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| Last updated: | March 2022 |

**JOB DESCRIPTION**

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| Post title: | **Trial Coordinator** | | |
| School/Service: | Primary Care, Population Sciences and Medical Education (PPM)  Primary Care | | |
| Faculty | Medicine | | |
| Career pathway: | Management, Specialist and Administrative (MSA) | Level: | 4 |
| \*ERE category: | N/A | | |
| Posts responsible to: | Chief Investigator | | |
| Posts responsible for: |  | | |
| Post base: | Office-based with travel for site visits | | |

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| Job purpose |
| To provide professional services within a specialist support field. To manage the set-up and running of the University of Southampton recruitment centre as part of a multi-centre trial being run by the University of Oxford. |

| Key accountabilities/primary responsibilities | | % Time |
| --- | --- | --- |
|  | To be responsible for provision of specialist/professional advice to aid management decisions and to ensure the trial is compliant with the protocol, ICH GCP, Research Governance Framework, Data Protection legislation, the requirements of the National Research Ethics Service and delegated sponsor’s responsibilities on behalf of the Chief Investigator to ensure the study is undertaken to the highest level. | 20 |
|  | To take responsibility for study set up and activation: ensure appropriate sites and principal investigators/research leads are identified; establish links with key members of staff; provide training at local sites; ensure essential documentation is in place at each participating site. | 20 |
|  | To ensure clear and effective communication is maintained with the recruiting sites, monitoring targets, providing feedback, and ensuring support is provided where necessary for the staff in those sites to promote good relationships. | 10 |
|  | To draft reports and deliver briefings and presentations as required. | 10 |
|  | To undertake day-to-day management tasks including monitoring recruitment, liaising with, and responding to queries from trial participants, coordinating collection of patient questionnaires/diaries, collection of primary outcome measures by post and telephone. | 20 |
|  | To attend internal and external meetings and act as the facilitator for the Trial Management Group, and Trial Steering Committees to guarantee continuity and consistency. | 10 |
|  | Any other duties as allocated by the line manager following consultation with the post holder. | 10 |

| Internal and external relationships |
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| Chief Investigator and study team  Other staff in PCRC to ensure good working relationships  Staff at participating sites e.g. GPs, Nurses, Pharmacists, Practice admin staff  Trial funders  Trial oversight committees (TMG, TSC, DMEC)  Sponsor representatives |

**PERSON SPECIFICATION**

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| Criteria | Essential | Desirable | How to be assessed |
| Qualifications, knowledge & experience | Skill level equivalent to achievement of HND, Degree, NVQ4 or basic professional qualification in a health-related discipline  Knowledge and experience of medical research methodology and statutory clinical trial regulations, GCP and research governance requirements  Experience of working on a clinical trial/experience of working in health care research  Excellent IT skills (including MS Word, Excel and Access) | Post graduate degree in a relevant discipline  GCP training in last 2 years  Experience of set-up, managing, and closing a primary care trial | CV and interview |
| Planning & organising | Able to seek opportunities to progress a broad range of activities within professional guidelines and in support of University policy.  Excellent organisational and time management skills  Ability to plan and organise own workload | Experience in setting up and managing trial databases  Experience of successful project management. | CV and interview |
| Problem solving & initiative | Able to work alone  Able to reach decisions either based on practical experience or as defined in the Standard Operating Procedures depending on the situation | Creative approach to overcoming challenges of recruitment to trials | CV and interview |
| Management & teamwork | Able to proactively work with colleagues to achieve outcomes.  Able to delegate effectively, understanding the strengths and weaknesses of team members to build effective teamwork. | Experience of managing research grants  Experience of successfully managing and developing staff | CV and interview |
| Communicating & 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.  Excellent verbal and written communication skills, particularly in dealing with external contacts by telephone or email  Experience of, or willingness to, perform public speaking |  | CV and interview |
| Other skills & behaviours | Ability to pay attention to detail  Personal drive and initiative |  | CV and interview |
| Special requirements | Willingness to travel | Driving licence |  |

**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 |  |  |  |