Position Description

Title: Head of Clinical Operations
HEW Level: HEW 10

Faculty/Office: Faculty of Medicine and Health Sciences
Position Number: NEW

Department/Team: Department of Clinical Medicine
Date: July 2018

Position Purpose: To lead the development and efficient management of all aspects of clinical research operations and ensure sustainable growth of the Clinical Trials Unit, in alignment with the Faculty research strategy.

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**

- In collaboration with the Medical Director, Clinical Trials Unit (CTU) and Associate Dean Research, develop and implement the strategic plan for sustainable growth of CTU that will support all clinical trials at the Faculty, in alignment with the Faculty’s research strategy.
- Identify and assess potential opportunities and oversee contract negotiations between the University and investigators, clients and/or sponsors in alignment with the Faculty’s strategic research priorities with the aim of generating and securing new study leads.
- Identify, qualify and manage relationships with all external vendors and continually monitor vendor performance.
- Build and foster relationships with external stakeholders, principal investigators, clients and sponsors to identify partnership opportunities with clients seeking to conduct new clinical trials.
- Develop and implement a financially sustainable business model for the Unit that supports its growth, longevity and performance and oversee the Unit’s financial performance against expectations.
- Identify, develop and implement quality and safety protocols and/or systems for the Unit, including assessing and managing the risks of new studies.
- Oversee and monitor the Unit’s compliance with Good Clinical Practice (GCP), government and University regulations, policies and procedures on the conduct of ethical human research.
- Prepare and respond to governance reporting requirements as per stakeholder demand and government regulations.
- Develop and implement business processes, protocols and systems to support clinical trials management and administration, including regularly reviewing current protocols to identify and address gaps.
- In collaboration with Group Marketing, ensure marketing plans are developed and implemented to promote the Unit and its activities.
- Generate and maintain regular reporting for the Executive team on the Unit and its performance against strategic goals.
- Manage, coach and set the direction for the Clinical Trials Unit.
- Comply with relevant EEO and WHS regulations.
- Perform any other duties as required and appropriate for this classification.

**POSITION CONTEXT**

| Reports to: | Director, Clinical Trial; dotted line to A/D Research |
| Positions Reporting to: | Direct: 3  
Indirect: 7 |
| Key Direct Clients: | Director, Medical Services  
Macquarie University Hospital  
Office of DVC (Research)  
Faculty Executive  
Staff and students undertaking clinical research projects  
Clinical Program Heads, MQ Health  
Clinical Trials Patients  
External partners; e.g. pharmaceuticals, other medical research funding bodies. |
| Other Key Relationships: | Medical Director, Clinical Trials  
Clinical Trials Unit  
Associate Dean, Research  
Office of DVC (Research); particularly the Human Ethics Secretariat  
FMHS Faculty Research Office  
Other Faculty Research Offices  
Office of General Council  
Director of Engagement, MQ Health  
Relevant government agencies  
Health organisation partners and sponsors  
Risk and Assurance |
| Budget Accountability: | Approximately $3M |
| Role-specific Conditions: | N/A |
| Scope and autonomy | Develops and/or modifies organisation wide policies or manages specialised projects which require a high level of interpretation and subject matter expertise. |
| Problem solving | Regularly develops and/or modifies organisation wide policies to identify, develop and implement new initiatives, processes and programs which impact at a University wide level or within an area of specialisation. |
# CAPABILITY FRAMEWORK

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

## COMPETENCIES

Clusters of behaviours required for successful performance.

**Influencing and Persuading:** Building commitment by convincing others and winning them over to a particular point of view.

**Planning and Execution:** Managing time and resources to complete tasks and achieve objectives.

**Implementing Systems:** Adopting a systematic and organised approach, and developing and utilising guidelines and procedures.

**Setting Expectations:** Stating clearly what is expected from others, clearly expressing ideas, and maintaining a precise and constant flow of information.

**Tracking Performance:** Taking nothing for granted and persistently monitoring the progress of activities to ensure they are completed on time.

**Giving Feedback:** Letting others know in a respectful, supportive and straightforward manner what is expected of them, how they have performed and if they have met needs and expectations.

**Leading and Directing:** Taking the lead and exercising influence when managing complex situations and/or making critical business decisions.

**Delivering Outcomes:** Holding high expectations for and ensuring self and others can achieve high levels of performance and outcomes.

**Developing Capability:** Coaching, mentoring and supporting others to develop their competence and confidence for performance and growth.

**Communication:** Effectively articulates key messages, both verbally and in writing, adapting to suit context and audience.

## ATTRIBUTES

Personal qualities related to successful performance.

**Flexibility:** Responding effectively to unexpected or changing circumstances.

**Resilience:** Dealing effectively with and recovering quickly from setbacks or pressure.

**Perseverance:** Persists in efforts despite obstacles or barriers, tries different strategies or approaches until one works.

**Accountability:** Assuming responsibility for making decisions and delivering agreed outcomes.

**Interpersonal Impact:** Making a positive impression on others in a range of interpersonal contexts.

**Creativity:** Questioning the status quo and suggesting non-traditional or original ideas and solutions.

**Integrity:** Maintaining confidentiality, discretion and professionalism.

**Initiative:** Taking action, on own accord, to address problems and prevent them from reoccurring.
**REQUIRED KNOWLEDGE**
Qualifications, technical and/or professional skills and information needed from day one for successful performance.

- Degree or Master's in life sciences or related discipline or equivalent combination of education and training in the conduct of clinical research with a strong business acumen.
- Strong computer literacy with knowledge of clinical trials software and MS Office suite.
- An in-depth understanding of the clinical trials processes.
- Knowledge of clinical research governance models and processes (e.g. NHMRC Research Governance Handbook).
- 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.
- Knowledge of the pharmaceutical industry, clinical research and medical terminology.
- Knowledge development and implementation of Phase I, II, III and IV clinical trials.

**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.
- Understanding the local and global market/context within which the University operates.

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

- Working in clinical research, particularly in clinical trials business development.
- Building and managing key stakeholder relationships.
- Ability to successfully lead and manage a diverse team in a busy environment, under time pressures, ideally in a clinical research environment.
- Ability to lead and deliver on projects involving risk management and process improvement in a clinical research setting.
- Developing and managing budgets.
- Communicating and influencing a diverse group of stakeholders e.g. committees, University and regulatory bodies.
- Writing business proposals, reports and delivering presentation to a wide range of stakeholders.