AGENDA FOR CHANGE: JOB DESCRIPTION

JOB DESCRIPTION

Post title:	**Senior Clinical Research Coordinator**
Directorate/department:	NIHR Clinical Research Facility – Southampton Centre for Biomedical Research Trust Headquarters
Agenda for Change band:	Band 6
Accountable to:	Director of the NIHR CRF CRF Manager CRF Senior Project Manager
Accountable for:	Trial Administrators Clinical Trials Assistants Co-manage Clinical Research Coordinator
Main purpose:	a) Manage a portfolio of trials within the NIHR Clinical Research Facility, including setting up clinical trials, trial management and budget management for CRF studies. b) This pivotal role will also raise the profile of clinical trials within the centre and ensure trials are properly conducted according to Good Clinical Practice (GCP), research governance framework and are compliant with the EU Directive for clinical trials. c) The post holder will also have Line Manager responsibility for Trial Administrator/ Clinical Trials Assistant or Clinical Research Coordinator.
Key working relationships:	**Internal & External Relationships:** - R&D departments within the University of Southampton and Southampton University Hospitals NHS Trust for Sponsorship issues. - Trial sponsors and funders. - University of Southampton Clinical Trials Unit. - Hampshire & Isle of Wight CLRN. - Principal Investigators and Multi-disciplinary team members from each interested and/or participating hospital to promote and manage trials - Regulatory agencies – Research Ethics Committees, R&D departments, PCTs, HTA, MHRA, FHEA, etc. - Collaboration with other clinical trials units.
General duties:	**Study Feasibility and Set-Up** 1. To support local investigators with study set up in the NIHR CRF. To meet with the Principal Investigator (PI) and study team to undertake study feasibility. 2. To liaise with support departments and assess capacity and capability requirements within CRF for studies. 3. To ensure that studies are costed correctly and review contracts. 4. To lead on national and local study submissions for allocated studies, e.g. REC, HRA, MHRA, R&D, EPSC, CRF registration forms completion and preparation of associated documents. 5. To ensure that all regulatory approvals are in place before the study starts. 6. To support the investigators with protocol and study document development. 7. To assist with preparation of costs for research grants for studies involving CRF resources. 8. To attend fortnightly Feasibility meetings between CRF and R&D. 9. To design Case Report Forms, create study documents and review Protocols. 10. To act as Study Manager for assigned studies. 11. To provide support to the Research Nurses in terms of study coordination from start until study ends. 12. To be main Point of Contact for the sponsor and organise Site Selection and Site Initiation visits. 13. To ensure that trials are properly conducted according to GCP and Research Governance Framework and are compliant with EU Directive for clinical trials.

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Study Management

14. To manage study amendments and to reassess study feasibility, costs and capacity for each amendment.
15. Monitor progress of study during set up, delivery and close out stages.
16. To perform Quality Control and Governance checks for studies, ensuring that ongoing conduct of trials adheres to the appropriate regulatory guidelines and legislation.
17. To perform internal audits and internal monitoring of studies.
18. To assist with Statutory Inspections, including from the MHRA.
19. To ensure that all training and Standard Operating Procedures applicable to the role is up to date.
20. To create, revise or assist with amendment of SOP's.
21. To manage the study budget with the R&D Finance. To ensure that all study activities are captured with an appropriate system and that R&D Finance is informed of these activities for each study. To support the Finance Manager with reviewing study invoicing and ensure all activities have been invoiced and re-charged to appropriate departments.
22. To manage the Investigator Site File (ISF) for allocated studies
23. To assist to study team plan study visit logistics and ensure that studies taking place in the CRF have all necessary resources.
24. To be responsible for coordination of Adverse Event reporting as specified within GCP guidelines.
25. To support study archiving processes as applicable.

Grant support/study design

26. To support investigators with reviewed of grant applications.
27. To provide investigators (in conjunction with UHS R&D finance and/or University of Southampton) with planning research delivery and associated costs.
28. To support the investigators with reviewing study protocols and other associated documents.

CRF Feasibility/New Projects/Research Management

29. To support the CRF feasibility, new projects and research management meetings management and administration.
30. To chair the meetings – if delegated by the Line Manager.
31. To coordinate the resolution of any queries associated with the studies discussed.
32. To ensure that studies being presented at New Projects have the appropriate approvals in place and have been costed appropriately.
33. To educate staff in the CRF research management processes – including feasibility, new projects and research management
34. To ensure that any changes to a study which impacts on the CRF are discussed at these meetings.

Phase 1 studies

35. To assist in the set up and coordination of assigned Phase 1 studies running in the CRF.
36. To assist with the submissions to the Early Phase Safety Committee and assist with the completion of all related forms as necessary.
37. To liaise with the sponsor in collecting necessary documents for Phase 1 studies.
38. To attend monthly Research Management meetings and feedback on the progress of Phase 1 studies.

