HR191	**POSITION DESCRIPTION**	UNIVERSITY OF CAPE TOWN IYUNIVESITHI YASEKAPA • UNIVERSITEIT VAN KAAPSTAD

NOTES
- Forms must be downloaded from the UCT website: http://forms.uct.ac.za/forms.htm
- This form serves as a template for the writing of position descriptions.
- A copy of this form is kept by the line manager and the position holder.

POSITION DETAILS

Position title	IMARI-SA Research Professional Nurse WSU (Nelson Mandela Academic Hospital, Mthatha)		
Job title (HR Practitioner to provide)	Research Professional Nurse		
Position grade (if known)	08	Position grade (if known)	
Academic faculty / PASS department	Health		
Academic department / PASS unit	Department of Medicine		
Division / section	Allergology and Clinical Immunology		
Date of compilation	08 May 2024		

ORGANOGRAM

(Adjust as necessary. Include line manager, line manager's manager, all subordinates and colleagues. Include position grades

Prof Ntobeko Ntusi
Head of Department of Medicine
UCT
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Prof Jonathan Peter
Head of Division
Allergology and Immunology,
Department of Medicine,
University of Cape Town

Dr Avumile Mankahla
Division of Dermatology
Department of Medicine
Nelson Mandela Academic Hospital
Walter Sisulu University

Dr Fungiwe Gxolo
Department of Dermatology
Cecilia Makewane Hospital,
Walter Sisulu University

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Research Professional Nurse

Research Medical Officer

PURPOSE

The main purpose of this position is to participate in clinical research studies conducted by investigators, perform a variety of duties involved in the collection, compilation and documentation of clinical research data and monitoring activities. The Study Coordinator will be responsible for participant care and execution of clinical care of study participants as specified in the applicable study protocol and according to International Conference on Harmonization (ICH) Good Clinical Practice (GCP).

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CONTENT

	Key performance areas	% of time spent	**Inputs** (Responsibilities / activities / processes/ methods used)	**Outputs** (Expected results)
E.g.	General and office administration	25%	• Takes, types up and distributes minutes and agendas for monthly departmental meeting. • Greets visitors, enquires as to the nature of their visit and directs them to the appropriate staff member.	· All staff members receive an electronic copy of accurate minutes and agendas, in the departmental template/format, a week before the meeting. · Visitors are directed to appropriate staff member in a professional and efficient manner.
1	Study Co-ordination	30%	• Coordinate all study related activities - enrolment, recruitment, informed consent and retention. • Collection of informed consent, information from participant folders, interviews, questionnaires and other sources in line with Good Clinical Practice • Obtain participant specimen samples; coordinate transportation thereof to the laboratories • Ensure research nursing standards and patient care meet good clinical practice standards and requirements • Monitoring study related activities, before, during and after the study • Following of all elements of the study protocols, ensuring accuracy and completeness of consent forms (Quality Control) • Deal with participant issues related to the study • Checking the return of the investigational products • Develop patient recruitment strategy with PI and medical officer • Provide recruiters with all relevant required recruitment material • Track enrollment status • Plan monitor visits with sponsor/monitor • Have all documentation in good order and available for monitor • Prepare patient files for monitor review • Interact with monitor on any queries, complete any you can • Obtain, file and monitor correspondence	• Daily • Adherence to recruitment strategy • Meeting recruitment/retention targets (3-5 patients per day) • Eligible participants signed onto the study • Informed consent obtained before any study related procedures are performed • Signed consent obtained from all participants and filed appropriately • 100% of consenting performed to GCP standards • Monitor/CRA visits captured on electronic calendar • Ensure well organized files • Real time query resolution • Relevant correspondence filed appropriately • Positive feedback from monitors

2	**Clinical**	30%	• Explain study procedures to potential participants and obtain informed consent from participants and their parents / legal guardians • Perform all delegated study procedures as per qualifications i.e. vital measurements, skin prick tests, patch tests, clinical documentation, collect laboratory specimens etc. • Responsible for gathering necessary information from the research participants • Capturing demographic and clinical detail, laboratory and other investigative findings from research participants, participant folders, interviews, questionnaires and other sources in line with Good Clinical Practice • Safely and effectively administer study medication and calculate compliance. • Report any Adverse Events (AEs) / Serious Adverse Events (SAEs) that are either noted by you or reported to you by the participant to the Investigator immediately.	• Positive feedback from patients • Queries responded to politely, professionally and within the required timeframe • Blood sample processing and sampling as per lab manual • Ensure sufficient clinical supplies • All defined study protocol adhered to at all times • All required protocol parameters followed and recorded accurately • Participants records up to date • Participants records stored securely at all times

