

POSITION DESCRIPTION – General Staff

Position Title: Clinical Operations Coordinator Level: 6/7
Faculty/Division: Illawarra Health and Medical Research Institute (IHMRI)

Primary Purpose of the Position:

Reporting to the IHMRI Operations Manager, this position involves coordination of operational activities taking place in the IHMRI Clinical Research and Trials Unit (CRTU). The role encompasses a great deal of activity around developing unit capabilities and capacity to host a variety of clinical research projects and taking strategic action to ensure ongoing growth of clinical trial activity. There is an operational focus in the role which includes coordination of administrative activities relating to clinical trials, including Clinical Trial Agreements, governance paperwork, and preparation of various reports, collating CRTU finance information, establishing and maintaining administrative systems for the unit, liaising with various internal and external stakeholders.

Position Environment:

The Illawarra Health and Medical Research Institute (IHMRI) is a collaborative venture of the University of Wollongong (UOW) and the Illawarra Shoalhaven Local Health District (ISLHD). Its goal is to further develop health and medical research undertaken in the Illawarra, with a focus on collaboration across the academic and clinical research contexts. The Institute is in its formative stages with its operations set to grow significantly over the next 12 months and beyond. In mid 2010 the Institute transferred its operations to its dedicated and specially designed building, on the University campus. Along with international standard PC2 and PC3 laboratories, the building includes a dedicated clinical research and trials space designed for the conduct of a range of investigator led clinical research (lifestyle intervention related in particular) and pharmaceutical company sponsored clinical trials.

This venture provides an exciting opportunity for highly motivated, flexible and multi-skilled individuals to work as part of a committed and outcomes-oriented team that will shape and build the Institute as a strategic priority for the University over the next few years. The position environment will be dynamic with changing demands as the Institute develops and grows; this environment will suit a multi-skilled professional who is adaptable and prepared to take initiative and step out-side job boundaries at times in the interests of achieving demanding deadlines and common goals.

Major Accountabilities/Responsibilities:

Responsibilities	Outcome	Percentage of time
1. Oversee establishment of, implement and maintain a comprehensive set of policies, systems, and procedures relating to IHMRI clinical research activities, clinical research governance and the CRTU	Documented and up-to-date policies and operating procedures; Governance and risk management of CRTU controlled	30
2. Ensure appropriate forward planning, progress tracking and coordination of CRTU projects and activities.	CRTU plans and objectives align with IHMRI development plans	20
3. Ensure the efficient administration of the CRTU by initiating quality control activities as required, and monitoring contracts,	All Unit deliverables and compliance met as required via efficient processes.	10

	insurance and OHS.		
4.	Ensure continuous quality improvement programs are in place and actioned by establishing and meeting key performance indicators for critical activities in the CRTU.	Ongoing improvement in services, processes and operations.	20
5.	Supervision and coordination of CRTU staff.	Staff managed according to current UOW Enterprise Agreement; performance agreements reflect IHMRI strategic planning documents and KPI targets.	10
6.	Contribute to strategic planning, budgeting, coordination of marketing/recruitment activity and development activity relating to CRTU operations.	Appropriate plans for strategy and resource allocation; plans implemented in timely manner.	10
7.	Work with the CRTU Clinical Coordinator to recruit staff.	Quality staff employed as appropriate.	Ongoing
8.	Communicate and consult with staff on workplace and staffing matters.	To foster direct relationships with staff and enhance engagement with the organisation.	Ongoing
9.	Observe principles and practices of Equal Employment Opportunity.	Ensure fair treatment in the workplace.	Ongoing
10.	Have OH&S responsibilities, accountabilities and authorities as outlined at: http://staff.uow.edu.au/ohs/commitment/responsibilities/	Ensure a safe working environment for self & others.	Ongoing

Reporting Relationships:

Reports to	IHMRI Operations Manager
Supervises	Senior Clinical Trials Coordinator; Clinical Trials Coordinator

Key Relationships:

Contact/Organisation:

IHMRI Chief Operating Officer & IHMRI Operations Manager
 IHMRI Finance and Administration staff
 IHMRI Senior Technical Officer
 Research Leaders and Groups
 Academics, clinicians and investigators

 Illawarra Shoalhaven Local Health District Clinical Trials Coordinators

Purpose & Frequency of contact

Policy, planning, administrative and operational matters

 Share information and arrange appropriate services
 Equipment and facility operations, technical support
 Access and use of facilities, reporting, planning activities
 Liaison with users of facilities/identification & provision CRTU services
 Maintain contact with professional networks, contribute to local expertise

Key Challenges:

1. Ongoing improvement of the CRTU documentation, policies, procedures and templates to support clinical trials.
2. Ensure the program of CRTU activities meets IHMRI's strategic and operational goals.
3. Maintain a high level of accuracy and detail in a continuously busy and demanding environment; working to a high standard in the administration and monitoring of CRTU Trials and Clinics
4. Develop and maintain effective communication with external and internal stakeholders, in the governance, start-up and continuing administration of clinical trials, clinics and other CRTU interests.

SELECTION CRITERIA - Knowledge & Skills:

Essential:

- Knowledge and understanding of wide range of administrative coordination principles within large organisations, including developing and documenting processes, quality control and basic finance principles
- Knowledge of issues and administrative processes associated with clinical research exceptional organisation skills
- Ability to manage conflict, solve problems and to follow through on issues and negotiate positive outcomes
- Excellent communication and interpersonal skills, customer service skills and sound business ethics
- Demonstrated ability to work under limited direction, prioritise and exercise judgement where documentation/information is not clearly defined
- Ability to interpret and apply contents of documents such as Legislation, Codes of Practice and Industry Guidelines
- Ability to liaise, negotiate and manage relationships with a variety of external stakeholders
- Competent user of Microsoft products

SELECTION CRITERIA - Education & Experience:

Essential:

- Relevant post-secondary qualifications in relation to Administration and/or combination of education, training and experience deemed to be equivalent
- Considerable administrative experience including development of administrative procedures, procedures relating to commercial clinical trials and trial start-up
- Experience preparing required documentation for trial start-up
- Experience using policy, strategy and operational principles to guide decision-making
- Experience in negotiation and problem-solving
- Experience in staff coordination/supervision role in clinical setting

Personal Attributes:

- Ability to maintain confidentiality and act professionally at all times
- Strong outcomes focus with flexibility to meet the demands of a changing work environment

Special Job Requirements:

- Flexibility to work outside of normal office hours as required
- Working with children check may be required

Organisational Chart:

Available on request.

Approval:

Approved by Head of Unit: _____

Date: _____

Approved by Personnel: _____

Date: _____