RESEARCH INTEGRITY

This report covers activities from **1 April 2023 to 30 April 2024**

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)	13/06/2024
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: 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: Nicholas Connor
	Email address: RGIO@lshtm.ac.uk

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

2A. Description of current systems and culture

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

Policies and systems

(1) ReDa System Infonetica (Cancelled), RedCap backup

After some time spent with the RGIO and the Project Management office a business case was compiled identifying the Infonetica System ReDA as the forerunner for purchase to modernise our research management. The Head of RGIO and the Research Ethics Facilitator as well as Strategic research had negotiated to begin moving our current Excel table which is used to track research projects and clinical trials to a modern system. This system, despite not foreseen to contain vulnerable data would provide multi-factor authentication and enact a Single-sign on (SS0) after 6-months. However, upon final contracting this project was cancelled after consultation with IT in December 2023 due to concerns about the SSO. In parallel a RedCap copy of the RGIO excel tracker was produced, while free of cost 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 a critical risk to Quality Assurance, oversight and a variety of Sponsor responsibilities such as green lighting.

The head of RGIO has sought advice from other counterparts at peer universities who have transitioned to modern systems such as cBrain F2 or WorkTribe however, this will necessitate high-level buy in and resourcing. Until then we continue to operate oversight of all research using an ever-increasing Excel table on sharepoint.

(2) Good Research Practice policy revision[1]

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. Following a high-level review of the GRP from the perspective of Equitable Partnerships (task and finish group) who provided guidance on revisions on 24 January 2023, changes have been made to the GRP towards version 6.0. This has also given 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.
- Clearing up 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

[1] Good Research Practice policy

- Allowance of broader fast-track ethics submissions from key partners provided that a robust system of reliance agreements are in place.

Difficulties remain, even since the initiation of the GRP online course and making this a mandatory course only 116 staff and students have completed it, the denominator is unknown. This highlights the **need for a robust training and certification regime, possibly led by Training Operations and/or HR.**

(3) Internal Human Tissue Audits

Since the last HTA audit which resulted in critical findings the person designate (PD) under the authority of the IHRG&I (the DI) has conducted a campaign to capture every HTA relevant specimen into the LORIS system. There are presently 99 users of the system and approximately 370,000 specimens logged across 125 studies, including 78,202 HTA relevant specimens. A series of 30 audits has been performed and the findings have been shared to the relevant stakeholders. If human tissue if found unlogged it has been quarantined for 1 month, during which owners are sought and if not located or specimens are left behind in error, they are destroyed with support from the DI and the DO. This is considered very good progress by the DI and the culture of logging specimens has been reinforced. Furthermore, a human tissue user group has been formed to discuss matters around human tissue, to maintain and improve our stewardship. Expansion of the number of PDs at the school is also under consideration.

Communications and engagement

Training

The RGIO has re-developed 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.

[2] RGIO training

Culture, development, and leadership

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 May 2024 meeting.

RQA Good Clinical Practice Committee

The IHRG&I is a member of the RQA Good Clinical Practice Committee contributing regularly and has participated as a chair of a session on GCP and AI and GCP Q&A panel in Belfast in November 2023. This has continually benefitted the IHRG&I and raised the profile of our school in those conferences. He also is a panellist for a diversity in STEM session upcoming at the next conference in Brighton in 2024.

London Research Integrity Consortium (LRIC)

The IHRG&I is an active participant in the revival of a group of London-based university Research Governance professionals. This group used to meet regularly prior to the COVID-19 pandemic and he has been a proponent of this group continuing. He has offered LSHTM to host the next LRIC group meeting in September 2024.

Conferences

As above the HRG&I attended the RQA Quality Assurance conference in Belfast in late 2023 and has been active in developing the programme for the next RQA conference in Brighton in 2024.

The Research Facilitator (Human Tissue) attended the OpenSpecimen Community Meet Conference in Amsterdam in May 2024 with peers using the OpenSpecimen platform (LORIS), this provided insight about the potential for this system and possibilities for its future use at the school.

Open Science

The Library, Archives and Open Research Services have developed an Open Science Report, detailing activities undertaken by the Open Science Working Group. Further work, including the Open Research Statement to be circulated to the LSHTM community in due course. The current HRG&I has also added Biological Specimens to the Open research workstream and explored the addition of biological specimens to the discussion of open science.

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

An ongoing discussion about how to go about levelling the ethics review landscape has moved forwards, a method to allow Ethics review commitees which meet criteria set out in the WHO REB benchmarking tool or other analogous agreed standard may be contacted and relied upon for the

[3] Research Governance Committee

primary review of projects, while our REB will maintain fast-track oversight. This will initially be rolled out to the most frequent partner REBs.

Also, our MRC-Gambia unit Ethics review will be harmonised by allowing one of our Ethics Co-chairs to be involved with the review process prior to finalisation of approval of projects, thus eliminating the need for the formal fast-tracking step of our projects there – as there will be one favourable opinion issued containing any questions/comments from the London-based board and the Gambia based board. The Gambia Unit will then confirm these comments have been addressed and the letter will be sent from LEO directly. These pathways are still in draft-form but are in the early stages of being deployed this upcoming year.

