ANNUAL RESEARCH INTEGRITY STATEMENT

This report covers activities from **1 April 2024 to 30 April 2025**

Section 1: Key Contact Information

Question	Response
1A. Name of organisation	London School of Hygiene & Tropical Medicine
1B. Type of organisation:	Higher Education Institution
1C. Date statement approved by governing body (DD/MM/YY)	11/06/2025
1D. Web address of organisation's research integrity page (if applicable)	https://www.lshtm.ac.uk/research/research-governance-integrity/research-integrity
1E. Named senior member of staff to oversee research integrity	Name: Professor Caroline Relton
	Email address: Caroline.Relton@lshtm.ac.uk
1F. Named member of staff who will act as a first point of contact for anyone wanting more information on matters of research integrity	Name: Dr Antony Walsh
	Email address: Antony.Walsh@lshtm.ac.uk

Section 2: Promoting high standards of research integrity and positive research culture

2A. Description of current systems and culture & 2B. Changes and developments during the period under review

The Research Governance and Integrity Office (RGIO) continues to develop training, refine policies, and undertake activities in research governance and integrity to mitigate risks, promote a positive research culture and prevent recurrence of issues related to research misconduct. These include:

Policies and systems

(1) RGIO database: RedCap backup (not fit for purpose), now WorkTribe system roll out for the finance/contracts team eventually leading to ethics & research governance

A RedCap copy of the RGIO Excel tracker was produced as an interim measure following the rejection of a business case to purchase the ReDa System , however, this system has not been well adopted as it does not allow dynamic changes to the data back-end.

Lack of a modernised, central database of active research projects at the school is still a critical risk to Quality Assurance, oversight and a variety of Sponsor responsibilities such as green lighting.

During 2024, the Interim Head of RGIO sought advice from other counterparts at peer universities who have transitioned to utilising systems such as cBrain F2 or WorkTribe. Following these discussions and the announcement of the removal of the Unit 4 Research Costing & Pricing module used to budget research funding applications, LSHTM has procured the Worktribe grant management system. Worktribe will provide end-to-end management of all grants at LSHTM including pre-award costings, contracting and post-award management, as well as ethical approval and due diligence. The system is being implemented over the next 14 months and when in place will provide RGIO will a complete oversight of all research projects replacing the current database. Until the post-award module is implemented in December 20205, the team will continue to operate oversight of all research using the RGIO Excel tracker.

(2) Good Research Practice policy revision[1]

The Good Research Practice (GRP) policy provides the essential criteria that all LSHTM staff and students are expected to follow in the conduct of their research. Following a high-level review of the GRP by the Equitable Partnerships Task and Finish Group that provided guidance on revisions on 24 January 2023, changes were made to the GRP towards version 6.0. This has also allowed the RGIO an opportunity to add a number of developments into the policy related to the following:

- The broadening of the language of the document and moving to an inclusive wording of in-country instead of overseas
- Clearer guidance on interacting with partners and funder expectations – via the EqiPar tool.
- Including guidance on use of and reporting on use of Artificial Intelligence in projects and publications in line with ICJME guidance.
- Gathering of multiple ethics approvals – in parallel
- Allowance of broader fast-track ethics submissions from key partners provided that a robust system of reliance agreements is in place.

[1] Good Research Practice policy

Since the initiation of the GRP online course and making this a mandatory course 1369 staff and students have enrolled, the denominator is unknown. This highlights the need for a robust training and certification regime. The Talent and Development Team (TD) are developing a Learning Management System (LMS) within LSHTM's new HR system to host and track completion of RGIO training courses and Standard Operating Procedure to help track compliance, the LMS is due to be launched in September 2025.

(3) Internal Human Tissue Audits

Since the last HTA audit in 2018 which resulted in thirteen minor and three major shortfalls, the person designate (PD) under the authority of the Designated Individual (DI) has conducted a campaign to capture every HTA relevant specimen into the LORIS system. There are presently 119 users of the system and approximately 530,000 specimens logged across 151 studies, including 85,620 HTA relevant specimens. A series of 56 audits has been performed since March 2024 and the findings have been shared to the relevant stakeholders. A process has been implemented where any human tissue found to be unlogged is quarantined for 1 month, during which owners are sought and samples must be recorded in LORIS. If samples are not claimed or logged within this period, they are destroyed with support from the DI and the PD. Progress has been reviewed and commended by the Research Governance Committee and the culture of logging specimens has been reinforced. Furthermore, expansion of the number of PDs at the school is also under consideration.

Communications and engagement

Training

The RGIO has a suite of online training modules that are open to all staff, students, as well as external collaborators[2]. The courses available are:

- Research Ethics
- Working with Human Tissue
- Good Clinical Practice
- Good Research Practice

The IHRG&I delivers training on the Ethical underpinnings of Clinical trials as well as the RD orientation sessions on Ethics and Approvals. The Ethics Facilitator also provides bespoke training to a variety of project and student groups. However, as above the Training oversight leaves much to be desired. There is a strong suggestion to make various training certificates required for project sponsorship.

