**Imaging Facilities Application Form**

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| **Instructions**  For all projects please complete **Sections 1- 5** followed by the subsequent relevant section(s);   * + 1. **Section 6 for MR**     2. **Section 7 for PET**     3. **Section 8 for simultaneous PET-MR**     4. If you require **both** MR and PET please complete both **Sections 6 & 7**   Please return the completed application form, with a copy of the documentation listed below via email to either;  Sarah Wood ([sarah.wood@manchester.ac.uk](mailto:sarah.wood@manchester.ac.uk)) or Denise Ogden ([denise.ogden@manchester.ac.uk](mailto:denise.ogden@manchester.ac.uk))  If your study involves the development of a new tracer you will need to complete additional/separate forms. Please contact Sarah Wood or Denise Ogden on the email addresses above for advice. |

**Please attach the following documents to your application (documents marked with \* are mandatory). Please note that without all relevant attachments and full information in the application form the study cannot be submitted for review.**

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| **Document** | **Attached N/A** |
| \*Study Protocol |  |
| PET Imaging Manual (if available) |  |
| MR Imaging Manual (if available) |  |
| MR Protocol (if available) |  |
| \*Medical Cover Risk Assessment Form (see section 4) |  |

**Useful contact details**

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Role | Email | Telephone |
| Sarah Wood | Research Project Manager | [sarah.wood@manchester.ac.uk](mailto:sarah.wood@manchester.ac.uk) | 0161 275 0007 |
| Denise Ogden | Senior Project Manager | [denise.ogden@manchester.ac.uk](mailto:denise.ogden@manchester.ac.uk) | 0161 275 0017 |
| Barry Whitnall | Lead Radiographer (MR) | [barry.whitnall@manchester.ac.uk](mailto:barry.whitnall@manchester.ac.uk) | 0161 206 5845 |
| Eleanor Duncan-Rouse | Lead Radiographer (PET) | [eleanor.duncan-rouse@manchester.ac.uk](mailto:eleanor.duncan-rouse@manchester.ac.uk) | 0161 275 0052 |
| Amy Watkins | Lead Radiographer (PET-MR) | [Amy.watkins@manchester.ac.uk](mailto:Amy.watkins@manchester.ac.uk) | 0161 701 0955 |

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| **Section 1 – Project Details** |

**Project Title**

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**Is the study a Clinical Trial:**  Yes  No

**Imaging Facilities required:**

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| --- | --- |
| PET scanning |  |
| MR scanning |  |
| PET-MR scanning |  |

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| **Approximate start date of imaging** |  |

**Principal Investigator Details**

|  |  |
| --- | --- |
| Name |  |
| Address |  |
| Department |  |
| E-mail |  |
| Telephone |  |
| Main Employer |  |
| Do you hold an Honorary Contract with the University of Manchester | Yes  No  *If yes please confirm the start date and end date if applicable;* |

Do you have a clinical research fellow who will be working on this study: Yes  No

*If yes please complete their contact details below*

**Clinical / Research Fellow** **Details** *(if applicable)*

|  |  |
| --- | --- |
| Name |  |
| Address |  |
| Department |  |
| E-mail |  |
| Telephone |  |
| Main Employer |  |
| Do you hold an Honorary Contract with the University of Manchester | Yes  No  *If yes please confirm the start date and end date if applicable;* |

**Co-Applicants Details**

|  |  |  |
| --- | --- | --- |
| Name | Role | Email |
|  |  |  |
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**Sponsor Details**

|  |  |
| --- | --- |
| Organisation |  |
| Contact Name |  |
| Contact Email |  |

**Brief outline of the study** *(max 200 words)*

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| **Section 2 – Funding Information** |

**Please note that scanning costs will be provided/confirmed by the Imaging Facilities project management team upon receipt of this completed application form.**

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| --- | --- |
| **Have you secured funding for this study?** | **Yes  No** |

**2.1 If you have secured funding secured**

|  |  |
| --- | --- |
| Funder |  |
| Please provide the R code and task code (for internal UoM grants) | R code:  Task code: |
| If the funding is commercial, you will need to provide a Purchase Order or we will issue a Sales Order. Please provide a contact name, address and email (this is for invoicing purposes) | Contact name:  Address:  Email: |

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| **Section 3 – Participant Details** |

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| --- | --- |
| Type of study participants | Healthy Volunteers  Patients |
| If the participants will be patients;  please provide details of patients’ medical condition(s) |  |
| Please list all recruitment sites |  |
| Are there any health and safety issues related to this study or the participants being recruited |  |

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| **Section 4 – Medical cover** |

For all projects involving a PET or PET-MR scan a Risk Assessment is required to assess if medical cover will be required. If medical cover is required for the project the name of a medically qualified person must be provided below. Please complete the attached Risk Assessment Checklist and return it with this application.

Please note for all MR scans involving the administration of contrast medical cover will be required for the duration of the scan.

