Quality with Excellence

Job Title: Clinical Research Nurse (CRN)	**Position Type:** Part-time / Full-time – Bank / Fixed-term / Permanent
Job Code: ACR-CRN-0001	**Professional Accountability:** Chief Operating Officer

Company Background	Ascend Clinical Research (ACR) is a clinical trials Site Management Organisation (SMO) offering innovative, agile and high impact solutions in clinical trial delivery, patient recruitment, and professional development of the clinical research workforce. Our organisation specialises in the delivery of multi therapy trials on investigator site level from set up to close out for Phase 2- 4 trials with quality and excellence at its core, as well as local and international partnerships for clinical research workforce training programmes. We place the patient at the core of our service; and actively promote diversity and inclusivity in our patient - centred processes. We are guided by our values of integrity, efficiency, commitment, and safety in practice with our organisational undertakings and stakeholder relations. The Clinical Research Nurse (CRN) is responsible for the planning and delivery of high quality and safe clinical research activities at the ACR site. This role is key to translating protocol assessments into operational delivery at the clinical site. The CRN will work closely with the Leadership, and clinical research teams.
Role Overview	• Provide patient study information, patient monitoring, and accurate data collection whilst adhering to relevant legislation, national frameworks and ACR-specific SOPs and policies. • Enhance the overall delivery of clinical research within ACR by providing clinical research experience and working collaboratively with the research team

Main duties and responsibilities	Overview

- Undertake clinical research nursing activities relating to clinical trials from the start-up to close-out, adhering to ICH/GCP guidelines.
- Review research protocols, identify, coordinate logistics and processes required to adhere to trial protocol, and communicate to the team
- Attend and participate during trial site selection, initiation visits and study-related trainings.
- Ensure the commercial success of the site by contributing to the recruitment and retention of patients into trials.
- Screening and randomisation of potential study participants.
- Conducting informed consent discussions and receiving informed consent (if approved by regulatory and ethics committee and as per protocol).
- Completing study procedures (such as phlebotomy, vital signs, ECG and as per protocol)
- Reviewing and recording of medical / surgical histories and concomitant procedures / medications.
- Safely administer medication/s as prescribed.
- Scheduling and conducting of trial visits and tracking of enrolled trial participants.
- Communicating with the Sponsor, CRO, clinical research associates / Monitors for trial related queries and activities
- Drug accountability and reconciliation.
- Processing and packaging specimens, per protocol and IATA guidelines.

Clinical Trial Management (CTIMPs and non-CTIMPs)

- Obtain informed consent from participants for CTIMP and non-CTIMP studies as delegated by Principal Investigator (PI) and within parameters of the protocol.
- Support participants considering their participation with the decision-making process, ensuring that their information needs are met sensitively and that they have a full understanding of the study, its requirements and their rights as participants.
- To ensure all safety reports are completed in line with the protocol reporting policy.
- Facilitate and maintain (written and verbal) communication between the PI, research, clinical and support services teams in ensuring that the study protocol is correctly implemented, and research governance standards are met and maintained.
- Ensuring that all equipment used in the trial is appropriately calibrated and that supporting documentation is retained.
- Perform all visits, observations, and clinical procedures such as monitoring vital signs, body measurements, height and weight, ECGs, venipuncture, cannulation, drug administration with the participants in accordance with the procedures and schedule of the study protocol.
- Undertake laboratory work as per study protocol, including processing, packaging, storing and transportation of samples.

- Provide ongoing support to patients and volunteers with regards to their trial participation.
- Facilitate a harmonious relationship with patients by building good rapport and establish a constant line of communication for queries and to raise concerns immediately to clinicians, research or leadership team whichever is appropriate
- Ensure that all clinical trial databases and logs are maintained including updating patient recruitment data on CRIO, our Clinical Trial Management System (CTMS), per patient visit, and as mandated by protocol and patient needs
- Ensure protocol amendments are incorporated into research practice in a timely manner.
- Work within the scope of research guidelines, ethical principles and protocols, whilst adhering to organisational policies and procedures.
- Always adhere to the confidentiality of patient information, in accordance with the Data Protection Act and Caldicott regulations.

General Clinical Duties

- Support colleagues in assessing, planning and implementing high quality care, and evaluating care options for patients in the clinical area, in line with ACR values and objectives.
- Ensure the safe custody, maintenance and administration of medication, in accordance with established ACR policies.
- Promote and maintain a safe therapeutic environment for patients, their families and staff, according to national and local Infection Control guidelines, Health & Safety legislation and ACR policies and objectives.
- Provide sound evidence based clinical advice as required to staff and patients.
- Maintain a good understanding and implementation of clinical escalation procedures as required.
- Understand the ACR clinical governance framework and participate in promoting and safeguarding high standards of care, through effective risk management and governance
- Uphold the values of ACR at all times.
- Adhere to ACR safeguarding policies.
- Undertake effective inter-disciplinary collaboration and work with colleagues to deliver care.
- Adhere to high quality standards of care in line with ACR objectives.
- Facilitate an excellent quality patient experience.
- Maintain a safe working environment ensuring equipment is safe and used in line with ACR policy and values.
- Always promote and maintain patient safety including proactively implementing falls prevention and infection control
- Support with the detection, management and prevention of safeguarding issues.
- Have an awareness of current professional and clinical developments within their area of practice and promote this to others.

	Clinical Trial Set Up (CTIMPs and non-CTIMPs) ● Ensure compilation and maintenance of all study related site files in accordance with ICH-GCP. ● Assist with the set-up of studies, and attend Site Selection / Site Initiation Visits and study training requirements ● Assist in identification of services needed per study **Study Close Out** ● Ensure all data clarification issues are resolved quickly. ● Assist with the archiving of study related documentation in line with the Trial Agreement and ICH-GCP. **Resource Management** ● Supporting senior colleagues in ensuring research delivery within capacity. ● Maintain shared responsibility for the safe use, maintenance and storage of computers, photocopiers and other office equipment. ● Contribute to effective stock control / maintenance by reporting usage and stock reduction to the COO by providing information during weekly audits. ● Managing the physical resources required to undertake research activity including monitoring of resources are fit for purpose, for example: within manufactures date and / or calibrated and that they are used accurately ● Prompt reporting of any faulty equipment and limited stock of resources to COO **Administrative Duties** ● Supporting the Clinical Research Coordinator in the safe storage and maintenance of investigator Site File, working file and patient research files. ● Completing Case Report Forms (CRFs) including eCRFs with a high degree of accuracy. ● Setting up and maintaining study trackers. ● Implementing study amendments. ● Locating and tracking of medical records. ● Managing and participating in monitoring visits. ● Overseeing filing of research material such as laboratory and imaging reporting.

Quality with Excellence

Requirements	**Essential** ● Qualified Level 1 Nurse (RN-Adult) registered with the Nursing and Midwifery Council Register. ● Demonstrable experience of a minimum of two years delivering clinical research, including CTIMPs. ● Evidence of a high commitment to Continuing Professional Development (CPD). ● Evidence of accuracy to detail in data collection. **Desirable** ● Accredited GCP training. ● Informed consent training. ● Venepuncture training. ● Experience of using clinical trials management systems.
Location & Working hours	● Will be assigned in 4B Vulcan House, Calleva Park, Aldermaston, Reading, UK RG7 8PA ● Working hours Monday to Friday (with potential "out of hours" as per business needs)
Compensation	● Competitive salary package plus performance incentives