**Clinical Research Facility**

**Senior Research Nurse (Band 6)**

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| **1. JOB IDENTIFICATION**  **Job Title:** Senior Research Nurse Respiratory (Band 6)  **Responsible to:** Research Nurse Manager  **Department:** Glasgow Clinical Research Facility (GCRF)  **Directorate:** Corporate |
| **2. JOB PURPOSE** |
| Deliver, as part of a multi-disciplinary team, a high standard of care to study participants for the duration of the study.  Act as lead nurse for an agreed number of Respiratory studies supported by GCRF with responsibility for study management and study specific staff training, ensuring compliance with the protocol, sponsor and CTU SOPs, clinical trial regulations, research governance and GG&C policies.  Act as Nurse Coordinator for day-to-day running of the clinical facility.  Develop and implement, in collaboration with the respiratory research team, a recruitment plan to identify, consent and retain study participants from primary, secondary or tertiary care.  Contribute to the on-going development of GCRF with identified key responsibilities whilst also assuming responsibility for clinical area and staff when required.  Maintain accurate records of study specific information using traditional paper records, NHS GG&C electronic patient management systems or web-based study specific IT systems and provide accurate reports to GCRF management team, sponsor and Principal Investigator as required. |
| **3. ROLE OF DEPARTMENT** |
| Glasgow CRF, an NHS facility set up to support clinical research across GG&C, is the clinical operational component of Glasgow Clinical Trials Unit (CTU). The CTU comprises of NHS Research & Innovation, Robertson Centre for Biostatistics and GCRF.  There are currently around 90 staff employed in GCRF. Core GCRF staff have substantive NHS contracts funded by Scottish Government (Chief Scientist Office (CSO) – NHS Research Scotland (NRS) Infrastructure funding) with additional staff employed on project specific fixed term contracts to meet service requirements.  The number of studies (approx 250-300 across the facilities/specialties), complexity and range of work supported is variable and includes Phase I-IV clinical trials, large scale observational studies, complex interventional studies (non-clinical trial), academic and commercial sponsors. GCRF staff provide support to academic and NHS clinical researchers from a range of specialties.    GCRF staffing comprises of a multi-disciplinary team working together to provide comprehensive clinical research support to investigators from study start-up to archiving. The core disciplines within the team are:   * Clinical (Research Nurses/Medical) * Project Management * Education & Quality * Clerical and administration   The facilities are in the Queen Elizabeth University Hospital and Glasgow Royal Infirmary however the GCRF is committed to supporting research projects across GG&C in primary, secondary and tertiary care. |
| **4. ORGANISATIONAL POSITION** |
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| **5. SCOPE AND RANGE** |
| As part of GCRF research team the post holder will:   * Co-ordinate and manage an agreed number of Respiratory studies acting as main contact for the study team for the PI, study participants, sponsor, R&D and GCRF management team. * Provide research nurse support to projects across GG&C in primary, secondary or tertiary care settings, university departments or other locations specified in the R&D approval. * Contribute, in collaboration with CRF education and training team, to study specific and generic research nurse training programme. * Require a flexible approach to working hours in order to meet the needs of research studies with a requirement to work unsocial hours and weekends as necessary. * Contribute to the ongoing development of GCRF and the role of the research nurse within GG&C. * Adopt the Nurse Coordinator role for day-today running of the facilities |
| **6.MAIN TASKS, DUTIES AND RESPONSIBILITIES** |
| **Professional:**   * At all times maintain a professional manner with patients, colleagues and the wider multi-disciplinary team. * Practice within the legal and ethical framework established by the Nursing and Midwifery Council (NMC) and national legislation to ensure patient care is of a consistently high standard and in the patient’s best interest. * Develop in the role by using evidence based practice and continuously improve own knowledge. * Conduct clinical research in accordance with the current research regulatory and governance requirements. * Develop and maintain an understanding and knowledge of the legal, ethical and professional issues surrounding the informed consent process for clinical trials. * Comply with Data Protection legislation at all times. * Understand and comply with NHS GG&C and Health and Safety Executive (HSE) legislation, policies, guidelines and procedures.   **Clinical / specialist knowledge:**  Assess, plan and prepare a safe environment to conduct study visits to ensure a high standard of care is delivered by utilising personnel, clinical experience and organisational skills.  Provide a high standard of nursing care to patients and volunteers participating in research projects and clinical trials ensuring other members of the team are fully trained and supported.  Organise and manage study team workload to ensure protocol compliance, objectives and the interest and safety of the patients or volunteers are fully met.  