

PROCEDURE

Research Management - PowerTrials Electronic Medical Record Research Support Module

PR2017/118
Version No. 1.0

PURPOSE

The Metro South Hospital and Health Service (Metro South Health) is committed to the highest standards and practices in the assessment, authorisation, oversight and conduct of research. This Procedure identifies a consistent and mandatory electronic management processes for research being conducted in or in collaboration with Metro South Health.

OUTCOME

Adherence to this Procedure will ensure all research conducted within Metro South Health or in collaboration with external entities, is of the highest ethical and scientific standard and is compliant with relevant legislation, standards and guidelines.

This Procedure applies to:

- All Metro South Health employees who conduct human research within or in association with Metro South Health facilities, or through access to Metro South Health participants; and
- All personnel (including researchers, students and visitors) involved in all aspects of human research in or in association with Metro South Health.

Failure to comply with this Procedure may amount to research misconduct on the part of the responsible individual. This Procedure must be read in conjunction with other Metro South Health Research Management Procedures.

KEY PRINCIPLES

The following key principles guide Metro South Health research in the PowerTrials - Electronic Medical Record (EMR) research support module.

- Metro South Health must ensure all research undertaken by Metro South Health employees, or within Metro South Health facilities, is conducted in accordance with the National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research 2007 ("National Statement"), Australian Code for the Responsible Conduct of Research and the Queensland Biotechnology Code of Ethics (where applicable).
- Metro South Health is committed to supporting the EMR and digitalised hospital initiative which enables patient's medical records to be available in an electronic format.
- Only research projects with Metro South Health Human Research Ethics Committee (HREC) and Site Specific Assessment (SSA) approvals will be built into the PowerTrials EMR system.

- Information relating to a research project will only be available within the patient's chart after the participant has been enrolled on a research project and therefore provided formal participation consent.
- Metro South Health is supportive of improved access for clinicians and researchers to study information which supports participant safety, streamlined recruitment, efficient documentation and access.
- Metro South Health is supportive of researchers and clinicians having visibility of existing research projects at Princess Alexandra Hospital and utilising pre-screening within PowerChart to assess whether their patients are suitable candidates.
- Researchers may utilise the EMR system to determine which patients may be suitable for a research project, and liaise directly with the clinicians who are caring for those patients.

LEGISLATION OR OTHER AUTHORITY

Legislation

- *Hospital and Health Boards Act 2011 (Qld)*
- *Information Privacy Act 2009 (Qld)*
- *Public Health Act 2005 (Qld)*
- *Therapeutic Goods Act 1989 (Cth)*
- *Statutory Bodies Financial Management Act (1982)*

Regulation

- Hospital and Health Boards Regulation 2012
- Information Privacy Regulation 2009

Statements, Papers and Guidelines

- National Health and Medical Research Council (NHMRC):
 - [Australian Code for the Responsible Conduct of Research 2007](#)
 - [National Statement on Ethical Conduct in Human Research \(2007\) - Updated May 2015](#)
 - [Guidance: Safety monitoring and reporting in clinical trials involving therapeutic goods](#)
 - [Values and Ethics - Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research 2003](#)
 - [Research Governance Handbook: Guidance for the national approach to single ethical review 2011](#)
- Therapeutic Goods Administration: [Note for Guidance on Good Clinical Practice \(CPMP/ICH/135/95\) 2000 - Annotated with TGA Comments](#)

Metro South Health Policies, Procedures, Manuals, Frameworks etc.

- [PAH - Confidentiality of Patients, Staff and Organisational Information \(60008/v7/07/2016\)](#)
- [Contract Management Framework](#)
- [Finance Management Practice Manual \(FMPPM\)](#)
- [Integrated Risk Management Framework](#)
- [Management of Conflict of Interest - All Staff Procedure \(PR2016-66\)](#)
- [Management of Conflict of Interest Policy \(PL 2014/0038\)](#)
- [Research Biorepositories Policy \(PL2017/53\)](#)

- [Risk Assessment Guide \(V12 6-11-2013\)](#)
- [Risk Management Policy \(PL2013-06\)](#)
- [PowerTrials - Access WBT](#)
- [PowerTrials - Create PowerPlan](#) [PowerTrials - Create Pre-Screening Rule](#)
- [PowerTrials - Locate Research Documentation](#)
- [PowerTrials - Message Centre Alert](#)
- [PowerTrials - Navigate Clinical Research Tab](#)
- [PowerTrials - POM - Associate Documents](#)

RESPONSIBILITIES

Executive Management Team

Ensure collaborative, harmonised, clear and detailed publicly available Policies and Procedures are in place for the ethical, scientific and governance review of research of all research conducted within Metro South Health.