Also, given the amount of Sponsor duty delegation we engage in when trials are sponsored a robust read-and-understand log or countersigned letter will be explored to ensure that the gravity of sponsorship is reflected.

The current Good Clinical Practice training is under review as the new ICH GCP R3 guidelines have now been approved and will be implemented as July 2025. All staff involved with Clinical Trials will need to complete training.

Due to the current RGIO capacity and the extensive changes required to the current online GCP training, we are considering what external providers of the training can offer. We could consider individual licences, but we now also can host such training on the new LSHTM Learning Management System.

[2] RGIO training

Culture, development, and leadership

Leadership

The RGIO reports into the Head of Strategic Research who is responsible all areas related to research governance and integrity, including acting as the DI under the HTA. The Interim Head of Research Governance & Integrity left LSHTM in August 2024. A new Head of Research Governance & Integrity has been appointed and will take up their post in June 2025.

Research Governance Committee

The Research Governance Committee[3] (RGC) has oversight of research governance and research integrity across LSHTM. The RGC meets termly and provides annual reports to Senate; the latest was submitted for the May 2025 RGC meeting.

LSHTM instructed KPMG to conduct an internal audit on research governance in August 2024. The findings were 'partial assurance with improvements required'. Actions such as updates to Terms of Reference documents, are to be completed by Autumn 2025.

London Research Integrity Consortium (LRIC)

The RGIO continue to be active within a group of London-based university Research Governance professionals. This group meets regularly with the Research Facilitator attending the last meeting held in January this year.

Conferences

The Research Facilitator (Clinical Trials) attended the MHRA Good Clinical Practice (GCP) Symposium that was held in February 2025, where the upcoming changes to the new Clinical Trials Regulations and Good Clinical Practice R3 guidelines and implementation plans for both were discussed.

The RF for clinical trials also attended the ICR conference in April 2025. This was a well-attended event with representatives from academic, NHS and commercial stakeholders with great speakers from the MHRA, HRA, Research Delivery Networks and a GCP & Regulatory Update.

Open Research

Library, Archive and Open Research Services (LAORS) has incorporated work developed through the Research Strategy Board Workstream on open research into its operational plan and BAU activities, ensuring that progress continues following the closure of the workstream. Current work includes liaising with HR/TD and other stakeholders to enhance recognition of open practices, with particular emphasis on recruitment, annual review, and promotion stages. This involves refinements to LSHTM guidance and templates to encourage recognition of open research activities, as well as enhancement to technical infrastructure to capture and surface a broader range of research outputs. Other priorities for the coming year are the launch of an Open Research Champions network across LSHTM, and exploration of an open research awards programme to showcase open research expertise across the LSHTM community.

LSHTM is now a full member of the UK Reproducibility Network (UKRN) and an Open Research Statement has been published. Links to relevant resources can be found at https://www.lshtm.ac.uk/research/open-research

Equitable Partnerships

Two Task and Finish Working Groups in Equitable Partnerships were constituted to investigate and advocate changes to current working practices; one T&F group reviewed ethics processes and the Good Research Practice policy from the Equitable Partnerships lens. This group have recommended changes to the Good Research

[3] Research Governance Committee

Practice policy which has been amended in due course including new resources for facilitation of equitable partnerships.

A review into levelling the ethics review landscape has moved forwards, including considering whether ethics review committees which meet criteria set out in the WHO REB benchmarking tool or other analogous agreed standard may be contacted and relied upon for the primary review of projects, while our REB will maintain fast-track oversight.

Monitoring and reporting

Research Audits

The Head of Research Governance & Integrity leads the Quality Assurance programme for research across LSHTM, which includes undertaking audits to assure LSHTM that research complies with all relevant legislation, standards of good practice, Standard Operating Procedures, and all applicable policies.

These require the Chief Investigator/Principal Investigator to respond outlining their Corrective and Preventive Action (CAPA) plan which is reviewed by the (former) HRG&I.

In the period 30 April 2024 - 1 April 2025

- CRASH 4 Trial (Clinical Randomisation of Antifibrinolytic in Symptomatic mild Head injury in older adults)

An audit was undertaken which resulted in 0 critical findings, 1 major finding and 1 minor finding.

This CRASH 4 trial is being conducted by the LSHTM Clinical Trials Unit. A CAPA was received in response to the findings. No further action required.

- APRIL Trial (Ayurveda for Promoting Recovery In Long Covid)

An audit was undertaken which resulted in 0 critical findings, 2 major findings and 2 minor findings.

The APRIL trial had some difficulties starting and remained quite far behind recruitment targets as initially envisioned by the trial at the time of the audit. Plans had been devised to account for this and address it but given the low recruitment success and proportionally high number of withdrawals (9, 15% of all recruited) and deviations in the application of the protocol, together this was a concern from a Sponsor point of view.