It is the responsibility of the study team to provide any medical cover deemed necessary during the internal review.

The named contact person is responsible for ensuring that **immediate medical assistance** is available for participants on scan days.

|  |  |
| --- | --- |
| Name |  |
| Email |  |
| Telephone |  |
| GMC registration number |  |

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| **Section 5 – Regulatory approvals** |

Please provide details of the named individual who will prepare and submit the necessary regulatory documents for the project including the documentation required for the Imaging Facilities sites

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| --- | --- |
| Contact Name |  |
| Contact Email |  |

|  |  |
| --- | --- |
| Please indicate if you would like support from the Imaging Facilities project management team | Yes  No  *Please note if you require support from the Imaging Facilities project management team for your submission an additional fee will be incurred.* |

Have regulatory submissions been made? Yes  No

*If yes please attach any approvals which have been granted and return it with this application.*

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| **Section 6 – MR Requirements** |

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| **Preferred clinical MR scanner** | 3T at MCRF  3T PET-MR at CMFT  1.5T at WMIC  3T at SRFT |
| Is the MR scanning protocol attached? If no please describe MR protocol to be used. | Yes  No |
| Will this project involve recruiting patients in cohorts? | Yes  No  *If Yes please indicate the number of cohorts and the number in each*  [ ] |
| Total number of participants to be scanned at the UoM Imaging Facilities **only** |  |
| Number of scans per participant (if this is different for separate cohorts please detail) |  |
| Number of phantom scans |  |
| Number of development scans |  |
| Scheduled time per scan |  |
| Total scan hours  *(N.B* *This should include any time to prepare the patient for the scan e.g. getting the patient on and off the bed , positioning and setting up any scanning equipment not just acquisition time)* |  |
| Expected number of scanning sessions per month *(approximately)* |  |
| Please indicate scan frequency requirements as per the protocol *i.e. Day 1, Week 5, every 8 weeks* |  |
| Are any contrast agents or medical gases required? |  |
| Are any special booking requirements?  *e.g. block-bookings, specific days of the week, short time window to scan* |  |

**Data Analysis Vendor**

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| --- | --- |
| Does the scanner need qualifying? | Yes  No |
| Data analysis vendor contact name |  |
| Data analysis vendor contact email (if available) |  |

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| **Section 7 – PET Requirements** | | | |
| **Unless specifically requested, all PET studies will be set-up for scanning on the PET-CT.**  **If you wish to request the use of the HRRT scanner, please indicate here and provide a justification for this request** | | |
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| **Tracer 1**  Name: | WMIC  Externally-sourced  *If the tracer will be supplied externally please provide the supplier name* [ ] *and the days that the tracer is available from the named supplier* [ ] | |
| **Tracer 2**  Name: | WMIC  Externally-sourced  *If the tracer will be supplied externally please provide the supplier name* [ ]  *and the days that the tracer is available from the named supplier* [ ] | |
| **Tracer 3**  Name: | WMIC  Externally-sourced  *If the tracer will be supplied externally please provide the supplier name* [ ]  *and the days that the tracer is available from the named supplier* [ ] | |
|  |  | |
| If your study is not commercial or an imaging manual is not available, have you discussed the project with a PET academic? | Yes  No  *If Yes please provide a contact name:* [ ] | |
| If no, please indicate if you would like support from the University’s imaging academics | Yes  No  *Please note if you require support from the University’s imaging academics for your submission an additional fee will be incurred.* | |
| ***Before any scanning can commence you will need to draft a Scanning Session Protocol (SSP) with Imaging Facilities Operational Staff.*** | | |
| Will this project involve recruiting patients in cohorts? | | Yes  No  *If Yes please indicate the number of cohorts*  [ ] |
| Total number of participants to be scanned at the Imaging Facilities **only** | |  |
| Number of scans per participant (if this is different for separate cohorts please detail) | |  |
| Number of phantom scans | |  |
| Total number of scans | |  |
| Expected number of scanning sessions per month | |  |
| Please indicate scan frequency requirements as per the protocol *i.e. Day 1, Week 5, every 8 weeks* | |  |
| Are any special booking requirements?  *e.g. block-bookings, specific days of the week, short time window to scan* | |  |

**Sampling and analysis requirements**

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| --- | --- |
| Venous sampling |  |
| Arterial sampling |  |
| Metabolite analysis |  |
| Other (please give details) |  |

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| Will samples be stored at WMIC? |  |
| What are the storage requirements? *E.g. -80°C freezer* |  |
| If yes, how many samples and for how long? |  |

*\*Please note due to HTA regulations, storage of cellular material only applies to NHS ethically approved projects. If you have any questions relating to cellular material please contact Alison Smigova* [*Alison.Smigova@manchester.ac.uk*](mailto:Alison.Smigova@manchester.ac.uk)

