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| Last updated: | 17/07/23 |

**JOB DESCRIPTION**

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| Post title: | Associate Director of Operations, Southampton Clinical Trials Unit (SCTU) | | |
| School/Department: | Cancer Sciences, SCTU | | |
| Faculty: | Medicine |  |  |
| Career pathway: | Management, Specialist and Administration (MSA) | Level: | 6 |
| \*ERE category: |  | | |
| Posts responsible to: | Director Southampton Clinical Trials Unit | | |
| Posts responsible for: | Senior Management Team and Operations/Administrative support (approx. 7 staff) | | |
| Post base: | Hybrid - Office-based (Southampton General Hospital): Home Working (approx. 3:2) | | |

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| Job purpose |
| To provide strategic and operational support to the Director of Southampton Clinical Trials Unit (SCTU) and take the lead role in the operational delivery of SCTU. Overseeing a team of over 100 staff, with responsibility to deliver the aims of the unit. Building and maintaining positive working relationships with stakeholders to ensure focus and engagement on the business of the SCTU. The post-holder will be instrumental in budgetary planning and management, collaborating closely with finance and business managers to ensure the effective management of all relevant financial activities and operational delivery at SCTU. Responsible for health and safety, communications and engagement and overseeing delivery of the business of the unit through the senior management team. |

| Key accountabilities/primary responsibilities | | % Time |
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|  | Leadership and management  * Lead and manage the SCTU operations and senior management team. * Lead in the development and submission of major funding rounds for core infrastructure funding (e.g. Cancer Research UK [CRUK] Quinquennial Review [QQR]) and monitor progress against agreed QQR Key Performance Indicators (KPI’s). * Lead in the development and submission of annual reports to funders of SCTU (e.g. CRUK core and NIHR Research Support Service/Biomedical Research Centre activity at SCTU). * Lead the development and implementation of SCTU strategic and business plans that are innovative, viable and sustainable, informed by comprehensive management information and are fully aligned with SCTU’s strategy, plans and priorities. | 20% |
|  | Financial ManagementEnsure the effective management of all relevant financial activities including the oversight of costing used in bids for further grant incomes.Provide reports and advice for the Directors group as required.Oversee future business activity through key stakeholder crossover activities.  * Responsible for managing resources and income. | 10% |
|  | Operational Delivery  * Oversee the operational delivery of the unit in close consultation with the SCTU Director and Associate Directors. * Ensure delivery through support for, and line management of, the senior management team. * Developing and implementing an operational/business plan and risk register, to ensure that delivery is in line with research governance, core funders of SCTU and UoS requirements (including enterprise opportunities). * Responsible for Health and Safety requirements for the unit. * Oversee UoS HR requirements and support staff as required. * Maintain accurate records of personnel and operational requirements. * Oversee the contractual development of studies with the sponsors of SCTU trials and develop and agree sponsorship models where needed. * Plan and oversee the periodic re-assessment of existing SCTU systems and processes to determine re-adjustment to enable more efficient ways of working and organisational resilience. * Act as a critical link between SCTU and University central professional services to ensure fit-for-purpose SCTU systems and processes for UK wide and international clinical trials. | 40% |
|  | Communications and Engagement  * Build and maintain positive working relationships with key stakeholders to ensure focus and secure their engagement to deliver the requirements of the SCTU. * Oversee effective communication planning to ensure a strong media presence supporting the business aims of the unit * Work to ensure an effective and supportive role for PPI (patient and public involvement) and EDI (equality, diversity and inclusivity) embedded throughout the work of the unit * To represent the SCTU, and the Director of SCTU, on national groups as required * To liaise with CRUK Head Office and sister CRUK CTUs to enable the adopting and sharing of new practices in clinical trials. | 20% |
|  | Other  * To liaise regularly with SCTU directors as required. To deputise for the Director of the SCTU when required. * Attend key meetings both locally and elsewhere, as appropriate. * Review and maintain working knowledge of the relevant standard operating procedures for the SCTU. | 10% |

| Internal and external relationships |
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| * Cancer Research UK (CRUK): the postholder will be expected to contribute to the CRUK CTU operational group and to maintain links with the charity as required. * UK Clinical Research Collaboration (UKCRC): the post holder will be expected contribute to the UKCRC operational group and to maintain links with the cancer research community and maintain UKCRC CTU registered status of SCTU. * Work with the Wessex NIHR director partnership where opportunity arise for ONE NIHR Wessex collaborations. * Chief Investigators and multi-disciplinary team members. * Sponsors of SCTU trials and the University central professional services. * The CRUK Institutes, Centres and ECMCs infrastructure across the UK. * Regulatory agencies – MHRA, R&D departments. * Trial funders, including NIHR and Cancer Research UK. * SCTU Clinical Trial Teams (comprising of Trial Management, Data Management, QA, Statistics and Translational staff) for day to day management and oversight of trial data. * Collaboration with other clinical trials units. * Collaboration with colleagues within Cancer Sciences, University Hospital Southampton NHS Foundation Trust, Faculty of Medicine and University wide as required to support and deliver the business aims of the unit. |

**PERSON SPECIFICATION**

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| Criteria | Essential | Desirable | How to be assessed |
| Qualifications, knowledge & experience | Skill level equivalent to achievement of a professional qualification or postgraduate degree (in science, business or other area relevant to the role).  Proven experience of managing significant change.  Proven strategic management skills in a specialist field  Knowledge of clinical trial methodology and regulatory requirements. | Formal training in GCP  Having worked within a UKCRC Clinical Trials Unit  PhD  In leading the development and submission of research infrastructure funding bids | Application and Interview |
| Planning & organising | Able to plan and shape the direction of specialist or professional area of activity.  Able to organise major new initiatives, with little or no precedent  Ability to identify priorities.  Methodical, practical, with excellent attention to detail.  Able to maintain judgement under pressure and meet deadlines.  Established organisational skills and ability to oversee a number of projects. | Leading in the development and implementation of business plan/cases. | Application and Interview |
| Problem solving & initiative | Innovative, able to problem solve and be decisive  Able to develop significant new concepts and original ideas within one’s field in response to intractable issues of importance to the University. |  | Interview |
| Management & teamwork | To be able to work both independently and collaboratively with medical, scientific and technical staff  Experience of management and supervision of others  Able to proactively develop team dynamics and performance, ensuring quality standards are consistently achieved.  Able to foster positive relationships both within and outside of own department.  Able to proactively work with senior managers across the University to achieve key deliverable |  | Application and Interview |
| Communicating & influencing | Writing skills for drafting, reports, funding applications etc  Able to communicate complex clinical trial information clearly to a range of staff groups and to potential investigators  Good communication with lay groups and potential study funders  Able to negotiate effectively on behalf of the department or University on key issues.  Able to develop and lead key communications strategies. |  | Interview |
| Other skills & behaviours | Willingness to work within a regulatory framework  Champion and lead on equality and inclusion aligning with the [Southampton Behaviours](https://sotonac.sharepoint.com/teams/EmbeddingCollegiality) |  | Interview |
| Special requirements | Willingness to travel  Flexibility |  |  |

**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: |  |  |  |
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| 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 |  |  |  |