Clinical Trials Coordinator
POSITION DESCRIPTION

Research Group:	Haematology Clinical Trials
Status:	Full-time for one (1) year, renewable based on performance and funding
Salary:	$65,000 to $80,000 per annum or pro rata, commensurate with experience and 9.5% super. Salary packaging is available
Reports to:	In the first instance, the Haematology Clinical Trials Manager, then the Director of the Haematology at Liverpool Hospital and for nonoperational purposes the Institute's Human Resources Manager

Background

The **Ingham Institute for Applied Medical Research** (the Institute) is a not-for-profit organisation located in Sydney's South West that conducts world-class medical research that is rooted in and driven by the needs of the local community and wider Australia.

The Institute is the pre-eminent research institute for South Western Sydney. It is home to 360 staff, over 40 research groups, and five (5) research streams that are committed to its vision of Inspiring Health and Transforming Care.

The Institute is integral to a unique collaboration with the South Western Sydney Local Health District, Western Sydney University and the UNSW Sydney. Through these collaborations the Ingham Institute is working to radically transform health outcomes both locally and globally.

The Liverpool Hospital Haematology Clinical Trials Unit operates in a family-friendly, supportive team environment. All team members of the team are provided ongoing support and training. Our team consist of 12 Haematologists, eight (8) Advanced Trainees, Clinical Trials Manger, clinical trials coordinators, and a Clinical Trials Pharmacist.

A Clinical Trials Coordinator is sought to work with the Haematology Clinical Trials Unit based at Ingham Institute.

Purpose of Position

The Clinical Trials co-ordinator is responsible for the conduct and implementation of clinical trial protocols and for the promotion of the health and wellbeing of the patient under care. This may involve collection of appropriate data and records as well as clinical care. The research coordinator is also responsible for coordinating the care and education of those participating in clinical trials as well as monitoring and reporting safety of the trials

Challenges

•Research Management:
- Liaise with and facilitate collaboration between relevant departments to ensure the

provision of quality clinical trials services in line with the divisions and organisation's core values and within the limits of the study protocol. This can be a major challenge as each study protocol is different and the Coordinator has to be able to organise the various tests and scan that the study requires within the timeline in the protocol.
- Responsible for recruiting and screening potential participants-If patients are not screened properly they may be made ineligible to go into the study and therefore not have access to a drug that may improve their outcome.

• Research Process and Data Collection:
-Responsible for complete, accurate and comprehensive records with verifiable source documentation, maintenance and provision of Case Record Forms, in order to allow their evaluation of the trial. This can be a challenge as different carers have to ensure that everything that happens to a patient on study must be documented and the coordinator is responsible for ensuring all carers are educated in this process.
- Respond to data queries as they arise. Data Queries can be ambiguous as they are raised by Data Management, who do not always have a clinical background.
- Uses clinical advanced assessment and problem solving skills in the evaluation and documentation of outcomes/endpoints including toxicity related to clinical trial treatments.

Decision Making

- Assist the Principal Investigator with appropriate selection and enrolment of participants in the clinical trial through a thorough knowledge and understanding of the current clinical trial protocols by viewing medical records with the protocol specific inclusion/exclusion criteria.
- Scheduling or undertakes protocol specified procedures such as blood taking and ECG monitoring.
- Responsible for ensure safe handling and transportation of blood products and tissue samples, within Australia and internationally, in accordance with IATA and Australian Customs and Quarantine guidelines.
- Scheduling protocol specified technological recordings (eg x-rays and MRIs scans) at appropriate time points within the protocol.
- Responsible for scheduling patient appointments within the protocol specified time points.
- Provides ongoing patient assessment, clinical advanced assessment and problem solving skills in the evaluation and documentation of outcomes/endpoints including toxicity related to clinical trial treatment
- Regular clinical assessment of each patient and ongoing physical assessments, including: - Measurement of vital signs and protocol requires assessments - Education of the disease processes, management, minimisation and prevention.

