Position Description

Title: Clinical Trials Coordinator

HEW Level: HEW 5

Faculty/Office: Faculty of Medicine and Health Sciences

Position Number: NEW

Department/Team: Department of Clinical Medicine

Date: September 2016

Position Purpose: To verify and enhance the quality of data collected across all clinical trials and coordinate small scale clinical trials within the Clinical Trials Unit.

ORGANISATIONAL CONTEXT

Macquarie University is developing the nation’s first fully integrated academic health sciences centre under a university's leadership. With a focus on patients and an ultimate goal of improving lives, the Macquarie University Health Sciences Centre will see true convergence of the learning and research endeavours of Macquarie’s Faculty of Medicine and Health Sciences with the clinical care provided at Macquarie University Hospital and Clinics. It brings together the excellent work of medical and allied health researchers across the University and around the country, with unparalleled access to the world-leading clinical resources and research facilities found only on our campus.

The Faculty of Medicine and Health Sciences has active research programs in biomedical, translational and health services domains, with current areas of strength including neurosciences (especially motor neuron disease, neurological rehabilitation, and the clinical neuroscience of pain), cancer medicine, and vascular science, amongst others. The Faculty hosts the Australian Institute of Health Innovation, an internationally acclaimed powerhouse researching health systems, e-health, and patient safety. In learning and teaching, the Faculty offers a unique suite of capability-based medical educational programs aimed at post-graduation subspecialty medical education and training, and a unique three-year extended masters-level, professional-entry Doctor of Physiotherapy degree.
### KEY ACCOUNTABILITIES

- Validate clinical trial data to ensure consistency, integrity and accuracy based on trial specific guidelines.
- Identify and query data inconsistencies and/or missing data with the relevant Clinical Trials Coordinator and coordinate the resolution of queries.
- Generate interim and summary reports for Clinical Trials Coordinators and Chief Investigators as requested.
- Maintain electronic databases and registries and train users on basic reporting, as required.
- Set up databases based on protocols and requirements for imaging and pathology.
- Coordinate and monitor the progress of assigned clinical trials and ensure that trials are conducted in accordance with Good Clinical Practice (GCP) protocols as advised by the Director and clinical trials team.
- Assist the chief investigator with patient recruitment in accordance with clinical trial protocols for assigned trials.
- Plan and prepare for assigned studies including ordering clinical trial materials, equipment and set up of relevant systems in accordance with approved clinical standards and Standard Operating Procedures (SOPs).
- Collect and process laboratory and biological samples and coordinate the movement of samples as required, in accordance with approved clinical standards and SOPs.
- Liaise with chief investigators to organise site initiation visits and monitoring visits.
- In collaboration with the clinical trials team and Department of Clinical Medicine, contribute to high quality patient care for clinical trial patients with confidentiality and sensitivity.
- Attend trial specific meetings, training and workshops.
- Comply with University research and ethics protocols and legislative requirements related to clinical trials and data.
- Comply with relevant EEO and WHS regulations.
- Perform any other duties as required and appropriate for this classification.

### POSITION CONTEXT

<table>
<thead>
<tr>
<th>Reports to:</th>
<th>Clinical Trials Manager</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positions Reporting to:</td>
<td>Direct: nil</td>
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<tr>
<td></td>
<td>Indirect: nil</td>
</tr>
</tbody>
</table>

#### Key Direct Clients:
- Patients
- Clinicians whose patients are involved in trials
- Independent or Government agencies auditing trials
- External organisations sponsoring trials
- Vendors for data systems
- Sponsor vendors
- Ethics and research committees

#### Other Key Relationships:
- Immediate team members in the Clinical Trials team and Department of Clinical Medicine
- MQ post-graduate students
- MQ Research and Clinical staff in general
- MUH staff
- Independent or Government agencies auditing trials
- Pharmacies, imaging and pathology
- Relevant allied health providers

#### Budget Accountability:
- Nil

#### Role-specific Conditions:
- Criminal checks
- NSW Working with children check, as required

#### Scope and autonomy
Work tasks may require interpretation, decisions and advice within the scope of defined systems, processes, procedures and techniques.

#### Problem solving
Draws on own knowledge and experience to analyse problems and develops and implements solutions.
# CAPABILITY FRAMEWORK

Capability Frameworks describe the behaviours, skills, attributes and experience required to successfully perform a position or group of similar positions.

<table>
<thead>
<tr>
<th>COMPETENCIES</th>
<th>Attributes</th>
<th>Personal qualities related to successful performance.</th>
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</thead>
<tbody>
<tr>
<td>Planning and Execution: Managing time and resources to complete tasks and achieve objectives.</td>
<td>Perseverance: Persevering despite obstacles to ensure tasks are completed.</td>
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<tr>
<td>Quality Focus: Ensuring accuracy and quality when completing tasks.</td>
<td>Reliability: Meeting commitments and responsibilities.</td>
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<tr>
<td>Communication: Effectively grasping and conveying ideas and concepts to others.</td>
<td>Initiative: Taking action, on own accord, to address problems and prevent them from reoccurring.</td>
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<tr>
<td>Service Focus: Making students, staff, key contacts and their needs a priority.</td>
<td>Accountability: Assuming responsibility for making decisions and delivering agreed outcomes.</td>
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<tr>
<td>Improvement Focus: Finding better ways of completing tasks or solving problems.</td>
<td>Integrity: Maintaining confidentiality, discretion and professionalism.</td>
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<tr>
<td>Teamwork: Working in collaboration with others to achieve shared goals.</td>
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### REQUIRED KNOWLEDGE
Qualifications, technical and/or professional skills and information needed from day one for successful performance.

- Bachelor degree in science, medical science, allied health or related discipline or equivalent combination of education/training and experience.
- Well-developed computer skills in database management, MS Word, Excel, and web based research.
- Knowledge of medical terminology
- Knowledge of ICH-GCP, the National Statement and other relevant Australian research guidelines.
- Venepuncture certification (desirable)

### ACQUIRED KNOWLEDGE
Organisational and/or professional skills and information to be developed within the first 3 to 6 months in the role for successful performance.

- Knowledge of clinical databases and modules.
- Knowledge of MQ Clinical Trials, protocols and document management
- Knowledge of how to work safely in Faculty of Medicine and Health Sciences
- Knowledge of the Faculty of Medicine and Health Sciences policies, systems, processes and procedures

### KEY EXPERIENCES
Practical experiences and exposure to specific environments or activities related to successful performance.

- Database management with an ability to navigate through medical records systems.
- Previous experience with Clinical Research and an established understanding of clinical trials protocols, particularly across phase 3 studies.
- Experience taking and processing patient samples
- Consulting with patients in a sensitive manner
- Handling confidential patient information and informed consent process
- Venepuncture experience or willingness to be trained (desirable)