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***“Our vision is to provide safe, high quality seamless service delivered with courtesy and respect. To achieve our vision we expect all our staff to uphold our Trust Values”***

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| **JOB DETAILS**  |
| **Job Title**  | Senior Research Administrator |
| **Reports to**  | Team Leads |
| **Accountable to** |  |
| **Band**  | 4 |
| **Department/Directorate**  | Research and Development |

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| **JOB PURPOSE**  |
| The post holder will work as part of the clinical research team to support the safe conduct of research in accordance with the Research Governance Framework and Good Clinical Practice guidelines and provide assurance that the rights, safety and well-being of trial participants are protected.The post-holder will work with the research team and act as a specialist resource in administrative, clerical and data management support for all aspects of research study delivery across an extensive portfolio of clinical trials. S/he will oversee and provide support to Research Administration Assistants within the team ensuring that studies are set up and delivered in an efficient and timely manner. |
| **KEY WORKING RELATIONSHIPS**  |  |
| * Director of Research & Development
* Clinical research team
* Research and development team
* Principal Investigators
* Trust multidisciplinary team
* Study participants and their families
* Clinical trials pharmacy team
* Diagnostic services
* Study sponsors and Clinical Research Associates.
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| **ORGANISATIONAL CHART**  |
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| **KEY RESULT AREAS/PRINCIPAL DUTIES AND RESPONSIBILITIES**  |
| **Research and Governance** * Assist the clinical research team in co-ordinating a portfolio of National Institute Health
* Research (NIHR) studies.
* Participate in Good Clinical Practice (GCP) training and ensures GCP compliance of self and team.
* Act as an expert resource with regard to trial administration procedures and guide other members of the research team.
* Take a leading role in the study set up process including:
* Assist in completing Expression of interest / study selection documents
* Liaise with the study sponsor and research team to gather all relevant study information
* Prepare submissions for local research and development approval
* Coordinate site initiation meetings
* Set up the local site file and any relevant databases and documents for the study
* Take a leading role in on-going study coordination including:
* Conduct regular site file maintenance to ensure study essential documents are version controlled and are maintained according to regulatory requirements
* Maintain effective communication between the study sponsor and the clinical research team
* Support local implementation of study amendments
* Update quality systems to record study information and enrolled patients details
* Coordinate and prepare documents for patient visits
* Respond to patients/carers telephone calls (who may at times be distressed) tactfully and professionally
* Book trial specific investigations and procedures
* Coordinate study monitoring visits
* Support the research team with data queries and reporting as required
* Take a leading role in study close out procedures including:
* Liaise with the sponsor for final monitoring visit
* Preparing study documents for archiving
* Liaise with R&D and following archiving procedures
* Assist the clinical research team to collect study data and ensure that data is transcribed accurately where required and as deemed appropriate by competency and study complexity.
* Receive, handle, analyse and resolve data queries promptly. Direct unresolved queries to appropriate team member.
* Support internal audit and monitoring.
* Support external monitoring by coordinating monitoring visits between the clinical research team and study sponsors and prepare essential documents for review. Assist the research team to put in place any corrective action required following a monitoring visit.
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| **COMMUNICATION/RELATIONSHIP SKILLS**  |
| * Facilitate and maintain effective communication within Research & Development and across the areas where you have key working relationships (see Key Working Relationships section above).
* Maintain effective communication between the research team and patients tactfully and empathetically.
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| **KNOWLEDGE & TRAINING EXPERIENCE** |
| * Participate in Good Clinical Practice (GCP) training and ensures GCP compliance of self and team.
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| **ANALYTICAL/JUDGEMENTAL SKILLS** |
| * Support local implementation of study amendments.
* Supporting the clinical research team with data queries and reporting as required
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| **PLANNING/ORGANISATIONAL SKILLS** |
| **Service Delivery and Improvement*** Provide all aspects of general administration and clerical work for the clinical research team as required, including but not exclusively:
* Document preparation
* Taking phone calls
* Email and fax correspondence
* Typing letters
* Maintaining databases
* Filing
* Patient records requests and collection
* Gaining signatures
* Office management (including diary management)
* Responsible for providing meeting support including coordinating meetings and taking accurate minutes.
* Where applicable, oversee and provide support to Research Administration Support Staff, delegate appropriate tasks and ensure competency. Contribute to PDRs.
* Support the implementation of new quality systems and processes across the department.
* Take responsibility for producing reports relevant to the specialty such as recruitment reports.
* Contribute to service development by actively participating in admin team meetings.
* Demonstrate an understanding of key performance indicators and support the clinical research team to achieve them.
* Adhere to and contribute to the development of Standard Operational Procedures and policies. Ensure that Admin Support Staff are aware of and follow departmental procedures.
* Prioritise a busy workload and manage multiple tasks when frequently interrupted.
* Provide cover during periods of absence for other trial administrators.
* Undertake all mandatory training and take part in personal development reviews.
* Treat all persons encountered during the course of duties with respect and courtesy and maintain a standard of conduct which best represents the clinical trials team and the Trust.
* Recognise the importance of and contribute to maintaining the health, safety and security of the clinical research team.
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| **PHYSICAL SKILLS**  |
| * Requirement to exert moderate physical effort. Research offices and teams may not be based where patients are seen or recruited, research team members are required to work across multiple sites at the RDE Wonford and where necessary Heavitree
 |
| **PATIENT/CLIENT CARE**  |
| * The post holder will contribute to ensuring the patient experience in the relevant trails is excellent ensuring patients are at the heart of service design and delivery.
* Ensure Trust policies are applied to support reporting of complaints and concerns by research participants that may be related to their participation in research and to ensure these complaints are appropriately managed and acted upon in accordance with requirements of the UK Policy Framework for Health and Social Care Research.
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| **POLICY/SERVICE DEVELOPMENT**  |
