MAC Clinical Research

JOB DESCRIPTION

NAME:

JOB TITLE: Early Phase Clinical Research Nurse

REPORTS TO: Head of Early Phase Unit

FOCUS OF THE JOB:

- To prioritise participant safety by ensuring adherence to ICH GCP.
- To carry out clinical trial procedures in accordance with ICH GCP.
- To participate in the effective running of research studies on a day-to-day basis maintaining the safety and well-being of study participants and utilising skill knowledge and judgement to provide a high standard of care whilst maintaining dignity and respect at all time.
- To undertake nursing procedures as per NMC guidelines in ensuring the smooth conduct of trials.
- To have responsibility and accountability for planning, organising and prioritising their daily workload working collaboratively as part of the multidisciplinary team.

KEY SKILLS, KNOWLEDGE AND QUALIFICATIONS REQUIRED:

- RGN / RMN or
- BSc Nursing.
- Current NMC registration with effective registration PIN number.
- Experience of working in an acute care setting such as ITU, CCU, HDU or A&E desirable
- Experience within the field of clinical trials desirable, early phase preferred.

RESPONSIBILITIES (including staff):

Clinical Activities

- Ensure participant safety and well-being in a variety of settings working collaboratively within a multidisciplinary team. Identify and report any potential or actual adverse events to a senior nurse or physician in a timely manner.
- Be competent in performing and supervising other members of the multidisciplinary team in core clinical skills, utilising clinical knowledge to identify potential clinical abnormalities and recognising and reporting any deviation from the parameters as stated in the study protocol.
- Perform clinical procedures as per SOP/protocol including but not limited to – 12 lead ECG, continuous cardiac monitoring, blood sampling both direct and via cannula, recording of vital signs, pulse oximetry.

- Perform protocol reviews regarding clinical activity and provide feedback to the project manager.
- Act as project nurse for individual studies supported by the Senior Early Phase Clinical Nurse to provide effective pre-study set-up, project planning and resourcing and associated documentation leading to the safe and successful clinical execution of the study whilst working within the remit of ICH GCP.
- Demonstrate and share understanding of the ABPI guidelines for phase 1 clinical trials and the MHRA accreditation process for phase 1 clinical units.
- Demonstrate and share knowledge and understanding of the research process, the volunteer process and study flow within the clinical unit.
- Be proactive in developing and implementing quality initiatives within the clinical area providing prompt feedback on procedural audit reports and attendance at Quality meetings.
- Attend immediate life support and medical emergency training at least annually and to be familiar with the Resuscitation Council Guidelines and the contents of the Resuscitation Trolley and the use of the defibrillator, checking the defibrillator is working daily and performing weekly resuscitation trolley checks.
- Maintain competency in the use of all equipment required within the clinical studies.
- Demonstrate consistently the ability to plan, organise, prioritise co-and co-ordinate daily workload.
- Monitor and appropriately report AE's / SAE's.
- Ensure that all participant visits are completed in accordance with the protocol.

Participant and Customer Care

- Prioritize and promote participant safety.
- Deal courteously and professionally with participants and customers at all times.
- Ensure a pleasant and safe environment for all visitors to the clinic.
- Ensure participants fully understand procedures and encourage them to express any concerns.
- Communicate efficiently and professionally with the rest of the clinical team to ensure optimal participant care.
- Deal with complaints in accordance with company policies.

Pharmacy

- Perform all drug administration procedures for which they have been competency assessed in accordance with the study protocol and the NMC guidelines for administration of medicines.
- Maintain accurate drug accountability logs and prescription records.

Laboratory

- Assist in the sample handling and storage of samples in the laboratory when necessary,

- Assist with laboratory procedures including, sample processing and packing (appropriate training and IATA certification required).
- Where delegated, ensure the monitoring and supply of study specific blood kits.
- Ensure that Company policy is adhered to in terms of relevant Health and Safety issues.

Data Management

- Ensure meticulous recording and transcription of data in both clinical and research notes.
- Ensure accurate and complete data is entered into source notes, case report forms and electronic data systems.
- Ensure timely resolution of data queries.

Recruitment

- Maintain an awareness of recruitment issues and deadlines.
- Promote and assist in recruitment activities where required.

Commercial Awareness

- Monitor and support site quality as per Company SOPs.
- Assist in the development, review and updating of SOPs as and when required.
- To be proactive in implementing company strategy and plans.

Professional and Self Development

- Maintain and regularly update personal professional development portfolio (NMC and MAC training file).
- Provide practical help and guidance to other members of staff.

General

- Compliance with MAC health and Safety policy
- Compliance with MAC policy on equality and diversity
- To maintain professional qualifications required for the role, including continuous personal development
- To work to the requirements of SI 2004 no 1031 and amendments thereof, which includes Good Clinical Practice
- To work according to MAC SOPs, guidelines and policies
- To work according to current data protection standards and practice good information management. Maintenance of strict confidentiality of patient and business related data.
- To maintain a high level of initiative and personal responsibility, liaising appropriately with team members and managers to ensure your job role is efficiently carried out
- To support the aims of MAC and to represent MAC appropriately in a professional way to all our customers.

PHYSICAL, WORK ENVIRONMENT, TRAVEL DEMANDS:

- Potentially long periods standing.

- Dealing with bodily fluids.
- Long periods looking at a computer screen.
- Meeting deadlines and working within strict timelines.
- Shift work including weekdays or weekends. Some night shifts will be required. Flexible approach to working hours with a requirement to work some unsocial hours to meet the needs of the clinical unit.
- Ability to travel between sites if required.
- Ability to travel to national/ international meetings.

LIMITATIONS AND DISCLAIMER

The above job description is meant to describe the general nature and level of work being performed; it is not intended to be construed as an exhaustive list of all responsibilities, duties and skills required for the position.

Employees signature……. Date…….

Head of Department signature…….. Date…….