# Position Description

**Title:** HREC & Regulatory Administrator, Clinical Trials Unit  
**HEW Level:** 5

**Faculty/Office:** Faculty of Medicine, Health and Human Sciences  
**Position Number:**

**Department/Team:** Faculty Administration  
**Date:** Feb 2020

**Position Purpose:** To provide support to the clinical trials unit in Faculty of Medicine and Health Sciences in the preparation and coordination of Human Ethics Research Committee applications.

## 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, MQ Health, the Macquarie University Health Sciences Centre will see true convergence of the learning and research endeavours of Macquarie’s Faculty of Medicine, Health and Human Sciences, the clinical care provided at Macquarie University Hospital (MUH) and Macquarie University Clinical Associates (MUCA). MQ Health 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.

Macquarie University Clinical Associates (MUCA) provides clinical services to MUH and Clinic and engages clinicians in innovative employment relationships within MQ Health, allowing them to undertake academic and clinical work within MUH, the Clinic and the University.

The Faculty of Medicine, Health and Human 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 cardiovascular science, amongst others. The Faculty hosts the Australian Institute of Health Innovation, an internationally acclaimed powerhouse researching health systems, e-health and health informatics, and patient safety.

## ORGANISATION CHART

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Director, Clinical Trials
  /           \                  /           \
 Head of Operations  Clinical Trials Manager  Clinical Trials Assistants
   \       \                     \       \                               /     
Clinical Trials Coordinators x5  HREC Team Leader
                             HREC & Regulatory Administrator
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Faculty of Medicine and Health Sciences/HREC Administrator, Clinical Trials Unit/ V.1.0  
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KEY ACCOUNTABILITIES

- Provide administrative support to the clinical trials unit for the preparation and submission of Human Research Ethics Committee (HREC) forms and documentation to the ethics committee, including handling the end-to-end processing of applications.
- Provide procedural advice to sponsors and researchers regarding HREC policies, guidelines and legislations relating to human research.
- Liaise with sponsors to verify Human Ethics Research Applications (HREAs) and ensure they are compliant with submission requirements including gathering further information and completing HREAs.
- Work with the ethics committee to respond to, resolve or escalate queries about HREC applications.
- Collate consent forms, resumes, certifications, site specific information and related other documents to satisfy regulatory compliance checks as part of the application process.
- Prepare annual progress reports in accordance with ethical protocols and protocol brochures per trial for the committee on clinical trials undertaken by the unit.
- Act as the key liaison between the Unit, the Faculty, the University Research Office and relevant other offices across the University regarding all types of internal and sponsor HREC applications and processes.
- Recommend and document standard operating procedures for dealing with HREAs and HREC processes.
- 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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<tbody>
<tr>
<td>Positions Reporting to:</td>
<td></td>
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<tr>
<td>Direct: nil</td>
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<tr>
<td>Indirect: nil</td>
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Key Direct Clients:
- External Sponsors
- Associate Dean, Research Faculty of Medicine, Health and Human Sciences
- Academic staff and researchers in Faculty of Medicine, Health and Human Sciences
- University Research Office, particularly Research Ethics & Integrity and Contracts teams
- MQ Ethics Committee

Other Key Relationships:
- MUH Pharmacy
- Macquarie Medical Imaging
- Immediate team members
- Clinical Research Manager
- Faculty Research Manager

Budget Accountability: Nil

Role-specific Conditions:
- Criminal 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>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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<tr>
<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>Integrity:</strong> Maintaining confidentiality, discretion and professionalism.</td>
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<td><strong>Teamwork:</strong> Working in collaboration with others to achieve shared goals.</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.

- Well-developed computer skills in database management, MS Word, Excel, PowerPoint and web-based research.
- Understanding of human ethics processes in a tertiary environment.
- Knowledge of legislation and regulations relating to medical research.
- Knowledge of Medicine Australia’s contracting guidelines.

### 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 the Faculty of Medicine, Health and Human Sciences functions and structure, as well as established policies, systems, processes and procedures.
- Knowledge of the Faculty of Medicine, Health and Human Sciences research, organisation, operation and processes.
- Understanding of how University policies, systems, processes and procedures are applied at the Faculty/Office level.
- Knowledge of other areas of the University, such as the Research Office, and how they interact with the Faculty.
- Knowledge and understanding of the impact of external regulatory frameworks e.g. The National Statement on Ethical Conduct in Human Research and the Australian Code for the Responsible Conduct of Research on HREC practice and processes.
- Knowledge of Macquarie Human Ethics and Animal Ethics web pages, policies, procedures and governance structures in the University.

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

- Experience working with/or supporting committees.
- Preparing reports.
- Providing advice and guidance on HREAs and HREC processes and documentation.
- Working in a high-volume service focused environment.
- Working to deadlines and timeframes.
- Working with a diverse range of internal and external stakeholders.
- Working within a complex organisation.