POSITION DESCRIPTION

ERH Clinical Trials Administrator

Supporting Everyone to be healthy and live well

PURPOSE OF THE ROLE

The Clinical Trials Administrator will work as part of the clinical research team to support the safe conduct of research in accordance with the Research Governance Framework and Good Clinical Practice guidelines and provide assurance that the rights, safety and well-being of trial participants are protected.

The Clinical Trials Administrator will work with the research team to provide administrative, clerical and data management support for all aspects of research study delivery across an extensive portfolio of clinical trials.

Position Details	
Position Title:	Clinical Trials Administrator
Department	Cancer and Wellness Centre
Reports to:	NUM CWC
Positions Reporting to this role:	None
FTE:	0.2
Budget:	Clinical Trail Activity Service Level Agreement
Enterprise Agreement:	HEALTH AND ALLIED SERVICES, MANAGERS AND ADMINISTRATIVE WORKERS (VICTORIAN PUBLIC SECTOR) (SINGLE INTEREST EMPLOYERS) ENTERPRISE AGREEMENT 2021-2025
Position Classification:	HS2
Position Description last reviewed:	January 2025

Key Accountabilities
Under direction take a leading role in providing all aspects of general administration and clerical work for the clinical research team including but not exclusively: Document preparation Telephone calls and accurate recording of communication Book Appointments Email and fax correspondence Typing letters Maintaining databases Filing / photocopying / scanning in a timely manner Patient records requests and collection Office management (including electronic diary management)
Provide meeting support by coordinating meetings and taking accurate meeting notes and action points.
Support the implementation of new quality systems and processes across the department.
Recognise the importance of key performance indicators and support the clinical research team to achieve them.
Recognise the importance of and adhere to Standard Operational Procedures and policies without supervision.
Prioritise a busy workload and manage multiple tasks when frequently interrupted.
Provide cover during periods of absence for other Cancer and Wellness Centre administrators and undertake general administration tasks related to service delivery.

ERH Clinical Trials Administrator

Treat all persons encountered during the course of duties with respect and courtesy and maintain a standard of conduct which best represents the clinical trials team and the practice.
Treat all persons encountered during the course of duties with respect and courtesy and maintain a standard of conduct which best represents the clinical trials team and the practice. Contribute to Patient and Public Involvement and Engagement activities across the practice including updating webpage content and poster boards etc. Ensure that all staff and patients are kept up to date with details of current studies.
Update the research management computer systems
Ensure that records for all study activities are kept up to date – this includes archive information and historical data.
Understand trial metrics and ensure that set up processes are managed and completed within the target timeframe.
Assist the clinical research team in co-ordinating a portfolio of studies.
Participate in Good Clinical Practice (GCP) training and ensures GCP compliance of self and team.
With support, coordinate the study set up process including: Assist in completing expression of interest / study selection documents Liaise with the study sponsor and research team to gather all relevant study information Prepare submissions for local research and development approval Coordinate site initiation meetings Set up the local site file and any relevant databases and documents for the study
Take a role in on-going study coordination including: Organisational skills to manage multiple clinical trials at various stages of development Conduct regular site file maintenance to ensure study essential documents are version controlled and are maintained according to regulatory requirements Support effective communication between the study sponsors and the clinical research team and appropriately managing all data requirements Support local implementation of study amendments Update quality systems to record study information and enrolled patients' details Coordinate and prepare documents for patient visits File preparation for monitoring visits Book trial specific investigations and procedures Collecting prescriptions or investigation results Coordinate study monitoring visits Support the research team with data queries and reporting as required Consistently demonstrate the ability to work accurately
Take a leading role in study close out procedures including: Liaise with the sponsor for final monitoring visit Preparing study documents for archiving Following archiving procedures
Support data entry according to study complexity and ensure that data is transcribed accurately where required.
Support and prepare for internal/external audit and monitoring.
Ensure that all Clinical Trials staff are up to date with their International Conference on Harmonisation-Good Clinical Practice (ICH-GCP) training and keep copies of certificates for file. Ensure that any other relevant training is kept up to date for Partners and the Clinical Trials Team.
Create financial schedule from Clinical Trial Authorisation (CTA) to check amounts owed/paid.
Generate invoices and manage payment schedule, chasing any outstanding payments.
Produce quarterly reports of Clinical Trial Finances.

Organisational Responsibilities
Positively promote ERH within and externally to the organisation

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Comply with the ERH and Victorian Public Sector Code (VPS) of Conduct
Each employee has a responsibility to comply and promote practices with all ERH policies and procedures and familiarise themselves with those relevant to their position
Comply with relevant registration bodies mandatory continuing professional development requirements
Carry out all work and interactions in alignment with the CARE values
Each employee has a responsibility to comply with and promote relevant legislation and professional standards in relation to safety, quality and risk relevant to their position
Each employee has a responsibility to comply with and promote compliance with the National Safety & Quality Health Service Standards and other industry standards and relevant regulatory requirements

CARE Values	
All staff are expected to behave in a way that is in alignment with our corporate values:	
Collaboration 	Works with a team focus Cooperates with others and gains input and support to assist in achieving objectives We work with others to achieve shared goals
Accountability 	Monitors the impact of one's own behaviour on others Supports a "no-blame" culture in reporting incidents and helping to effectively resolve them
Respect 	Treats people fairly and openly Treats people with dignity Demonstrates personal standards of consistency, tolerance and patience
Excellence 	Consistently supports and follows organisational policies and procedures Actively participates in identifying opportunities to improve what we do

Key Relationships	
Internal	**External**
NUM Clinical research team Research and Innovation team Principal Investigators Multidisciplinary team	Study participants and their families Diagnostic services Study sponsors and Clinical Research Associates

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Selection Criteria
Essential:
Qualifications: • Proven administration experience in healthcare service
• Microsoft Office software proficiency
• High level communication and interpersonal skills
• Must have excellent time management skills and commitment to deliver high quality results per PD
• Adaptable and shows initiative to collaborate and escalate appropriately.
• Able to work independently and effectively in a team.
• Medical Terminology training or experience
Satisfactory evidence of; National police check, Working with Children's and Vaccination status in line with policy and procedure at this time.
Desirable:
• Previous experience in clinical trial administration support

TERMS & CONDITIONS OF EMPLOYMENT:
Terms and conditions are in accordance with the Letter of Offer and Contract of Employment.

I acknowledge that I have received a copy of this position description. I have read (or have had read to me) and understand the requirements of this position. I agree to work in accordance with this position description.

Signed: Date: / /

Print Name:

cc: Employee File