Manchester University
NHS Foundation Trust

JOB DESCRIPTION

POST: Senior Clinical Research Nurse

DEPARTMENT: Oncology Research Team

GRADE: Band 6

HOURS: 37.5 hrs per week

RESPONSIBLE TO: Nurse Manager

LIAISES WITH: Assistant Chief Nurse R&I, Head of Nursing and Midwifery R&I, Lead Research Nurse and Midwifery Manager R&I, Matrons R&I, Clinical Research Nurses/ Midwives, Consultants, R&I Management team, Hospital Research & Innovation Managers, Clinical Trials Managers, Clinical Trials Assistant, Clinical Research Practitioners, Principal Investigators, General Practitioners, Manchester Clinical Research Facilities at ORC and Wythenshawe.

RESPONSIBLE FOR: Clinical Research Nurses, Clinical Research Practitioners

WORKBASE: Nightingale Centre, MFT, Wythenshawe hospital

JOB PURPOSE

The post holder will be a key member of the clinical research team. They will assist in the management, co-ordination and facilitation of clinical trial activities to support delivery of current and future studies in the research team to time and target. They will provide specialist research and clinical care for participants and patients enrolling in a variety of research studies and project.

The post holder will work across Research & Innovation, to support research studies across MFT as the service need dictates.

The post holder will have a key role in providing and maintaining appropriate patient/ participant – focused environment within the research setting. They will work with clinical investigators and sponsor companies to assist in the management of trial protocols. They will ensure data collection is to its highest standards, facilitating the production of good quality research with a commitment to the patient's safety and wellbeing.

The post holder will be expected to participate fully in their own personal development and review process in order to achieve the knowledge and skills identified in the competency framework and competencies for this post.

MAIN DUTIES & RESPONSIBILITIES

Research:

- Take the lead on delegated studies being responsible for their development, implementation and progress, co-ordinating clinical team responses
- Lead on programmes for recruitment, enrolment, screening and retention of research participants in accordance with the protocol and ICH-Good Clinical Practice (GCP) guidelines and the Research Governance Framework
- Assist in the feasibility and selection for the Trust Portfolio of research studies
- Has knowledge of research specific guidelines e.g. Good Clinical Practice, Research Governance and EU Clinical Trials Directives and ensures all studies run in accordance with these guidelines
- Lead the team in the implementation of protocols, in accordance with research parameters as set out by the Chief and Principal Investigators
- Contributes to the development of new research protocols, funding applications and relevant approval processes
- Assist in the development and execution of relevant Standard Operating Procedures (SOP's) ensuring these are updated as required.
- Share with clinical colleagues research knowledge
- Support the effective and efficient use of research and clinical resources
- Following training and competency assessment – obtain informed consent from participants for qualitative non-CTIMP and CTIMP trials as deemed appropriate and delegated to do
- Demonstrates excellent communication skills throughout the research process to provide ongoing advice and information to participants with regard to their participation in research in order to facilitate effective informed consent and assent.
- Manage research studies independently as deemed appropriate by the nurse manager
- To contact suitable participants face-to-face, by post & telephone; to explain study protocols/visits in detail
- Contribute to appropriate data collection for participant data and to monitor data in accordance with the research protocol and standard operating procedures
- Ensure all data is completed within a timely manner
- Ensure all study documentation is developed in order to accurately record research activity raise concerns and seek to address incomplete, inaccurate or misleading documentation.
- Ensure familiarity with risk issues pertaining to confidentiality of participant and research related documentation (Data protection Act, GDPR legislation and Caldicott Guidelines)
- Assist with the development of new databases/ spread sheets to monitor participant progress within studies
- Identify and recruit participants into clinical trials, assisting in the management, coordination and facilitation of the concurrent trials ensuring recruitment targets are met.
- Take responsibility as appropriate for liaising with sponsor sites regarding data queries and for checking/ resolving data queries
- Maintain participant follow up in the form of telephone/ face to face contact for data collection ensuring study visit timescales are adhered to
- Take appropriate action in the event of both adverse events and serious adverse events within the required time frame under the guidance of a clinical research nurse/ midwife or principal investigator
- Where delegated to do so, set up and maintain study site files in accordance with ICH GCP and Trust SOPs
- Record recruitment figures using RPEAK and provide the necessary information for the NIHR CRN database
- Demonstrate excellent communication skills throughout the research process by communication with face to face meetings and telephone discussions
- To prepare and make available study documentation for monitoring and audit by sponsor company representatives
- To assist in the preparation and presentation of research reports as required
- Provide advice and support to other members of the multidisciplinary team with regard to ICH

GCP, ethics approval and amendments, project development, implementation and completion.
- Contributes to the financial processes of planning, running and closing clinical research studies.

