Radiation Exposures in Clinical Research: Oversight and Funding Guidance for Research Teams

Background

The management, oversight and safety of radiation exposures for research studies are overseen by a regulation (IRMER) and a licencing process in Nuclear Medicine (ARSAC). These are overseen in NuTH FT by the Nuclear Medicine/Radiology department and the Northern Medical Physics and & Clinical Engineering Directorates. This document explains the roles of each directorate, the staff involved and the funding/costing processes.

Key Staff/contact details

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Clinical Radiation Expert (CRE) / ARSAC Holder for Nuclear Medicine and PET Dr George Petrides george.petrides@nhs.net
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IRMER

IRMER Review

All research radiation exposures are required to comply with the ionising Radiation Medical Exposure Regulations 2017 (IRMER) as such they must have an estimation of the dose of radiation the patient will be exposed to, a maximum dose the patient can be exposed to and an assessment of risk (generally the risk of developing a fatal cancer in 10-15 years from the exposure) that can be explained to the patient in the Patient Information Leaflet. Prior to 2018 this followed a 2 tier system. Part B Section 3 of the IRAS form required completion by the MPE – IRMER and CRE. This central application was charged by the CRE and MPE to the Applicant and recovered in the grant.

Following this a local IRMER review for each site was carried out as a safety assessment to ensure the site exposure was able to be met by the equipment / procedures of the site.

In 2018 the HRA introduced a panel of central specialist IRMER reviewers with the intention (as with HRA central pharmacy review) that as part of the HRA/IRAS application radiation assurance will be carried out centrally to national standards, so that independent review at participating sites should be minimised to establishment of a dose constraint and adherence to local IRMER procedures. Currently this process has been introduced intermittently in cancer studies but no other disease sites and therefore the two tier review is still required.

IRMER Costs

The costs for HRA radiation assurance, which are charged by the CRE and MPE to the Applicant and may be recovered in the grant are:

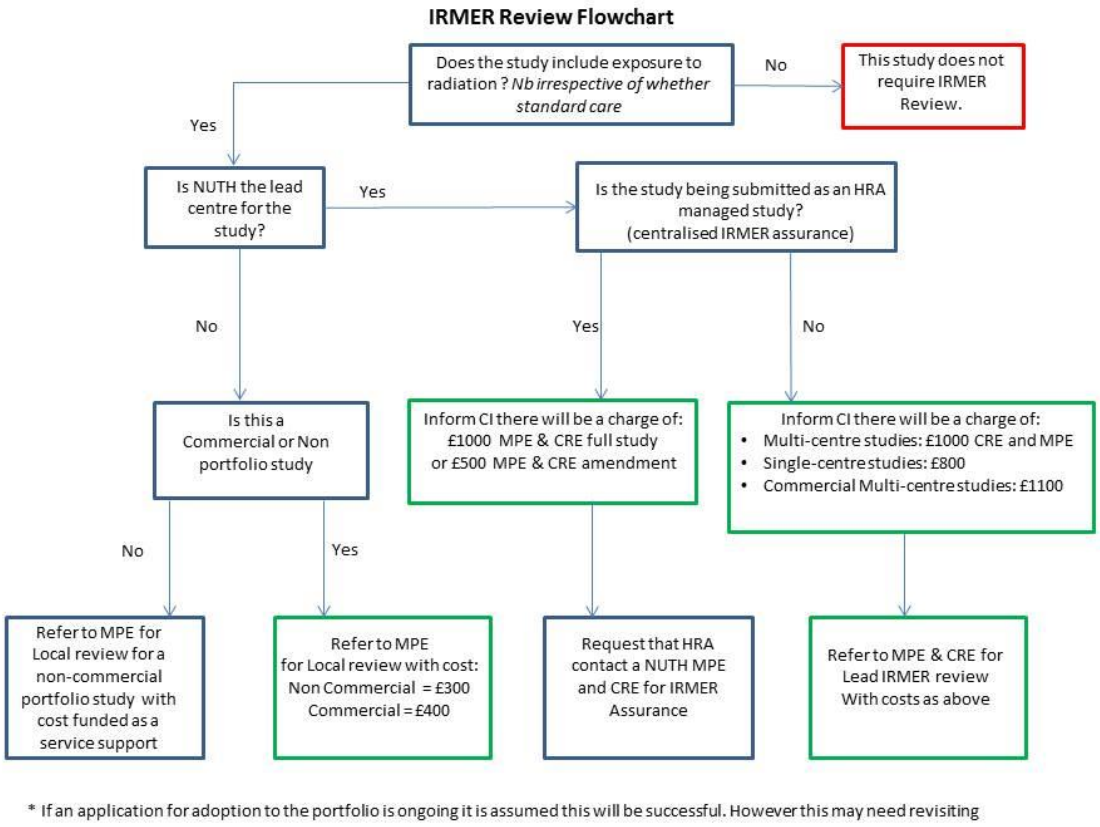
CRE review of new study: £500
MPE review of a new study: £500
CRE review of amended study: £250
MPE review of amended study: £250

