RD&I	NHS University Hospitals Plymouth NHS Trust **STANDARD OPERATING PROCEDURE**

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

The definitive versions of all UHPNT RD&I Dept SOPs appear online, not in printed form, to ensure that up to date versions are used. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the Trust's website: https://www.plymouthhospitals.nhs.uk/researchers

Gaining permission for research involving medical exposures (using Ionising Radiations)

SOP No: P12

Version No: 4.1

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Page: **1** of **7**

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	APPROVED BY
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Job Title:	Research Governance Manager
Signature:	
Date:	21st Jan 2019

1 Purpose and Scope

This Standard Operating procedure (SOP) sets out the approval process for all research radiation exposures in the Trust. The procedure ensures that all clinical research trials restrict any dose of ionising radiation to the minimum required to achieve the intended clinical objective and comply with regulatory requirements.

All exposures of individuals to ionising radiation for medical purposes (All x-ray, Nuclear Medicine and Radiotherapy), must satisfy the requirements of the Ionising Radiation (Medical Exposure) Regulations 2000 (IR(ME)R).

Definition of Research Exposures
A research exposure is any medical exposure (to ionising radiations) that is carried out as part of a research trial.

Procedures for research exposures therefore include exposures that are part of normal patient management, as well as exposures, which are additionally required by the trial.

1.2. Ionising Radiations Legislation and Research

IRMER requires specific procedures to be followed for Medical Exposures

- The employer must establish written procedures.
- All medical exposures must be justified by a Practitioner. A Practitioner (usually a Radiologist) justifies the exposure in terms of the risk / benefit consideration to the individual concerned. Any exposure may only take place following justification including research exposures where ethics approval has already been given. Details of who can act as a Practitioner are specified in Directorate Operating Procedures.
- Risks from research exposures must be considered by the REC as part of the ethics approval process.
- Where there is no direct benefit to the individual from the exposure, a dose constraint must be set. Where there is benefit to the individual a target dose must be specified.
- Participants in research trials must have any additional risk due to medical exposures clearly explained to them.
- Research exposures should not normally be carried out on children or pregnant women.
- Operators may not undertake research exposures unless it has been approved by a research ethics committee

1.3. Requirements of other regulations for ionising radiations

The Medicines (Administration of Radioactive Substances) Regulations (MARS) require licence holder administration of radionuclides to a person. Specific Research licences may need to be obtained for a project.

The Environmental Permitting Regulations (EPR) require the Trust to be registered to hold radioactive substances on its premises, and authorised to dispose of radioactive substances. Where a trial involves the use of a substance not covered by the Trust's existing permits a variation will be required.

The Ionising Radiations Regulations (IRR) require prior risk assessments to be carried out for novel techniques or for use of new radionuclides. Such risk assessments must consider the health and safety of staff and members of the public.

In scope: All research hosted by, and/or sponsored by UHPNT involving ionising radiation.

Definitions

ARSAC	Administration of Radioactive Substances Advisory Committee. The person administering radioactive materials must hold an ARSAC certificate which is site-, holder- and procedure-specific. In some cases a “research ARSAC certificate” may need to be applied for.
CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
EPR	Environmental Permitting Regulations
GCP	Good Clinical Practice
HCA	Health Care Assistants
HRA	Health Research Authority
IRAS	The Integrated Research Application System
IRMER	Ionising Radiation (Medical Exposure) Regulations 2000
IRR	Ionising Radiations Regulations
IRR	Ionising Radiations Regulations
Lead CRE	Clinical Radiation Expert - registered health professional with clinical expertise in the modality (imaging/treatment method) involved in the study, appointed as the lead Clinical Radiation Expert for the study, responsible for providing a clinical assessment of additional exposures for the REC application, in consultation with

other CREs as appropriate.

