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| |  |  | | --- | --- | |  | Department of Molecular Imaging & Therapy (MIT)  Austin Health  Level 1 Harold Stokes Building  145 Studley Road Heidelberg Victoria 3084  Telephone (613) 9496 5718  Facsimile (613) 9457 6605 |   **Clinical Trials – Department approval form, MIT**  This form cannot be processed without relevant sections being completed and required documents attached. The Signature of the Principal Investigator (PI) must be obtained AFTER the signed MIT department approval form is sent back to the requesting body. A copy of the approval form with the PI signature MUST be emailed back to [Kunthi.Pathmaraj@austin.org.au](mailto:Kunthi.Pathmaraj@austin.org.au) | | | | | | |
| **PART 1 – General Information (must be completed for all modalities)** | | | | | | |
| **DATE**: | | | | | | |
| Study Protocol submitted to department? (If no, please submit a copy along with this form) | | | | Yes | | No |
| **Study/Trial Title:** | | | | | | |
| Protocol Number: | | Ethics Number/Project Number: | | | | |
| Principal Investigator/ Study/Trial Coordinator: | | | | | | |
| Department/Institute – Please tick | | | | | | |
| Cancer Clinical Trials Centre | MIT Neuroscience Research | | Other Research - | | | |
| Contact Numbers: | | | | | | |
| E-mail Address: | | | | | | |
| SPONSORSHIP/FUNDING (Please Tick) | | | | | | |
| Pharmaceutical Company: | | | | Yes | No | |
| Other: (Please Specify) | | | | | | |

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| **SECTION A – PET : Oncology Scans** | | | | |
| Number of Patients: | |  | | |
| Number of Scans Per Patient: | |  | | |
| How many of these scans are SOC: | |  | | |
| Is there a study specific manual | | Yes  No | | |
| Is there a site specific technical form | | Yes  No | | |
| Is data transfer required | | Yes  No  CD burning cost $30 | | |
| Are there PET specific CRF’s to complete | | Yes  No | | |
| **Administrative Costs for trial start up:** $500 | | | | |
| **Cost of FDG PET scans:** | | | **Scan** | **Report** |
|  | **SOC scans** | | No Charge | No charge |
|  | **Above SOC scans**  **(Commercially sponsored)** | | $1500 | $350 |
|  | **Investigator Initiated** | | Trial dependent |  |
| **Cost of non-FDG tracers :** Specify tracer (cost will be specified depending on tracer) | | | | |
| Date of Study/Trial Commencement: | |  | | |
| Study/Trial Completion Date (estimate): | |  | | |

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| **SECTION B – Nuclear Medicine** | | | | | |
| Type of scan required: | | | Bone Scan  MUGA | | |
| Number of Patients: | | |  | | |
| Number of Scans Per Patient: | | |  | | |
| How many of these scans are SOC: | | |  | | |
| Is there a study specific manual | | | Yes | | No |
| Is there a site specific technical form | | | Yes | | No |
| Is data transfer required | | | Yes  CD burning cost $30 | | No |
| Are there Nuclear Medicine specific CRF’s to complete | | | Yes | | No |
| **Administrative Costs for trial start up:** $500 | | | | | |
| **Cost of scans:** | | **Scan** | | **Report** | |
|  | **SOC scans** | No Charge | | No Charge | |
|  | **Above SOC scans** | Dependant on type of scan required | | $350 | |
| Date of Study/Trial Commencement: | | | | | |
| Study/Trial Completion Date (estimate): | | | | | |

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| **SECTION C – BMD : DXA Scans** | | | | | | | |
| Type of scan required: | | BMD | | | | | |
| Number of Patients: | |  | | | | | |
| Number of Scans Per Patient: | |  | | | | | |
| DXA Exams Involved:  Please tick appropriately | |  | Lumbar Spine | | | | |
|  | Hip | | | | |
|  | Total Body | | | | |
|  | Forearm | | | | |
|  | VFA | | | | |
| How many of these scans are SOC: | | | Yes | | | No | |
| Is there a study specific manual | | | Yes | | | No | |
| Is there a site specific technical form | | | Yes | | | No | |
| Is data transfer required | | | Yes  CD burning cost $30 | | | No | |
| **Administrative Costs for trial start up:** $500 | | | | | | | |
| **Cost of scans:** | | | | **Scan** | | | **Report** |
|  | **SOC scans** | | | No Charge | | | No Charge |
|  | **Above SOC scans** | | | Internal studies | $100 | | No Charge |
|  |  | | | Non Austin studies | $150 | |
| Non Austin studies | $150 | |
| Date of Study/Trial Commencement: | | | | | | | |
| Study/Trial Completion Date (estimate): | | | | | | | |

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| Signature of Principal Investigator: |
| Signature of Principal Investigator: |

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| Please return this form to:  Kunthi Pathmaraj, Chief Technologist, Department of Molecular Imaging & Therapy [Kunthi.Pathmaraj@austin.org.au](mailto:Kunthi.Pathmaraj@austin.org.au)  Telephone: 9496 5712 |

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| **OFFICE USE ONLY** |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_  Prof Andrew M Scott  Scientific and Medical Director, Department of Molecular Imaging and Therapy  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_  Nicole Hosking  Operations Director, Radiology / Department of Molecular Imaging and Therapy |

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| Form returned to Principal Investigator Date: |