The costs of CRE/MPE lead review for non-HRA managed studies, which are charged to the applicant and may be recovered in the grant are:

- Multi-centre studies: £500 MPE review and £500 CRE review
- Single-centre studies: £300 MPE review and £500 CRE review
- Commercial Multi-centre studies: £600 MPE review and £500 CRE review

The cost of local review for portfolio studies is 0.1 WTE IRMER MPE salary. For Commercial or non-portfolio work the costs are as follows:

- Multi-centre studies: £300
- Single-centre studies: N/A
- Commercial Multi-centre studies: £400



* If an application for adoption to the portfolio is ongoing it is assumed this will be successful. However this may need revisiting

ARSAC (Administration of Radioactive Substances Advisory Committee Licencing)

Introduction

ARSAC licences are a requirement under the IR(ME)R regulations 2017. They are required for all procedures which involve the administration of radioactive substances, e.g. bone scans, MUGAs, I-125 seeds implants, FDG PET scans etc. They are not required for procedures using external radiation, e.g. plain film X-rays, CT or external beam radiotherapy.

There are two types of ARSAC licences:

- An Employer licence - for the site at which the procedure will be carried out.
- A Practitioner licence - held by the clinician responsible for the administration.

Both of these licences must be held in order for the procedures to be carried out.
NuTH already has appropriate ARSAC licences in place which allow us to carry out commonly used procedures for both clinical and research purposes. ARSAC compliance will be confirmed as part of the Capacity and Capability Assessment within Nuclear Medicine.

In addition to the locally held licences above, all research studies which involve the administration of radioactive substances, must be approved by ARSAC. This process should be initiated by the sponsor using the Preliminary Research Assessment (PRA) form on IRAS. The research sponsor is then obliged to notify the Practitioner prior to any administrations taking place. It would be prudent for the NuTH trial coordinator to ensure this process has been carried out.

In cases where a novel tracer is used, the Trust may need to make an application to ARSAC in order to add the procedure to the licences. This process can take up to 6 weeks and will incur a cost.

Central ARSAC Costs

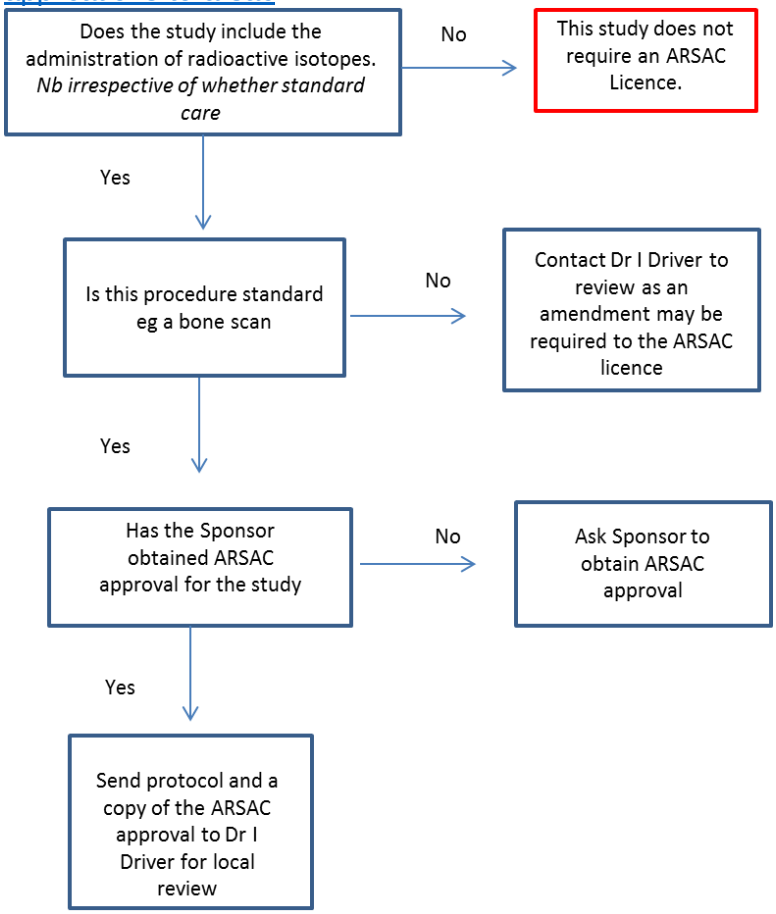
The Central review and issuing of a study licence by ARSAC costs:

