Acknowledgement: Parkville Cancer Clinical Trial Unit (PCCTU)

YOUR UNIT NAME PROFILE

MONTH & YEAR

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YOUR UNIT NAME BACKGROUND

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| YOUR UNIT NAME PROVIDES | Investigators with expertise and experience in:   * 3- 4 dot points about your clinical trials expertise   Who else do you collaborate with?   * Who are your professional partners?   What do you specialise in?   * 3 – 4 points   What specific trials facilities do you have for patient care?   * XX treatment chairs * XX overnight night beds * Dedicated processing lab?   Do you have SiteDocs / Trial Docs or similar portal?   * An electronic investigator site file and an electronic source folder created in SiteDocs for each clinical trial, providing offsite monitor access   Do you have electronic medical records, eg. EPIC?   * Electronic medical record, with offsite monitor access to facilitate remote monitoring of patient source documents |

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| PRECINCT SERVICES | Is your unit part of a wider medical precinct or network? What resources do you have access to? Examples include:   * Shared pathology service * Clinical trials pharmacy * Imaging * Ophthalmology * Intensive Care Unit * Shared Electronic Medical Record * Specialty clinics |

YOUR UNIT NAME CONTACTS

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| INSTITUTION DETAILS | **Institution name**  **Address details**  **ABN:** | YOUR UNIT NAME DETAILS | **Address** Phone number:  Fax number:  **Postal Address**  **Supplies Address (Kits/ePROs/ECGs)** |

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| MANAGEMENT | **Director** Name  Email address  **Deputy Director** Name  Email address  **Manager** Name  Email address  **Deputy Manager**  Name  Email address  **Training and Development Manager** Name  Email address | SENIOR STAFF | Clinical Nurse Specialists etc. |
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| Feasibility | **Feasibility and Communications Specialist** Name  Email address  **Feasibility Coordinator** Name  Email address |

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| Specialty disease group Leads | | **Specialty name** Name  Email address  **Specialty name** Name  Email address |
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| SPECIALTY NURSING STAFF | | **Specialty name** Name  Email address  **Specialty name** Name  Email address | |
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EXPERIENCE

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| **Therapeutic Area** | What disease groups do you treat? |
| **Trial Phase Capabilities** | What phase trials are you able to conduct? |
| **Research Experience** | Commercially sponsored trials, investigator initiated? |
| **Patient Population** | What patient age range do you treat? |
| **Open and Recruiting Studies** | How many trial do you currently have open? |
| **Active and Follow-Up Studies** | How many trials are active or in follow up? |
| **Audit History** | What agencies have conducted audits at your site? |

QUALIFICATIONS

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| **Unit Policies** | YOUR UNIT NAME Standard Operating Procedures (SOPs) available on request / provided electronically? |
| **Staff Training** | * XXXX (or other TransCelerate accredited) GCP certification * Civil Aviation Academy Australia Safe Transport of Infectious Substances * Clinical Trials Essential Modules * YOUR UNIT NAME SOPs records available on request |
| **Specialist Clinical Trial Education and Training Program** | * Role specific competency frameworks * Interactive Learning Module System (LMS)? * Online interactive training modules for specific roles, including PIs * What other ongoing trial specific education do you provide to your staff? |
| **Curriculum Vitae** | YOUR UNIT NAME template CVs completed every two years, available on request / provided electronically? |
| **Medical Licences** | Available on [AHPRA website](https://www.ahpra.gov.au/) |
| **Staffing** | How do you to ensure staff medical cover? How should sponsors communicate with your site in an efficient way? |

FACILITIES

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| **Type** | Public / Private Hospital? |
| **Hours** | 24/7 Emergency Department?  24/7 Inpatient care?  Monday to Friday XX am to XX pm ambulatory care?  SAE notification out of hours business days is provided by? |
| **Government Affiliation** | Is your health service affiliated with a government department? |
| **Affiliated Clinical Trial Sites or Satellite Sites** | Who else is part of your healthcare network? |

INFORMED CONSENT

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| **Unit Policies** | SOPs available on request / provided electronically? |
| **Language** | How do you consent non-English speaking patients? What is your SOP? |

MONITORING

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| **Unit Policies** | SOP available on request / provided electronically? |
| **Onsite Monitoring** | SOP available on request / provided electronically? |
| **Onsite Facilities** | Access to EMR, computer, photocopier and phone? |
| **Bookings** | How frequently can monitors book in for site visits either in person or remotely? Who do they need to contact to make a booking? |
| **Offsite Monitoring** | Do you provide EMR remote access to electronic investigator site file? |
| **Co-monitoring / Multiple Days** | Who would approve extra monitoring requests? |

