

MEDICAL PHYSICS PROCEDURE

RESEARCH INVOLVING IONISING RADIATION

Staff this document applies to:

Anyone involved with research where ionising radiation may be used

Related Austin Health policies, procedures or guidelines:

[Research Policy](#)

[Radiation Management Plan](#)

Purpose:

The purpose of this procedure is to outline the processes **before** and **after** submitting a research project involving ionising radiation to Human Research Ethics Committee (HREC).

Austin Health must comply with conditions listed in its Radiation Management Licence with regard to procuring, arranging or conducting research involving the irradiation of persons. The licence holder must meet the requirements set out under the [“Code of Practice for the Exposure of Humans to Ionising Radiation for Research Purposes \(2005\)”](#) published by the Australian Radiation Protection and Nuclear Safety Agency and inform the Department of Health and Human Services’ Radiation Team.

All researchers should be familiar with the “Code of Practice for the Exposure of Humans to Ionising Radiation for Research Purposes (2005)” published by the Australian Radiation Protection and Nuclear Safety Agency.

Medical Physicist Radiation Research Assessment Report (MPR)

An approved Medical Physicist can provide a MPR for your research project. At Austin Health, the Medical Physics Department can provide this for a fee.

The Principal Investigator and project co-coordinator will need to decide which procedures in their project are considered “Standard Care” and “Additional to Standard Care” and the frequency of these procedures. Complete the Medical Physics Risk Assessment Interventional, Diagnostic & Nuclear Medicine Procedures Supporting Information.

This information will inform the Medical Physicist on how to assess the radiation dose and provide a report and additional information for the Participant Information and Consent Form (PICF).

Process:

1. Provide required documents to Medical Physicist to obtain MPR (refer to flowchart 1)
2. Revise PICF with radiation risk statement provided in MPR
3. Obtain Ethics approval
4. Send required documents to, Austin Health Radiation Safety Officer (RSO) for site approval; and if necessary the RSO will complete Department of Health Human Services (DHHS) notification.
5. You **cannot** commence a research project until site approval as been obtained by the Austin Health RSO (or delegate); and when relevant DHHS notification has been completed.

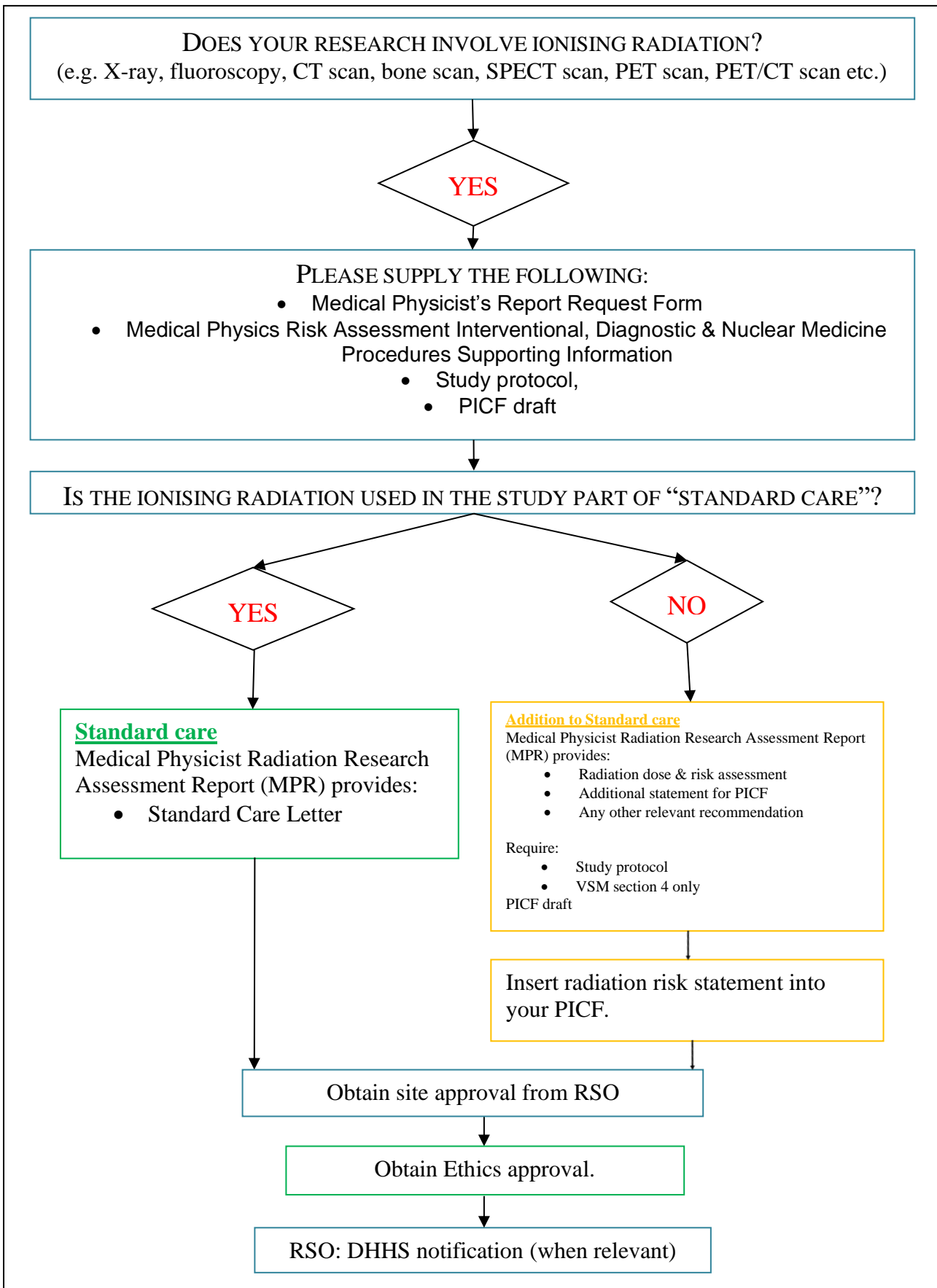
.Notifying the DHHS

The following documents are required to notify the DHHS:

- Ethics approval letter
- PICF final version
- Completed all sections and Appendix 1.7 of the Medical Physics Risk Assessment Interventional, Diagnostic & Nuclear Medicine Procedures Supporting Information with particular attention to:
 - The reasons why it is necessary to expose research participants to ionizing radiation for the purpose of the research;
 - The justification for the radiation exposure particularly if the radiation dose exceeds the dose constraints.

The DHHS will perform audits of the HREC process and selected research projects from time to time.

Flowchart 1 - Does your research involve ionising radiation?



Document Author/Contributors:

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Legislation/References/Supporting Documents:

1. [Australian Radiation Protection and Nuclear Safety agency. Code of Practice Exposure of human Ionizing Radiation for Research Purposes \(2005\).](#)
2. Radiation Safety Section, Victorian Department of Health and Human Services, Standard Radiation Risk Statements, April 2015.

Endorsed by:

Radiation Safety Committee

Human Research Ethics Committee

Clinical Policy and Procedure Committee

Document Owner /Person Responsible for Document:

Radiation Safety Officer