**Job Description**

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| **1. JOB IDENTIFICATION** | Job Title | **Project Administrative Assistant** | |
| Department(s)/Location | **Clinical Research Centre (CRC), Ninewells Hospital** | |
| Number of Job Holders | **1** | |
| 1. **JOB PURPOSE**   The post holder will work closely with the CRC Project Manager/Senior Clinical Research Nurse and the clinical research teams, providing administrative assistance for specific aspects of the set-up, co-ordination and management of clinical research studies including clinical trials of investigational medicinal products.  They will be a flexible, team player with a keen interest in developing knowledge and understanding of the delivery of clinical research. . The post holder will be expected to work with minimal supervision providing support to the Project Manager and Research Nurse teams, and will support specific projects as directed. They will be required to show initiative and manage their workload on a day to day basis and work with a high degree of accuracy and with attention to detail.  All work will be carried out in accordance with UK Clinical Trials Regulations and ICH-GCP. | | | |
| 1. **ORGANISATIONAL POSITION** | | | |
| 1. **SCOPE AND RANGE**   The post holder will be based within the Clinical Research Centre (CRC) at Ninewells Hospital. The CRC is the hub facility of the Tayside Medical Science Centre (TASC) Clinical Research Facilities. It is a state-of-the-art facility providing dedicated space, equipment, an imaging suite that includes MRI and PET/CT scanning, and teams of clinical research staff to support researchers in delivering high quality research studies and clinical trials across Tayside. The CRC currently supports approximately 200 studies across a wide range of clinical areas.  The post holder, a member of the CRC Team, will provide high quality, comprehensive, support to the CRC Project Manager/ Senior Research Nurse, Principal Investigators and clinical research staff with the set-up and ongoing management of research studies/clinical trials. | | | |
| 1. **MAIN DUTIES/RESPONSIBILITIES**  * Assists the Project manager in the development of the New Study/Project set-up plan and take forward workstreams as delegated by the Project manager. * The post holder will be responsible for obtaining and tracking all relevant completed study and organisation documents in a timely manner. They will also manage inventory of study specific equipment, documents and supplies. Once a clinical study is active, the post-holder will be responsible for the set-up and maintenance of study Investigator Site Files (ISF). They will ensure that all essential documentation is up-to-date, disseminated to members of the research teams and filed throughout the duration of the clinical study. * The post holder will coordinate the set-up of Site Selection and Site Initiation Visits for Non-Commercial studies, communicating with sponsors, funding bodies, Chief Investigators, Principal Investigators, Research Nursing team, R&D and other departments as applicable. * Use CRF Manager (and other CRC databases) and keep these updated with study activity, documents, feasibility and resource information. The post holder will relay this information to the CRC Operational Management Team and TASC to assist with metric reporting to the Chief Scientist Office. Establish and maintain electronic index and file of research staff current CVs and Good Clinical Practice certificates. The post holder will also be responsible for Maintain CRC Standard Operation Procedures (SOPs) Index and alert appropriate team member when SOPs are due for review. * Liaise with R&D with regard to maintaining effective communication in relation to speculative and proposed studies * Assist in the completion of the Study Intensity Tool in liason with the TASC Research Nurse Service Manager and The Project Manager. * Responsible for developing and implementing Project management team procedures and work instructions and ensure compliance with all other TASC and relevant NHS Tayside policies * Prepare for monitoring and audit and assist the co-ordinating Clinical Research Nurse with the resolution of any findings * Transcribe accurately clinical research data from source documentation/study specific worksheets into paper or electronic Case Report Forms * Prepare and assist the Clinical Research Nurse and sponsor representative with study close out visits * Prepare documents and files for archiving * Up-date CRC Serious Adverse Event Log * Assist with the implementation of CRC Quality Assurance Audit Programme and carry out audits as applicable. * Check CRC Study email inbox on a daily basis and action as appropriate * Responsible for monitoring and ordering stationary and supplies for the project team * Participate in annual review and personal development plan using the e-KSF System * Complete statutory and mandatory training * In the absence of the Project Manager act as a point of contact   **Induction Standards & Code of Conduct**  Your performance must comply with the national “Mandatory Induction Standards for Healthcare Support Workers in Scotland” 2009; and the Code of Conduct for Healthcare Support Workers. | | | |