DOCUMENTATION

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| **Unit Policies** | Link to your unit SOP on Essential document management  Link to your Source data and essential document location form  Link to your Electronic medical record and Electronic site investigator Qualification form |
| **Unit Templates** | Do you have site specific templates?  Examples:  Investigator Site File Table of Contents  Delegation Log  CV Template  Trial Patient Alert contact details card |
| **Investigator Site File** | Where is the study specific electronic investigator site file available? |
| **Patient Source Data Location** | Link to your unit SOP on Essential document management  Link to your Source data and essential document location form |
| **EDC Capabilities** | Experience with Inform, Medidata Rave, Oracle, RedCap etc.? Are certificates available? |
| **Safety Reporting Procedure** | YOUR UNIT NAME endorses the NHMRC safety monitoring and reporting in clinical trials involving therapeutic goods guidance (2016)  Link to your unit SOP on management of safety information |
| **Archival Procedure** | Link to your SOP on Archiving |
| **Archival Facilities** | Name and address of where you store archival documents? |

INVESTIGATIONAL PRODUCT

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| **Investigational Product Comments** | How does your unit manage investigational product?.  How do sponsors contact your clinical rials pharmacy to arrange monitoring? | |
| **Contacts** | **Clinical Trial Pharmacy Manager** Name:  Email address:  Phone: | |
| **IV Infusion Capabilities** | Yes / No? | |
| **IP Storage** | Is it secure with controlled access? | |
| **IP Accountability** | How is IP reconciled and accounted for? | |
| **IP Shipment** | **Hospital name** Attn: Name Address:  Telephone number: |  |
| **Temperature Monitoring** | Room, refrigerator (2 to 8) and freezer (-20 and -80) temperature monitored? Where are records available? | |
| **Temperature Excursions** | Alarmed systems in the event of excursion? | |
| **Power Outage** | Department power outage or system failure plan in place? | |
| **Blinded IP Procedure** | Adequately staffed to perform blinded and un-blinded IP monitoring? | |
| **IP Destruction** | Link to your SOP on IP destruction | |

INVESTIGATIONAL PRODUCT ADMINISTRATION

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| **Main Treatment Area** | Where is treatment provided, how many chairs, beds, trained staff to administer treatments? |
| **Complex/Early Phase** | Do you have a dedicated trials treatment area? |
| **Overnight Admissions** | Where will patients be admitted for overnight stays? |
| **Emergency Equipment** | Do all treatment areas have full emergency equipment available (including crash cart)? |
| **ICU** | Where will patients requiring intensive care be treated? |

CONTROLLED SUBSTANCES

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| **Facilities** | Can controlled substances be handled at your site? |
| **Unit Policies** | Where can unit policies be found? |
| **Radio labelled IP** | Is this available and able to be safely managed at your site? |

GENETICALLY MODIFIED ORGANISM

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| **Facilities** |  |
| **Unit Policies** |  |
| **Requirements** |  |
| **Contacts** |  |

DIAGNOSTIC SERVICES

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| **Services** | YOUR UNIT NAME utilise the following diagnostic services:  Example text:   * *Imaging: CT, MRI, X-Ray* * *Nuclear medicine: MUGA, Bone Scan, CT/PET* * *Ultrasound* * *Cardiac: ECG, ECHO, Holter monitoring, Angiogram* * *Ophthalmology* * *Fresh tumour biopsy* * *Is your facility able to provide central review?* |
| **Contacts and Capabilities** | Provide detailed information about CT, PET, MRI machine capabilities |

lOcal pathology

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| **Local Pathology Comments** | Describe how samples are processed at your site. Are they in-house or out-sourced to another provider? |
| **Address** | Address of site Pathology |
| **Accreditation** | NATA and Medicare? |
| **Reference Ranges** | Where these are available? – provide link. |

CENTRAL Pathology

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| **Location** | YOUR UNIT NAME dedicated laboratory for central sample processing and shipping |
| **Pick Up Address** | Attn: YOUR UNIT NAME  Address |
| **Hours** | Monday to Friday XX am to XX pm  Same day collection available?  Can out of hours samples be performed and processed? |
| **Kit Storage** | Secured PK kit room with controlled access? |
| **Staff** | YOUR UNIT NAME Laboratory Staff, per SOP available on request or through SiteDocs |
| **Equipment** | Refrigerator, -20 and -80 freezers?  Ambient and refrigerated centrifuges?  Dry ice and liquid nitrogen available for snap freezing? (couriers to provide dry ice for shipping) |
| **Temperature Monitoring** | Where are these documents available? |
| **Temperature Excursions** | Alarmed systems in the event of excursion? |
| **Power Outage** | Department power outage and system failure plan in place? |
| **Accreditation** | How is the laboratory accredited – via the hospital or company? |
| **Calibration** | Describe who is responsible for calibration and how often this is done. |

EQUIPMENT

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| **Sponsor Supplied Equipment** | YOUR UNIT NAME can utilise sponsor supplied equipment such as; electronic quality of life tablets, ECG machines, halter monitors etc.  Example text:  *Sponsor supplied equipment must comply with Australian electrical standards and be supplied with a function, electrical safety and factory calibration test reports. Any equipment, which require plug adapters are not permitted.*  *Our physical sciences department will test and calibrate all equipment prior to the site initiation visit; therefore, all equipment should arrive at site at least one week prior. Calibration will occur annually thereafter.* |
| **Hospital Equipment** | Example text:  *The physical sciences department annually service and calibrate hospital patient monitoring and observation equipment (i.e. scales, ECG). Service and calibration processes and records are audited as part of hospital accreditation. This database is not accessible for routine monitoring.* |

