

Job title	Research Governance Coordinator	Job family and level	Administrative, Professional and Managerial Level 3
School/ Department	Research & Innovation	Location	Jubilee Campus

Purpose of role

To provide administrative support to the University Research Governance Team to ensure that research projects are managed in line with the University's policies and requirements of relevant legislation, Government research funders, Research Councils and other funders within frameworks of governance and administration to meet the University's legal and policy requirements.

	Main responsibilities (Primary accountabilities and responsibilities expected to fulfil the role)	% time per year
1	 Administer the documentation and processes for all types of research protocols to ensure timely processing, tracking and that accurate records are made. Be aware of and maintain awareness of Health Research Authority, UK Research Ethics Committee and the Medicines and Healthcare products Regulatory Agency (MHRA) application and ongoing study processes in order to understand queries and respond accordingly. Manage the shared email inbox of the Research Governance Team and allocate work to individuals, monitoring progress and workload. Check research protocol applications (received via email) for adherence to HRA, REC, MHRA and NHS Trust R&D set requirements (i.e., validate the application) and allocate to the Research Governance Officers for full governance review. Liaise with researchers where applications are not valid and ensure that correct documentation is sent. Log each protocol on an Excel ledger and research database and prepare computer and paper files for record storage. Track the review progress through to completion. Prepare standard letters and contracts for each application and obtain authorising signatures as required. Accountable for consolidating and processing Governance records via in-house databases and Excel ledgers. Attention to detail is very important to ensure that accurate records are kept to meet regulatory requirements and to ensure prompt retrieval of records as required. 	40%

2	 Process all types of documents, sending to and liaising with relevant researchers within the University and other external organisations, and then tracking and chasing for responses as appropriate. Organising the documents to ensure easy access for queries. Review and adjust office procedures to improve office efficiency and effectiveness and be responsible for the day-to day running of the administrative processes of the Research Governance Team. Attend Team meetings, take minutes and make recommendations. 	25%
3	Receive and respond to internal and external queries from within the University and external enquirers to provide advice and resolve complex queries and ensure a prompt efficient service is provided. Use judgement to resolve queries. Query resolution will require knowledge of legislation and research governance policies	10%
4	 Support in-house audits of clinical trials of investigational medicinal products, preparing paperwork and arranging meetings. Provide administrative support for audit reports. Track corrective action and preventative action plans and ensure the audit is signed off. Monitor progress towards CAPA completion and report any issues or delays. 	12%
5	Track REC and regulatory reporting (safety and annul progress) pertinent to each clinical research study and process accordingly. Upload study documents to clinical research platforms to meet regulatory requirements. Ensure researchers meet regulatory timelines and that reporting is recorded.	8%
6	 Manage Governance records, both paper and electronically according to standard procedures and to ensure regulatory compliance. Track end of study dates and communicate with researchers to ensure timely study closure. Upload end of study reports to international online platforms to meet regulatory requirements. 	2%
7	 Compose letters, memos and emails to communicate information or to liaise with internal and external contacts. Add to and update the Research Governance Workspace. Compile and issue news bulletins relevant to research governance issues and communicate regulatory updates to researchers on behalf of the Head of Research Governance and the Research Governance Team. 	2%
8	Support the Senior Data Manager in the maintenance of clinical trials databases and assisting in delivering training for the set-up of such databases	1%

Person specification

	Essential	Desirable
Skills	 Ability to work independently to resolve complex internal and external queries and to provide and maintain a high level of customer service whilst working to deadlines. Accuracy, reliability and willing and adaptable to learn new skills and procedures as required by changing University procedures and legislation. Excellent oral and written communication skills 	Advanced typing/secretarial skills/shorthand.
Knowledge and experience	 Extensive I.T. knowledge (MS Office, email) Well organised and able to prioritise conflicting tasks and meet operational deadlines. Ability to build working relationships within the department, University, and external collaborators. Experience of planning own work activities in response to differing needs of the team and deadlines Have knowledge of Good Clinical Practice 	 Experience of using Excel and databases Awareness of University procedures and relevant legislation. An understanding of different types of research types, Health Research Authority, Research Ethics Committee and MHRA roles and processes. Proven experience in a relevant role.
Qualifications, certification and training (relevant to role)	Vocational qualification (NVQ2 Administration with Secretarial Skills) or equivalent and experience of an office/administrative environment, or considerable work experience in relevant role.	









Expectations and behaviours

The University has developed a clear set of core expectations and behaviours that our people should be demonstrating in their work, and as ambassadors of the University's strategy, vision and values. The following are essential to the role:

Valuing people Understands that it is essential to provide a structure that people can

thrive in. Knows how to communicate with people to create a healthy

working environment and get the best out of people.

Taking ownership Communicates vision clearly, providing direction and focus. Knows how

to create a productive environment where people are inspired and can

work cross-departmentally in partnership.

Forward thinking Has the ambition to be a pioneer in own area, anticipating the future

change, needs and challenges. Knows how to innovate within their work context and champions others to be inspired to be part of this ambition

Professional pride Keeps up to date on latest thinking, trends and work practices. Supports

team to be thought leaders; willing to challenge if obstacles get in the

way.

Always inclusive Establishes far reaching partnerships, well beyond own area across a

broad range of networks. Understand role to pay due regard to the needs

of the whole community.

Key relationships with others

