UNIVERSITY OF WOLLONGONG

POSITION DESCRIPTION – General Staff

Position Title: Clinical Trials Coordinator | Level: 5

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 clinical trial activity within the CRTU with responsibilities including provision of clinical services, undertaking clinical procedures as required in a variety of clinical trials, screening and recruitment, administrative coordination of trials, records, and /data, as well as quality control/compliance activities.

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, attendance at investigator meetings, recruitment, inventory, trial documentation, data management, governance requirements and file management.	30	
3	Performing clinical procedures or collection of specimens for a variety of trials as required, in accordance with trial protocols and ICH GCP.	30	
4	Contribute to establishing, and then maintaining, a comprehensive set of policies, systems, procedures and inventory for the conduct of clinical trials in accordance	10	

	with ICH GCP.		
5	A range of trials-related duties, including regular correspondence with investigators, arranging participant appointments and follow-up, providing written or verbal reports of trial progress and undertaking other project activities.	10	
6	Up keep of common stocks and stores of the CRTU, e.g. clinic and lab stock purchasing, maintenance and stock take; waste disposal; equipment maintenance, cleaning and laundering.	10	
7	Contribute to continuous quality improvement programs and strategic planning by contributing to their development and meeting key performance indicators for critical activities in the CRTU.	5	
9	Observe principles and practices of Equal Employment Opportunity.	Ongoing	
10	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 Operations Coordinator; 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
Clinical Research Authorities	Trials progress, regular daily/weekly correspondence

SELECTION CRITERIA - Knowledge & Skills:

Essential:

- Knowledge of issues associated with clinical trials, including: trial data collection and management, collection of source documents, using and updating case record forms, registration and management of adverse events, filing and archiving, managing monitoring visits and dealing with trial-related queries
- Recruitment and co-ordination of the trial subjects covering informed consent, screening and inclusion of the subjects adhering to safety and compliance issues
- Excellent data entry skills with high level of accuracy
- Experience working to documented policies, processes and experimental protocol

Desirable:

- Ability to prioritise work and multi task to effectively support a number of clinical trials simultaneously

SELECTION CRITERIA - Education & Experience:

Essential:

- Experience working as a Clinical Trials Coordinator
- 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
- Highly competent user of Microsoft products, including Excel and Outlook.

- Demonstrated ability to maintain confidentiality and comply with privacy requirements.
- Current ECG and venepuncture certification or recent workplace training and experience.
- Current certificate for Transport of Infectious Substances by Air

Personal Attributes:

- High level of written and oral communication skills
- Well developed understanding 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: _____