|  |  |
| --- | --- |
| Last updated: | 08/05/2015 |

**JOB DESCRIPTION**

|  |  |  |  |
| --- | --- | --- | --- |
| Post title: | Clinical Trials Manager | | |
| Academic Unit/Service: | Centre for Innovation and Leadership | | |
| Faculty: | Health Sciences | | |
| Career Pathway: | Management, Specialist and Administrative (MSA) | Level: | 5 |
| \*ERE category: | n/a | | |
| Posts responsible to: | Chief Investigator (CI) | | |
| Posts responsible for: | N/A | | |
| Post base: | Office-based, with travel to participating sites as appropriate | | |

|  |
| --- |
| Job purpose |
| The Clinical Trials Manager (CTM) will act as the project manager and co-ordination of the OTTER II Clinical effectiveness and efficacy trial.  The CTM will work closely with Oxford Clinical Trials Research Unit, all the co-applicants, researchers, clinicians and patient and public involvement representatives ensuring that the research is properly conducted according to Good Clinical Practice (GCP) and the Research Governance Framework.  The CTM will work with the CI and other members of the team to ensure the project is effectively and efficiently run, to time and within the budget.  Once trials are funded, the CTM ensures they are conducted in compliance with regulations and within the agreed timelines. |

| Key accountabilities/primary responsibilities | | % Time |
| --- | --- | --- |
| **Strategic and Operational Management and Coordination of the Programme** | |  |
|  | Close liaison with sites and the Oxford Clinical Trials Research Unit to ensure that the trial is designed, developed and delivered according to national legislation, CTU SOPs, and as agreed with the funder. This includes obtaining and maintain approvals and amendments monitoring recruitment and data collection | 15% |
|  | Support the Chief Investigators and/or planning groups with applications for new trials, including on-going oversight of the project, offering advice on regulatory requirements and collaborators. Support writing and designing all trial documents including protocols, patient documents using appropriate level English, and to agreed timelines. | 10% |
|  | Support the CI in preparation and submission of reports to Arthritis Research UK, and publication and dissemination of findings | 5% |
|  | Provide strategic management support to the research programme, to ensure successful set-up, maintenance and delivery, as well as stakeholder engagement and prioritisation activities. | 10% |
|  | **Governance** |  |
|  | To manage and have overall oversight of conduct and delivery of trials within the OTTER II Trail portfolio ensuring compliance to GCP, regulatory requirements and SOPs. Monitor trial progress against the Gantt chart activities, deliverables, and milestones. | 15% |
|  | Responsibility for reporting any Serious Adverse Event (SAE) affecting patients enrolled into the experimental studies and the clinical trial within required timeframe (usually 24 hours). | 10% |
|  | **Communication and Internal and External Liaison** |  |
|  | Manage and co-ordinate project meetings, events and dissemination activities and liaise between members of the team. Prepare meeting agendas, documents and minutes | 5% |
|  | Develop trial databases and maintain trial master file ensuring data is accurate and participant confidentiality is maintained. | 5% |
|  | Coordination of internal and external communications, including the maintenance of the trial website | 5% |
|  | Oversee the agreed project plan to ensure the project runs to time and budget, and to contractual obligations with multiple partners. Be the main point of contact for external partners (funder, sponsor) in the development and oversight of clinical 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. | 5% |
|  | Be responsible for budget management, obtaining information from the Faculty finance team and CI. Assist the CI to develop grant applications and manage clinical trial grants. Regularly communicate with trial funders to provide progress and meeting reports, query funding arrangements, and meet as appropriate. | 10% |
|  | Any other duties as allocated by the line manager following consultation with the post holder. |  |

| Internal and external relationships |
| --- |
| * Accountants within the University finance department * Internal: Members of the project team, researchers, subcontractors and clinical colleagues * External: Ethics committees, co-applicants; patients and other participants, NIHR, Other university and NHS staff * Members of the public, media |

| Special Requirements |
| --- |
| Must be willing to work off site and be able to visit collaborating NHS sites if required.  Possible flexibility in hours of work |

**PERSON SPECIFICATION**

|  |  |  |  |
| --- | --- | --- | --- |
| 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  Demonstrable specialist knowledge and experience of Good Clinical Practice (GCP) and NHS ethical and regulatory requirements  Experience in managing clinical trials  Experience of developing new trials, writing and maintaining clinical trial documents (protocol, PIS, SOPs etc)  Ability to work to deadlines and multi-task  Experience of working across organisational boundaries within multidisciplinary teams  Advanced IT skills specifically in database management and the use of Microsoft Office applications | Skill level equivalent to achievement of a PhD  PRINCE2 or similar project management qualification. | Application or interview |
| Planning and organising | Proven experience of ability to work within a team to manage complex projects and meet tight deadlines  A high degree of organisational skill to ensure that correct trial and ethical procedures are followed  Able to plan and manage major new projects or significant new activities, ensuring plans complement broader organisational strategy. |  | Application or interview |
| Problem solving and initiative | Able to identify broad trends to assess deep-rooted and complex issues.  Able to apply originality in modifying existing approaches to solve problems.  Proven ability to analyse and propose recommendations for improvements in the running of research projects |  | Application or interview |
| Management and teamwork | Proven team work and interpersonal skills, and good written and verbal communication skills  Able to provide expert guidance and advice to colleagues to resolve complex problems.  Ability to lead, support, motivate, delegate and develop a team |  | Application or interview |
| Communicating and influencing | Proven ability to network and build relationships across professions  Proven ability to write reports and regulatory documents.  Ability to communicate complex research information to a variety of individuals with differing levels of understanding  Able to persuade and influence in order to foster and maintain relationships.  Able to resolve tensions and difficulties as they arise. | Experience of writing reports, papers, posters and presenting data | Application or interview |
| Other skills and behaviours | High level of general computer literacy  Understanding of the Data Protection Act  Calm under pressure, able to prioritise workload, work independently and within tight timescales to deliver agreed objectives  Personal drive and initiative |  | Application or interview |
| Special requirements | Some flexibility in hours  Able 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 | x |  |  |
| Lone working | x |  |  |
| ## Shift work/night work/on call duties |  |  |  |