Study Start-Up

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| **Start-Up Contacts** | **Name, Feasibility and Communications Specialist** Email address:  Phone: |
| **Ethics and Governance Submission Department** | Do you process your own ethics and governance or out-source to another provider (eg. Cancer Trials Australia)?  Provide details.  Example text:  *Cancer Trials Australia (CTAus) undertake the Site management of YOUR UNIT NAME clinical trials, including administrative components of ethics and governance submissions, budget and contract negotiations and financial operations on behalf of the principal investigator. CTAus are engaged three weeks prior to ethics submission to begin ethics / governance preparations* |
| **Ethics & Governance Contacts** | **Name, Position**  Email address:  Phone: |
| **Ethics and Budget / Contracts Contacts** | Example text:  *The Ethics and Governance Submission Specialist (ESS) and Budget and Contracts Specialist are allocated three weeks prior to ethics submission, governance slot. At that time, the feasibility coordinator will provide CTAus contacts.* |
| **Timelines** | Provide your unit timelines.  Example text:   * *Median start-up timelines is 90 days from ethics submission to site initiation visit* * *First in human clinical trials prioritised to open (must meet YOUR UNIT NAME requirements) have a median timeline of 55 days from ethics submission to site initiation visit* * *Average timelines for participating submissions are dependent on the lead site / sponsor engagement* * *Timelines are impacted by amendments, delay of sponsor documents and communication between CRO and global sponsor. To avoid unnecessary delays ensure all relevant documents (listed below under submission documents) are made available in allocated timeframes and ensure open timely communication with site about upcoming or potential amendments* |
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| **Ethics Committee** | Provide details of your ethics committee |
| **Governance Office** | Provide details about your local Research Governance Office |

ETHICS

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| **Name** | Name of ethics committee |
| **Address** | Address |
| **Website** | [Website](http://www.petermac.org/research/doing-research-us/ethics-governance) |
| **Registration Body** | NHMRC (registered and certified) |
| **Registration Number** | Provide Ethics committee number |
| **Type** | Central and local? |
| **Relevant Registration Categories** | Clinical trials phase 0, I, II, III, IV? Clinical trials drugs and devices? Adults, 15 years up? |
| **Meeting Frequency** | Provide frequency, eg. monthly |
| **Other Review Boards** | Example text:  *Scientific review / Clinical Research Committee (CRC) part of ethics review*  *Clinical trials that will be administering investigational product to humans for the first time require an expert review or FDA IND safe to proceed letter equivalent. Expert review can be arranged through the feasibility coordinator and CTAus.*  *Clinical trials involving the use of genetically modified organisms (GMOs) require review by the local Institutional Biosafety Committee (IBC). This includes both exempt dealings and new clinical trials which are already covered by a DNIR Licence issued by the Office of the Gene Technology Regulator (OGTR)* |
| **Payment** | Payment required prior to submission / prior to release of final documents? |
| **Safety Reporting Policy** | [Provide](http://www.petermac.org/research/doing-research-us/ethics-governance/useful-resources-training-forms) link to hospital safety policy or detail where it can be sourced. |
| **CTN Details** | Contact Officer:  Position: Ethics Coordinator Email address  Phone: |
| **Approving Authority Name** | Institution name Contact Officer:  Position: Manager, Human Research Ethics & Governance Email address  Phone: |

ETHICS DEADLINES

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| **Committee** | **Documents Provided By** | **HREC Submission** | **HREC Review** |
| **Committee name** | **Date** | Date | Date |
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\* Earlier or later date due to public holiday

Submission Documents

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| **Documents Required for Lead Multi-Site and Single Site Submission** | **Example text (recommended inclusions):**  **Documents to be provided 3 weeks prior to ethics submission:**   * Final Protocol * IBs * Draft PICFs in NHMRC template * Number and names of participating sites (for multi-site submission only) * Reason for non-NMA submission if other NHMRC registered ethics committee is submitting other site(s) * Where IBC review is required, confirmation of submission to IBC * For FIH trials, confirmation of expert review / IND status   **Documents to be provided prior to ethics submission:**   * Patient related materials i.e. dosing diary, patient cards etc. * Standard Indemnity * HREC Indemnity (for multi-site submission only) * Certificate of Insurance * Draft HREA * Draft Budget/CTRA * Draft CTN * Pharmacy manual (final draft acceptable) * Lab manual (final draft acceptable) * Other manuals as required (final draft acceptable) |
| **Documents Required for Participating Site Submission** | **Mandatory Documents:**   * Final Protocol * IB’s * Draft Budget/CTRA * Pharmacy manual (final draft acceptable) * Lab manual (final draft acceptable) * Other manuals as required (final draft acceptable) * Where IBC review is required, confirmation of submission to IBC   **Documents to be provided as soon as available:**   * HREC Indemnity * Standard Indemnity * Certificate of Insurance * CTN * HREC approval letter(s) * HREC approved documentation (including transfer from Sponsor of HREA, VSM etc.) |