

**RADIOLOGY INFORMATION SHEET**

Radiology & Nuclear Medicine Department Guideline:  
Services for Clinical Trials

**1 SERVICES**

The Radiology & Nuclear Medicine Department provides services for research for departments across Alfred Health, AMREP, Monash University and external research institutions. Imaging modalities include:

- General x-ray,
- Computed Tomography (CT),
- Magnetic Resonance Imaging (MRI),
- Fluoroscopy,
- Ultrasound,
- Bone Densitometry (DEXA),
- Mammography,
- Angiography, and
- Nuclear Medicine and PET.

**1.1 'Radiology, Nuclear Medicine & Radiation Oncology Services' Form**

Please complete the 'Radiology, Nuclear Medicine & Radiation Oncology Services' Form. To provide you with the services you need, the Radiology and Nuclear Medicine Departments will need to know the imaging modality, how many subjects are expected, the frequency of visits, duration of the study and any other study specific requirements.

**1.2 Imaging Protocol**

A copy of your imaging protocol is essential. If your imaging protocol is different to the standard protocol used by the department it will be incorporated into the suite of protocols programmed into the appropriate imaging system. A meeting with the modality supervisor to discuss your imaging protocol should be arranged prior to the commencement of your study. The contact details will be forwarded to you.

**1.3 Submission of 'Radiology, Nuclear Medicine & Radiation Oncology Services' Form**

Please email your completed form to the Resource Centre Manager as specified at the top of page 1 after you have been allocated a HREC number. Submit your form to The Alfred HREC for the emailed submission.

The form will be signed by the Resource Centre Manager and returned to you and The Alfred HREC within 10 working days of receiving the completed necessary paperwork and the Medical Physicist's Report.

If you are using the Victorian Specific Modules (VSM) for your ethics application remember to also send section "1.40 Declaration by Head of Supporting Department" to be signed.

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Please note that all studies involving either diagnostic or therapeutic ionising radiation are to be reviewed by a Medical Physicist and a Section 4 (Use of Ionising Radiation Form) must be completed. Obtaining a report from a Medical Physicist should not be confused with completing the 'Radiology, Nuclear Medicine & Radiation Oncology Services' form. The Medical Physicist's report includes an assessment of the radiation dose and potential risks, whereas the 'Radiology, Nuclear Medicine & Radiation Oncology Services' form ensures provision of services when your study is undertaken. Further information on the Medical Physicist report and Section 4 is available on the [Radiation & laser safety](#) webpage.

**1.4 Request Form Templates**

You will also receive via email a customised Request Form Template for your trial. This requisition has the technical and billing information required for correct registration and imaging. It ensures that the correct imaging is performed on all your participants and it will specify whether the imaging should be bulk billed or charged to the trial.

Please note: even if the required imaging is standard of care there are trials where the Sponsor or Investigators require the imaging to be done differently to what is routinely done at Alfred Health. This technical information will be captured on your Request Form Template, so please ensure that you use it for all your participants, that is for both standard and additional to standard of care imaging. You will not be billed for standard of care imaging when you use the Request Form Template. The Template will specify if the imaging should be charged to the trial.

**1.4.1 Scheduling**

Every effort will be made to provide you with reliable scheduling for research procedures. Often designated days are set aside for research appointments. You can discuss streamlining your scheduling requirements with the modality supervisor. Using the customised Request Form Template will ensure that you will be contacted if any changes to your scheduling need to be made.

**1.4.2 Copies of Images and Reports**

Imaging at Alfred Health is digital. Copies of de-identified images on CD can be requested (DVDs are available on request from Nuclear Medicine). If you require the study name, participant and site ID number to be printed on the CD/DVD this will be included on your customised Request Form Template.

For reporting, please specify the number of reports you require and who they should be forwarded to.

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**1.5 Imaging Equipment**

Sponsors of clinical trials often require information regarding the type of imaging equipment that is available at the site. Any Site Survey Forms required by sponsors will be completed for you.

**2 FEES**

**2.1 Establishment Fee - \$350 (for funded trials), \$150 (for non-funded trials)**

The Establishment Fee covers the costs associated with:

- review of study protocol and imaging protocol
- incorporating your study specific imaging and reporting protocol
- training radiology staff of the study requirements
- coordination with investigators and/or meeting with sponsors
- completing site survey forms
- attending initiation meetings
- issuing a billing number
- issuing a study specific Request Form Template

Please note that separate Establishment Fees are applicable if both Radiology and Nuclear Medicine services are utilised.

**2.2 Imaging Fee**

The imaging required for a research study can be classified as either 'additional to standard of care' or as 'standard of care'. Imaging that is above standard of care will be billed to the trial.

In addition to the imaging, including that which is standard of care, you may require other trial specific services to be completed for compliance with the study protocol e.g. providing de-identified images, data dumps, specified reporting. These activities are additional to the standard procedures in radiology, they take time to complete and if required a fee will be calculated and charged to the study.

The imaging fee applies on a per image request basis, it is determined using the Medicare Benefits Scheme and the time required for any other study specific requirements. The fee will be specified on the 'Radiology, Nuclear Medicine & Radiation Oncology Services' Form when it is returned to you. Fees include but are not limited to:

- Copies of images on CD - \$22
- 3D reconstructions of images (1/2 hour of radiographer's time) - \$17.50
- Data dumps - \$35/hr

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**2.3 Other Fees**

If your research study requires additional services such as (but not limited to) RECIST reporting, baseline and/or quarterly Quality Control phantom scans and data dumps please indicate this on the 'Radiology, Nuclear Medicine & Radiation Oncology Services' Form and advise us as soon as possible so that the additional activities can be reviewed by the relevant modality to determine whether the trial's requirements can be resourced and then costed accordingly.

**2.4 Payment of Fees**

The invoice for the Establishment Fee will be processed upon completion of the Form by the Resource Centre Manager.

If the imaging for the study is additional to standard of care a trial-specific **Billing Number** will be included on the customised Request Form Template and an invoice will be sent to you or your Sponsor on a monthly basis.

If the imaging required is part of standard of care it will be bulk billed as per standard procedures. The cost of other study specific requirements will be calculated and the fees will be due either with the Establishment Fee or as they arise.

Please complete the shaded sections on the ICAN or ECAN (as appropriate) on the 'Radiology, Nuclear Medicine & Radiation Oncology Services' Form before submission for review, requests will not be processed if the information required is absent.

**3 CONTACT DETAILS**

Radiology Research Coordinator,  
Radiology Department,  
The Alfred, 55 Commercial Road, Melbourne 3004.  
Telephone: 03 9076 3606  
Fax: 03 9076 2153  
Email: [RadSafeRes@alfred.org.au](mailto:RadSafeRes@alfred.org.au)

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