Demonstrate a comprehensive understanding of research protocol, clinical interventions and procedures involved, ensuring study procedures comply with the research protocol and trial design.  Utilise advanced research skills to carry out study specific procedures ensuring patient safety is maintained.  Act as a role model through the provision of professional leadership and demonstration of competent and effective practice within the research team.  Update and maintain accurate patient hospital and research specific records in line with NMC, Good Clinical Practice guidelines, Glasgow CRF and trial sponsor Standard Operating Procedures.  Propose and develop policies/ procedures and working practices within clinical research area and ensure they are implemented.  Initiate/assist in the development and implementation of research initiatives in liaison with other Glasgow CRF staff.  **Education /Training**  Demonstrate a commitment to personal continuing development and lifelong learning.  Participate in the teaching of staff and the implementation of staff personal development plans to facilitate on-going development.  Participate in the development and delivery of the GCRF induction programme of internal/external research staff in order to ensure that the policies, SOP and working practices of the GCRF and NHS GG&C are adhered to during the conduct of clinical research.  Identify new educational needs and staff training requirements to ensure that research protocols are safely and effectively implemented.  Undertake additional training in order to acquire the knowledge and skills needed to implement new study protocols from a variety of clinical specialities.  Maintain level of clinical skills necessary to perform highly specialised procedures and support and encourage staff to develop their skills in areas of special interest.  Recognise and use spontaneous and formal learning opportunities sharing knowledge and expertise with other staff.  **Organisational/Managerial:**  Lead study nurse for agreed number of respiratory studies with responsibility for implementation and management of the project from start-up to closure focusing on compliance with policies, regulations, timelines, targets, resources and patient safety.    Contribute to the on-going development of the GCRF with identified key responsibilities.  Participate in feasibility assessment of potential projects involving CRF focusing on clinical deliverables.  Promote effective teamwork, initiate and support management of change within the Glasgow CRF.  Assume delegated responsibility for operational issues and safety in the clinical area taking appropriate action as required.  Communicate effectively with all relevant research personnel ensuring information, written and verbal, is cascaded and managed as appropriate.  Undertake a link coordinator role and support junior staff to undertake these roles, ensuring implementation of policies, cascading information and delivering training as required e.g. manual handling, fire, Health & Safety, Infection Control or resuscitation  Ensure clinical equipment is maintained, used in compliance with SOPs, user manuals and protocols and CRF staff are trained and competent.  Recognise importance of resolving complaints effectively at local level intervening as appropriate.  Report adverse events to senior nurse manager and ensure completion of appropriate documentation, training less experienced staff on reporting procedures.  Responsible for ensuring critical incidents are reported to the Senior Nurse Manager and investigated in order to make certain that Health and Safety Guidelines are being observed.  Actively contribute to the planning and implementation of long term Glasgow CRF Strategic plans through participation in relevant working groups.  Participate in mentoring programme in GCRF acting as a mentor for identified staff. |
| **7. SYSTEMS** |
| **IT**   * Microsoft Office Applications e.g. Outlook, Word, Excel, PowerPoint * Web-based technologies including study specific electronic data capture and sample management system. * GG&C electronic patient management systems * EDGE (electronic research management system for studies, patient and resource scheduling). * Trakcare and Clinical Portal * Web-based SOPs * Adverse event reporting software. * GG&C laboratory systems – tracking results. * Intranet – access to NHS Greater Glasgow & Clyde policies * Faxing/scanning documents   **Paper based systems.**   * Maintenance, secure storage and archiving of Study Site Files * Study specific patient case records files. * Patient case notes. * Study specific documentation |
| **8. DECISIONS AND JUDGEMENTS** |
| Use own initiative and act independently within the bounds of existing knowledge and skills with reference to research regulations and guidelines, NMC code of conduct and GG&C policies.  Make clinical and professional decisions on a daily basis, including the provision of advice to the research and multidisciplinary team.  Demonstrate sound judgement in assessing the emotional and physical care of the patient and act accordingly to ensure patient eligibility, safety and compliance throughout the duration of the study.  Use clinical skills to assess and monitor patients/volunteers condition throughout the study escalating any concerns to PI/manager taking appropriate action to ensure patient safety.  Monitor quality of work undertaken by study team dealing promptly and appropriately where there are concerns around competence, quality and safety escalating as required.  Make decisions on the use of departmental resources based upon study requirements, procedures, patient safety and potential risks.  Ensure Serious Adverse Events (SAE) and Suspected Unexpected Adverse Reaction (SUSAR) are reported to PI/co-ordinating centre and nurse manager within required timelines. |
