

JOB DESCRIPTION



Job Title: Head of Research Governance and Integrity
Department: Research Governance and Integrity Office
Faculty/Professional Service: Central Services
Location: London
Reports to: Head of Strategic Research
Responsible for: 1x Research Facilitator 1x Ethics Facilitator 1x Human Tissue Research Facilitator 1x Research Governance Administrator
Full Time/Part Time/Casual: Full Time
Grade: Grade 8
Overall Purpose of the job: <p>The Head of Research Governance and Integrity is responsible for all aspects of research governance, quality, ethics and integrity. They are responsible for ensuring that appropriate systems, processes and procedures are developed and maintained to enable LSHTM to fulfil its responsibilities with respect to research governance.</p> <p>The Head of Research Governance and Integrity is responsible for management of the Research Governance and Integrity Office, which provides comprehensive support and expert advice to LSHTM staff and students conducting research involving human participants. The Office oversees clinical research sponsorship requiring external regulatory, ethics approvals and management of human tissue samples. The Office is responsible for managing LSHTM's research ethics review process and providing the secretariat to LSHTM Research Ethics Committees.</p> <p>The Head of Research Governance and Integrity will provide expert guidance to staff and students on the legislative framework for research involving human participants, their tissue and data. They are responsible for ensuring that all research conducted by LSHTM is compliant with relevant legislation in the UK and overseas. The Head of Research Governance and Integrity is responsible for the development and maintenance of relevant policies and processes including Good Research Practice, Good Scientific Practice and Research Misconduct.</p> <p>The Head of Research Governance and Integrity will work closely with the Pro-Director of Research & Academic Development to promote the understanding of good research conduct and embed a positive culture of research integrity across LSHTM, in line with our obligations under the Concordat to Support Research Integrity.</p>

General Information

The London School of Hygiene & Tropical Medicine (LSHTM) is one of the world's leading public health universities.

Our mission is to improve health and health equity in the UK and worldwide; working in partnership to achieve excellence in public and global health research, education and translation of knowledge into policy and practice.

Staff and students are committed to helping create a more healthy, sustainable and equitable world for everyone, because we believe our shared future depends on our shared health.

We embrace and value the diversity of our staff and student population and seek to promote equity, diversity and inclusion as essential elements in contribution to improving health worldwide. We believe that when people feel respected and included, they can be more creative, successful, and happier at work. While we have more work to do, we are committed to building an inclusive workplace, a community that everyone feels a part of, which is safe, respectful, supportive and enables all to reach their full potential.

To find out more please visit our [Introducing LSHTM page](#).

Our Values

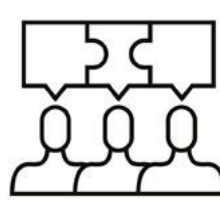
Our values establish how we aspire to achieve our mission both now and in the future - demonstrating what it means to work and study at LSHTM. Please visit our [LSHTM Values page](#) for further information.



**Act with
integrity**



**Embrace
difference**



**Work
together**



**Create
impact**

FACULTY/DEPARTMENT INFORMATION

The Strategic Research Office provides comprehensive support to academics throughout the research lifecycle. The Office is responsible for:

- Strategic support for the preparation of high quality research funding applications.
- Management of all aspects of the School's Research Excellence Framework submissions.
- Support for Knowledge Exchange activities, including oversight of LSHTM's intellectual property portfolio, preparation of Knowledge Exchange Framework submissions and implementation of the Knowledge Exchange Concordat.
- Oversight of strategic international partnerships.
- Provision of Pre-Award support for all research funding applications, including reviewing budgets to ensure financial viability and compliance with

LSHTM policies and funder terms and conditions, and approving application submissions in funder portals.

- Management of all aspects of Research Governance and Integrity, including the development of research governance policies and procedures, sponsorship of clinical trials, management of the ethical review of applications and oversight of LSHTM's Ethics Committees, and management of human tissue and compliance with the Human Tissue Act.
- Support the delivery of the HR Excellence in Research Award action plan and implementation of the Concordat to Support the Career Development of Researchers in collaboration with the Talent and Educational Development Team.

