

JOB DESCRIPTION
Clinical Research Support Officer
Vacancy Ref: A2520

Job Title:	Clinical Research Support Officer	Present Grade: 7
Department/College:	Research and Enterprise Services	
Directly responsible to:	Line Manager: Claire O'Donnell; Reporting Manager: Professor Fiona Lobban	
Supervisory responsibility for:	N/A	
Other contacts: Internal: Academics, clinical trials staff, Data Integrity and Governance Manager, other members of Research Enterprise Services, Governance and Information Security staff, Health Engagement & Innovation Team (HEIT). External: Academics and clinicians at other Universities and NHS Trusts; staff in NHS Trust R&D departments, CTU staff.		
Job summary/Purpose of the job: Working under minimal supervision, the Clinical Research Support Officer will lead the establishment of a proactive service to (clinical) academics from across the University to support the University'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/or 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. As this is a relatively new role within the University the role-holder will be required to shape the role to support our developing clinical research portfolio in new areas including e.g., Clinical Trials of an Investigational Medicinal Product (CTIMPs).		
Major Duties: To fulfil the requirements of the role, the Clinical Research Officer will: <ol style="list-style-type: none">1. Lead the establishment and development of processes and systems to ensure that all elements to support clinical research are in place and are co-ordinated across the university. The role holder will liaise with colleagues across the university including, Research Support and Contracts, Intellectual Property, Governance, Information Security to facilitate the smooth running of clinical research at Lancaster.2. Take responsibility for ensuring that study teams conduct clinical research in accordance with the relevant guidelines such as ICH GCP Guidelines, EU Clinical Trials Directive, Data Protection, and Research Governance Framework 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 on e.g., protocol development, trial set up and close out, ethics approvals including completion of IRAS, and adverse events reporting and to communicate changes to regulations and policies in a timely manner.4. Act as the Institutional Sponsor's (Pro-Vice Chancellor for Research) 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. Lead the establishment, development and maintenance of a Standard Operating Procedures library and other resources for clinical research management, ensuring consistency across studies and updating in response to regulatory or policy changes as necessary.6. Take a proactive approach to developing working relationships with key CTUs and provide advice to		

Principal Investigators 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 as are consistent with the responsibilities of the grade as required by the line manager.