| * Take a leading role in providing all aspects of general administration and clerical work for the clinical research team including but not exclusively:
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| **FINANCIAL/PHYSICAL RESOURCES**  |
| * Oversees the handling of petty cash and travel expense claims for patients and may act as an impress holder.
* Recognisees and understands the study costing procedure including an awareness of attributing costs of research and the various income streams.
* Supports the clinical research team with study costings and helps maintain records of patient visits in order to accurately invoice study sponsors.
* Responsible for liaising with other Trust departments to ensure that equipment is suitably maintained and in good working order.
 |
| **HUMAN RESOURCES**  |
| * Participate in Good Clinical Practice (GCP) training and ensures GCP compliance of self and team.
* Where applicable, oversee and provide support to Research Administration Support Staff, delegate appropriate tasks and ensure competency. Contribute to PDRs.
 |
| **INFORMATION RESOURCES**  |
| * Take a leading role in ensuring study and office supplies are sustained using local procurement systems and policies.
 |
| **RESEARCH AND DEVELOPMENT**  |
| * Assist the clinical research delivery team in co-ordinating a portfolio of National Institute Health Research (NIHR) studies.
* Participate in Good Clinical Practice (GCP) training and ensures GCP compliance of self and team.
 |
| **FREEDOM TO ACT**  |
| * The post holder will work autonomously within general policies and procedures guided by national policy and regulations and the Trust’s own
 |
| **PHYSICAL EFFORT** |
| * The post holder will be required to use their IT skills including MS Office, Google docs, internet, databases etc. in order to monitor activity, systems and processes and to produce reports including in time-bound circumstances.
* Standard/good keyboard skills are required for the inputting and manipulating of data and/or information on computer databases.
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| **MENTAL EFFORT** |
| * Prolonged concentration with complex research information, statistics and preparing reports and figures.
* Ability to manage multiple tasks at once and to prioritise tasks by importance.
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| **WORKING CONDITIONS** |
| * The nature of clinical research is such that flexibility is required from the workforce. Periodically it may be necessary to move staff within the different specialties in order to meet the needs of the portfolio and maintain the required skill mix. Research provides a flexible service to research participants including the opportunity for evening and weekend appointments, the post holder will need to be flexible with working patterns in order to meet participant and study requirements.
 |
| **OTHER RESPONSIBILITIES**  |
| * To take part in regular performance appraisal.
* To undertake any training required in order to maintain competency including mandatory training, e.g. Manual Handling.
* To contribute to and work within a safe working environment.
* The post holder is expected to comply with Trust Infection Control Policies and conduct him/herself at all times in such a manner as to minimise the risk of healthcare associated infection.
* As an employee of the Trust, it is a contractual duty that you abide by any relevant code of professional conduct and/or practice applicable to you. A breach of this requirement may result in action being taken against you (in accordance with the Trust’s disciplinary policy) up to and including dismissal.
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| **APPLICABLE TO MANAGERS ONLY** |
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| **THE TRUST- VISION AND VALUES**  |
| Our vision is to provide safe, high quality seamless services delivered with courtesy and respect. To achieve our vision we expect all our staff to uphold our Trust values. Our Trust values are:Honesty, Openness & IntegrityFairness,Inclusion & CollaborationRespect & DignityWe recruit competent staff that we support in maintaining and extending their skills in accordance with the needs of the people we serve. We will pay staff fairly and recognise the whole staff’s commitment to meeting the needs of our patients.We are committed to equal opportunity for all and encourage flexible working arrangements including job sharing. We are committed to recruiting and supporting a diverse workforce and welcome applications from all sections of the community, regardless of age, disability, gender, race, religion, sexual orientation, maternity/pregnancy, marriage/civil partnership or transgender status. We expect all staff to behave in a way which recognises and respects this diversity, in line with the appropriate standards. |
| **GENERAL**  |
| The nature of clinical research is such that flexibility is required from the workforce. Periodically it may be necessary to move staff within the different specialties in order to meet the needs of the portfolio and maintain the required skill mix. It may also be necessary to be flexible in working patterns in order to meet study requirements.This is a description of the job as it is now. We periodically examine employees' job descriptions and update them to ensure that they reflect the job as it is then being performed, or to incorporate any changes being proposed. This procedure is conducted by the Manager in consultation with the jobholder. You will, therefore, be expected to participate fully in such discussions. We aim to reach agreement on reasonable changes, but if agreement is not possible, we reserve the right to insist on changes to your job description after consultation with you.The RDE is a totally smoke-free Trust. Smoking is not permitted anywhere on Trust property, including all buildings, grounds and car parks. For help to quit call: 01392 207462. |
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| **Requirements** | **Essential** | **Desirable** |
| **QUALIFICATION/ SPECIAL TRAINING**GCSE or equivalent (A-C Grade) in at least 2 subjects –Including Maths and English (Minimum requirement for all posts)European Computer Driving License (or equivalent computerskills qualification)NVQ in Business and Administration (level 3)Good Clinical Practice Training | EEEE | E |
| **KNOWLEDGE/SKILLS**Excellent organisation skillsWorking knowledge of Microsoft office packages (spreadsheets,databases, word processing and e-mail)Ability to communicate with staff and patientsAbility to prioritise workload to respond to changing demandsExcellent telephone manner and written communicationUnderstanding of National Institute for Health Research ClinicalResearch NetworkUnderstanding of the clinical research process including GoodClinical PracticeUnderstanding of clinical information | EEEEEEEEE |  |
| **EXPERIENCE** Substantial administrative or clerical experiencePrevious experience in a hospital / healthcare settingClinical research experienceData management experienceProject management experienceFinance experience | EEDDDD |  |
| **PERSONAL ATTRIBUTES** Enthusiastic, motivated and committed to developing a professional serviceA flexible approach to work and the needs of the serviceAble to prioritise and use own initiativeRemain calm in difficult situationsProven ability to work as part of a multi-disciplinary teamExcellent communication skills; confidentiality, tact and diplomacy | EEEEEE |  |
| **OTHER REQUIRMENTS** The post holder must demonstrate a positive commitment to uphold diversity and equality policies approved by the Trust.Committed to further professional developmentAbility and willingness to work across multiple sites | EEE |  |