Criteria

ESSENTIAL:

- Degree qualification in science (e.g. Pharmacist, EEN) Australian, NSW Registered Nursing (RN) and/ or equivalent experience.
- Demonstrated excellent time management skills.
- Demonstrated excellent interpersonal skill.

- Working rights in Australia
- Ability to Strictly follow SOP
- Demonstrated ability to communicate effectively with basic skills in written and oral communication and demonstrate co-operation within a team environment.
- Demonstrated strong customer focus and responsiveness and caring towards patients and their significant others.
- Demonstrated high level of accuracy and attention to detail.
- Experience in the administration of patient services in a large complex organisation.
- Experience using Microsoft Windows programs, willingness and ability to learn local software as required (i.e. Aria, EMR etc).
- Experience working in research and / or clinical trials and / or cancer services.
- Interest in pursuing further training in clinical research will be considered for new graduate from nursing or pharmacy background
- Demonstrated initiative and considered decision making under broad supervision.

DESIRABLE:

- Ability to work between 7:00 am to 7:00 pm. Early start or late finish occasionally based on protocol requirement
- Experience with venepuncture and cannulation with blood collection (Training can be
- provided)
- Previous experience in clinical trials in Australia.
- Basic Knowledge of clinical research practices, ethical obligations, ICH and GCP.

Key Accountabilities	Key Performance Indicators
Ensure accurate conduct of the clinical trial according to the trial protocol by:	• Liaising with Chief Investigator, pharmaceutical company representatives, collaborative groups, other sites, clinicians, other health professionals, other departments, Ethics Committee representatives • Preparing of Ethics Committee submissions and ongoing trial reports and advice of any amendments and safety notifications • Accurately completing trial Case Record Forms and maintaining trial documentation for regular monitoring visits by Clinical Research Associates from pharmaceutical companies or others as required. Participate in an audit by regulatory authorities if required • Financial tracking and invoicing of trial payments • Undertaking patient recruitment; explanation of trials to patient, obtaining informed consent, undertake follow-up • Organise specimen taking/delivery • Organising diagnostic investigations/reports/study drug or intervention as per trial protocols
Research Process:	• Co-ordination of clinical trials at this site. • Overview of coordination of clinical trials conducted at other sites as a multi-centre trial coordinator. • Demonstrate knowledge of a range of research approaches and their application in Clinical Trials. • Responsible for reading, taking active steps to understand and maintaining a working knowledge of Study Protocol/s for which you are responsible. • Responsible for prioritising workload and maintaining effective records
Communication :	Clinical Trials Co-ordinators works closely with: • Clinical Trials Manager • Clinical Trials Co-ordinator/s

	• NUM of the CTC • Sponsor representative • Investigators • Patients • Pharmacy • Pathology • And other departments where applicable
Demonstrates effective communication skills by:	• Communicating appropriately and effectively with patients at all times • Seeking to identify current patient needs • Educating patients appropriate to their needs • Ensuring all staff involved in patient treatment and care are educated, according to need, in the following areas- trial treatment mode of action, dose and administration, drug interactions and side effects.
Be familiar with and comply with relevant State and Federal Privacy Legislation for the access, use, handling and storage of health data.	▪ Adheres to legislative requirements. ▪ Complies with legislative requirements regarding access and reporting.
Understand and uphold WHS requirements and responsibilities.	▪ Complies with the Institute's WHS Statement and WHS Policy and Procedures. ▪ Is always mindful of workplace safety as it pertains to self. ▪ Reports all accidents within 24 hours. ▪ Makes proper use of relevant safety equipment. ▪ Attends training programs as directed.
Contribute to the team-work culture at the Institute.	▪ Is an effective and positive team member. ▪ Attends Institute staff meetings and, where applicable, shares information available at these meetings with colleagues.

	▪ Complies with the Institute Code of Conduct. ▪ Actively contributes to the research culture at Ingham Institute. ▪ Participates in Ingham Institute supporting activities, as required.