Centres for Health Research

Update Metro South Health research compliance documents in accordance with Metro South Health requirements. Provision of secretariat/administrative support to maintain and uphold principles outlined in the [Metro South Health Research Management Policy](#) and related Procedures. Complete due diligence by ensuring adherence to legislative and institutional policy requirements and recommend authorisation by the Metro South Health Chief Executive Officer or delegate as appropriate.

Metro South Health Chief Executive Officer or Delegate

Provide authorisation on research applications and contracts according to the Metro South Financial Delegation Schedule and the Contract Management Framework.

Principal Investigators/Research Team

Conduct research in accordance with national guidelines and the Metro South Health Research Management Compliance Framework. Ensure research practices reflect current professional (ethical and legal) standards for research, including promptly responding to reporting and monitoring requirements. Ensure compliance with the approval given by a Human Research Ethics Committee (HREC), legislative and Policy requirements for participant contact, consent and confidentiality of patient information.

Only conduct clinical intervention studies with the essential approved credentialing privileges and clinical experience. Adhere to all relevant Policies, Procedures, Research Protocols and Standard Operating Procedures (SOPs) when conducting research.

Departmental Directors/Clinical Trial Coordinators

Responsible for reviewing research projects within their departments separate to the Metro South Health Research Governance (Monitoring) process outlined within [Research Governance \(Monitoring\) Procedure \(PR2017/117\)](#).

All Metro South Health Employees

Are required to be aware of and comply with this Procedure when conducting research.

SUPPORTING DOCUMENTS

Attachments

Attachment 1 - [Application](#)

Forms

[MSF11 Notification of Commencement Form](#)

[Metro South Research Contracts Approval and Study Execution Form](#)

PowerTrials Application Form: Data Collection Worksheet

Application for an Exemption Form

DEFINITIONS

See the [Metro South Health Research Management Glossary](#)

PROCEDURE - POWERTRIALS ELECTRONIC MEDICAL RECORD RESEARCH SUPPORT MODULE

Step 1: Human Research Ethics Committee (HREC) and Site Specific Assessment (SSA) Approval

Only research projects that have both Metro South Health HREC approval and Site Specific Assessment (SSA) authorisation will be built within the PowerTrials Research Support Module.

Step 2: Submit Research Project for PowerTrials Build

All research projects occurring within Metro South Health must complete a 'minimal build' or 'full build' in PowerTrials. Researchers are encouraged to consult with the Metro South Health Research Governance Manager via email PAH-Research@health.qld.gov.au to ascertain if a 'minimal build' or 'full build' is required.

Step 3: Application for Exemption

In certain circumstances some research projects may be exempted from uploading the research project into the PowerTrials Research Support Module. Researchers are encouraged consult with the Metro South Health Research Governance Manager via email PAH-Research@health.qld.gov.au to ascertain if a research project may be excluded.

If exclusion is supported the Metro South Health Research Governance Manager may request a researcher complete an [Application for An Exemption Form](#). Research projects that have met the exclusion criteria must adhere to Site Specific Assessment (SSA) process and must notify the PowerTrials Support Team of formal authorisation.

Step 6: PowerTrials Build

Following formal notification of authorisation by the Metro South Health Research Governance Manager the PowerTrials Support Team will enable access to allow researchers to build within the PowerTrials Research Support Module. Researchers must be mindful of the confidentiality of patient, staff and organisational information in accordance with relevant Metro South Health Policies and Procedures.

Step 7: Activation of Study with PowerTrials

Upon receipt of the Site Specific Assessment (SSA) Authorisation letter, the PowerTrials Support Team will activate the study within PowerTrials allowing the research team to commence recruitment and enrolment of participants onto their research project.

