|  |  |
| --- | --- |
| Last updated: | 22 Jul 2020 |

**JOB DESCRIPTION**

|  |  |  |  |
| --- | --- | --- | --- |
| Post title: | **Clinical Trial Monitor -** | | |
| School; | Cancer Sciences – Southampton Clinical Trials Unit (SCTU) | | |
| Faculty: | Medicine | | |
| Career Pathway: | Management, Specialist and Administrative (MSA) | Level: | 3 |
| Posts responsible to: | Senior Quality Assurance Manager | | |
| Posts responsible for: | N/A | | |
| Post base: | Office-based, with travel to participating sites as appropriate | | |

|  |
| --- |
| Job purpose |
| The post holder will act as the Clinical Trial Monitor for a number of Cancer and Non-Cancer trials. The post holder will undertake the day to day monitoring of the trials managed by SCTU. The post holder will be responsible for ensuring that the trials are conducted to the highest scientific and regulatory standards. The postholder will be expected to travel to sites within the UK that are recruiting patients into the trials with some overnight stays. |

| Key accountabilities/primary responsibilities | | % Time |
| --- | --- | --- |
|  | To perform Source Data Verification (SDV) at sites and to follow up on unresolved queries ensuring that Good Clinical Practice (GCP) regulations and guidance are adhered to. To ensure that the sites comply with the clinical trial protocol and other trial related documents adhered to. To visit and monitor data in other related departments such as Pharmacy and Laboratories | 20% |
|  | To write monitoring reports to agreed timelines and to follow up on unresolved issues identified during monitoring visits | 20% |
|  | To carry out central monitoring tasks, such as verifying Informed Consent Forms (ICFs), | 15% |
|  | To train and liaise with study staff in the research sites | 10% |
|  | To perform site initiation visits and study closeout visits as required | 10 % |
|  | To provide input into the trial monitoring plan and organise site visits according to the TMP, liaise with site staff for visits and manage travel arrangements | 10 % |
|  | To escalate issues found during monitoring to Trial Teams, Senior Monitor and Senior QA Manager as appropriate. Participation in trial team meetings may be required. | 10 % |
|  | To stay up-to-date with trial requirements and legislation which affect trial conduct. To carry out any other duties appropriate to the role as determined by the Senior Clinical Trial Monitor. | 5 % |

| Internal and external relationships |
| --- |
| 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 oversight committees  Pharmaceutical companies  Collaborating organisations e.g. tissue banks, central laboratories, clinical suppliers |

| Special Requirements |
| --- |
| The Clinical Trial Monitor 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. A full clean UK driving licence is desirable |

**PERSON SPECIFICATION**

|  |  |  |  |
| --- | --- | --- | --- |
| Criteria | Essential | Desirable | How to be assessed |
| Qualifications, knowledge and experience | Skill level equivalent to achievement of HNC, A-Level, NVQ3 with proven work experience acquired in relevant roles and job-related training.  Able to make effective use of standard office computer systems including word-processing and spreadsheets.  Knowledge of medical or medical research terminology  Excellent communication in written and spoken English | Relevant degree in a life science subject (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 or non-commercial health research sector  Previous experience of working in a health care or research environment | Application  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. | Experience of successful project management. | Application/Interview |
| Problem solving and initiative | Able to identify and solve problems by applying judgement and initiative to tackle some situations in new ways and by developing improved work methods. |  | Interview |
| Management and teamwork | Able to positively influence the way a team works together.  Able to proactively work with colleagues in other work areas to achieve outcomes.  Able to effectively allocate to, and check work of staff, coaching/ training and motivating staff as required. |  | 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 offer proactive advice and guidance.  Able to deal with sensitive information in a confidential manner. |  | Application/Interview |
|  |  |  |  |
| Special requirements | Flexible working arrangements  Ability to travel |  | Interview |

**JOB HAZARD ANALYSIS**

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

|  |  |
| --- | --- |
| 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.

|  |  |  |  |
| --- | --- | --- | --- |
| **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 |  |  |  |
| Lone working |  |  |  |
| ## Shift work/night work/on call duties |  |  |  |