| 1. **COMMUNICATIONS AND RELATIONSHIPS**   There is a need for well developed interpersonal and communication skills as clinical research information is often complex and sensitive and the post holder will be responsible for ensuring relevant parties are provided with and act upon the most up to date information. This will require the post holder to use persuasive and negotiating skills, as the agreement and cooperation of others is required.   * Communicate with staff at all levels, this includes CRC Directors and Management team, Chief, Principal and co-investigators, clinical and administration staff and other members of the research team * Communicate with the Project Manager/ Senior Clinical Research Nurse regarding daily operational and project matters * Communicate with Representatives from pharmaceutical companies, Clinical Research Organisations and Trial Co-ordinating Centres with regards to documentation, queries, monitoring etc * Communicate with staff in TASC, clinical and non-clinical support departments (e.g. pharmacy, medical records, imaging, procurement) * Participate in CRC and interdepartmental meetings * Prepare and present training regarding the use of CRC systems, study-specific systems and the role of Project Management. * Participate in the orientation of new members of staff. * Act as the Project Manager’s delegate in his/her absence. | | | |
| 1. **KNOWLEDGE, TRAINING AND EXPERIENCE REQUIRED TO DO THE**   **JOB**   * HNC/HND Secretarial/admin qualification or relevant experience/training, ideally in a health care or scientific setting * Excellent IT skills including use of Excel and databases * Requires working knowledge and understanding of clinical trials regulations, research governance and ICH Good Clinical Practice. * Ability to deal with routine and non-routine enquiries and activities * Ability to work calmly and effectively under pressure * Ability to communicate effectively and deal tactfully with people * Ability to work as part of a team * Proficient/accurate keyboard and data entry skills * Organisational and time management skills with the ability to prioritise work * Excellent attention to detail | | | |
| 1. **SYSTEMS AND EQUIPMENT**  * NHS Systems (intranet, email, Trak-Care, Learn-Pro, Training Database, Datix, ) * Regular use of the Microsoft Office software – Word, Excel, Access, Publisher, PowerpointClinical study-specific electronic case report forms will be used although training will be given. * Desk top PC * Photocopier * Printer * Scanner * FAX * Telephone * Shredder * Laminator   **Responsibility for Records Management**  All records created in the course of the business of NHS Tayside are corporate records and are public records under the terms of the Public Records (Scotland) Act 2011. This includes email messages and other electronic records. It is your responsibility to ensure that you keep appropriate records of your work in NHS Tayside and manage those records in keeping with the NHS Tayside Records Management Policy and with any guidance produced by NHS Tayside specific to your employment. | | | |
| 1. **PHYSICAL DEMANDS OF THE JOB**   Physical Demands   * A large proportion of the work is desk/computer based therefore required to sit in a restricted position for long periods. * Frequent requirement to walk to other departments both on site and other sites across NHS Tayside * The operation of VDU equipment and other office equipment. * Lifting and filing of patient records and other documents * The post may require occasional travel to other sites within NHS Tayside   Mental Demands   * Post holder will be required to work to set deadlines therefore speed and accuracy * The workload is subject to interruptions and work is not predictable as priorities may change * Long periods of concentration for accurate data input   Emotional   * Exposure to distressing or emotional circumstances on occasion when accessing patient records. * Occasionally exposed to conflict when negotiating with senior staff over trial-related issues | | | |
| 1. **DECISIONS AND JUDGEMENTS**  * Exercise judgment when dealing with internal and external telephone and email communication * The postholder will be required to make decisions in relation to workstreams they are responsible for within the project to ensure outcomes are achieved within timescales set. * The postholder will be required to monitor progress of the project against the project plan flagging areas of concern to the Project Manager. * The postholder will be expected to confidently make decisions on a daily basis. He/she must be proactive and use his/her own initiative to take responsibility for decisions relating to workload priorities, given the range of competing demands made on the teams, information relayed on behalf of senior staff and their teams when dealing with enquiries; this requires tact and careful consideration to ensure that only appropriate information is disseminated and when managing diary conflicts of the team, including arranging someone to deputise for the Project manager should it be required.   . | | | |
| 1. **MOST CHALLENGING/DIFFICULT PARTS OF THE JOB**   Dealing with a diverse workload, range of competing priorities and being able to identify, access and utilise the information appropriately  Meeting deadlines to assist the efficient set up and the ongoing admin requirement of research studies  Ability to make judgments/decisions  Constant interruptions throughout each working day from staff, telephone calls, and  visitors to the department.   * The diversity and complexity of the work and the range of different tasks required, e.g. when organising an event this involves preparation before the event, tasks for the actual event on the day and the follow up work that is required afterwards | | | |
| 1. **JOB DESCRIPTION AGREEMENT**   A separate job description will need to be signed off by each postholder to whom the job description applies. | | | |
| **Job Holder’s Signature:** | | | **Date:** |
| **Head of Department’s Signature:** | | | **Date:** |