**POSITION DESCRIPTION**

**POSITION TITLE:**

Neurology Trials Nurse

**REPORTS TO (Title):** Dr Mason & Dr Wu

**PRINCIPAL OBJECTIVES**

The Clinical Trials Nurse:

* Will plan, coordinate and administer clinical trials as required
* Ensures that all activities are carried out in accordance with the study protocol and standards and in compliance with all applicable laws, regulations, guidelines (ICH/GCP), policies, and Standard Operating Procedures (SOPs).
* Serves as a primary point of liaison and coordination between investigators, staff, research participants, sponsors, and Ethics committees. Provides information, education and assistance where required.
* To recruit, supervise and coordinate research subjects and serve as principle administrative liaison for the project.
* Is a resource person and support to the sponsor and clinicians, regarding tasks associated with the implementation and compliance with protocols and guidelines for the clinical trial.
* Promotes clinical trials as a means to determining best practice and improved health outcomes for patients within the Neurology Service.
* Completes operational requirements for studies; including contract and budget negotiation and CDHB Locality approvals.
* Develops and maintains accurate and complete files and record keeping systems, in accordance with CDHB and sponsor requirements.

**KEY PERFORMANCE OBJECTIVES:**

**Task**: **Co-ordinate the efficient running of studies throughout the complete process and demonstrate an extensive knowledge and understanding of designated study protocols. Ensure the research protocols are adhered to.**

* Demonstrates the ability to analyse large amounts of information to deliver quality advice and recommendations.
* Works in a collaborative framework with clinical and non-clinical research and neurology team members to support the “right person doing the right tasks”.
* Co-ordinates the initial process of setting up a clinical trial within the Neurology Service.
* Organises and monitors ongoing care and procedures required for study participation in collaboration with the patient and clinician.
* Ensures study protocol criteria are always observed and promptly reports any variances to the principal investigator for the study. Ensure that study protocol and regulatory requirements are followed.
* Ensures recruitment targets are met accurately and on time by developing and implementing efficient screening systems to identify eligible study participants.
* Ensures the patients receive comprehensive education regarding specific clinical trial patient information so they can give a truly informed consent.
* Liaises with Canterbury Health Labs for correct processing of blood sample specimen, and special storage requirements if needed. Ensure sample flow from set up, to laboratory, to shipping.
* Liaises with Pharmacy Clinical Trial Technicians re: budgeting, supply of study drug, prescriptions, and any other specific trial requirements.
* Ensure patient source documentation, clinical research files (CRFs) and investigator files are maintained in accurate, complete and up to date manner and are available when required. Maintains well documented, organised and up to date study files including study schedule, protocol and correspondence.
* Perseveres with tasks and achieves objectives despite obstacles. Resolves any problems that may arise in order to ensure that the quality of data collected is error free.
* Creation of study specific documents. Consistently performs tasks correctly – following set procedures and protocols.
* Ensure clinical trials adhere to the policies and practices of the Neurology Service as defined by the service guidelines and standard operating procedures (SOPs).
* Contributes to creating and updating internal SOPs.
* Plans and organises work, allocating time to priority issues, meeting deadlines and coping with the unexpected. Can adjust work style to fit with requirements.
* Participates in initiation and other study related meetings as required.
* When required, coordinates the review of financial and legal agreements with the research office ensuring all documentation required for start-up and continued conduct of the trial is received by the sponsor in a timely manner.

**Task**: **Conducts clinical trials in compliance with all national regulatory and ethics agencies, including the Declaration of Helsinki, nad GOOD Clinical Practice (ICH-GCP) guidelines.**

**Expected Result:**

* Obtains full ethical approval prior to starting trial (via NZ HDEC).
* Ensure study contracts and indemnities are completed accurately and signed.
* Determine and review clinical trial budgets and monitor throughout trial.
* Ensure all CDHB required locality approvals are obtained prior to starting study.
* Develops patient information sheets and consent forms and ensures their accuracy for our population.
* Works closely with NZ Ethics Committees for the duration of trials and ensures that GCP guidelines are strictly adhered to.
* Liaise with CRAs at the monitoring visits and be available to answer questions pertaining to the trial.
* Ensure all study documentation is kept up to date and archived appropriately – as required by the ethics committee and regulatory requirements.
* Is familiar with electronic databases in use for most clinical trials.
* Reports all adverse events (AEs) and serious adverse events (SAEs) as required by the protocol outlined in a timely manner and in accordance with GCP.
* Ensure Clinical Trials are conducted according to current and relevant Standard Operating Procedures (SOPs)