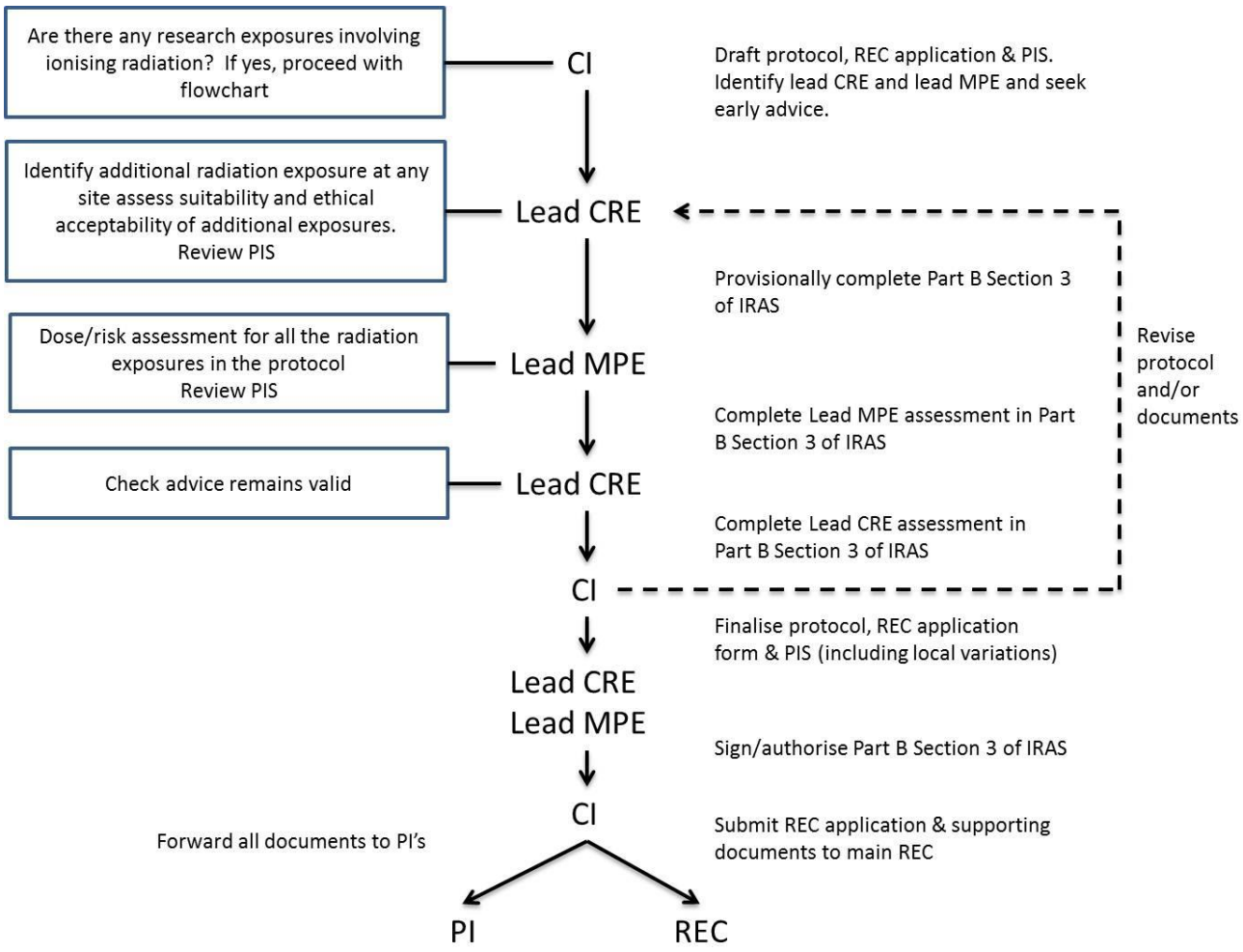
Lead MPE	Medical Physics Expert - registered health professional with relevant expertise relevant to the proposed procedures, appointed as the lead Medical Physics Expert for the study, responsible for providing a dose/risk assessment of the proposed investigations for the REC application, in consultation with other MPEs as appropriate.
Local MPE	Medical Physics Expert at site who is a registered health professional and has expertise relevant to the proposed procedures.
Local Practitioner	A registered health professional at a research site with clinical expertise in the modality (imaging method) involved.
MARS	The Medicines (Administration of Radioactive Substances) Regulations
MHRA	Medicines and Healthcare products Regulatory Agency
UHPNT	University Hospitals Plymouth NHS Trust
PI	Principal Investigators
PIS	Patient/Participant Information Sheet
RD&I	Research Development & Innovation
REC	Research Ethics Committee
RO	Research Office
SOP	Standard Operating Procedure

2 Who should read this document?

All Chief Investigators (CI) Principal Investigators (PI) and study Co-ordinators/Managers should read and follow the procedure to ensure restricted use of Ionising Radiation to Human Subjects.

