Position Description

Title: Clinical Quality Manager  
Faculty/Office: Faculty of Medicine and Health Sciences  
Department/Team: Department of Clinical Medicine  
Date: November 2018

Position Purpose: To develop and implement clinical quality management systems to ensure that clinical trials are conducted within applicable regulations, guidelines and standards.

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 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

- Implement clinical quality management systems for Phase I to IV clinical trial studies.
- Establish GCP system/process training needs, develop appropriate training materials and deliver and document training compliance.
- Drive system and process improvement initiatives and develop appropriate tools and standard operating procedures to further enhance quality management activities.
- Plan, manage and perform regular quality reviews for clinical trials and document internal systems and processes, in order to ensure compliance with regulatory requirements, ethics committees and University policies and procedures.
- Prepare quality review reports and communicate findings and recommendations to relevant internal and external stakeholders.
- Review and assess quality review responses and make recommendations for solutions and corrective and preventative action (CAPA) plans to adequately address findings and root cause analysis.
- Evaluate, track and follow up on CAPAs to ensure actions are adequately completed in a timely manner.
- Lead and/or participate in the planning, conduct and follow-up of Regulatory GCP inspections and sponsor audits.
- Contribute to assessment of reports and results from Regulatory Inspections and audits.
- Participate in regular trial team meetings and provide quality oversight and advice at trial level.
- Maintain ongoing awareness of trials issues related to quality, safety and efficacy.
- In collaboration with Risk and Assurance, identify and mitigate potential and/or identified quality related issues with the conduct of clinical trials.
- Evaluate audit and/or inspection trends and other information sources to support planning to optimise clinical trials quality and compliance.
- Communicate identified lessons learned from audits and inspections and provide training as appropriate to resolve issues.
- Resolve or appropriately escalate quality/compliance issues.
- Maintain current industry knowledge of applicable regulations, guidelines, and standards.
- Comply with relevant EEO and WHS regulations.
- Perform any other duties as required and appropriate for this classification.

### POSITION CONTEXT

#### Reports to:
Head of Clinical Operations

#### Positions Reporting to:
Direct: nil
Indirect: nil

#### Key Direct Clients:
- Macquarie University Hospital
- Office of DVC (Research)
- Staff and students undertaking clinical research projects
- Principal Investigators
- Clinical Program Heads, MQ Health
- Staff in the Clinical Trials Unit
- External partners; e.g. pharmaceuticals, other medical research funding bodies.

#### Other Key Relationships:
- Medical Director, Clinical Trials
- Staff in the Clinical Trials Unit
- Office of DVC (Research); particularly the Human Ethics Secretariat
- FMHS Faculty Research Office
- Relevant government agencies
- Health organisation partners and sponsors
- Risk and Assurance

#### Budget Accountability:
Nil

#### Role-specific Conditions:
- Criminal checks

#### Scope and autonomy
Develops and/or modifies programs, processes, systems and/or policies that may impact University-wide projects, process improvements and/or initiatives

#### Problem solving
Draws on own knowledge, experience and expertise to identify, develop and implement new initiatives, processes and programs.
## CAPABILITY FRAMEWORK

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

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<thead>
<tr>
<th>COMPELNCIES</th>
<th>ATTRIBUTES</th>
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<tr>
<td><strong>Clusters of behaviours required for successful performance.</strong></td>
<td><strong>Personal qualities related to successful performance.</strong></td>
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<td><strong>Quality Focus:</strong> Ensuring accuracy and quality when completing tasks.</td>
<td><strong>Flexibility:</strong> Responding effectively to unexpected or changing circumstances.</td>
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<td><strong>Influencing and Persuading:</strong> Building commitment by convincing others and winning them over to a particular point of view.</td>
<td><strong>Resilience:</strong> Dealing effectively with and recovering quickly from setbacks or pressure.</td>
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<td><strong>Planning and Execution:</strong> Managing time and resources to complete tasks and achieve objectives.</td>
<td><strong>Perseverance:</strong> Persists in efforts despite obstacles or barriers, tries different strategies or approaches until one works.</td>
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<td><strong>Implementing Systems:</strong> Adopting a systematic and organised approach, and developing and utilising guidelines and procedures.</td>
<td><strong>Accountability:</strong> Assuming responsibility for making decisions and delivering agreed outcomes.</td>
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<td><strong>Delivering Outcomes:</strong> Holding high expectations for and ensuring self and others can achieve high levels of performance and outcomes.</td>
<td><strong>Interpersonal Impact:</strong> Making a positive impression on others in a range of interpersonal contexts.</td>
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<td><strong>Communication:</strong> Effectively articulates key messages, both verbally and in writing, adapting to suit context and audience.</td>
<td><strong>Creativity:</strong> Questioning the status quo and suggesting non-traditional or original ideas and solutions.</td>
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<td><strong>Relationship Management:</strong> Establishing effective working relationships with others.</td>
<td><strong>Integrity:</strong> Maintaining confidentiality, discretion and professionalism.</td>
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<td><strong>Initiative:</strong> Taking action, on own accord, to address problems and prevent them from reoccurring.</td>
<td><strong>Influencing and Persuading:</strong> Building commitment by convincing others and winning them over to a particular point of view.</td>
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**REQUIRED KNOWLEDGE**
Qualifications, technical and/or professional skills and information needed from day one for successful performance.

Bachelor's degree in relevant discipline or equivalent relevant work experience in clinical research.

Working knowledge of national and international regulations, guidelines and best practice related to the conduct of Phase I, II, III and IV clinical trials.

Strong computer literacy with knowledge of clinical trials software and MS Office suite.

An in-depth understanding of the clinical trials processes.

Knowledge and understanding of the impact of external regulatory frameworks e.g. The National Statement on Ethical Conduct in Human Research on HREC practice and processes.

**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 Faculty of Medicine and Health Sciences functions and structure.

Knowledge of the Faculty of Medicine and Health Sciences policies, systems, processes and procedures.

Knowledge of how the University works and how relevant functions across the University interrelate.

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

Demonstrated experience in clinical research and/or GCP-related environment

Experience with clinical quality management and GCP

Strong analytical skills with ability to problem solve.

Experience working with clinical trials teams in a multidisciplinary environment.

Ability to work both independently and as part of a team.

Ability to lead and deliver on projects involving risk management and process improvement in a clinical research setting.