Step 8: PowerTrials Monitoring

The PowerTrials Research Support Module enables the Metro South Health Research Monitoring Office/r to periodically monitor research projects. Please see [Research Governance \(Monitoring\) Procedure \(PR2017/117\)](#) for more information regarding this process.

PROCEDURE DETAILS

Procedure Number

PR2017/118

Procedure Name

Metro South Health Research Management -
PowerTrials - Electronic Medical Record
Research Support Module Procedure

Policy Reference

PL2017/55

Metro South Health Research Management
Policy

Supersedes

Nil

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Approving Date

30 June 2017

Effective From

30 June 2017

Date of Last Review

30 June 2017

Date of Next Review

30 June 2020

1.0 PowerTrials

The Princess Alexandra Hospital (PAH) is a fully digitalised hospital with all patients' medical records now available in an electronic format. PowerTrials is the Electronic Medical Record (EMR) research support module that was released in March 2017. Consequently, all research activities that involve Princess Alexandra Hospital patients and their medical records are to be conducted via PowerTrials.

1.1 Benefits of PowerTrials

PowerTrials includes a variety of benefits for researchers and Metro South Health. It supports and strengthens clinical trial activity by ensuring research project information is available to support clinical decisions leading to strengthened communication between clinicians and researchers.

In relation to patient safety, PowerTrials ensures:

- Clinicians have access to research project information at the point of care and therefore can take research project information into consideration when caring for the patient.
- A patients' involvement in a research project can be quickly identified in the event of an adverse event of presentation to the Emergency Department.
- If a participant on a clinical trial comes in to the Emergency Department, clinicians can see the research project's information on the patient's record; and the presentation of the participant to the Emergency Department is automatically communicated to the research project contact or Clinical Trial Coordinator.
- Customised protocol specific PowerPlans built for research projects at the Princess Alexandra Hospital set out the complete plan for a patient's participation in a research project.

PowerTrials also impacts on streamlining research project recruitment:

- The process of identifying and recruiting patients as participants for research projects utilises electronic data rather than manual processes to gather and analyse patient information.
- Researchers can utilise PowerTrials to determine which patients may be suitable for a research project, and liaise directly with the clinicians who are caring for those participants.
- Clinicians have better visibility of existing research projects within the Princess Alexandra Hospital and can use pre-screening within PowerChart for assess whether their patients are suitable candidates.

Efficient research project documentation and access is also improved through/by:

- Ensuring the documentation of research information is clearly visible in PowerTrials for participating patients, providing more efficient access to research information for clinicians when treating those patients.
- Easier and faster access to clinical trial documentation is provided to external auditors who conduct reviews to verify trial findings and outcomes for the trial sponsors
- Improved ability for researcher to generate reports on research projects being conducted at the Princess Alexandra Hospital.

1.2 PowerTrials Research Support Module Acronyms

The PowerTrials Research Support Module utilises specific acronyms. Below is a list to assist researchers in interpreting to electronic system:

Acronym	Meaning
CHR	Centres for Health Research
DCW	Data Collection Worksheet
EMR	Electronic Medical Record
Full Build	All high risk interventional research projects will be required complete PowerTrials 'Full-Build' along with the design of a PowerPlan and Pre-screening Rule.
GCP	Good Clinical Practice
HREC	Human Research Ethics Committee
MARS	Medication, Anaesthetics and Research Support
Minimum Build	Research projects classed as low risk or observational will only need to complete a PowerTrials 'Minimum Build' and have the option to utilise a PowerPlan and/or Pre-screening rule.
Mnemonic	Unique name of that protocol (Please follow your facility naming conventions)
NHMRC	National Health and Medical Research Council
Opt-Out	Research projects that are exempt from being built into the PowerTrials module meeting specific criteria
PAH	Princess Alexandra Hospital
PI	Principal Investigator
PICF	Participant Information and Consent Forms
Patient Protocol Manager (PPM)	The research module used for the management of all participants involved in a research project. This includes; pre-screening, managing referrals, enrolments and editing participant enrolment statuses (off treatment/off study).
Protocol	Document that describes the research project and how it is to be conducted
Protocol Office Manager	Protocol Office Manager (POM) is used for the creation of the electronic research protocol. It also houses all the research project documentation, research roles, milestones and amendments. All data entered into the PowerTrials modules must reflect the most recently approved ethics documentation.
R4 Auditor	R4 Auditor clinical roles have the ability to set a patient's/participant's interest in pre-screening status within PowerChart when advised of a change from the participant.
RGM	Research Governance Manager
SNOMED	SNOMED codes
SOP	Standard Operating Procedure
SSA	Site Specific Authorisation

