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| Last updated: | 29 June 2018  |

**JOB DESCRIPTION**

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| Post title: | Trial Manager |
| Academic Unit/Service: | Southampton Clinical Trials Unit (SCTU) |
| Faculty: | Faculty of Medicine |
| Career Pathway: | Management, Specialist and Administrative (MSA) | Level: | 4 |
| \*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 take responsibility for the set-up and operational management of one or more clinical trials within the SCTU. |

| Key accountabilities/primary responsibilities | % Time |
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|  | Responsible for 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, taking responsibility for writing and designing all trial documents including the protocol, and contributing to the development of the trial database, Identifying when protocol amendments become necessary and taking appropriate action. | 15 % |
|  | Ensuring regulatory requirements are fulfilled and that all approvals and authorisations are secured. Taking responsibility for 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. | 5-50%Variable depending on trials allocated |
|  | Acting as the main point of contact for the relevant trial/s. Additionally working with other trial managers to provide a ‘buddy’ system which ensures appropriate trial cover within SCTU. | 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 % |
|  | Leading and representing SCTU at relevant meetings, including Investigator Meetings and trial oversight meetings e.g. Chair or facilitator of Trial Management Group and/or Trial Steering Committee. Attendance at relevant conferences and meetings, presenting information about trials, and if appropriate presenting results. | 10 % |
|  | Writing and submitting trial progress reports as and when required, including reports for trial funders and REC. | 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 | 3% |
|  | Any other duties appropriate to the band assigned by the Senior Trial Manager. This may include assisting with new grant applications. | 2 % |

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

| Special Requirements |
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| The Trial Manager 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 | Degree (or equivalent) in a health or science disciplineKnowledge and experience of medical research methodology and statutory clinical trial regulations, GCP and research governance requirements.Experience of clinical trials in the NHS or the commercial health research sectorGood IT skills | Postgraduate qualification in relevant area.Health care background / nursing qualificationEvidence of continuing professional developmentGCP training within last 2 years. | ApplicationApplicationApplication / InterviewApplication / Interview |
| Planning and organising | Able to seek opportunities to progress a broad range of activities within professional guidelines and in support of University policy. | Experience of successful project management. | Application / Interview |
| Problem solving and initiative | Able to develop understanding of long-standing and complex problems and to apply professional knowledge and experience to solve them. |  | 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. | Experience of successfully managing and developing staff. | Application / Interview |
| Communicating and influencing | Able to provide accurate and timely specialist guidance on complex issues.Able to use influencing and negotiating skills to develop understanding and gain co-operation.  |  | Application / Interview |
| Special requirements | Flexible working arrangementsAbility to travel |  | Interview |

**JOB HAZARD ANALYSIS**

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

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| [x]  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 |  |  |