# Position Description

<table>
<thead>
<tr>
<th>Title:</th>
<th>Clinical Trials Coordinator</th>
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</thead>
<tbody>
<tr>
<td>HEW Level:</td>
<td>HEW 5</td>
</tr>
<tr>
<td>Faculty/Office:</td>
<td>Faculty of Medicine, Health and Human Sciences</td>
</tr>
<tr>
<td>Position Number:</td>
<td></td>
</tr>
<tr>
<td>Department/Team:</td>
<td>Clinical Trials Unit</td>
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<tr>
<td>Date:</td>
<td>October 2020</td>
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## Position Purpose

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

### ORGANISATIONAL CONTEXT

The Faculty of Medicine, Health and Human Sciences is ambitiously pushing the boundaries of progressive thinking and challenging what’s possible to solve some of the big issues of our time, both nationally and on a global scale. The Faculty forms part of MQ Health, an integrated academic health sciences enterprise which incorporates Macquarie University Hospital and primary and speciality clinics. We have active research programs in biomedical and clinical sciences, cognitive and brain sciences, health systems, linguistics, physiotherapy, psychology and public health, amongst others. Our Faculty hosts the Australian Institute of Health Innovation (AIHI), an internationally acclaimed powerhouse researching health systems, e-health and patient safety. In learning and teaching, the Faculty offers a unique suite of undergraduate and postgraduate courses in many areas, including clinical, health and human sciences, linguistics, medicine, psychology, physiotherapy, speech pathology and audiology.

### ORGANISATION CHART

![Organisation Chart Image]
### 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

#### Reports to:
Clinical Trials Manager

#### 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><strong>COMPETENCIES</strong></th>
<th>Clusters of behaviours required for successful performance.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Planning and Execution:</strong></td>
<td>Managing time and resources to complete tasks and achieve objectives.</td>
</tr>
<tr>
<td><strong>Quality Focus:</strong></td>
<td>Ensuring accuracy and quality when completing tasks.</td>
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<tr>
<td><strong>Communication:</strong></td>
<td>Effectively articulates key messages, both verbally and in writing, adapting to suit context and audience.</td>
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<tr>
<td><strong>Service Focus:</strong></td>
<td>Making patients, staff, and other key contacts and their needs, a priority.</td>
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<tr>
<td><strong>Relationship Management:</strong></td>
<td>Establishing effective working relationships with others.</td>
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<tr>
<td><strong>Teamwork:</strong></td>
<td>Working in collaboration with others to achieve shared goals.</td>
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<tr>
<td><strong>Improvement Focus:</strong></td>
<td>Finding better ways of completing tasks or solving problems.</td>
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<table>
<thead>
<tr>
<th><strong>ATTRIBUTES</strong></th>
<th>Personal qualities related to successful performance.</th>
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<tbody>
<tr>
<td><strong>Perseverance:</strong></td>
<td>Persevering despite obstacles to ensure tasks are completed.</td>
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<tr>
<td><strong>Flexibility:</strong></td>
<td>Responding effectively to unexpected or changing circumstances.</td>
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<tr>
<td><strong>Reliability:</strong></td>
<td>Meeting commitments and responsibilities.</td>
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<tr>
<td><strong>Interpersonal Impact:</strong></td>
<td>Making a positive impression on others in a range of interpersonal contexts.</td>
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<tr>
<td><strong>Resilience:</strong></td>
<td>Dealing effectively with and recovering quickly from setbacks or pressure.</td>
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<td><strong>Integrity:</strong></td>
<td>Maintaining confidentiality, discretion and professionalism.</td>
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<tr>
<td><strong>Initiative:</strong></td>
<td>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
- 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)*