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| |  |  |  | | --- | --- | --- | |  | **Department of Molecular Imaging & Therapy (MIT)**  **Austin Health** Level 1, Harold Stokes Building145 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** |

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| **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.) | | | | | | Please Tick : Y 🞎 | | |
| **Study/Trial Title:** | | | | | | | | |
| Protocol Number: | | | | Ethics Number/Project Number: | | | | |
| Principal Investigator/ Study/Trial Coordinator: | | | | | | | | |
| Department/Institute – Please circle below | | | | | | | | |
| 1. Cancer Clinical Trials Centre | | 1. MIT Neuroscience Research | | | | | 1. Other Research | |
| Contact Numbers: | | | | | | | | |
| E-mail Address: | | | | | | | | |
| SPONSORSHIP/FUNDING (Please Tick) | | | | | | | | |
| Pharmaceutical Company: | | | | | | Yes 🞎 | | No 🞎 |
| If Yes, which company? Novartis | | | | | | | | |
| NH&MRC: | | | | | | Yes 🞎 | | No 🞎 |
| AHMRF: | | | | | | Yes 🞎 | | No 🞎 |
| Other: (Please Specify) | | | | | | | | |
| PART 2 – MODALITY SPECIFIC | | | | | | | | |
| If approval for PET Oncology scans is required, complete Section A  If approval for Nuclear Medicine scans is required, complete Section B  If approval for DXA scans is required, complete Section C | | | | | | | | |
| **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** | $1500 | | | | $350 | | | |
| **Cost of non-FDG tracers :** Specify tracer (cost will be specified depending on tracer) | | | | | | | | |
| Date of Study/Trial Commencement: | | |  | | | | | |
| Study/Trial Completion Date (estimate): | | |  | | | | | |
| **SECTION B – Nuclear Medicine** | | | | | | | | |
| Type of scan required: | | |  | | | | | |
| 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 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: | | |  | | |
| 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: | | |  | | |
| 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 | | |
| **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 | |
| Date of Study/Trial Commencement: | | | | | |
| Study/Trial Completion Date (estimate): | | | | | |
| Signature of Principal Investigator: | | | | | |
| **Please return this form to Kunthi Pathmaraj, Chief Technologist, PET, Dept of Molecular Imaging & Therapy (**[**Kunthi.Pathmaraj@austin.org.au**](mailto:Kunthi.Pathmaraj@austin.org.au)**; ext 5728)** | | | | | |
| **OFFICE USE ONLY** | | | | |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_ / \_\_\_\_\_ / \_\_\_\_  Prof Andrew M Scott, Medical Director, Scientific Director - P.E.T, Department Of Molecular Imaging and Therapy  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_ / \_\_\_\_ / \_\_\_\_  Colin Baker, Director of Radiology/ Department of Molecular Imaging and Therapy | | | | |
| Date this form returned to Principal Investigator: Date: \_\_\_ / \_\_\_\_ / \_\_\_\_ | | | | |

Version # 3

25th October 2016