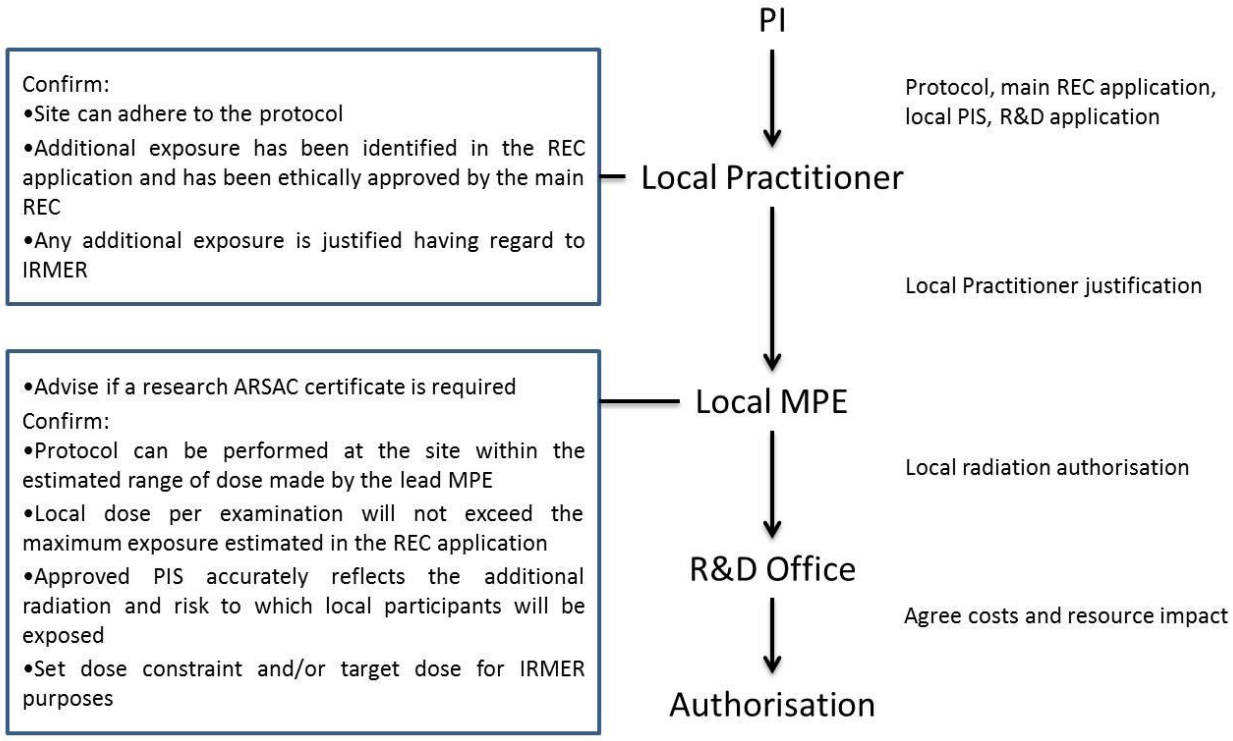
3 Procedure to Follow

Process for finalising protocol and obtaining favourable opinion from REC



Process for meeting local requirements and NHS permission

Local processes for internal authorisation should be followed – contact the R&D office. Consult local experts as early as possible.



4 Document Ratification Process

The review period for this document is set as ***default of three*** years from the date it was last ratified, or earlier if developments within or external to the Trust indicate the need for a significant revision to the procedures described.

This document will be approved by the ***RD&I Manager or their Deputy***.

Non-significant amendments to this document may be made, under delegated authority from ***a Senior RD&I manager***, by the nominated author. These must be ratified by ***a Senior RD&I manager***.

Significant reviews and revisions to this document will include a consultation with ***appropriately knowledgeable staff***. For non-significant amendments, informal consultation will be restricted to ***staff*** who are directly affected by the proposed changes.

Dissemination and implementation

4.1. Dissemination of this SOP

4.1.1. New SOPs and new versions of existing SOPs: The Research Governance Manager will be responsible for ensuring authorised SOPs are uploaded on the RD&I internet site. Internal Trust Staff are expected to use the RD&I internet site to access

latest versions of SOPs and to check the website regularly for updates.

Notice of new or amended procedural documents that have undergone a major amendment will be given *via* the following routes:

- Inclusion in the Trust weekly e-bulletin Vital Signs
- Direct email to Trust Researchers and or teams

4.2. Training in this SOP

4.2.1. All staff whose activities are subject to this SOP should ensure that they read and understand the content of the SOP.

5 Reference material

HRA website; Ionising radiation, resource page:
http://www.hra.nhs.uk/resources/before-you-apply/types-of-study/knowledgebase-ionising-radiation-2/

6 Amendment History

Version Number:	4.1
Date Of Amendment:	Jan 2019
Details Of Amendment:	Updated Trust and Dept. name; Reduce signature requiremer to single senior RD&I Manager.

Version Number:	4.0
Date Of Amendment:	Aug 2017
Details Of Amendment:	Updated Template and SOP numbering system. SO reviewed and updated.

Version Number:	3.1 (minor amendment)
Date of Amendment:	Mar 2012
Details of Amendment:	Cover page - Change of SOP location address.

Version Number:	3.0
Date Of Amendment:	Nov 2010
Details Of Amendment:	SOP redrafted and simplified in light of national IRAS guidance.