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: August 2019

Position Purpose: To provide the clinical trials team with trial coordination for clinical Phase I - IV clinical projects.

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, cancer medicine, and vascular science, amongst others. In addition to the Clinical Trial Unit, 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 education programs including a unique three-year extended masters-level, professional-entry Doctor of Physiotherapy degree, a Graduate Diploma of Anatomy program, a Master of Public Health, an accelerated 2 year Bachelor of Clinical Science program and the Macquarie MD (Doctor of Medicine).
### KEY ACCOUNTABILITIES
- Coordinate the implementation of clinical trials from study start up to database lock and archiving.
- Ensure compliance of trials with Good Clinical Practice (GCP), protocols and requirements of MQ Ethics and the TGA, and MQ CTU SOPs.
- Liaise with relevant parties of Macquarie University, Macquarie University Hospital and external organisations including trial sponsor and CRO staff to support quality and service standards of clinical trials.
- Actively contribute to participant recruitment and screening to ensure trial recruitment targets are met.
- Contribute to high quality patient care for clinical trial participants in collaboration with the Clinical team and staff of the Department of Clinical Medicine.
- Actively follow up participants to ensure no study participants are lost to follow up.
- Coordinate the collection, handling and reporting of participant data to ensure protocol compliance and data that accurately reflects participant experience in the trial.
- Coordinate appointments, and communicate clinical trial processes and results with participants with empathy and accuracy.
- Respond to and/or appropriately escalate participant issues in a confidential and sensitive manner that respects patient privacy.
- Create and maintain clinical trial site files for each trial so they are up to date and compliant with GCP and study sponsor requirements throughout the trial.
- Report on patient and trial status and outcomes to the operations team, sponsors, Ethics committee and participants.
- Maintain CTMS to ensure accurate tracking of trial costs.
- Contribute to the development of processes to support the efficient coordination of clinical trials by the CTU.
- 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>
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</table>
| Positions Reporting to: | Direct: nil  
Indirect: nil |
| Key Direct Clients: | • Patients  
• Clinicians whose patients are involved in trials  
• Staff in the Clinical Trials Unit and Clinical staff managing trial participants  
• External partners e.g. pharmaceutical companies and their vendors, medical research funding bodies  
• Vendors associated with the trial eg pharmacy, imaging, pathology, MUH staff |
| Other Key Relationships: | • Research Governance and Ethics  
• Independent or government agencies auditing trials  
• Office of DVC (Research)  
• Medical Director, Clinical Trials  
• Head of Clinical Operations  
• Office of the General Counsel  
• Finance Officer – Clinical Trials  
• Staff in the Clinical Trials Unit  
• Office of DVC (Research)  
• FMHS Faculty Research Office  
• Other Faculty Offices  
• Relevant health organisation partners and sponsors |
| Budget Accountability: | Nil |
| Role-specific Conditions: | Immunisation and vaccination checks  
Criminal History Checks |
| 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>
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<tbody>
<tr>
<td><strong>Planning and Execution:</strong> Managing time and resources to complete tasks</td>
<td><strong>Perseverance:</strong> Persevering despite obstacles to ensure tasks are completed.</td>
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<td>and achieve objectives.</td>
<td><strong>Flexibility:</strong> Responding effectively to unexpected or changing circumstances.</td>
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<td><strong>Quality Focus:</strong> Ensuring accuracy and quality when completing tasks.</td>
<td><strong>Reliability:</strong> Meeting commitments and responsibilities.</td>
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<td><strong>Communication:</strong> Effectively articulates key messages, both verbally and</td>
<td><strong>Interpersonal Impact:</strong> Making a positive impression on others in a range of interpersonal contexts.</td>
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<td>and in writing, adapting to suit context and audience.</td>
<td><strong>Resilience:</strong> Dealing effectively with and recovering quickly from setbacks or pressure.</td>
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<td><strong>Service Focus:</strong> Making patients, staff, and other key contacts and their</td>
<td><strong>Integrity:</strong> Maintaining confidentiality, discretion and professionalism.</td>
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<td>needs, a priority.</td>
<td><strong>Initiative:</strong> Taking action, on own accord, to address problems and prevent them from reoccurring.</td>
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<td><strong>Relationship Management:</strong> Establishing effective working relationships</td>
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<td>with others.</td>
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<td><strong>Teamwork:</strong> Working in collaboration with others to achieve shared goals.</td>
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<td><strong>Improvement Focus:</strong> Finding better ways of completing tasks or solving</td>
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<td>problems.</td>
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### REQUIRED KNOWLEDGE
Qualifications, technical and/or professional skills and information needed from day one for successful performance.

- Degree in life sciences, health or equivalent
- Intermediate to advanced MS Excel skills and ability to use the Microsoft Office Suite and database management.
- Knowledge of medical terminology.
- Knowledge of the clinical trials processes and research protocols including ICH-GCP, National Statement and other relevant Australian research guidelines.
- 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 MQ Clinical Trials, protocols and document management.
- Knowledge of the CTU’s systems, processes and procedures.
- Knowledge of the Faculty of Medicine and Health Sciences policies, systems, processes and procedures
- Knowledge of what other areas of the University do and how they interact with the CTU / Faculty
- Knowledge of how to work safely in Faculty of Medicine and Health Sciences

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

- Previous experience in clinical research.
- Managing key stakeholder relationships.
- Patient interaction skills or experience and ability to perform key trial observations *(desirable)*.
- Database management with an ability to navigate through medical records systems.
- Handling confidential patient information and informed consent.
- Venepuncture experience or willingness to be trained *(desirable)*