3	**Study Administration**	20%	• Ensure that the necessary documents are available and ready for each study visit (visit form, con meds form, AE / SAE form, IC process form and other required forms) • Report and track critical events and protocol deviations. • Management of participant records: maintain, retrieve and file according to study visits. This includes laboratory and procedure results after the Investigator has reviewed, signed and dated it. • Complete laboratory forms for specimen transfer/transport logs • Ensure all study procedures and tests are properly documented in source according to ICH GCP guidelines. • Review subject's information in preparation for the investigator's review. • Filing and updating patient records in patient files • Site file maintenance • Arrange for all systems access • Quality Control-Review participant records • Scheduling and contacting of patients for appointments, procedures as required by protocol • Follow up on scheduled visits • Ordering of new lab kits, equipment • Arranging and transport/shipping of samples	• Organised filing system in place • Accurate, updated patient records • Relevant study documentation available • Sufficient supply of project material • Study logs- Prescreening, Screening, Identification, Enrollment, IMP logs are completed and up to date • All randomization information (IVRS) filed in patient files
4	**IP Management**	5%	• Be responsible for all receipt, storage and return of medications • Be responsible for monthly IMP checks (check expiry dates) • Temperature control checks • Maintain accurate recording of study medication	· Drug Accountability and Compliance logs up to date · Printed weekly/monthly temperature records Drug filed appropriately
5	**Data Management**	5%	• Source data completion • Electronic Data Capturing • Electronic Data Capturing query resolution	• Accurate data capturing • Data captured within sponsor required timelines • EDC query resolution in a timeous manner

6	**Site Maintenance**	5%	• Ensure freezer temperature controls are adhered to • Ensure any equipment used is always correctly functioning • Implement immediately any corrective action necessary when malfunction is discovered • Maintain ongoing records of equipment checks and scheduled maintenance checks when appropriate • Report any problems to PI • Organize space for study equipment supplies	• Daily checking and recording of freezer temperature • Report any temperature excursions • Equipment calibration reports on file
7	**Financial management**	2%	• Manage petty cash: • Reimburse purchases against till slips and receipts. • Participant reimbursements tracked, and cash given to RA for disbursement. • Working with Finance manager to ensure payments by sponsor	• Participant records up-to-date. • Participant records stored securely at all times. • Petty cash float reconciled regularly • Participant re-imbursements available as required
8	**Ad-Hoc / General Duties**	3%	• Maintain own professional registration • Attend conferences and seminars to maintain current knowledge of clinical studies • Identify relevant career development opportunities • Attend monthly ALLSA training sessions • Attend weekly study team meetings • Any other Research administrative functions as required	• Current SANC receipt on file • Updated knowledge on current clinical studies • Upskill on knowledge of current practices

MINIMUM REQUIREMENTS

Minimum qualifications	• Registration with South African Nursing Council (SANC) • NQF level 7 (Degree or Diploma in General Nursing Science)
Minimum experience (type and years)	• Keen interest in Clinical Research (particularly Allergy, Immunology and Dermatology)
Skills	• Computer Literacy ((proficiency in Microsoft Office and electronic data capture) • Excellent communication skills (verbal and written) • Excellent interpersonal skills • Excellent phlebotomy skills • Strong organizational skills • Detail-orientated • Proactive and self-motivated • Ability to work as part of a team • Ability to work under pressure and in a fast-paced environment • Ability to maintain the integrity of research studies. • Open-minded and always willing to learn • Flexible; able and willing to make changes in work schedule to meet the demands of the company • Good interpersonal skills • Ability to work independently
Knowledge	• Knowledge of Medical Terminology • Current knowledge of principles and practices of Clinical Research and Good Clinical Practice Standards (preferable)
Professional registration or license requirements	Registration with the South African Nursing Council (SANC)
Other requirements (If the position requires the handling of cash or finances, other requirements must include 'Honesty to handle cash or finances'.)	• Valid Driver's License (minimum requirement) • Dispensing License (advantageous) • Based in Mthatha or surrounds or willingness to relocate (minimum requirement) • Computer Literacy (proficiency in Microsoft Office and electronic data capture) (minimum requirement) • Excellent organisational skills (minimum requirement) • Relevant clinical research experience (preferable) • Bilingual (English and isiXhosa or Afrikaans) (preferable) • Valid Good Clinical Practice (GCP) Certification or willingness to attain (preferable)

Competencies (Refer to UCT Competency Framework)

Competence	Level	Competence	Level
Analytical thinking	1	Teamwork/Collaboration	1
Client/student service and support	2	Building interpersonal Relationships	1
Planning and Organizing	2	Resource Management	2
Communication	2		

SCOPE OF RESPONSIBILITY

Functions responsible for	Screening, enrollment, consent taking, data documentation, electronic database recording, reporting, contacting participants, scheduling, stock management (lab/clinical items and research stationary),
Amount and kind of supervision received	Will work closely together with the Clinical team from Units/Departments within IMARI. Supervision otherwise minimal as observational research.
Amount and kind of supervision exercised	Will work closely collaborating with the Research Medical Officer.
Decisions which can be made	Enrollment, Samples type and timing. Scheduling of appointments.
Decisions which must be referred	Clinical Management decisions.

CONTACTS AND RELATIONSHIPS

Internal to UCT	Unit Head / Principal Investigators, Sub-Investigators, Departmental Staff, Ward and Clinic Clinical and Nursing Staff, Receptionist, Records
External to UCT	Internal to IMARI – Other site's Research Doctors, Research Nurses, Laboratory Staff, Study Coordinator. External to IDM/IMARI – Study Monitors, CRO's, Sponsors, Associated Physicians (involved in studies), Specialists Allergy Medicine Physicians and Registrars