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|  | **FREQUENCY****(Rare/ Occasional/ Moderate/ Frequent)** |
| **WORKING CONDITIONS/HAZARDS** | **R** | **O** | **M** | **F** |
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| **Hazards/ Risks requiring Immunisation Screening** |  |  |  |  |
| Laboratory specimens | N |  |  |  |  |
| Contact with patients | N |  |  |  |  |
| Exposure Prone Procedures | N |  |  |  |  |
| Blood/body fluids | N |  |  |  |  |
| Laboratory specimens | N |  |  |  |  |
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| **Hazard/Risks requiring Respiratory Health Surveillance** |  |  |  |  |  |
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| Solvents (e.g. toluene, xylene, white spirit, acetone, formaldehyde and ethyl acetate) | N |  |  |  |  |
| Respiratory sensitisers (e.g isocyanates) | N |  |  |  |  |
| Chlorine based cleaning solutions (e.g. Chlorclean, Actichlor, Tristel) | N |  |  |  |  |
| Animals | N |  |  |  |  |
| Cytotoxic drugs | N |  |  |  |  |
|  |  |  |  |  |
| **Risks requiring Other Health Surveillance** |  |  |  |  |
| Radiation (>6mSv) | N |  |  |  |  |
| Laser (Class 3R, 3B, 4) | N |  |  |  |  |
| Dusty environment (>4mg/m3) | N |  |  |  |  |
| Noise (over 80dBA) | N |  |  |  |  |
| Hand held vibration tools (=>2.5 m/s2) | N |  |  |  |  |
|  |
| **Other General Hazards/ Risks** |  |  |  |  |
| VDU use ( > 1 hour daily) | Y |  |  |  | x |
| Heavy manual handling (>10kg) | N |  |  |  |  |
| Driving | N |  |  |  |  |
| Food handling | N |  |  |  |  |
| Night working | N |  |  |  |  |
| Electrical work | N |  |  |  |  |
| Physical Effort  | N |  |  |  |  |
| Mental Effort  | Y |  |  |  | x |
| Emotional Effort  | N |  |  |  |  |
| Working in isolation | N |  |  |  |  |
| Challenging behaviour | N |  |  |  |  |