Due to these concerns, a panel of LSHTM academic trial experts were convened to advise the Sponsor on the future of this trial. The feasibility of the trial was a concern. Recommendations for recruitment with stop-go criteria was agreed and regular review of this planned.

After discussion with the funder and TSC, it was decided by the PI to wrap up the trial and analyse and publish the data thus far.

2C. Reflections on progress and plans for future developments

The new online training in Good Research Practice/ Responsible Conduct of Research will be part of the mandatory training for all staff at LSHTM. Following the pilot of the course, and any further refinements, work will be undertaken to monitor the uptake and effectiveness of the course.

Resourcing of the RGIO remains an ongoing issue, with formal requests made to Senior Management in recent years to provide for a Quality Manager post to improve oversight of research. This was noted in the Clinical

Trials Review in 2021, commissioned as part of the LSHTM strategy to strengthen delivery of clinical trials. Costing for this position was strongly advised in 2021 but due to financial constraints has not been approved. With the imminent implementation of GCP Revision 3 the stringent nature of the quality assurance expectations within Sponsor oversight will become even more pronounced. The new Head of Research Governance & Integrity will work with the Head of Strategic Research to develop a business case for a Quality Manager post and develop a process for recouping the salary cost on clinical trial grants to make this cost neutral for LSHTM. This post would centralise QA resources, knowledge, advice, harmonise approaches to CAPAs, establish living memory of QA.

Training and Effectiveness, this is a function of governance and integrity as we have the responsibility to ensure that our staff are qualified by both experience and education. The launch of a new Learning Management System in September 2025 will all tracking of adherence to mandatory training and awareness of the SOPs, Good Research Practice Policy, HTA and other core documents.

Audit capability and sustainability, the RGIO includes the audit function for all projects. This has been prioritised based on risk. LSHTM has highly capable QA and monitoring staff based in the MRC Units. Areas to be added to the routine information about projects is a Public and Patient Inclusion statement in the registration of the research project.

Section 3: Addressing research misconduct

3A. Statement on processes that the organisation has in place for dealing with allegations of misconduct

The amended procedure for investigating allegations of research misconduct (v3.0) was utilized a number of times in the past year. Following feedback from investigations it has been agreed that the procedure should undergo a review to streamline the process and ensure transparency for all involved. This will further ensure that LSHTM addresses allegations of misconduct intelligently, prudently using limited resources while remaining transparent, timely, robust, and fair.

The Good Research Practice policy provides the essential criteria that all LSHTM staff and students are expected to follow in the conduct of their research. As noted above, this policy undergoing a major revision.

All changes to policies and procedures are planned to be circulated to the LSHTM community through the regular RGIO newsletter. This includes notification of amendments to the Standard Operating Procedures which cover all aspects of conducting research.

The Head of Research Governance & Integrity is the point of contact for all informal discussions on research integrity and allegations of research misconduct. They are responsible for providing regular reports to RGC as a way of monitoring the research culture and environment at LSHTM. In addition, the Report + Support tool[4] is available for the submission of allegations of research misconduct as well as for bullying and harassment.

[4] Report + Support tool

3B. Information on investigations of research misconduct that have been undertaken				
Type of allegation	Number of allegations 1 April 2024 to 31 March 2025			
	Number of allegations reported to the organisation	Number of formal investigations	Number upheld in part after formal investigation	Number upheld in full after formal investigation
Fabrication	0	0	0	0
Falsification	0	0	0	0
Plagiarism	0	0	0	0
Failure to meet legal, ethical and professional obligations	2	1	1	1 *1 pending
*Subset Failure to obtain appropriate permissions (Ethics and/or MTAs)	1	1	1	1
Misrepresentation (eg data; involvement; interests; qualification; and/or publication history)	1	0	0	*1 pending
Improper dealing with allegations of misconduct	0	0	0	0
Multiple areas of concern (when received in a single allegation)	0	0	0	0
*Other**	0	0	0	0
Total:	3	1	1	1
*If you listed any allegations under the 'Other' category, please give a brief, high-level summary of their type here. Do not give any identifying or confidential information when responding.				
None				

Concluding Statement

LSHTM is dedicated to upholding the highest standards of research excellence and integrity, and is committed to delivering high quality, relevant research, underpinned by the highest ethical standards across the globe. LSHTM fully supports the Concordat for Research Integrity and maintains the Research Governance and Integrity Office (RGIO) dedicated to research governance, ethics and integrity to assure compliance with the Concordat, as well as regulations, guidance, and standards of good practice governing research around the world.

This report provides an annual summary of actions and activities undertaken to support research integrity at LSHTM and provides the required details for the annual report required by the Concordat to Support Research Integrity (Commitment 5).

Dr Hannah Whiteman

Head of Strategic Research (acting Head of Research Governance and Integrity)

16 May 2025