Clinical:

- Act in a manner consistent with The Code NMC (2015) carrying out their role in accordance with locally agreed policies and procedures.
- Practice at a level which demonstrates advanced knowledge and skill and requires a high level of precision.
- Facilitate the delivery of highly specialised, participant focused, protocol driven research in collaboration with participants, relatives and the multidisciplinary team.
- Assist in the delivery of clinical expertise in all aspects of the clinical setting, acting as a visible practitioner in the Ward/Department.
- Maintain compassion, empathy, dignity, comfort and sensitively to participants and their relatives at all times
- Ensure that care delivered is participant centred and where possible evidence based whilst in accordance with the research protocol and maintaining the rights of the participant.
- Continuously evaluate the quality of care given, regularly reassessing the needs of the research participants and effect changes as required in consultation with the participant and the multidisciplinary team.
- Ensure participant care is delivered according to Manchester Foundation Trust policies and procedures and within the nursing philosophy of Research & Innovation
- Following training and competency assessment completion perform clinical tasks (for example venepuncture/ cannulation, ECG recording) as indicated in the research study protocol and as delegated to do.
- Assist senior clinical research nurse/ midwife and research medical staff with various clinical procedures when trained, competency assessed and as delegated to do
- Direct or escort participants between departments
- Collect participant medication for pharmacy, as required
- Clean equipment after use, reporting to the appropriate department when repairs are needed
- Assist in the development of core practice standards and contribute to clinical audit to maintain and improve clinical and research practice.
- Ensure clear accurate records to support and record all research activity including design and/or use of databases as required.
- Promote and collaborate in developing good working relationships, maintaining good communication systems with departments both within and outside the department to ensure that participants have an effective and efficient research experience
- Contribute to clinical and research governance processes including adverse event/incident reporting collaborating with any investigations and management of these
- Seek opportunities to develop own research skills adapting to any changes in the research requirements of new studies
- Ensure safeguarding principles and policies are adhered to
- Maintain relevant professional registration and revalidation requirements as per NMC governing body

Administration/ clerical:

- Maintain electronic databases and paper records, ensure that patients schedules to have follow up visits are tracked and have fulfilled all study assessments according to the protocol
- Ensure all documentation is filed in a timely manner and ready for inspection
- Assist with inspections as required
- Arrange couriers/post for clinical research samples
- Possess IT skills – Word, PowerPoint and email correspondence and electronic patient record system i.e., HIVE/EPIC
- Data entry including research study databases

- Analysis of data, as appropriate, within the research setting

Leadership & Management:

- Provide visible clinical leadership to the clinical research team promoting a culture of leadership by example to all staff.
- Develop and maintain organisational and managerial skills relevant to the role.
- The post holder will recognise and understand the delegation of responsibility and accountability for participant care in the absence of the senior nurse
- Be responsible for the day-to-day supervision of junior staff and students ensuring ongoing staff development.
- Act as a support for the Nurse Manager/ Senior Clinical Research Nurse
- Support the team manager in delivering the core values and beliefs of the team and Trust
- Act as a professional role model, through commitment to the integration into practise of Trust policies and procedures (i.e., Uniform policy)
- Act as an advocate for staff, participants and their relatives at all times
- Support senior staff in the day-to-day supervision of junior staff and students ensuring on going staff development.
- Coordinate, delegate and supervise clinical research activity on a daily basis
- Act as a 'buddy' to colleagues
- Keep abreast of innovations and developments in research governance, ethics and other regulatory and legal guidelines governing clinical research
- Assist with the orientation and induction of new staff
- Be responsible and accountable for all aspects of own work, including management of participants in your care
- Be actively involved in promoting the research work of the department.
- Attend and contribute to clinical team meetings.
- Ensure that working practices adhere to health and safety polices, and be responsible for reporting of any incidents
- Ensure appropriate and effective communication with all nursing, medical, allied health professionals, research staff and other external agencies
- Ensure planning and organisation of complex activities across a range of studies requiring collaboration with other professionals and agencies
- Undertake staff appraisals as requested by the Nurse Manager/ Senior Clinical Research Nurse
- To assist in and maintain Trial Study Files taking responsibility for the day-to-day project administration and document control
- To ensure booking of all appointments within the time limits set by the study protocol
- Input clinical data onto the study database Maintain good co-operation and communication with sponsor companies as necessary
- Maintain appropriate records, adhering to Nursing and Midwifery Council and Trust guidelines on record keeping
- Adhere to the Nursing & Midwifery Council (NMC) Code of Conduct and associated guidelines
- Maintain confidentiality in all aspects of care and employment issues
- Maintain relevant professional registration