Monitoring and reporting

Research Audits

The (former) HRG&I 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.

In the period 1 April 2024 – 30 April 2023, **1** audit was undertaken which resulted in **0** critical findings, **2** major findings and **5** minor finding; 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. A summary of the upcoming audit programme is reviewed annually by the RGC.

2B. Changes and developments during the period under review

The Good Research Practice/Responsible Conduct of Research online training was completed and released following a pilot to ensure that the content is appropriate for the research community. It was decided to make this a mandatory training for all staff and students conducting research.

The ongoing modification to the GRP, developments with research misconduct cases and other developments will necessitate some changes and expansion of this course. Training and Professional development has been contacted to review the training effectiveness.

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 a major ongoing issue, with formal requests made to Senior Management in 2022, 2023 and 2024 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 Grade 7 position was strongly

advised in 2021 and despite being included in every funding round, this post has been passed over. With the advent of GCP Revision 3 the stringent nature of the Quality Assurance expectations within Sponsor oversight will become even more pronounced. Ideally a QA Manager post should be implemented without delay and funded in whole or in part by clinical trials at the school. This post would centralise QA resources, knowledge, advice, harmonise approaches to CAPAs, establish living memory of QA and permit the Head of RGIO to more fully commit to management, leadership and devotion to Integrity and Governance of research. QA would be fundamental to establishing public faith in our Clinical Operations, Pharmacy, Laboratory and Data sectors related to research.

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. There have been too many cases where our staff have plausibly denied being aware of contents of SOPs the Good Research Practice Policy, HTA and other core documents. This should be addressed urgently.

Audit capability and sustainability, the role of the head of RGIO includes the audit function for all projects globally. This has been prioritised based on risk. However, we have capable QA and monitoring staff based in the MRC Units who should be made available to perform Sponsor GCP/GCLP audits of trials not directly under their units. In the 2024-25 audit plan the HRG&I has planned a pilot cross-over audit to demonstrate this possibility. Also, use of external Contract Research Organisations should be considered in Africa and Asia for this purpose – to perform audits on the Sponsor's behalf in the templates we require. Also, this will likely reduce our carbon footprint.

Areas to be added to the routine information about projects is a Public and Patient Inclusion statement in the registration of the research project.

Supplementation of the IT capability (or access to IT assistance in the creation of a useful database) in the RGIO would be welcome as related to the development, onboarding and usage of IT technology – primarily development of a future RGIO Database.

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. However, some issues have been found during the careful application of this procedure over the past year, in the mandatory interview of the complainant, the pre-sharing of findings with complainants to crosscheck facts, etc. This procedure should undergo

further modernisation with the ease of accusation possible by external persons, groups and internet-based activists. To ensure that LSHTM deals with 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 above this policy also is under another major revision subsequent to the last revision in December 2021.

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 Interim HRG&I is the point of contact for all informal discussions on research integrity and allegations of research misconduct. He summarises these discussions in 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. Anonymous allegations are allowed via this tool, however, none have come in to the current HRG&I this year.

3B. Information on investigations of research misconduct that have been undertaken

Type of allegation	**Number of allegations 1 April 2022 to 31 March 2023.**			
	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			
Falsification	0			
Plagiarism	0			
Failure to meet legal, ethical and professional obligations	*8*	*6*	0	*4*
*__Subset__ Failure to obtain appropriate permissions (Ethics and/or MTAs)	*4*	*4*	0	*4** All Pending close.*
Misrepresentation (eg data; involvement; interests; qualification;	*2*	*1*	*0*	*0*

[4] Report + Support tool

and/or publication history)				
Improper dealing with allegations of misconduct	*1 (appeal)*	*1*	*1*	*0*
Multiple areas of concern (when received in a single allegation)	*(all)*			
*Other**	*1*	*0*	*0*	*0*
Total:	**12**	**8**	**1**	**8**
***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.**				
Authorship of a WASH paper – joint first authorship rescinded. No further contact.				

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.

LSHTM continues to support and embed a research environment underpinned by a culture of integrity. The interim Head of RG&I, both through her role as head of the department, is in tune with the issues that arise in the global arena and is an active participant in conferences and meetings focussing on research integrity. Staff and students are reminded when releasing new procedures and policies, that he can be approached both formally and informally to discuss integrity issues. This will be further enhanced with the proposed development of research integrity champions across the faculties and units. However, a comprehensive research database, training tracking, verified signature capability and a dedicated quality assurance staff member (funded in whole or in part by costing-back to clinical trials) would greatly enhance the department's ability to carry out its duties.

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).

The Audit and Risk Committee are asked to note that this report will be made publicly available.

Nicholas Connor
Interim Head of Research Governance and Integrity
13 May 2024