**Administration of Radioactive Substances Advisory Committee (ARSAC)**

Every research project using ionising radiation must be reviewed by the Administration of Radioactive Substances Advisory Committee (ARSAC). Each study will need both global (study wide) ARSAC approval and a WMIC site Research Certificate to be issued.

|  |  |
| --- | --- |
| WMIC ARSAC research certificate applicant |  |
| Contact Email |  |

Do you require the WMIC ARSAC certificate applicant to act as Clinical Radiation Expert for the study wide regulatory applications? Yes  No

**Data Analysis Vendor**

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| --- | --- |
| Does the scanner need qualifying? | Yes  No |
| Data analysis vendor contact name |  |
| Data analysis vendor contact email (if available) |  |

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| **Section 8 – Simultaneous PET-MR Requirements** |

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| **Tracer 1**  Name: | WMIC  Externally-sourced  *If the tracer will be supplied externally please provide the supplier name* [ ] *and the days that the tracer is available from the named supplier* [ ] | |
| **Tracer 2**  Name: | WMIC  Externally-sourced  *If the tracer will be supplied externally please provide the supplier name* [ ] *and the days that the tracer is available from the named supplier* [ ] | |
| **Tracer 3**  Name: | WMIC  Externally-sourced  *If the tracer will be supplied externally please provide the supplier name* [ ] *and the days that the tracer is available from the named supplier* [ ] | |
|  |  | |
| If your study is not commercial or an imaging manual is not available, have you discussed the project with a PET-MR academic? | Yes  No  *If Yes please provide a contact name:* [ ] | |
| If no, please indicate if you would like support from the University’s imaging academics | Yes  No  *Please note if you require support from the University’s imaging academics for your submission an additional fee will be incurred.* | |
| ***Before any scanning can commence you will need to draft a Scanning Session Protocol (SSP) with Imaging Facilities Operational Staff.*** | | | |
| Is the MR protocol attached? | | Yes  No | |
| If no please describe the MR protocol to be used; | | |  | | --- | |  | | |
| Are any contrast agents or medical gases required? | | Yes  No | |
| Will this project involve recruiting patients in cohorts? | | Yes  No  *If Yes please indicate the number of cohorts*  [ ] | |
| Total number of participants to be scanned at the Imaging Facilities **only** (if this is different for separate cohorts please detail) | |  | |
| Number of scans per participant | |  | |
| Number of phantom scans | |  | |
| Number of MR development scans | |  | |
| Total number of scans | |  | |
| Expected number of scanning sessions per month | |  | |
| Please indicate scan frequency requirements as per the protocol *i.e. Day 1, Week 5, every 8 weeks* | |  | |
| Are any special booking requirements?  *e.g. block-bookings, specific days of the week, short time window to scan* | |  | |

|  |  |
| --- | --- |
| Are you considering any sampling or analysis as part of this protocol *e.g. Venous sampling, arterial sampling* | Yes  No  ***Please note if you have answered YES this will require further discussion with Imaging Facilities operational staff*** |

**Administration of Radioactive Substances Advisory Committee (ARSAC)**

Every research project using ionising radiation must be reviewed by the Administration of Radioactive Substances Advisory Committee (ARSAC). Each study will need both global (study wide) ARSAC approval and a CMFT PET-MR site Research Certificate to be issued.

|  |  |
| --- | --- |
| CMFT PET-MR ARSAC research certificate applicant |  |
| Contact Email |  |

Do you require the CMFT PET-MR ARSAC certificate applicant to act as Clinical Radiation Expert for the study wide regulatory applications Yes  No

**Data Analysis Vendor**

|  |  |
| --- | --- |
| Does the scanner need qualifying? | Yes  No |
| Data analysis vendor contact name |  |
| Data analysis vendor contact email (if available) |  |

**Next Steps**

1. This application form and any supporting documentation you have attached will be reviewed internally by the Imaging Facilities within 21 days of receipt. During this review period, you may be contacted for additional information. If further information has to be requested from the study team the clock will stop on the review process until the information has been received.
2. All costs will be confirmed by the Imaging Facilities as part of this review process. We are unable to negotiate on the costs we provide.
3. If your project is approved by the Imaging Facilities, a full list of documentation required to set up the project at the scanning site(s) will be sent to you.
4. The study team will be required to attend operational set up meetings with Imaging Facilities staff during set-up and prior to launch to discuss scanning logistics.
5. If your study involves PET or PET-MR scanning, at this point you will need to liaise with members of the Imaging Facilities operational team to complete an SSP.
6. Once the project management team is in receipt of all required documentation and all operational arrangements have been confirmed, your project will be formally launched and scanning can commence.

**Things to note**

1. The Imaging Facilities are unable to provide any clinical report/scan readings.
2. The Imaging Facilities reserve the right to allocate studies to scanners based on availability and scheduling.
3. All studies are subject to a set-up fee which will be confirmed with the study teams at the point of costing.