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| Last updated: | 08/05/2015 |

**JOB DESCRIPTION**

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| Post title: | Clinical Trials Manager / Project Manager | | |
| Academic Unit/Service: | Southampton Clinical Trials Unit (SCTU) – Faculty Operating Service (FOS) | | |
| Faculty: | Medicine | | |
| Career Pathway: | Management, Specialist and Administrative (MSA) | Level: | 5 |
| \*ERE category: | n/a | | |
| Posts responsible to: | SCTU Senior Clinical Trials Manager, Level 5 | | |
| Posts responsible for: | Clinical Trial Coordinators, Level 4  Clinical Trial Assistant, Level 2a | | |
| Post base: | Office-based, with travel to participating sites as appropriate | | |

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| Job purpose |
| The Clinical Trials Manager (CTM) will act as the project manager for a portfolio of trials within SCTU.  The CTM will manage a team of staff to ensure trials are developed, coordinated and maintained effectively within the SCTU, and conducted to required standards.    The CTM will provide research support to staff and working parties, to assist with the development and operational management of clinical trials before grant approval and/or activation.  Once trials are funded, the CTM ensures they are conducted in compliance with regulations and within the agreed timelines. |

| Key accountabilities/primary responsibilities | | % Time |
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|  | To manage a team of staff at SCTU responsible for the coordination of a portfolio of clinical trials ensuring adequate and effective staff cover at all times. To be responsible for relevant Human Resource (HR) requirements including recruitment, induction, appraisal, staff development, discipline and grievance procedures. | 15% |
|  | To be responsible for the oversight of conduct and delivery of trials within the SCTU portfolio ensuring compliance to GCP, regulatory requirements and SOPs | 15% |
|  | To ensure good working practices and policies are maintained within the CTU. To provide professional leadership and act as an accessible resource on clinical trial management. To help resolve the more complex matters arising from the team. To identify and participate in initiatives and developments relevant to the management and conduct of clinical trials | 10% |
|  | Assist the Directors of SCTU, Chief Investigators and/or planning groups with applications for new trials, including offering advice on regulatory requirements and collaborators outside the SCTU. Assist with writing and designing all trial documents including protocols, patient documents using appropriate level English, and to agreed timelines. Contribute to the development of trial specific database and contribute to trial promotion including producing newsletters, attendance at scientific conferences and meetings, presenting information about trials and if appropriate, presenting results. | 15% |
|  | Ensure sponsorship in place for all trials. | 5% |
|  | Ensure SOPs reflect best practice and are adhered to by all staff. | 5% |
|  | Contribute to the preparation of posters and papers for publication, and prepare and present written and oral reports as required. | 5% |
|  | Oversee the agreed project plan to ensure the project runs to time and budget, and to contractual obligations with multiple partners. | 5% |
|  | Be the main point of contact for external partners (funder, sponsor) in the development and oversight of clinical trials. | 5% |
|  | Contribute to the development of annual reports for SCTU and external groups as appropriate. | 5% |
|  | Ensure knowledge of national / international legislation and sponsor requirements remains up to date as appropriate for ongoing trials. | 5% |
|  | Ensure practice within the unit continues to develop. To include communication with other trials units / clinical trial managers to share best practice. Ensure knowledge of all policies, legislative and guidance documents, including national and international variations, is kept up to date. Ensure SCTU staff receive necessary training and induction. |  |
|  | Be responsible for budget management. Cost new trials, help to develop grant applications and manage clinical trial grants. Set up agreements and systems for investigators to claim funds from the research grant. Regularly communicate with trial funders to provide progress and meeting reports, query funding arrangements, and meet as appropriate. Communicate with industry, sponsor, NHS and other partners to ensure research, NHS excess treatment and NHS support costs are met before commencement of the trial. | 5% |
|  | Any other duties as allocated by the line manager following consultation with the post holder. | 5 % |

| Internal and external relationships |
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| * NCRI Clinical Studies Groups * Southampton’s NIHR and CR UK infrastructure – including but not limited to CRF and ECMC/CR UK research nurses infrastructure * Accountants within the University finance department * Relevant departments within the University of Southampton and University Hospital Southampton NHS Trust for Sponsorship issues or external sponsors as appropriate. * Research Networks. Regular communication with Network Leads. * Chief Investigators, Principal Investigators and Multi Disciplinary Team members from each interested and/or participating hospital to promote and manage trials * Regulatory agencies – MHRA, Research Ethics Committees, R&D departments * Trial funders, e.g. Cancer Research UK, NIHR, pharmaceutical companies * Nationals trial management groups (e.g. Trial Managers Network) to share best practice * TSC / TMG / DMEC for specific trials |

| Special Requirements |
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| The Clinical Trial Manager will be based at Southampton General Hospital. There will however be a requirement to travel to participating centres, meetings and conferences throughout the UK and occasionally internationally |

**PERSON SPECIFICATION**

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| Criteria | Essential | Desirable | How to be assessed |
| Qualifications, knowledge and experience | Skill level equivalent to achievement of a Postgraduate Degree in a relevant area or relevant experience  Evidence of continuing professional development, including recent training in aspects of clinical trial conduct  Demonstrable specialist knowledge and experience of Good Clinical Practice (GCP), the Research Governance Framework (RGF), the EU Clinical Trials Directive  Experience in managing clinical trials  Experience of developing new trials, writing and maintaining clinical trial documents (protocol, PIS, SOPs etc)  Management experience including staff and budget management  Ability to work to deadlines and multi-task  Experience of presenting to groups  Good IT skills | Skill level equivalent to achievement of a PhD  Experience of working on different trial designs and phases  Training in project management and presentation skills  Evidence of use and dissemination of research findings  Budget management / accountancy training  Knowledge and experience of the NIHR, NCRI, UKCRN, Primary Care Trusts and non-commercial trial funders  Experience of clinical trials in a non-commercial setting  Staff development and appraisal  Evidence of contribution to publications in scientific journals  Experience of applying for research grants | Application or interview |
| Planning and organising | A high degree of organisation  Proven ability to deliver projects to time and target  Ability to manage multiple projects at various stages of development |  | Application or interview |
| Problem solving and initiative | Ability to prioritise tasks  Ability to deal with problems, identifying cause and solution/s |  | Application or interview |
| Management and teamwork | Proven management experience  Ability to lead, support, motivate, delegate and develop a team |  | Application or interview |
| Communicating and influencing | Excellent interpersonal skills  Ability to facilitate collaborative working relationships with cross disciplines/agencies  Communicates effectively in both spoken and written English  Good presentation skills | Experience of writing reports, papers, posters and presenting data | Application or interview |
| Other skills and behaviours | Personal drive and initiative  Assertiveness  Flexibility |  | Application or interview |
| Special requirements | Ability to travel and stay overnight when meetings necessitate |  | 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 |  |  |  |
| 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 | x |  |  |
| Lone working |  |  |  |
| ## Shift work/night work/on call duties | x |  |  |