Quality with Excellence

Job Title: Sub- Investigator/Clinical Research Physician/Clinical Rater	**Position Type: Contract/Part- time/Full time**
Job Code: ACR-SI-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.
Role Overview	The post holder will primarily focus on provision of medical care and oversight of clinical trial participants, assisting the Principal Investigator in ensuring the safe, compliant and excellent delivery of the study. Post holder will work closely with the other members of the team to ensure efficient conduct and safety monitoring of study processes in accordance with the International Conference on Harmonisation Good Clinical Practice (ICH-GCP). The post holder will be a flexible, motivated team leader and possess expertise in conducting and overseeing clinical trial delivery as well as high familiarity to the legislation applicable to running clinical trials. The work requires initiative, accuracy, high attention to detail at all times, and excellent time management. The post holder will be required to communicate with a broad professional group including clinical staff, as well as members of the public and research sponsors (and CRO). The post holder will be expected to represent ACR. All work will be carried out in accordance with the EU Directive, ICH-GCP, Research Governance and local Standard Operating Procedures and Policies.

	The post holder will be working on site at ACR and conduct trial – related procedures.
Main duties and responsibilities	Research Governance - Responsible in conducting clinical trials according to approved clinical trial protocol - Adheres to the Good Clinical Practice guidelines and principles in the conduct of research and in leading the trial delivery team - Provides oversight for the overall conduct of the clinical trial with clearly documented evidence - Complies with the relevant laws, regulations, disciplinary standards, ethics guidelines and institutional policies related to responsible clinical trial conduct - Ensuring that appropriate approvals are obtained prior to the commencement of the trial, and that conditions of any approvals are adhered to during the trial - Delegated to receive informed consent from trial participants adherent to ICH-GCP guidelines and GDPR regulations. - Advocates and ensures that the appropriate process for receiving informed consent from trial participants and its further documentation is adhered across the team - Ensuring participants' welfare during the clinical trial - Provide the necessary medical care to study participants required due to any adverse events experienced during or following the study that are related to the study - Informing the participant's primary clinician about the participant's involvement in the project. That is, if the participant has a primary clinician and if the participant agrees to the primary clinician being informed - Supports PI in providing timely reports to trial sponsor mandated by the MHRA on *All significant safety issues (SUSAR, AESI, SAE) * Information that might affect the continued ethical and scientific acceptability of the project - Ensures the timely and accurate adaptation an execution of approved amendments by the trial delivery team and dissemination of follow through communication of changes to clinicians and participants as warranted by the amendment

	- Ensures that necessary re- consenting of trial participants is done in timely fashion and with adherence to protocol and GCP guidelines - Disclosing and managing actual, potential or perceived conflicts of interest - Responsible for ongoing consent - Responsible in establishing trial participants level of compliance and establishing reasons for withdrawal with proper documentation and communication to Sponsor if participant so wishes - Retaining clear, accurate, secure and complete records of all clinical trial documentation including clinical trial data and primary materials. Where possible and appropriate, allow access and reference to these by interested parties under GDPR governance. - Complying with the applicable regulatory requirement(s) related to the reporting of unexpected serious adverse drug reactions to the regulatory authority and the Sponsor or CRO as required by the approved clinical trial protocol - Reporting suspected breaches of the code to the relevant institution and/or authority - Supervising and working with Site Study Coordinator/Research Nurse - Attending study investigator meetings, monitoring appointments, site data reviews - Timely review of clinical data and sign off of electronic data records Leadership and Professional Development - Provides mentorship and supervision for the responsible delivery of clinical trials to other clinicians and research staff - Promotes education and training in responsible clinical trial conduct and works closely with COO in developing performance objectives and mentorship programme plan for clinicians Clinical Excellence -Regularly assesses ongoing safety of participant during trial involvement and raises concerns promptly to PI and clinical team for risk assessment and evaluation - Responsible for prescribing emergency and supplemental medications required during the conduct of the trial and stock for the site - Performs medical procedures such as physical exam, medication reviews, diagnostic reviews and confirmation, psychometric assessments, clinical rating assessments, confirmation of eligibility and review of participants fitness for discharge - Regularly attends discussions/ meetings relevant to clinical trial involved with in relation to patient safety, quality and key metric improvements

	- Provides continuous mentorship to sub- investigators and clinicians involved in the clinical trial and develops - Conducts clinical procedures according to protocol and auxiliary procedures as warranted for participant's wellbeing and safety.
Requirements: **Personal Profile –** **(E) = Essential** **(D) = Desirable**	**Knowledge and Experience** • General Medical Council full registration to practice (E) • Evidence of post-registration clinical experience(E) • Previous research experience as Sub/I or PI leading a study (E) • Experience in conducting psychometric and neurological assessments (D) • GMC Registration with full license to practice (E) • Willingness to mentor and train junior research physicians as part of the Learning and Development Programme (D) **Aptitudes** • Articulate and confident (E) • Able to work alone and as a member of a multidisciplinary team (E) • Self-motivated (E) • Flexible and adaptive approach (E) • Excellent attention to detail (E) • Patience and enthusiasm for working with people (E) • Innovative (D) • Organised approach (E) • Positive approach to change (D) • Committed to providing a high-quality pharmacy service (E) **Skills and Abilities** • Team Leadership (E) • Excellent oral and written communication skills (E) • Good interpersonal skills (E) • Problem identification and solving (E) • Evidence of ability to complete work on time (E) • Personal time management (E) • Research skills (D) • Evidence of continuing professional development (E) • Ability to use judgement to challenge discrepancies in participant eligibility outcomes and safety reports (E) • Knowledge of the legal framework for the conduct of clinical trials and the critical role of PI Oversight (E) • Understanding of medical and nursing practice, record keeping and terminology (E)

	• Computer literate e.g. word processing, use of spread sheets and presentations (E) **Qualifications and Training** • Professional registration with General Medical Council (E) • Membership of the Royal College of Physicians(D) • Up to date GCP training (D)
Location & Working hours	• Will be assigned in 4B Vulcan House, Calleva Park, Aldermaston, Reading, UK RG7 8PA • Working hours Monday to Friday as assigned (with potential "out of hours" as per business needs)
Compensation	• Competitive salary package plus performance incentives