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| Last updated: | 9th June 2020 |

**JOB DESCRIPTION**

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| Post title: | Trial Coordinator | | |
| School: | Cancer Sciences, Southampton Clinical Trials Unit (SCTU) | | |
| Faculty: | Faculty of Medicine | | |
| Career Pathway: | Management, Specialist and Administrative (MSA) | Level: | 3 |
| \*ERE category: | n/a | | |
| Posts responsible to: | Senior Trials Manager | | |
| Posts responsible for: | Where appropriate and as required:  Trials Assistant | | |
| Post base: | Office-based, with travel to participating sites as appropriate | | |

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| Job purpose |
| Southampton Clinical Trial Unit (SCTU) designs, initiates, conducts and analyses high quality national and international clinical trials to directly influence routine clinical practice.  The appointed person will assist in the set-up and operational management of one or more clinical trials within the SCTU. |

| Key accountabilities/primary responsibilities | | % Time |
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|  | Be involved in trial set-up in collaboration with Chief Investigators, the Senior Trials Manager and other relevant personnel. This may include identifying sponsor specific processes and requirements, assisting with the creation of trial documents, contributing to the development of the trial database, and assisting with protocol amendments. | 15 % |
|  | Be involved in ensuring regulatory requirements are fulfilled and that all approvals and authorisations are secured. Assisting with applications as appropriate and assisting/advising participating investigators with local requirements. | 10 % |
|  | Taking responsibility for site set up and activation; identifying appropriate centres and a clinical lead in each, establishing links with key members of staff and ensuring essential documentation is in place. | 10 % |
|  | Visiting clinical centres and monitoring trial conduct and drug accountability as appropriate to ensure protocol compliance, good patient management and ensuring Good Clinical Practice guidelines are adhered to. | 10-50%  Variable depending on trials allocated |
|  | Acting as the main point of contact for the relevant trial/s, and working with the trial team to ensure all queries are resolved and the trial is managed effectively. This will require regular communication with staff at participating sites. | 20 % |
|  | Explaining and promoting the trial (including newsletter production, website updates) to ensure wide participation and good accrual of patients. Ensuring screening data is reviewed regularly and used effectively to ensure the trial recruits at an acceptable rate at each centre. Suggesting and implementing strategies for improving recruitment. | 15 % |
|  | Attending relevant meetings, including Investigator Meetings and trial oversight meetings. Attendance at relevant conferences and meetings. Organise internal and external activities/events e.g. collating and presenting relevant information or documentation as requested, booking venues and speakers, co-ordinating diaries and ensuring activities/events are run efficiently. | 5 % |
|  | Drafting trial progress reports as and when required, including reports for trial funders and REC. Oversee the circulation of information/findings to ensure awareness of key issues/data. | 5 % |
|  | As appropriate, assisting with the development and maintenance of SOPs. Participation in the development and maintenance of quality systems and clinical audit of research activity. Ensuring practice adheres to all relevant University policies and procedures | 5% |
|  | Any other duties appropriate to the band assigned by the Senior Trial Manager. | 5% |

| Internal and external relationships |
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| Other staff within SCTU to ensure good working relationships  Chief Investigators and other members of Trial Management Group  Staff at participating sites eg investigators, Research Nurses, Pharmacists  Trial funders  Trial oversight committees (DMEC, TSC, TMG)  Sponsor representatives  Regulatory agencies e.g. MHRA, Research ethics committees  Pharmaceutical companies  Collaborating organisations e.g. tissue banks, central laboratories, clinical suppliers, unblinding services. |

| Special Requirements |
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| The Trial Coordinator will be based at Southampton General Hospital within SCTU. There will however be a requirement to travel to participating centres, meetings and conferences across the UK and possibly internationally. |

**PERSON SPECIFICATION**

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| Criteria | Essential | Desirable | How to be assessed |
| Qualifications, knowledge and experience | Skill level equivalent to achievement of HNC, A-Level, NVQ3 and proven work experience, acquired in relevant roles and job-related training  Knowledge of medical or medical research terminology  Previous experience of working in a health care, research, or busy office environment  Good IT literacy – MS office applications  Excellent communication in written and spoken English | Relevant degree (or equivalent qualification or experience)  Experience of a clinical trials environment  Knowledge and experience of medical research methodology and statutory clinical trial regulations and GCP.  Experience of clinical trials in the NHS or the commercial health research sector | Application  Application /Interview  Application / Interview  Application / Interview  Application/  Interview |
| Planning and organising | Able to plan and prioritise a range of one’s own, and the team’s, standard and non- standard work activities.  Ability to successfully plan and deliver projects over a period of several months (e.g. to co-ordinate trial activities). | Experience of successful project management. | Application / Interview |
| Problem solving and initiative | Able to identify and solve problems by applying initiative to tackle some situations in new ways and by developing improved work methods. |  | Interview |
| Management and teamwork | Able to proactively work with colleagues in other work areas to achieve outcomes.  Able to delegate effectively, understanding the strengths and weaknesses of team members to build effective teamwork.  Able to formulate development plans for own staff to meet required skills. | . | Application / Interview |
| Communicating and influencing | Ensure regular liaison and communication with colleagues involved in managing the clinical trial/s, and at participating sites.  Able to elicit information to identify specific site/trial needs.  Able to offer proactive advice and guidance. |  | Application / Interview |
| Special requirements | Flexible working arrangements  Ability to travel |  | Interview |

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