Main Duties and Responsibilities

Research Governance

1. Lead on the development, maintenance, review and improvement of policies, processes and systems to ensure compliance with the regulatory requirements for clinical trials and research studies involving human participants, their tissue and data. This includes but is not limited to, the UK Policy Framework for Health & Social Care Research 2017; Medicines for Human Use (Clinical Trials) Regulations 2004 and amendments; Guidelines for Good Clinical Practice (GCP); Human Tissue Act 2004; Mental Capacity Act 2005; UK General Data Protection Regulation and relevant international equivalents to the abovementioned regulations.
2. Oversight of regulations and guidance relevant to the conduct of research in all countries where LSHTM conducts research, including clinical trial regulations, good clinical practice guidance, data protection regulations and ethical regulations.
3. Ensure that the conduct of relevant external regulatory inspections are coordinated and conducted appropriately and efficiently, acting as the lead contact and coordinating formal responses to inspections.
4. Oversee the development and delivery of training in clinical research governance, human tissue governance, ethics training and good research practice, ensuring that staff and students are updated on any changes to regulatory requirements.
5. Membership of the Research Governance Committee, working closely with the Chair to prepare reports and ensure that information is cascaded to other committees.

Clinical Trials

6. Maintain effective oversight of monitoring and auditing of clinical trials and clinical research studies to ensure compliance with the relevant regulations and guidelines. To include ensuring that appropriate systems and processes are in place for the oversight of safety reporting in clinical trials.
7. To act as the responsible party, including Sponsor Representative duties, for all research governance and regulatory approvals for LSHTM.
8. Support and advise LSHTM researchers on the conduct of clinical trials.
9. Ensure that all clinical trials are appropriately registered and results are recorded in accordance with relevant legislation and best practice.
10. Respond to trial participant complaints, leading on any investigations within LSHTM and the relevant project teams.
11. Oversee the development, review and updating of LSHTM Standard Operating Procedures to ensure continuing compliance with the UK and international regulations and best-practice standards.

Quality Assurance

12. Establish auditing mechanisms to ensure that all research is compliant with the relevant legislation, guidelines, international standards of good practice, policies and procedures.
13. Develop and oversee LSHTM's research audit programme for clinical trials, other clinical studies and research involving human tissue for review annually by the Research Governance Committee.
14. Conduct on-site and remote audits, including investigator site audits, vendor audits, lab audits, human tissue audits and system audits. Following the identification of any areas of non-compliance, perform root cause analyses and

instigate corrective and preventive actions (CAPA), ensuring that all CAPA plans are implemented.

Research Ethics

15. Responsible for the management of LSHTM's Research Ethics Committees, working closely with the Chairs to ensure good practice and consistency in reviewing applications, ensuring that research ethics policies and procedures are updated and reflect best practice.
16. Liaise with academic and professional services colleagues to ensure that all research grantees are aware of the ethical requirements and that relevant approvals are in place prior to commencement of research activities.

Human Tissue

17. Work closely with the Licence Holder, Designated Individual and Persons Designated under the Human Tissue Act to ensure that statutory and regulatory requirements are met, supervising licensed activities and ensuring suitable practices are taking place.
18. Develop procedures to ensure compliance with HTA standards and that all samples are recorded in the LSHTM laboratory Organisational Research Information System.
19. Support and advise LSHTM researchers on the collection and storage of human tissue samples.

Research Integrity and Research Misconduct

20. Responsible for carrying out initial investigations into research misconduct, in accordance with LSHTM policy and procedures.
21. Maintain a database of all investigations into research misconduct, reporting cases to the Research Governance Committee, reviewing cases on an annual basis to identify any trends, and preparing the annual statement of research integrity and research misconduct as required by the Universities UK Concordat to Support Research Integrity.
22. Responsible for reporting misconduct cases to research funders (and other interested parties) to ensure compliance with funder's terms and conditions and contractual obligations.

Others

23. Working with colleagues across research support services to collect and maintain high quality data on all research activities, with specific responsibility for clinical trials and research involving human tissue.
24. Identify opportunities to improve systems and processes, overseeing the development, scoping and implementation of new systems and processes.
25. To undertake other duties as required by your line manager.
26. Manage your own continuing professional development, internal collaborations and external networks in order to contribute to service quality and research excellence.

