PowerTrials - ieMR research support module

PURPOSE

This work instruction identifies a consistent and mandatory electronic management processes in the use of the Integrated Electronic Medical Record (ieMR) research support module 'PowerTrials' for research being conducted within or in collaboration with Metro South Health (MSH).

OUTCOME

This work instruction aims to:

- Ensure the digitalised health service initiative is supported which enables patients' medical records to be available in an electronic format by enabling:
    - improved access for clinicians and researchers to research information which supports participant safety, streamlined recruitment, efficient documentation and access,
    - clinicians to have visibility of existing research projects within PowerChart to assess whether patients are suitable candidates for research, and
    - an increase in patient safety via patient enrolment within PPM – leading to real time banner bar visibility of active patient enrolment in clinical research.
- Outline the process for interventional research (clinical trials) that have MSH Site Specific Assessment (SSA) authorisation and require patient consent to be built into PowerTrials to enable integration of research activities with clinical care delivery.

This work instruction outlines processes described in MSH procedure PR2023-413 Research administration and compliance and upholds principles outlined within the Research Administration and Compliance Handbook.

SCOPE

This work instruction applies to all MSH employees and collaborators who conduct human research within or in association with MSH, or through access to MSH participants, health records or data.

WORK INSTRUCTION

1. STEP 1: POWERTRIALS USE IN RESEARCH

- Research projects must be approved by a National Health and Medical Research Council (NHMRC) Certified Human Research Ethics Committee (HREC) and have MSH SSA approval to be active within PowerTrials in ieMR.
- The ieMR system can be used to determine which patients may be suitable for a research project, with direct liaising with the clinicians who are caring for those patients.

- Researchers conducting authorised studies that do not involve contact with patients or their data are not required to use the digital research application PowerTrials but may choose to do so.

2. STEP 2: POWERTRIALS PROTOCOL OFFICE MANAGER (POMANAGER)

- All interventional research (clinical trials) requiring both direct or indirect (via a substitute decision making or parent/guardian) patient consent occurring within MSH must be built within the PowerTrials Protocol Office Manager (POManager).
- Metro South Research will liaise with the Principal Investigator (PI) or approved delegate to commence completion of this build during the MSH SSA review and approval process.
- Resources are available to assist with PowerTrials:
    - Attachment 1: Electronic Health Record Checklist
    - PowerTrials Quick Reference Guides: Metro South Digital

3. STEP 3: POWERTRIALS BUILD

- For all projects requiring a PowerTrials build, the study will be built within POManager, with support if required from Metro South Research.
    - To request PowerTrials build support, send an email to MSH-Research@health.qld.gov.au
    - If a PowerTrials build is performed by Metro South Research, the research team will receive a notification when the PowerTrials build is complete.
- Researchers may complete their own builds if preferred.
- All documents in PowerTrials need to be PDF version not Word.
- Researchers are required to ensure that the PICF and Protocol documents are the current approved versions.

4. STEP 4: ENROLMENT USING PATIENT PROTOCOL MANAGER (PPMANAGER)

- Following the PowerTrials build being completed, the research team will be responsible for managing patient enrolments into the PowerTrials module through the Patient Protocol Manager (PPManager) and ensuring appropriate documentation of research activity in the patients' electronic medical record – PowerChart.
- Information relating to a research project will only be available within the patient's chart (PowerChart) after the patient has been enrolled in a research project.

