RESEARCH INTEGRITY

2020 –2021

1. Preamble

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[1] 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 from the Concordat to Support Research Integrity (Commitment 5).

This report covers activities from 1 April 2020 to 31 March 2021.

2. Executive Summary

The RGIO continues to develop training, refine policies and undertake activities in Research Integrity to mitigate risks and prevent recurrence of issues related to research misconduct. A summary of actions and activities include:

- **Organisation and Policy Analysis**. This was focussed on Good Research Practice and was completed as part of the Head of Research Governance and Integrity (Head of RG&I)'s DrPH. Recommendations were presented to the Research Governance Committee in October 2020.
- **Training.** The RGIO continues to deliver training on Ethics, Good Research Practice, Working with Human Tissue and Good Clinical Practice[2]. A full online version of the Good Research Practice course is in development but unfortunately has been delayed due to staff shortage and other priorities that have arisen due to the Covid-19 pandemic.

[1] Universities UK (2019) Concordat to Support Research Integrity

[2] RGIO online training

- **Virtue ethics approach to research integrity.** Following attendance at a 'train the trainer' programme offered by the VIR2TUE Horizon 2020 project in virtue ethics[3], a half-day session ran on 24 May 2021 with 14 delegates made up of both RD students and staff. Feedback has been positive and further courses are planned.
- **Trials transparency audit.** This audit was undertaken to determine whether all LSHTM-sponsored clinical trials are registered on a public registry and where results are available, that these have been added to the registry. It is considered best practice to submit results on the publicly accessible registers for all trials, but is a legal requirement for UK and EU clinical trials of investigational medicinal products. Initial results were presented to the Research Governance Committee in May 2021. These demonstrated that 64% of LSHTM-sponsored trials have posted their trial onto a publicly accessible registry, and that 18% of completed clinical trials have posted their results in the registry, but 78% have published their results via the more traditional route of manuscript/publication. LSHTM is 100% compliant with the EU Clinical Trials Register[4]. Further work is underway to investigate this further.
- **Concordat to Support the Career Development of Researchers[5].** The Head of RG&I is a member of the Concordat Monitoring Group to oversee progress of the action plan ensuring compliance with the Concordat to Support the Career Development of Researchers, of which LSHTM is a signatory. As part of this, LSHTM ran the Culture, Employment and Development in Academic Research Survey (CEDARS) which included questions on research integrity. Results are due Summer 2021. The Research Staff Forum has developed a Research Culture Sub-Group which is looking at research integrity and the research environment, with activities planned for Autumn 2021.

3. Research Governance Committee

The Research Governance Committee[6] (RGC) has oversight of research governance and research integrity across LSHTM. The RGC meets termly: (13 October 2020, 24 February 2021 and 26 May 2021) and provides annual reports to Senate; the latest was submitted for the 9 June 2021 meeting.

4. Policies and Procedures

4.1 Procedure for inquiring into allegations of research misconduct[7]

The procedure (v2.3; 30/09/2020) was reviewed and approved by the RGC following minor amendments. This procedure is kept under review to ensure that it meets the needs of the organisation, and to ensure that how LSHTM deals with allegations of misconduct are transparent, timely, robust and fair. A fuller review will take place when the UK Research Integrity Office (UKRIO) publish their revised guidance.

[3] Virtue Ethics from the Embassy of Good Science
[4] EU Clinical Trials Register
[5] Concordat to Support the Career Development of Researchers
[6] https://www.lshtm.ac.uk/aboutus/organisation/governance/committees
[7] Procedure for inquiring into allegations of research misconduct

4.2 Good Research Practice policy[8]

Version 4.2 of the policy (27/01/2020) provides the essential criteria that all LSHTM staff and students are expected to follow in the conduct of their research. A gap analysis of the policy was undertaken against Russell Group universities, funders and regulators to benchmark the LSHTM policy and highlight any areas for improvement. The gap analysis demonstrates that LSHTM fulfils many of the commitments, but improvements can be made. Additions will be made to the policy in Summer 2021.

A summary of policies related to research governance and integrity is listed in Appendix 1.

5. Allegations of Breaches of Research Integrity/ Research Misconduct

In the period 1 April 2020 – 31 March 2021, seven complaints were made to the RGIO. Six investigations were completed, three were confirmed as breaches of research integrity and one has been referred to a formal investigation panel. Breaches of ethics approval account for more than half of the complaints, and the RGIO are looking into prevention measures more generally in this area.