Education & Development:

- Take a lead role in the clinical and professional development of new research nursing staff to the department and act as mentor/preceptor to junior nurses encouraging a high level of motivation in all involved.
- To undertake annual mandatory training in accordance with Trust policy
- To continuously work to develop skills and knowledge utilising the competency framework

- Attend investigation meetings and site initiation visits to ensure an in-depth knowledge of all study protocols
- Maintain own training records
- Attend study specific training as required and complete all necessary competency assessment documentation
- Attend team meetings contributing to the development of the team and Research & Innovation
- Be familiar and adhere to team, Research & Innovation and Trust wide research and clinical standard operating procedures
- Undertake continuous professional development, seeking opportunities to enhance skills
- Keep abreast of innovations and developments in Research Governance, Ethics and other regulatory and legal guidelines governing clinical research
- Participate in the development and delivery of teaching and education programmes.
- Participate in the development and delivery of participant and carer education.
- Act as a resource for investigators and staff.
- Act as a resource for members of the multi-disciplinary team from Trusts and Universities.
- Assist with the preparation of the results of research and present as posters or scientific presentations at meetings and conferences as appropriate.
- Contributes to supervision and meeting educational needs of staff.

.

WORKING PATTERNS

Staff will be required to work a variety of shifts, including weekends, throughout the 24 hour period if appropriate to the post and it is a condition of your employment that you work such additional or different hours (including working shifts) as may be deemed necessary to perform your role satisfactorily to meet the needs of the Trust.

INFECTION PREVENTION AND CONTROL

It is the requirement for all staff to comply with all infection control policies and procedures as set out in the Trust's Infection control manual. The post Holder is also responsible for ensuring that they and all their staff attends mandatory training, including infection prevention and control.

HEALTH AND SAFETY

The trust has a statutory responsibility to provide and maintain a healthy and safe environment for its staff to work in. All employees of the Trust have a statutory duty of care for their own personal safety and that of others who may be affected by their acts or missions. Safe working practices and safety precautions must be adhered to. Protective clothing and equipment must be used where appropriate. The Trust's Health and Safety Policies outline your responsibilities regarding Health and Safety at work.

RISK MANAGEMENT

It is a standard element of the role, and responsibility of all staff of the Trust, that they fulfil a proactive role towards the management of risk in all of their actions. This entails the risk assessment of all situations, the taking of appropriate actions and reporting of all incidents, near misses and hazards.

SAFEGUARDING

Ensure that the policy and legislation relating to child protection and safeguarding of Children, young people and vulnerable adults are adhered to. It is the responsibility of all staff to be aware of their individual responsibilities and to report any concerns to the identified person within your department or area of responsibility.

CONFIDENTIALITY AND SECURITY

The post holder is required to maintain confidentiality at all times in all aspects of their work. All employees must maintain confidentiality and abide by the Data Protection Act.

TEAM BRIEFING

The Trust operates a system of Team Briefing, which is based on the principles that people will be more committed to their work if they fully understand the reason behind what is happening in their organisation and how it is performing.

NO SMOKING POLICY

The Trust operates a no smoking control policy, which applies to all staff, patients and visitors and extends to the hospital grounds as well as internal areas.

THE TRUST IS AN EQUAL OPPORTUNITIES EMPLOYER

This job description indicates the main functions of the post holder and may be subject to regular review and amendment in the light of service development. Any review will be undertaken in conjunction with the post holder and in line with Trust policy.

ORGANISATIONAL CHART

Please click below to insert the organisational chart/structure as a text, or upload the organisational structure below the text box.

Senior Clinical Research Nurse
(Band 6)
Organisational Chart