be required to provide the researcher with site details and Radiation Management Licence information confirming they meet the normal regulatory requirements for the use of medical radiation i.e. the 3rd party researcher will need to complete Section 1.7b of the Medical Physics Risk Assessment for their application.