The complaints can be summarised as:

Category of Breach of Research Integrity	Number of complaints
Falsification	1
Breach of ethics approval	4
Breach of duty of care / harm on study	2
TOTAL	7

The following were confirmed as breaches of research integrity:

References	Topic Area	Specifics of Complaint	Outcome	Prevention
RM-2020-048	Breach of ethics approval	Staff removed and used human tissue (whole blood) for research purposes without written consent and without ethics approval	Investigation upheld the complaint. Lack of knowledge on what constitutes human material vs relevant material according to the Human Tissue Act contributing factor	Human Tissue training to be mandatory for all laboratory staff. HTA policy to be amended and circulated to all staff in faculty.
RM-2020-044U	Breach of ethics approval	Failed to obtain the necessary LSHTM ethics approval although did receive local approval	No further action as necessary approvals in-country received.	Reminders sent to team that all approvals must be in place before starting research.
RM-2021-049G	Falsification and breach of duty of care	Staff members were alleged to have taken payment for Covid-19 tests by registering them onto a research project: 185/770 participants are suspected to be ineligible and paid for the tests which should have been free.	Referred to the formal investigation panel	To be determined by investigation panel

[8] Good Research Practice policy

One complaint was determined to have a 'not determined' outcome:

References	Topic Area	Specifics of Complaint	Outcome	Prevention
RM-2020-046	Breach of ethics approval	Failed to submit amendment when changing MSc project from secondary data analysis to a primary data analysis involving accessing NHS medical records without consent.	Amendment to be submitted. Determined that there is a lack of consistency on how taught MSc programme cases are handled as not all cases are referred to the RGIO.	Further discussions with the taught course directors and other senior staff on how best to align the processes.

One complaint was determined to not be a breach, however, due to the nature of the issue, further details are provided here for the Audit and Risk Committee's information:

References	Topic Area	Specifics of Complaint	Outcome	Prevention
RM-2021-050	Breach of duty of care / harm on study	Participant died on a clinical trial. Whilst there is no link with the trial, nor with the Investigational Medicinal Product, the family decided to pursue a civil case of non-assistance to a person in danger. This led to the prosecutor pursuing a criminal case.	Consortium partners agreed to compensate family even though there was no suggestion or evidence of wrongdoing. Local feedback stated that it was extremely unlikely that the trial team could win the court case.	It is difficult to prevent this happening in the future as there is no link from the death to the trial or to the trial team actions. Further review of insurance policies will be undertaken.

In last year's Audit and Risk Committee report (2019-2020), there were 2 investigations listed as ongoing at the time the report was issued; both have now been completed and the complaints are upheld (one in part):

References	Topic Area	Specifics of Complaint	Outcome	Prevention
RM-2020-041G	Breach of duty of care / harm on study	Several complaints regarding breach of care on a research project.	Most of the complaints not upheld. One upheld complaint centred on registering with the in-country medical council.	Amendment of processes to ensure that all study doctors have appropriate registration before starting research.
RM-2020-042	Breach of ethics approval	Failed to obtain full ethics approval from LSHTM ethics committee. Ethics approval received in country. Human tissue samples sent to LSHTM without ethics, or MTAs in place, jeopardising the LSHTM research licence with the HTA.	Complaint upheld. Full investigation report sent to PI.	Report contains recommendations for PI and LSHTM to improve practice, including amending steps prior to starting research in the labs to remind lab staff of the HTA requirements.

6. Concluding Statement

LSHTM continues to support and embed a research environment underpinned by a culture of integrity. The Head of RG&I, both through her role as an RD student and 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 that she 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. Alongside the Research Staff Forum, activities to enhance a positive research culture are planned over the next year.

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

Patricia Henley
Head of Research Governance and Integrity
03 June 2021

Appendix 1: Summary of Research Governance and Integrity policies and procedures

RGIO Policies

- Good Research Practice Policy, v4.2; 27 January 2020
- Human Tissue Act policy, v5.2; 10 April 2019
- Procedures for Inquiring into Allegations of Scientific Misconduct, v2.3; 30 September 2020
- Ethics Committee Terms of Reference, v2.2; 25 March 2019
- Statement on contact with the tobacco industry, from Prof Peter Piot, February 2018

Other relevant LSHTM policies

- Animal research policy
- Anti-bribery conduct policy and procedures
- Anti-bullying and harassment policy
- Conflicts of interest
- Data protection policy
- Dissemination of health and safety information
- Freedom of Information
- Information management and security policy
- Intellectual property policy
- Open-access publishing policy
- Records management policy
- Research data management Policy
- Whistleblowing

Under review:

- Engaging with External Partners guide

On the RGIO intranet page:

- Standard Operating Procedures and templates on research oversight, regulatory applications and approvals, design, management, conduct, and completion of research