| **9. COMMUNICATIONS AND RELATIONSHIPS** |
| Conduct all communication in a professional, respectful and non-discriminatory manner in the workplace.  As part of the research team and lead for identified studies the post holder will communicate effectively using verbal and written information as appropriate.  Communicate complex and sensitive information to the research patient/volunteers, their relatives and the multidisciplinary team involved in the research study.  Communicate with the research team regarding subjects’ condition and safety, protocol and compliance issues.  Provide regular reports to the PI/sponsor/co-ordinating centre/ R&D/CRF management team as agreed.  Participate in CRF meetings including regular meetings with line-manager, senior management team, training team and CRF sub-groups e.g. SOP group providing feedback and raising concerns as appropriate.  Act as a point of contact for patients, volunteers, clinicians, sponsor, internal and other external organisations involved in research.  Fulfil mentoring role by meeting regularly with assigned staff.  Represent the CRF at professional meetings providing feedback to colleagues and manager. |
| **10. PHYSICAL, MENTAL, EMOTIONAL AND ENVIRONMENTAL DEMANDS OF THE JOB** |
| **Physical Demands:**  Flexible working with the potential to work unsocial hours in order to meet the requirements of the research protocols and facilitate subject recruitment.  Frequent travel+ transport of study equipment across GG&C required to support study visits (occasional travel outside GG&C required).  Occasional requirement to manoeuvre patients using trolleys, wheelchairs.  Frequent requirement to lift and manoeuvre research equipment and study supplies (e.g. positioning for pulse wave analysis measurement).  Stand/walking for several long periods each shift.  Frequent VDU use (30%)  **Mental demands of the job**  Responding to competing demands on time when managing a number of studies.  Maintaining an in-depth knowledge of study protocols.  Responding to critical events to meet both sponsor requirements and regulatory timelines.  Managing study cover to ensure patient safety is maintained.  Periods of intensive concentration required when conducting complex study visits, reading/reviewing protocols and reading/completing study documentation.  Attending intensive training courses/meetings for studies, new equipment and drug management/delivery procedures.  **Emotional demands of the job**  Working within a multi-disciplinary team where priorities may be different and taking action to resolve conflicting demands if required  Communicating with distressed/anxious/worried/abusive research participants or their relatives or seeking informed consent from research participants or their legal representative in situations where tact and motivational skills need to be balanced with respect for the individual’s autonomy.  **Environmental and working conditions**  Frequent exposure to biological samples e.g. blood/urine samples taken in compliance with GG&C policies.  Requirement to travel and undertake outreach work in a variety of hospital and community settings.  Comply with GG&C policies and manufacturers recommendations when using equipment (e.g. Infection Control, Moving and Handling, H&S). |
| **11.MOST CHALLENGING/DIFFICULT PARTS OF THE JOB** |
| Developing new skills and knowledge to meet requirements of changing CRF study portfolio.    Supporting members of the research team to fully understand and comply with regulations and guidelines governing research.  Managing complex, sensitive and contentious information when working as part of a multi-disciplinary teams across multiple specialities  Managing staff and the needs of the service to ensure participant safety at all times.  Meeting recruitment targets and project deliverables in a challenging clinical environment. |
| **12.KNOWLEDGE, TRAINING AND EXPERIENCE REQUIRED TO DO THE JOB** |
| First Level Registered Nurse with significant, current and relevant clinical experience.  Ability to demonstrate competencies in relation to experience with evidence of highly developed clinical and technical skills.  Experience of working in both academic and commercial research.  Experience demonstrating the post holders ability to lead a clinical research or comparable project e.g. audit or clinical effectiveness, including the management of staff and resources.  Evidence of continuing personal and professional development, educated to degree level (or working towards).  Knowledge of current research regulations and governance requirements.  Experience of working effectively in a multi-disciplinary team with key responsibilities within the team.  Motivated and able to demonstrate excellent team management skills.  Excellent organisational and time management skills/ability to work under pressure and prioritise workload across different clinical areas and clinical trials to meet project timelines. Ability to use IT systems proficiently including Microsoft Office, electronic patient management systems and web-based technologies.Evidence of highly developed current clinical and technical skills in the clinical setting. |