2.0 PowerTrials System Requirements

2.1 Build Requirements

The Metro South Health [Risk Management Policy \(PL2013-06\)](#), [Integrated Risk Management Framework](#) and [Risk Assessment Guide \(V12 6-11-2013\)](#) will be used to determine the level of risk of the research project.

All research projects that are considered as high risk and are interventional in nature are recommended to complete the 'full build' of the protocol within the PowerTrials. The implementation of full build requirements will be introduced in a phased manner in 2017 and 2018.

Planned Mandatory 'full build' requirements include:

- PowerTrials Application Form (DCW);
- Research Protocol;
- Research Protocol Summary;
- Participant Information Sheet and Consent Form (PICF); and
- Other project related documents as required

Research projects which are classified as low risk or observational are able to enter research project specific information as required within the Protocol Office Manager (POM) and have the option to utilise the use of a PowerPlan and/or Pre-screening rule. For any technical assistance during this process, researchers must contact via email PowerTrialsSupportPAH@health.qld.gov.au.

2.1 Creation of a PowerTrials Protocol

All approved research projects being undertaken in Metro South Health must be built into PowerTrials as a 'protocol' unless 'Opt-Out' approval has been provided by Metro South Health Research Governance Manager. Mandatory requirements the PowerTrials creation/build includes ensuring:

- Participant Information and Consent Forms (PICFs) and research project summaries are uploaded against the protocol in PowerTrials.
- Each research project has a coordinating institution, Principal Investigator and Clinical Trial Coordinator assigned within the roles. All roles assigned to the protocol must be approved by a HREC.
- A position is never assigned to any role given within the Protocol Office Manager (POM).
- A research project contact is identified for every protocol created within PowerTrials. It is recommended that this is an active member of the research team.
- Research project milestones are included in the protocol such as:
 - site notification date;
 - applications received (Governance Committee);
 - approved HREC and Site Specific Assessment (SSA) applications received (this milestone must only be completed once approval to conduct the research project has been received from HREC);
 - open HREC and Site Specific Assessment (SSA) applications submitted (Governance Committee);
 - HREC and Site Specific Assessment (SSA) applications submitted to HREC; and
 - HREC and Site Specific Assessment (SSA) to Accrual (this milestone must only be completed once approval to conduct the research project has been received).
- The creation of a protocol is only be completed by the Principal Investigator, Clinical Trial Coordinator or an approved delegate.
- The addition of a visiting auditor/monitor role is done only on a temporary basis and removed when no longer needed.
- All visiting auditor/monitors have completed the required training in MARS prior to being given access to PowerTrials.

- All visiting auditor/monitors are given R4 Auditor access within the EMR on a temporary basis only and must be cancelled once monitoring has been completed.

1.3 Creation of Research PowerPlans

Research PowerPlans will become mandatory for research projects considered high risk interventional, in a phased approach through 2017 and 2018. Any research project considered low risk or observational, the creation of a PowerPlan is optional. This will be indicated to the research team when applying for the Site Specific Assessment (SSA) approvals. The inclusion criteria matrix for PowerTrials builds will also guide research teams as to whether this needs to be completed for their research projects. The following points must be considered when using research PowerPlans:

- At this time, research pathology orders will not be completed within a research PowerPlan and must remain on paper. Any standard of care pathology can continue to use electronic ordering.
- The Principal Investigator or an approved delegate must order and plan any PowerPlans containing prescribing orders, such as trials medication, radiology and diagnostic Imaging.
- The research PowerPlan is a cross encounters PowerPlan and will sit across all encounters created for the participant.
- Hard and soft stop functionality maybe selected when creating the research PowerPlan. The hard stop functionality will not allow a research PowerPlan to be ordered on a participant who is not enrolled on the associated research project. The soft stop functionality will alert the user to that the participant is not enrolled in the associated research project and allow the user to select an override reason to continue ordering the PowerPlan.
- All PowerPlans with trial medications or devices are recommended to have a hard stop in place for increased safety when ordering.
- The creation of research PowerPlans must be designed by the Principal Investigator or an approved delegate.
- The PowerPlan must be designed in alignment with the HREC approved schedule of events.
- The naming convention for PowerPlans must follow the research naming of; Research-Institute-Protocol mnemonic.
- All existing research projects that will be built into PowerTrials as a part of the backlog build will not have a PowerPlan built for the research protocol.

