# Position Description

<table>
<thead>
<tr>
<th>Title:</th>
<th>Clinical Trials and Contracts Coordinator</th>
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<tbody>
<tr>
<td>HEW Level:</td>
<td>HEW 6</td>
</tr>
<tr>
<td>Faculty/Office:</td>
<td>Faculty of Medicine and Health Sciences</td>
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<tr>
<td>Position Number:</td>
<td>NEW</td>
</tr>
<tr>
<td>Department/Team:</td>
<td>Department of Clinical Medicine</td>
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<tr>
<td>Date:</td>
<td>July 2019</td>
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## Position Purpose
To provide the clinical operations team with contract set up support and 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 (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).

## ORGANISATION CHART
![organisation chart]

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### KEY ACCOUNTABILITIES

- Coordinate, implement and monitor how assigned clinical trials are conducted, in accordance with Good Clinical Practice (GCP) protocols and with guidance from the Director and relevant Clinical Trials team.
- Liaise with relevant parties of Macquarie University, Macquarie University Hospital and external organisations to support quality and service standards of clinical trials.
- Coordinate the collection, handling and reporting of patient and trial data.
- Assist the Principal Investigator with participant recruitment and reporting on trials and ethics submissions according to clinical trial protocols.
- Comply with University research and ethics protocols and legislative requirements related to clinical trials and data.
- Manage the collection of patient biological samples in accordance with approved clinical standards and Standard Operating Procedures.
- Contribute to high quality patient care for clinical trial participants in collaboration with the Clinical team and staff of the Department of Clinical Medicine.
- Coordinate appointments, communicate clinical trial processes and results with patients, and resolve and/or escalate any related matters in a highly confidential and sensitive manner.
- In collaboration with the Clinical Trials Manager, contribute to the development of processes to support the efficient set up of clinical trials contracts, agreements, reviews and execution.
- Review and prepare clinical trials contracts, financial disclosures and confidentiality agreements/deeds, including costs agreements and arrange for sign off/execution with CROs and sponsors for each trial.
- Liaise with relevant University offices and trial sponsors to ensure prompt execution of agreements and contracts and any Amendments or Addendums when required.
- Maintain relationships with external and internal stakeholders, particularly Contract Research Organisations (CROs), collaborative groups, sponsors and relevant University Offices to identify efficiencies in study start-up activities, especially the contracting process.
- Record all clinical trial feasibilities with status update.
- In collaboration with the Clinical Trials Manager and Finance Officer (Clinical Trials Unit), review market costing trends and contribute to standardising chargeable costs of clinical trials activities and revise these in keeping with market benchmarks.
- Create and maintain physical and electronic files/records related to clinical trials projects and contracts in the Clinical Trials folders, PURE and other systems as required by the site or sponsor.
- Respond to, follow up and resolve or escalate enquiries on study start up activities and contract administration processes and as the key point of contact for contract administration.
- Generate and maintain regular reports for the CTU team on study start up activities.
- Comply with relevant EEO and WHS regulations.
- Perform any other duties as required and appropriate for this classification.

### POSITION CONTEXT

| Reports to: | Clinical Trials Manager |
| Positions | Direct: nil |
| Reporting to: | Indirect: nil |
| Key Direct Clients: | Clinical Researchers, Patients, Research Governance and Ethics, External partners e.g. pharmaceuticals, other medical research funding bodies, Staff in the Clinical Trials Unit, Office of University General Counsel |
| Other Key Relationships: | Research and clinical staff, Macquarie University Hospital staff, 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: | Nil |
| Scope and autonomy | Within defined parameters, adapts and develops processes, procedures, systems and/or techniques that impact how work is performed. |
| Problem solving | Regularly identifies designs, develops and implements improvements to work procedures, practices, systems and/or techniques. |
### 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>COMPETENCIES</th>
<th>ATTRIBUTES</th>
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<tbody>
<tr>
<td><strong>Planning and Execution</strong>: Managing time and resources to complete tasks and achieve objectives.</td>
<td><strong>Perseverance</strong>: Persevering despite obstacles to ensure tasks are completed.</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>Communication</strong>: Effectively articulates key messages, both verbally and in writing, adapting to suit context and audience.</td>
<td><strong>Reliability</strong>: Meeting commitments and responsibilities.</td>
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<td><strong>Service Focus</strong>: Making students, staff, alumni and other key contacts and their needs a priority.</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>Relationship Management</strong>: Establishing effective working relationships with others.</td>
<td><strong>Resilience</strong>: Dealing effectively with and recovering quickly from setbacks or pressure.</td>
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<td><strong>Teamwork</strong>: Working in collaboration with others to achieve shared goals.</td>
<td><strong>Integrity</strong>: Maintaining confidentiality, discretion and professionalism.</td>
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<td><strong>Improvement Focus</strong>: Finding better ways of completing tasks or solving problems.</td>
<td><strong>Initiative</strong>: Taking action, on own accord, to address problems and prevent them from reoccurring.</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 experience in clinical trials.
- 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.
- Knowledge of the development and implementation of Phase I, II, III and IV clinical trials.
- Basic understanding of budgets and accounting.
- Ability to interpret and review clinical trial contracts.
- 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, including University processes and departments for contract execution.
- Understanding the local market/context for clinical trial budgets.
- 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.

- Working in clinical research, particularly in clinical trials start-up procedures and contracting.
- Taking patient samples.
- Consulting with patients in a sensitive manner.
- Handling confidential patient information and informed consent processes.
- Ability to independently track and manage contracts administration processes through to execution in a busy environment, under time pressures.
- Managing key stakeholder relationships.
- Experience contributing to projects involving risk management and process improvement in a clinical research setting.
- Working in a Clinical Trials team.