POSITION DESCRIPTION – General Staff

Position Title:	Senior Clinical Trials Coordinator	Level:	6/7
Division:	Illawarra Health and Medical Research Institute	Unit::	Clinical Research and Trials Unit

Primary Purpose of the Position:

Reporting to the Clinical Operations Coordinator, this position will support commercial clinical trial activity within the CRTU. Responsibilities include provision of clinical services, undertaking clinical procedures as required across a variety of clinical trials, screening and recruitment procedures, and review of trial protocols to determine feasibility. Liaison with the Clinical Operations Coordinator to develop budget forecasts, administrative coordination of trials, records and data, as well as quality control/compliance activities.

This position takes a lead role in coordination and management of the Commercial Clinical Trials, providing guidance and expertise to less experienced Clinical Trials Coordinators.

The position is full-time but flexible working arrangements may be considered. Working outside of business hours may be required from time to time.

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.

The existing Clinical Research and Trials Unit (CRTU) is a well-equipped state of the art facility and is currently utilised for commercial sponsored pharmaceutical and Investigator-Initiated Trials with expected continued growth in both these areas. The CRTU provides an exciting opportunity for a highly motivated, flexible and multi-skilled individual to work as part of a committed and outcomes-oriented team that will shape and build the unit as a strategic priority for the University over the next few years. The position environment is dynamic with changing demands as the Unit develops and grows; this environment suits a multi-skilled professional who is adaptable and prepared to take initiative and step outside job boundaries at times in the interests of achieving demanding deadlines and common goals.

Major Accountabilities/Responsibilities:

Responsibilities		Percentage of Time	Office Use Only
1.	Coordination of trials by adherence to relevant protocols and principles of GCP. This includes but is not limited to coordination of ethics applications, fulfilling governance requirements, attendance at investigator meetings, subject recruitment, inventory, trial documentation, data management, and file management.	50	
2.	Performing clinical procedures or collection of specimens for a variety of trials as required in accordance with trial protocols and ICH GCP.	20	
3.	Mentoring Clinical Trials Coordinators in regulatory aspects of trials and trial coordination.	5	
4.	Contribute to establishing and maintaining a comprehensive set of policies, systems, procedures and inventory for the conduct of clinical trials in accordance with ICH GCP.	5	
5.	Maintain accountability records for investigational products adhering to regulations set by TGA, protocol and other governing bodies	5	
6.	Attendance at Investigator meetings as an integral part of site preparedness for Trial initiation-may involve national and/or International travel.	5	
7.	Maintain Workplace Health & Safety lines of communication through representation on and reporting to the appropriate Workplace committees, regarding activities and procedures occurring in the CRTU.	5	
8.	Continuous quality improvement activities and strategic planning through contribution to their development and meeting key performance indicators for critical activities in the CRTU.	Ongoing	
9.	Communicate and consult with staff on workplace and staffing matters.	Ongoing	
10.	Observe principles and practices of Equal Employment Opportunity.	Ongoing	
11.	Have OH&S responsibilities, accountabilities and authorities as outlined at: http://staff.uow.edu.au/ohs/commitment/responsibilities/	Ongoing	

Reporting Relationships:

Position Reports to:	Clinical Operations Coordinator
The position supervises the following positions:	n/a
Other Key Contacts:	IHMRI Operations Manager; Clinical Coordinator; other CRTU Clinical Trial Coordinators; CRTU Director; Clinical Co-Investigators; IHMRI reception staff; trial sponsors, CRA's and suppliers.

Key Relationships:

Contact/Organisation:	Purpose & Frequency of contact
Clinical Operations Coordinator	Trials progress, regular contact
Clinical Coordinator	Clinical support and direction, regular contact
Principal and Associate Investigator	Trials progress, regular contact
Clinical Research Authorities	Trials progress, regular daily/weekly correspondence

SELECTION CRITERIA - Knowledge & Skills:

Essential:

- Working knowledge of issues associated with clinical trials, including: trial data collection and management, completion of source documents, using and updating electronic case record/report forms, registration and management of adverse events, filing and archiving, managing monitoring visits and dealing with trial-related queries
- Demonstrated experience interpreting and adhering to clinical trials protocols
- Experience in recruitment and co-ordination of trial subjects covering informed consent, screening and inclusion of subjects adhering to protocol, safety and compliance issues

SELECTION CRITERIA - Education & Experience:

Essential:

- Experience coordinating clinical trials
- Experience working in pre-analytical laboratory and knowledge of laboratory practice
- Sound working knowledge of good clinical practice (ICH GCP), research ethics and quality control principles
- Demonstrated ability to maintain confidentiality and comply with privacy requirements.
- Current ECG and venepuncture certification
- Current certification for Transport of Infectious Substances by air
- Highly competent user of Microsoft products, including Excel and Outlook
- Recent experience in a variety of phase III-IV trials

Desirable

- Spirometry experience
- Registered Nurse

Personal Attributes:

- High level written and oral communication skills.
- A well developed understanding of and commitment to providing excellent customer service.
- Proven ability to work as a member of a team in a dynamic environment without close supervision.
- Ability to be proactive, personable, flexible and motivated
- Strong attention to detail

Special Job Requirements:

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

Organisational Chart:

Available on request

Approval:

Approved by Head of Unit: _____

Date: _____

Approved by Personnel: _____

Date: _____