2.2 Amendment of a PowerTrials Protocol

All research project amendments must be completed within Protocol Office Manager (POM). The following activities must be completed for any protocol amendments:

- complete the required amendment within the PowerTrials protocol;
- complete the amendment milestone;
- if required, transfer any participants needing to be moved onto the new protocol amendment;
- all data entered must reflect the newly HREC approved Research Protocol; and
- any protocol changes must not occur until all required ethics approvals have been received.

2.5 Suspending a PowerTrials Protocol

The suspension of a research project can be for an adverse event, or a change in circumstances. The following processes must be completed:

- Suspensions must be completed with the approval of the Principal Investigator and can be completed by the Principal Investigator, Clinical Trial Coordinator or an approved delegate.

- The suspension milestone must be completed in order to temporarily suspend a protocol.
- For therapeutic studies any participant with an active enrolment on the suspended research project must be taken 'Off Study'. For non-therapeutic studies the participants must be taken 'Off Study' temporarily.
- Once the research project has been cleared to continue, the reactivation process will need to be followed.
- If the research project needs to be closed or discontinued to complete protocol process will need to be followed.

2.7 Reactivating a Suspended PowerTrials Protocol

If a research project has been suspended for any reason and cleared to continue, the researcher must complete the reactivation milestone to re-open the research project for treatment and/or recruitment. The reactivation of a research project must not be completed until the Principal Investigator or an approved delegate gives the approval to do so. If any amendments are required, the protocol amendment process must be completed prior to reactivating the protocol. Please see Protocol amendments section within this document. All participants that were taken 'Off Treatment' or 'Off Study' must be placed back 'On Study'.

2.3 Completing a Research Project in PowerTrials

Completing a research project is documented within Protocol Office Manager (POM). Whether this is done for the reasons of early termination or research project completion the workflow remains the same:

- The corresponding milestone must be completed; and
- All active participants must be taken 'Off Study' within Patient Protocol Manager (PPM) unless remaining on for follow up, in this case the participant is only taken 'Off Treatment' (therapeutic studies only), until the end of the follow-up period.

2.4 PowerTrials Reports

There are standard reports available to the researchers within Protocol Office Manager (POM) and Patient Protocol Manager (PPM). These reports will provide information regarding the progress or status of a Research Protocol. No participant information is generated through these standard reports.

3.0 Management of Participants

3.1 Pre-screening

The pre-screening for eligible participants can be done against a nominated protocol within Patient Protocol Manager (PPM) in PowerTrials. This allows the researcher to use a rule that has been created by the research team and the PowerTrials Site Support team. This rule looks at codified data within the patient database within the EMR. The rule consists of; SNOMED codes for diagnoses, past medical history, medications both active and home medication, patient vital signs, patient results and patient demographics.

The design and creation of a Pre-Screening rule within PowerTrials must always:

- be submitted for build once all approvals for the commencement of the research projects has been received;

- ensure the final sign off of the pre-screening rules is provided by the Principal Investigator or an approved delegate;
- align to the most recent HREC approved inclusion/exclusion criteria;
- ensure all Pre-Screening within PowerTrials is executed by an approved research team member;
- ensure, when launching the patient's/participant's PowerChart, that the researcher is aware of the encounter they are in and if needed change to the correct encounter for the participant.

All R4 Auditor clinical roles will have the ability to pre-screen and refer their participants in PowerChart if:

- they have a direct role within a research project that is recruiting;
- they have been approached by the research project team to assist with the recruiting process; or
- they have in-depth knowledge of both the participant and/or the research project the research team is pre-screening for.