Generic duties and responsibilities of all LSHTM employees

This job description reflects the present requirements of the post but may be altered at any time in the future as duties and responsibilities change and/or develop providing there is consultation with the post-holder.

The post-holder will carry out any other duties, tasks or responsibilities as reasonably requested by the line manager, Dean of Faculty, Head of Department or Head of Professional Service.

The post holder will be responsible and accountable for ensuring all LSHTM policies, procedures, regulations and employment legislative requirements are adhered to including equality and diversity and health and safety.

This job description is not a definitive or exhaustive list of responsibilities but identifies the key responsibilities and tasks of the post holder. The specific objectives of the post holder will be subject to review as part of the individual Performance and Development Review (PDR).

PERSON SPECIFICATION

This form lists the essential and desirable requirements needed by the post holder to be able to perform the job effectively.

Applicants will be shortlisted solely on the extent to which they meet these requirements.

Competency	Evidence	E / D
Education, Qualifications and Training	• A relevant undergraduate degree or equivalent substantial relevant experience	E
	• A relevant higher degree or equivalent experience	D
Experience	• Recent experience working in a senior research governance and integrity role	E
	• Experience of the following areas of research governance: clinical trial management; auditing and monitoring research; compliance with the Human Tissue Act; hosting regulatory inspections; and conducting investigations into research misconduct.	D
Knowledge	• Broad knowledge of research governance related legislation and policies	E
	• Knowledge of the governance of large, multi-centre trials, particularly those run in low and middle-income countries	D
General	• Experience of developing and maintaining positive and effective working relationships with a wide variety of stakeholders, including senior colleagues.	E
	• Excellent communication skills, including the ability to summarise and disseminate complex information.	E
	• Experience of developing written guidelines and training materials.	E
	• Excellent organisational and planning skills, including proven ability to organise and prioritise workload, work efficiently and meet deadlines.	E
	• The ability to work confidentially and professionally with sensitive information and in sensitive situations	E
	• Knowledge and behaviours that support equality, diversity and inclusive practice	E

E-Essential: Requirement without which the job could not be done

D-Desirable: Requirements that would enable the candidate to perform the job well

Date compiled: August 2024

Salary and Conditions of Appointment

The post is permanent and full-time 35 hours per week, 1.0 FTE. The salary will be on the Professional Services salary scale, Grade 8 scale in the range £62,928 - £72,092 per annum pro rata (inclusive of London Weighting).

The post will be subject to the LSHTM terms and conditions of service. Annual leave entitlement is 30 working days per year, pro rata for part time staff. In addition to this there are discretionary "Wellbeing Days." Membership of the Pension Scheme is available.

LSHTM has a Hybrid Working Framework, which alongside agreed service requirements, enables teams to work more flexibly (if the role allows), promoting a greater wellbeing and work/life balance.

Application Process

Applications should be made on-line via our [jobs website](#). Applications should also include the names and email contacts of 2 referees who can be contacted immediately if appointed. Online applications will be accepted by the automated system until 10pm of the closing date. We regret that late applications cannot be accepted. Any queries regarding the application process may be addressed to jobs@lshtm.ac.uk.

The supporting statement section should set out how your qualifications, experience and training meet each of the selection criteria. Please provide one or more paragraphs addressing each criterion. The supporting statement is an essential part of the selection process and thus a failure to provide this information will mean that the application will not be considered. An answer to any of the criteria such as "Please see attached CV", "Yes" or "No" will not be considered acceptable and will not be scored.

Please note that if you are shortlisted and are unable to attend on the interview date it may not be possible to offer you an alternative date.

Asylum and Immigration Statement

LSHTM will comply with current UKVI legislation, which requires all employees to provide documentary evidence of their legal right to work in this country prior to commencing employment. Candidates will be required to email a copy of their passport (and visa if applicable) to HR prior to their interview and if appointed will be asked to bring the original documents in to be copied and verified before their start date.

Applications from candidates who require sponsorship to work in the UK will be considered alongside other applications. Applicants who do not currently have the right to work in the UK will have to satisfy UK Visas & Immigration regulations before they can be appointed.

Further information about Sponsorship and eligibility to work in the UK, can be found on the [government immigration rules page](#).