Volunteer Management

39. To manage the Healthy Volunteers Database.
40. To lead on study recruitment and volunteer management for assigned studies.

	41. To ensure volunteers and patients are paid correctly for their study participation, where this is applicable. **Education and Training** 42. To ensure study specific training is carried out by the PI and study team and this is documented in the ISF. 43. To ensure that Study Management practices within the CRF are running at the correct and appropriate standards. 44. To develop and deliver training material on Study Management 45. To assist with Training and Education days. **Line Management** 46. To co-manage Trial Administrators, Clinical Trial Assistants and co-manage Clinical Research Coordinators. **Systems** 47. To support the Operations Manager with producing NIHR reports. 48. To ensure that study information if recorded appropriately on EDGE and provide updates to the EDGE team regarding study changes. 49. To ensure that study information is appropriately recorded on CRF Manager. **Communications** 50. Maintain good relationships and develop regular communication with R&D, especially during the study set up stage. 51. Maintain good relationships and communication with research departments, including (but not limited to) Pharmacy, Radiology, Cancer Research UK, BRU and Trustwide teams. **General** 52. Support the work of colleagues during periods of absence and peak workload, where necessary. 53. Escalate issues and concerns to the CRF Senior Project Manager. 54. The post holder is expected to keep themselves aware and up to date with National, Trust and Divisional policies, guidelines and decisions.

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IMPORTANT ADDITIONAL INFORMATION RELATING TO YOUR EMPLOYMENT

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Duty of care	You are responsible for ensuring that the patient, family and carers are at the centre of everything you do. Be open, honest, and willing to acknowledge when something has gone wrong. Make timely apologies and take action to report incidents, including near misses; to ensure that as an organisation we learn. You should continuously seek to reduce harm by speaking up to managers and leaders if you believe that a lack of skills, knowledge, or resources place patients at a risk of harm or if your concerns are not being listened to. Managers and leaders must listen to others when they raise concerns and take action. Wholeheartedly commit to learning about safety, continually striving to improve excellent care. Develop your own ability to detect and correct defects.
NHS standards of business conduct and professional registration	All employees must abide by the guidance set out in the NHS Code of Conduct and Standard Business Conduct for NHS Staff (HSG 93/5), as amended or replaced from time to time. Managers must also comply with the NHS Code of Conduct for Managers. All clinical professionally regulated staff must abide by the codes of conduct issued by their respective regulatory bodies (e.g. NMC, GMC, HPC) and ensure that they maintain updated registration as required by the role.
Living our values every day	All staff are expected to strive to make the Trust values 'what we do' – to inspire, develop and support every one of us to live our values; every patient, every colleague, every day. Each post holder is expected to ensure they live the values of: 1. Patients First 2. Always Improving 3. Working Together These values are about us all helping each other to deliver great patient experience more consistently – involving people who use our services, their families, carers, staff and partners in continuing to improve the experience people have using and delivering our services
Health and safety:	Staff are reminded of their responsibility to take care of their own personal safety and others whilst at work. In addition, no person shall interfere with, or misuse anything provided in the interests of health, safety and welfare
Infection prevention and decontamination of equipment:	All staff are reminded of their responsibility to adhere to Trust and departmental infection prevention policies, including policies for the cleaning and decontamination of equipment, in order to protect their own health and that of other employees, visitors and patients.
Child protection/safeguarding	All staff providing services to patients and children are reminded of their responsibility to adhere to Trust and departmental child protection and safeguarding policies including employment checks.
Confidentiality	All employees of University Hospital Southampton NHS Foundation Trust are reminded of the need to treat all information, particularly clinical and management information, as confidential. **Any employee who wilfully disregards Trust and departmental policies may be liable to serious disciplinary action including dismissal.**

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	This job description will be reviewed yearly as part of the annual appraisal, to ensure that it reflects the responsibilities of the post. No changes will be made without full consultation with the postholder.
Mental Capacity Act 2005	All Staff are required to ensure knowledge regarding the Mental Capacity Act 2005 (MCA) at a level deemed essential for their role. The level of training required will be specified to members of staff and is dependent on their role. It is important that staff understand and comply with local policies and procedures relating to MCA to ensure the Trust can act in an individual's best interest when providing care. This helps to ensure ongoing adherence to our legal obligations and ensuring we put the needs of our patients first.
Sustainability	Staff are reminded of their responsibility to take care of the resources used whilst at work. These include careful use of energy and water; for example, ensuring unnecessary equipment is turned off when not in use. Waste needs to be segregated properly. UHS policies and strategies for sustainability should be followed whilst undertaking daily duties. We encourage staff to be involved with sustainability at work, through participation in the Green Guardians network.
Last updated	25 April 2024