

JOB DESCRIPTION

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| Job Title: Clinical Research Governance Officer  | Present Grade: 7  |
| Department/College: Research and Enterprise Services  |
| Directly responsible to: Head of Research Quality and Policy  |
| Supervisory responsibility for: N/A  |
| Other contacts: Internal: Faculty Associate Directors for Research, departmental Directors of Research, academics, clinical research staff, other members of Research and Enterprise Services, Governance and Information Security staff. External: Academics, clinicians and professional service staff at other Universities and NHS Trusts; staff in NHS Trust R&D departments; and Clinical Trial Unit staff.  |
| Purpose of the job: Working under minimal supervision, the two Clinical Research Governance Officers will lead the proactive service to academics from across the university to support Lancaster’s ambitions to develop clinical research capability. Specific key functions of the role are: * To establish, develop and maintain systems, processes and governance arrangements to support the conduct of clinical research at Lancaster University.
* To provide proactive advice and guidance to Principal Investigators (PIs) and research teams on the set-up, conduct and close out of clinical trials and clinical studies.
* To be responsible for ensuring that clinical research is undertaken in compliance with the International Conference on Harmonisation Good Clinical Practice Guidelines (ICH-GCP), EU Clinical Trials Directive, Data Protection, and the NHS Research Governance Framework for Health & Social Care.
* Support our developing clinical research portfolio in new areas including e.g., Clinical Trials of an Investigational Medicinal Product.

 Major Duties: 1. Develop and monitor clinical research support processes and systems across the university.
2. Ensure that study teams conduct clinical research in accordance with the relevant external guidelines in order to protect the rights of the research participants and ensure the quality of research.
3. Provide proactive advice and guidance to PIs and their teams and communicate changes to regulations and policies in a timely manner. Guidance to include protocol development, trial set up and close out, ethics approvals including completion of IRAS, and adverse events reporting.
4. Act as the Institutional Sponsor’s representative for clinical trials, ensuring appropriate approvals are undertaken for CTU documentation and attending Clinical Study and Trial Steering Committees on behalf of the Sponsor where appropriate.
5. Develop and maintain a Standard Operating Procedures library and other resources for clinical research management, ensuring consistency across studies and updating to regulatory or policy changes.
6. Take a proactive approach to developing working relationships with key CTUs and provide advice to PIs on the appropriate CTU for the research question to be addressed, brokering relationships where necessary.
7. Establish and maintain good working relationships with various professionals including investigators and their teams as well as external stakeholders (e.g. REC, MHRA, CLRN, NHS Trust R&D departments, other universities and research teams) and provide them with timely information when required.
8. Update and develop personal skills in clinical trial management, methodology and coordination and keep up with developments in research governance and relevant legislation and guidelines, attending courses, meetings and conferences as deemed relevant.
9. Undertake any other duties consistent with the roles and responsibilities as required by the line manager.
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