**Task**: **Provides support to other members of the team and contributes to the effectiveness and efficiency of resource utilisation of the Clinical Trials Unit.**

**Expected Result:**

* Works in collaborative manner to support all staff contributing to the running of successful trials.
* Manages own workload and assists other team members when able. Works cooperatively – willingly sharing knowledge and expertise with colleagues.
* Shows an understanding of how one’s own role directly or indirectly supports the health and independence of the community.
* Assists in the development of team resources.
* Works as a close member of the research team to ensure its continued cohesion, Develops constructive working relationships with other team members.
* Shows flexibility – is willing to change work arrangements or take on extra tasks in the short term to help the service or team meet its commitments. Supports in word and action decisions that have been made by the team.

**Task**: **The Clinical Trials Nurse is responsible for maintaining own levels of skill and knowledge.**

**Expected Result:**

* Is up to date with current technical and operational knowledge around the coordination of clinical trials to be able to deliver the outcomes required for this role.
* Attends and participates in relevant meetings and/or education sessions within the Neurology Service, CDHB, nationally and internationally.
* Has a written plan of goals which is evaluated annually as part of the professional performance appraisal.
* Is willing to help develop and present material at meetings, seminars and conferences.
* Fulfils requirements for maintenance of professional registration and indemnity insurance.
* Provides a quality service. Looks for ways to improve work processes – suggests new ideas and approaches. Willing to trial suggestions for improvement made by others.
* Demonstrates a working knowledge of current treatment delivery modalities; is familiar with current literature and developments in own professional field.
* Shows commitment to continuous learning and performance development.

**COMPETENCY PROFILE:**

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| **Dimension** | **Key accountabilities** |
| **Excellence in Clinical Practice** | * Provide expert knowledge in the management of patient care working with the patient, family/whanau or other health professionals to provide timely care to optimise outcomes * Uses advanced health assessment skills in the assessment of patients. * Recommends advanced evidence-based therapeutics, pharmacological/non-pharmacological interventions, diagnostic measures and treatments to meet the needs of patients, families and groups, in accordance with professional preparation, institutional policies and scope of practice |
| **Self-Management** | * Utilises a high level of emotional intelligence to behave professionally at all times, especially in situations of conflict or divergent viewpoints * Actively manages their own area of work and/or allocated project-based activities and initiatives * Uses initiative as well as effectively managing time and resources * Effectively manages and prioritises competing demands * Maintains confidentiality and security of information and data at all times |
| **Works Collaboratively** | * Actively initiates and proactively maintains highly effective internal and external relationships in a sensitive and professional manner * Shares knowledge and information, making it readily available in a way that is coordinated, accurate and containing all the information to meet the internal or external customers’ needs * Proactively seeks out and learns from collective experiences * Has a strong customer focus |
| **Specialist Knowledge** | * Current technical and operational knowledge around the coordination of clinical trials * The ability for critical-thinking and to analyse large amounts of information to deliver quality advice, recommendations and outcomes. * An appropriate knowledge of clinical trials processes and practices required to deliver the outcomes |
| **Professional Development** | * Maintain own clinical competence within specialty area * Develops and maintains a professional portfolio * Networks nationally and intentionally to maintain current knowledge of trends and developments in specialty area * Attends educational opportunities and conferences relevant to role and scope of practice * Participates in annual performance appraisal |
| **Partnership with Maori** | * Understands the principles of Te Tiriti o Waitangi and how these apply within the context of health service provision * Applies the notion of partnership and participation with Maori within the workplace and the wider community * Promotes and participates in targeting Maori health initiatives by which Maori health gains can be achieved * Implements strategies that are responsive to the health needs of Maori * Is aware of Te Ara Tika -Guidelines for Maori research ethics |