RESPONSIBILITIES

Position	Responsibility	Audit criteria
Metro South Research	• Liaise with the MSH researchers and aid in PowerTrials conduct. • Provision of administrative support to maintain and uphold principles outlined in the MSH Research Policy Framework.	N/A

Principal Investigator (PI)/ Coordinating Principal Investigator (CPI) - responsible officer	• Conduct research in accordance with national guidelines, the Metro South Research Policy Framework and 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 HREC, legislative and policy requirements for participant contact, consent, and confidentiality of patient information. • Only conduct clinical trials with the essential approved credentialing privileges and clinical experience. Adhere to all relevant policies, procedures, Good Clinical Practice (GCP) processes, research protocols and Standard Operating Procedures (SOPs) when conducting research. • Take responsibility for oversight of the research team and ensure appropriate training and research conduct.	N/A
Employees, researchers, research student supervisors and students	• Are required to be aware of and comply with this work instruction when conducting research.	N/A

DEFINITIONS

Term	Definition
Clinical Trial *(National Clinical Trials Governance Framework definition)*	A clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Clinical trials include but are not limited to: • Surgical and medical treatments and procedures • Experimental drugs • Biological products • Medical devices • Health-related service changes • Health-related preventative strategies • Health-related educational interventions.
Good Clinical Practice (GCP)	A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance

	that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.
Principal Investigator (PI)/Coordinating Principal Investigator (CPI)	An individual responsible for the conduct of a clinical trial at a trial site ensuring that it complies with GCP guidelines. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the CPI/PI In this instance they may delegate tasks to other team members.

RELATED AND SUPPORTING DOCUMENTS

Legislation and other Authority	**Legislation (as updated and replaced from time to time)** • *Hospital and Health Boards Act 2011* (Qld) • *Information Privacy Act 2009* (Qld) • *Privacy Act 1988* (Cth) • *Public Health Act 2005* (Qld) • *Statutory Bodies Financial Arrangements Act 1982* (Qld) • *Therapeutic Goods Act 1989* (Cth) **Regulations** • *Hospital and Health Boards Regulation 2012* (Qld) • *Information Privacy Regulation 2009* (Qld) • *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth) **Department of Health** • Health Service Directive: Research Ethics and Governance Directive QH-HSD-035:2023 • Research Management Policy QH-POL-013:2022 • Research Management Standard QH-IMP-013:1:2022 **Metro South Health** • Metro South Health Research Strategy • PowerTrials Quick Reference Guides: Metro South Digital

Standards	• National Clinical Trials Governance Framework
	• National Safety and Quality Health Service (NSQHS) Standards 2nd Ed.
	  ○ Standard 1 – Clinical Governance
	  ○ Standard 2 – Partnering with Consumers

Supporting documents	**Procedures** • PR2023-411 Research excellence • PR2023-412 Research support and management • PR2023-413 Research administration and compliance **Work instructions**

	• WI2023-299 Ethical and scientific review of research • WI2023-300 Exemptions from research review • WI2023-301 Site specific assessment in research • WI2023-302 Research contracts and study execution • WI2023-303 Metro South Health sponsorship of Clinical Trial Notification (CTN) scheme trials • WI2023-305 Research monitoring • WI2023-306 Post approval – research amendments, reporting and closure **Guidelines** • GL2023-99 Planning a research project • GL2023-100 Research Participant Information and Consent Form (PICF) • GL2023-101 Research contract clauses • GL2023-102 Use of electronic signatures in research contracts • GL2021-77 Clinical trials • GL2023-103 TeleTrials **Attachments** • Attachment 1: Electronic health record checklist

HUMAN RIGHTS ACT 2019

Metro South Hospital and Health Service is committed to respecting, protecting and promoting human rights. Under the *Human Rights Act 2019*, Metro South Health has an obligation to act and make decisions in a way that is compatible with human rights and, when deciding, to consider human rights. When deciding about research, decision-makers must comply with that obligation. Further information about the *Human Rights Act 2019* is available at: https://www.forgov.qld.gov.au/humanrights.

WORK INSTRUCTION DETAILS

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Executive Sponsor	Chief People, Engagement and Research Officer
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REVIEW HISTORY

Version	Approval date	Effective from	Authority	Comment
1.0	7/12/2023	14/12/2023	Chief People, Engagement and Research Officer	• Supersedes PR2017-118 ieMR Research Support Module Powertrials Procedure