**COMPETENCY REQUIREMENTS**

To be completed for all new positions

Please tick which of these essential learnings is applicable to this role

(**NB** those that are mandatory for all staff with no variation on frequency are pre-populated with a tick)

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| Safeguarding Children | Group 1 | 🞏 | Blood Transfusion | BDS18 collection | 🞏 | Consent Training | 🞏 |
|  | Group 2 | 🞏 |  | BDS 19 & 20 Preparing & Administering  | 🞏 | VTE Training | 🞏 |
|  | Group 3 | 🞏 |  | BDS 17 Receipting | 🞏 | Record management and the nhs code of practice | 🞏 |
|  | Group 4 | 🞏 |  | Obtaining a blood sample for transfusion | 🞏 | The importance of good clinical record keeping  | 🞏 |
|  |
|  | Group 5 | 🞏 |  | Annual Update | 🞏 | Antimicrobial Prudent Prescribing  | 🞏 |
|  | Group 6 | 🞏 |  |  |  | Control & Restraint Annual | 🞏 |
| Not mapped this one |  | 🞏 | Safeguarding Adults Awareness  | Clinical Staff  | 🞏 | Mental Capacity/DOL’s | 🞏 |
|  | Group 8  | 🞏 | Non Clinical Staff  | 🗹 |  |  |
| Manual Handling – Two Year | 🗹 | Falls, slips, trips & falls  | Patients | 🞏 |  |  |
| Equality & Diversity – One-Off requirement | 🗹 |  | Staff/Others | 🞏 |  |  |
| Fire | Annual | 🞏 | Investigations of incidents, complaints and claims | 🞏 |  |  |
|  | Two Yearly | 🗹 | Conflict Resolution – 3 yearly | 🞏 |  |  |
| Infection Control/Hand Hygiene | Annual requirement | 🞏 | Waterlow  | 🞏 |  |  |
|  | One-Off requirement | 🗹 | PUCLAS  | 🞏 |  |  |
| Information Governance | 🗹 | Clinical Waste Management | Application principles for clinical staff  | 🞏 |  |
| Harassment & Bullying (Self Declaration – One off requirement) | 🗹 | Application principles for housekeeping  | 🞏 |  |  |
|  |  | Application principles for portering and waste  | 🞏 |  |  |

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| Manager’s Signature: | Print Name: | Date: |
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| Divisional Director Signature: | Print Name: | Date: |
|  |  |  |
| Chief Operating Officer Signature: | Print Name: | Date: |
|  |  |  |