AGENDA FOR CHANGE: JOB DESCRIPTION

JOB DESCRIPTION

Post title:	**Clinical Trials Administrator**
Directorate/department:	Pharmacy Division C
Agenda for Change band:	Band 4
Accountable to:	Clinical Trial Team Manager
Accountable for:	
Main purpose:	To carry out ordering, invoicing and other administrative support for the Clinical Trials department, ensuring an efficient, effective and high-quality service is provided. Performs general duties under the supervision of the Senior Clinical Trials Administrator.
Key working relationships:	Clinical Trial Pharmacy Technicians Clinical Trial Pharmacists UHS Principal Investigators / Research Team Commercial Pharmaceutical companies Sponsors Clinical Trial Units (CTUs) R&D Department Other administrative staff within Clinical Trials pharmacy
General duties:	1. Communicating effectively, both verbally and in writing, with members of the research team, sponsors and pharmacy team to ensure a seamless clinical trial service. 2. To manage stock levels of office stationery. 3. Responsible for establishing and maintaining essential paper and electronic filing systems associated with regular meetings, ongoing projects, training file and agreed staff files. 4. Responsible in training new and junior members of staff, pre-registration pharmacy technician and other trainees. 5. Supervising work of pre-registration pharmacy technician and other trainees ensuring you act as a role model and provide support, training and guidance as needed or referring appropriately. 6. Attend any relevant study days and other training events considered of benefit to the service including all statutory and mandatory requirements and Good Clinical Practice regulatory training. 7. To take part in the recruitment and selection of new administrative staff, in conjunction with the clinical trial team manager. 8. Responsible for keeping the work area safe, clean and tidy with suitable supplies of relevant sundry items. Ensuring all relevant local checks and housekeeping are done in accordance with standard operating procedures. 9. Carrying out other clinical trial duties as may be required by the pharmacist or senior pharmacy technician. 10. To participate in audits and error monitoring according to service requirements. 11. To assist in the collation of data for clinical trial activities performed in each study and create invoices accordingly. 12. To assist the Head of Clinical Trials in maintaining the shared drive through updating and archiving of documents as required. 13. To set up pharmacy file for each new study and to ensure maintenance of these files through spot checking.

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	14. To organise monitoring visits with sponsors and prepare all relevant paperwork and returned IMPs as required by the CRA or sponsor. 15. To organise close down visits and complete close out document checklist. 16. To coordinate the closing of clinical trials following standard operating procedures. 17. To liaise with the R&D administrator with the retrieval of archived clinical trial files as necessary in the event of a product recall, MHRA inspections, or if requested by the sponsor. 18. Responsible for managing the global clinical trial inbox and dealing with emails in a timely manner or forwarding to the appropriate member of the team. 19. Responsible for collating Key Performance Indicator data for dispensing times on a monthly basis. 20. Maintain GCP and awareness throughout the work area following written procedures and COSHH guidelines to ensure the safety of the product, patient and staff. 21. To provide clerical support for the clinical trials pharmacy department, such as answering telephone calls, mail distribution and filing. 22. To support the maintenance of the photocopier by ordering supplies, and arrange the call out of engineers if required. 23. To develop and maintain effective communication links between oncology/haematology staff and oncology pharmacy / clinical trial department. To provide support to oncology pharmacy team with regard to clinical trial activities 24. To liaise with oncology/haematology staff over patient identification and treatment schedule / prescription requirements, ensuring sufficient IMP supplies are available. 25. To view patient data on relevant electronic databases / e-prescribing systems. 26. To maintain appropriate levels of clinical trial materials in stock in conjunction with clinical trial team. 27. Responsible for good stock control, including manual ordering of some Investigational Medicinal Products, expiry date checks, stock rotation and ensuring that stock is stored under correct conditions and adequately segregated. 28. Responsible for receiving and counting returned IMP and accurately recording onto specific study accountability logs. 29. Responsible for the assessment of clinical areas and associated equipment in compliance with GCP standards for IMP storage. Responsible for validation of clinical trial equipment and auditing. 30. To act as first telephone pharmacy contact for enquiries about oncology prescriptions.

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IMPORTANT ADDITIONAL INFORMATION RELATING TO YOUR EMPLOYMENT

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	22 April 2024