- Multi-centre studies: £350
- Single-centre studies: £300
- Low-dose studies (<1mSv total participant dose): £200

In 2018 ARSAC changed so that the fee for the study licence is paid directly to ARSAC and can be recovered as a research cost in a grant.

If your study involves a nuclear medicine or PET scan that is not part of the trusts current ARSAC license there will be an additional charge (currently £200) to the nuclear medicine department independent of whether we are the lead site or not. This is the fee charged to the Nuclear medicine department for altering ARSAC licenses.

For further information on ARSAC when setting up a clinical trial and for up to date costs please refer to: https://www.gov.uk/guidance/how-and-when-to-submit-research-applications-to-arsac .



Local NM Study Costs

Studies containing Nuclear Medicine Investigations (Not PET)
The local review, oversight and management of the site ARSAC licence is carried out by the ARSAC holder and ARSAC MPE. For non-commercial portfolio studies this is funded as 0.1 WTE ARSAC MPE salary and within the 0.5 PA award for the CRE. For Commercial or non-portfolio work the costs are as follows:

- £300 – Single site local non commercial study
- £500 – Multicentre non commercial study
- £700 – Commercial study

Please contact Mrs Elizabeth Jefferson and Dr George Petrides for reviews.

NM per scan fees
If NM scans are part of a non commercial trial, the fees are as per the NUTH costings tool. If there are further sheets to be filled in, such as a response scoring sheet, a further fee may be applied as part of discussion. If NM scans are part of a commercial study please refer to the commercial costings template.

Additional Requirement for PET/CT and PET/MR

Central support and costs
PET requires additional assessments and costs as they are not performed by NuTH owned equipment. PET-CT is owned by ALLIANCE Medical and PET-MR by Newcastle University. If you require support for a research trial including this imaging please contact Dr George Petrides (ARSAC holder) george.petrides@nhs.net for support.

For trial set up there will be a PET support fee. This includes review of the protocol, ascertaining trial needs, ensuring ARSAC cover and establishing support. 2019 costs are as follows:

- £300 – Single site local non commercial study
- £500 – Multicentre non commercial study
- £700 – Commercial study

PET-CT scans
PET-CT scans are performed on the Alliance Medical Ltd PET-CT scanner at Freeman hospital. Alliance need to approve each research study that will use their scanner to ensure they can provide the standards needed. This will require trial protocols and imaging manuals to be shared with Alliance. If non disclosure agreements are needed these will need to be signed. Once protocols and imaging manuals have been reviewed by Alliance and the ARSAC holder (Dr George Petrides), an agreement will be signed between the trust and Alliance.

PET-CT per scan fees

If scans are part of a non commercial trial and are standard of care they can be performed on NHS tariff and are paid for centrally by NHS England. If they are in addition to NHS standard of care or part of a commercial trial, Alliance will give a price for performing a scan (currently £900 for a non commercial study and £1500 for a commercial study but these may vary depending on scan complexity and future negotiations).

In addition to the scan cost paid to Alliance, for each scan performed, the trust will charge a fee for report, storage and transfer. The costs for 2019 are £175 for non commercial studies (£100 report fee, £75 storage and transfer) and £350 for commercial studies (£200 report fee and £150 storage and transfer). This is payable to the trust radiology, not Alliance. For standard of care, non commercial trial scans, the reporting fee is included in the NHS tariff paid centrally by NHS England. If there are further sheets to be filled in, such as a response scoring sheet, a further fee may be applied and should be raised in support/costings discussions.

PET-MRI scans

PET-MRI scans are performed at the university CAV site. For costings and support please contact Dr George Petrides and civi@ncl.ac.uk.

If you have any queries, please contact Dr George Petrides or Mrs Elizabeth Jefferson on the emails above.