

**Agenda for Change: Job Description**

<b>Post Title:</b>	<b>BRC Assistant Project Manager/Study Manager</b>
<b>Directorate/Department:</b>	Trust Headquarters NIHR Biomedical Research Centre
<b>Agenda for Change Band</b>	AfC6
<b>Accountable to:</b>	Director of the NIHR BRC Project Management Team BRC Manager BRC Project Manager
<b>Accountable for:</b>	Trial Administrators Clinical Research Coordinator
<b>Main Purpose:</b>	<ul style="list-style-type: none"> <li>• Manage a portfolio of trials within the NIHR Biomedical Research Centre, including setting up clinical trials, trial management and budget management for BRC studies.</li> <li>• 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</li> <li>• The post holder will also have Line Manager responsibility for Trial Administrator/ Clinical Trials Assistant or Clinical Research Coordinator</li> </ul>
<b>Key Working Relationships:</b>	<p><b>Internal &amp; External Relationships:</b></p> <ul style="list-style-type: none"> <li>- R&amp;D departments within the University of Southampton and Southampton University Hospitals NHS Trust for Sponsorship issues.</li> <li>- Trial sponsors and funders.</li> <li>- University of Southampton Clinical Trials Unit.</li> <li>- Hampshire &amp; Isle of Wight CLRN.</li> <li>- Principal Investigators and Multi-disciplinary team members from each interested and/or participating hospital to promote and manage trials</li> <li>- Regulatory agencies – Research Ethics Committees, R&amp;D departments, PCTs, HTA, MHRA, FHEA, etc.</li> <li>- Collaboration with other clinical trials units.</li> </ul>
<b>General Duties:</b>	<p><b>Study Feasibility and Set-Up</b></p> <ol style="list-style-type: none"> <li>1. To support local investigators with study set up in the NIHR BRC. To meet with the Principal Investigator (PI) and study team to undertake study feasibility.</li> <li>2. To liaise with support departments and assess capacity and capability requirements within BRC for studies.</li> <li>3. To ensure that studies are costed correctly and review contracts</li> <li>4. To lead on national and local study submissions for allocated studies, e.g. REC, HRA, MHRA, R&amp;D, EPSC, CRF (Clinical Research Facility) registration forms completion and preparation of associated documents.</li> <li>5. To ensure that all regulatory approvals are in place before the study starts</li> <li>6. To support the investigators with protocol and study document development.</li> <li>7. To assist with preparation of costs for research grants for studies involving BRC resources.</li> <li>8. To attend fortnightly Feasibility meetings between CRF and R&amp;D.</li> <li>9. To design Case Report Forms, create study documents and review Protocols.</li> </ol>

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.

**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 BRC 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 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/BRC research management processes – including feasibility, new projects and research management
34. To ensure that any changes to a study which impacts on the BRC/CRF are discussed at these meetings

**Phase 1 studies**

35. To set up, coordinate and manage assigned Phase 1 studies running in the CRF
36. To lead 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 have oversight of Phase 1 study activities and notify the EPSC of

	<p>any study changes and Dose Escalation events.</p> <p>39. To attend monthly Research Management meetings and feedback on the progress of Phase 1 studies</p> <p>40. To educate and support PIs and study teams in the CRF Phase 1 processes.</p> <p><b>Volunteer Management</b></p> <p>41. To manage the Healthy Volunteers Database.</p> <p>42. To lead on study recruitment and volunteer management for assigned studies.</p> <p>43. To ensure volunteers and patients are paid correctly for their study participation, where this is applicable.</p> <p><b>Education and Training</b></p> <p>44. To ensure study specific training is carried out by the PI and study team and this is documented in the ISF.</p> <p>45. To ensure that Study Management practices within the BRC are running at the correct and appropriate standards</p> <p>46. To develop and deliver training material on Study Management</p> <p>47. To assist with Training and Education days.</p> <p><b>Line Management</b></p> <p>48. To co-manage Trial Administrators and Clinical Research Coordinators</p> <p><b>Systems</b></p> <p>49. To support the Operations Manager with producing NIHR reports.</p> <p>50. To ensure that study information is recorded appropriately on EDGE and provide updates to the EDGE team regarding study changes.</p> <p>51. To ensure that study information is appropriately recorded on CRF Manager.</p> <p>52. Support the CRF Systems Analyst with CRFManager development – specifically study management related functionalities.</p> <p><b>Communications</b></p> <p>53. Maintain good relationships and develop regular communication with R&amp;D, especially during the study set up stage.</p> <p>54. Maintain good relationships and communication with research departments, including (but not limited to) Pharmacy, Radiology, Cancer Research UK, BRC and Trustwide teams.</p> <p><b>General</b></p> <p>55. Support the work of colleagues during periods of absence and peak workload, where necessary</p> <p>56. Escalate issues and concerns to the BRC Senior Project Manager</p> <p>57. The post holder is expected to keep themselves aware and up to date with National, Trust and Divisional policies, guidelines and decisions.</p>
	20/12/2023

IMPORTANT ADDITIONAL INFORMATION RELATING TO YOUR EMPLOYMENT

<p><b>Duty of Care</b></p>	<p>You are responsible for ensuring that the patient, family and carers are at the centre of everything you do.</p> <p>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.</p> <p>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.</p> <p>Wholeheartedly commit to learning about safety, continually striving to improve excellent care. Develop your own ability to detect and correct defects.</p>
<p><b>NHS Standards of Business Conduct and Professional registration</b></p>	<p>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.</p> <p>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.</p>
<p><b>Living our values every day</b></p>	<p>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.</p> <p>Each post holder is expected to ensure they live the values of:</p> <ol style="list-style-type: none"> <li>1. Patients First</li> <li>2. Always Improving</li> <li>3. Working Together</li> </ol> <p>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</p>
<p><b>Health and Safety:</b></p>	<p>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</p>
<p><b>Infection Prevention and Decontamination of Equipment:</b></p>	<p>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.</p>
<p><b>Child Protection/Safeguarding</b></p>	<p>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.</p>
<p><b>Confidentiality</b></p>	<p>All employees of Southampton University Trust are reminded of the need to treat all information, particularly clinical and management information, as confidential.</p>

	<p><b>Any employee who wilfully disregards Trust and Departmental policies may be liable to serious disciplinary action including dismissal.</b></p> <p>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.</p>
<b>Mental Capacity Act 2005</b>	<p>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.</p>
<b>Last Updated</b>	20 December 2023