The clinician must ensure the participant understands that the research is as a whole throughout the facility and not research project specific. If 'Not Interested' is selected then this deactivates the pre-screening button and will no longer allow the clinician to pre-screen the participant both within PowerChart and within Patient Protocol Manager (PPM).

3.2 Enrolment

Enrolment within Patient Protocol Manager (PPM) in PowerTrials can be initiated three main ways, via; pre-screen results list, URN search and/or a PowerChart referral.

The enrolment of the participant must always be in alignment with the most recent HREC approved Research Protocol.

All business as usual communication must be made with both the participant and any active treating teams prior to contact with the participants to discuss enrolment.

Enrolment must only commence once the participant consent has been received. The participant may wish to take home the Participant Information and Consent Form (PICF) to discuss the enrolment with family and/or support networks. The participant must be transferred to the 'Consent Pending View' until the signed consent form or participant decline has been returned to the research team.

The function of batch enrolment can only be completed on research projects that are not stratified. The participant enrolment will allow the researcher to enrol multiple participants at a time but will mark them all with the same enrolment date and will not allow different consent processes.

If the patient's/participant's enrolment status requires modification, for example taking the participant 'Off Treatment' (therapeutic studies only) or 'Off Study', due to a change in either participant circumstances (e.g. participant withdraws from research project) or a change in Research Protocol this will be completed by the Principal Investigator, Clinical Trial Coordinator or approved delegate.

It is recommended that a comment regarding the reason for the change in enrolment status be documented within the provided notes section and as a research progress note within the correct encounter in the patient's/participant's PowerChart.

3.3 PowerChart

Launching PowerChart from within Patient Protocol Manager (PPM) can be done via the Patient Protocol Manager (PPM) tool bar or via right clicking on the selected participant and clicking 'Launch PowerChart'.

The researcher must be mindful of the encounter in which the PowerChart launches. Patient Protocol Manager (PPM) will always launch the most recent encounter. The researcher must change to the correct encounter if ordering or documenting.

3.4 Research Progress Note

The recommended note type for all research documentation is the 'Research' note type. When using the research note type, all documentation will be organised into a research folder within the Clinical Notes View. This will allow for easier identification of all research documentation.

3.5 Trial Medication

All new research projects from 1 July 2017 must have the trial medication built into the orders catalogue before it can be added into a PowerPlan or ordered individually within the participants chart. All existing research projects being built into PowerTrials as a part of the backlog build will continue to use paper medication ordering and administration processes.

All trial medications built into the catalogue will need to be aligned to the HREC approved Research Protocol and be approved by the Princess Alexandra Hospital trials pharmacist. The unlisted medication order will be utilised for all inpatients needing ordering or administration of their trial medications. The naming conventions for trial medications are required to always commence with the wording of TRIAL, for example: TRIAL-ABC-123/Placebo.

All trial medications do not have the system smart functionalities applied. This mean interactions checking, allergy checking and dose/range checking, duplicates, early/late administration warnings. This mean the clinician will need to complete these functions manually.

2.0 PowerTrials - Monitoring

2.1 Research Auditor

Research auditors/monitors will not have access to PowerTrials unless the following has been undertaken:

- required training is completed;
- the Clinical Trial Coordinator or approved delegate has organised access to the EMR with the role of R4 Auditor;
- the Clinical Trial Coordinator or approved delegate has added the auditor/monitor to the roles within Protocol Office Manager (POM) using the PowerTrials role of auditor/monitor to ensure the correct access right are maintained; and
- the access to the protocol and to the EMR must be removed once the auditor/monitor has completed all work.

2.1 Internal Monitoring

The PowerTrials Research Support Module allows the Metro South Health to periodically electronically monitor the progress of open research projects across the Health Service. Additionally, it facilitates the on-site monitoring process undertaken by the Metro South Health Research Monitoring Office/r. Further details on the Metro South Health monitoring process can be found in the [Research Governance \(Monitoring\) Procedure \(PR2017/117\)](#).

2.2 External Monitoring

As a result of the privacy settings, the PowerTrials Research Support Module facilitates the monitoring of a research project from an external entity, such as a sponsor or other regulatory body. The nominated research project contact can add an R4 'Monitor Role' to the research team which will enable access to only enrolled research projects participants' electronic medical record.