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| Last updated: | Mar 2024 |

**JOB DESCRIPTION**

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| Post title: | **Trial Assistant** | | |
| Academic Unit/Service: | Cancer Sciences | | |
| Faculty: | Faculty of Medicine | | |
| Career Pathway: | Management, Specialist and Administrative (MSA) | Level: | 2b |
| \*ERE category: | n/a | | |
| Posts responsible to: | Trial Manager | | |
| Posts responsible for: | None | | |
| Post base: | Office-based | | |

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| Job purpose |
| Southampton Clinical Trials Unit (SCTU) designs, initiates, conducts and analyses high quality national and international clinical trials of treatments to directly influence routine clinical practice.  The post-holder will provide effective, efficient administrative support for the research study team. |

| Key accountabilities/primary responsibilities | | % Time |
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|  | To assist the Trial Manager and contribute to the development of suitable study administrative systems, carrying out administrative processes including general administrative duties eg, photocopying, printing, scanning, preparation of trial documents, collating the trial centre manuals, maintenance of Trial Master Files (TMF) and mailshots. | 15 % |
|  | To assist the Trial Manager with set-up and day to day operational management of one or more trials within the SCTU and being aware of regulatory requirements. | 15% |
|  | Responsible for arranging internal and external meetings and teleconferences, and preparing agendas, meeting documents, taking minutes | 5% |
|  | Assisting with the maintenance of tracking logs of submissions & approvals for studies | 10 % |
|  | Where applicable, to contact study participants by telephone,text or email to assist with the completion of patient outcome data and to remind participants to complete other study processes such as returning data and unused medication. | 5% |
|  | Printing and sending out materials to research sites. Assisting with the ordering, tracking and re-ordering of trial supplies. Tracking of site/investigators payments. | 10% |
|  | Where appropriate for the trial to organise the transportation of Trial Medication to and from sites. This will involve liaising with the courier and local site staff to ensure all processes are accurately followed and records kept. To take receipt of returned medications and following logging procedures accurately. Maintain all drug accountability logs, including medication movement and the temperature of all storage facilities. Arrange for quarantine of returned medication until destruction.  Alternatively, the role may involve liaising with the drug distribution company to ship direct to sites. | 20% |
|  | Assisting the Trial Manager with site close out duties at the end of the trial following SCTU Standard Operating Procedures | 5% |
|  | Acting as a point of contact for the clinical trial teams. Providing general support to the SCTU team, working closely with the Trial Management Team to facilitate good communication with trial sites. Acting as a secondary point of contact for trial enquiries. | 10% |
|  | Any other duties that fall within the scope of the job and band, as allocated by the line manager following consultation with the post holder. | 5% |

| Internal and external relationships |
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| The post holder will work closely with the Senior Trial Manager, Trial Manager, Data Management team and the Chief Investigator.  They will also liaise with collaborating centres outside of the University of Southampton as necessary. |

| Special Requirements |
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| Ability to work flexibly to contact participants outside of normal working hours if required.  Comfortable using the telephone to contact participants if required. |

**PERSON SPECIFICATION**

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| Criteria | Essential | Desirable | How to be assessed |
| Qualifications, knowledge and experience | Skill level equivalent to achievement of NVQ2, GCSE or City and Guilds.  Previous work experience within an administrative or secretarial support role within a research environment.  Able to demonstrate a sufficient knowledge of work systems, equipment processes and standard IT packages.  Able to demonstrate a good knowledge of the role and its context.  Ability to produce clear, accurate and concise written documentation.  Experience of analysing data and presenting summary information clearly. | RSA II word-processing, or equivalent level of skill or qualification.  Experience of monitoring a small scale budget (e.g. stationery)  Knowledge of NHS organisation structure  GCP trained  Experience of University administration systems  Experience of creating and maintaining databases  Experience of communicating directly with patients or public  Experience of working in primary care research | All by CV and interview |
| Planning and organising | Able to effectively organise allocated work activities and assist in the effective organisation of non-standard tasks and events.  Ability to work well with minimum supervision. |  |  |
| Problem solving and initiative | Able to independently solve a range of problems by responding to varying circumstances, whilst working within standard procedures. |  |  |
| Management and teamwork | Able to contribute to team efficiency through sharing information and constructively supporting others.  Able to ensure any staff managed or supervised are focused on allocated tasks and aware of service standards.  Ability to effectively allocate work and check the work of others ensuring required service standards and deadlines are met.  Ability to adapt well to change and service improvements. |  |  |
| Communicating and influencing | Able to seek and clarify detail.  Experience of providing advice on administrative procedures to colleagues and external customers.  Able to demonstrate own duties to other colleagues as required. | Able to analyse data and present a summary of information in a clear and precise format |  |
| Other skills and behaviours | Flexibility to work on a number of different tasks to reflect the needs of the study team at any one time |  |  |
| Special requirements | Ability to work flexibly outside of normal working hours. To include phoning patients out of hours in homeworking environment. |  |  |

**JOB HAZARD ANALYSIS**

**Is this an office-based post?**

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| 🗸Yes | If this post is an office-based job with routine office hazards (eg: use of VDU), no further information needs to be supplied. Do not complete the section below. |
| No | If this post is not office-based or has some hazards other than routine office (eg: more than use of VDU) please complete the analysis below.  Hiring managers are asked to complete this section as accurately as possible to ensure the safety of the post-holder. |

## - HR will send a full PEHQ to all applicants for this position. Please note, if full health clearance is required for a role, this will apply to all individuals, including existing members of staff.

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| **ENVIRONMENTAL EXPOSURES** | **Occasionally**  (<30% of time) | **Frequently**  (30-60% of time) | **Constantly**  (> 60% of time) |
| Outside work |  |  |  |
| Extremes of temperature (eg: fridge/ furnace) |  |  |  |
| ## Potential for exposure to body fluids |  |  |  |
| ## Noise (greater than 80 dba - 8 hrs twa) |  |  |  |
| ## Exposure to hazardous substances (eg: solvents, liquids, dust, fumes, biohazards). Specify below: |  |  |  |
| Frequent hand washing |  |  |  |
| Ionising radiation |  |  |  |
| **EQUIPMENT/TOOLS/MACHINES USED** | | | |
| ## Food handling |  |  |  |
| ## Driving university vehicles(eg: car/van/LGV/PCV) |  |  |  |
| ## Use of latex gloves (prohibited unless specific clinical necessity) |  |  |  |
| ## Vibrating tools (eg: strimmers, hammer drill, lawnmowers) |  |  |  |
| **PHYSICAL ABILITIES** | | | |
| Load manual handling |  |  |  |
| Repetitive crouching/kneeling/stooping |  |  |  |
| Repetitive pulling/pushing |  |  |  |
| Repetitive lifting |  |  |  |
| Standing for prolonged periods |  |  |  |
| Repetitive climbing (ie: steps, stools, ladders, stairs) |  |  |  |
| Fine motor grips (eg: pipetting) |  |  |  |
| Gross motor grips |  |  |  |
| Repetitive reaching below shoulder height |  |  |  |
| Repetitive reaching at shoulder height |  |  |  |
| Repetitive reaching above shoulder height |  |  |  |
| **PSYCHOSOCIAL ISSUES** | | | |
| Face to face contact with public |  |  |  |
| Lone working |  |  |  |
| ## Shift work/night work/on call duties |  |  |  |