

RESEARCH GOVERNANCE AND SCIENTIFIC MISCONDUCT

Note by Quality & Governance Manager

This paper reports an annual summary of issues concerning research governance and scientific misconduct at the School. The Audit and Risk Committee is asked to note the report covering activities from *1 May 2016 to 30 April 2017*.

Research Councils UK (RCUK) require organisations in receipt of funding to annually report to respective Audit Committees (or other appropriate fora) on matters concerning research governance and scientific misconduct including confirming the existence of appropriate policies and procedures, their review (if relevant) and any issues which have arisen (in particular concerning scientific misconduct). This report is in accordance with RCUK reporting requirements, and in compliance with the Research Integrity Concordat's commitment to produce an annual public statement outlining the activities undertaken by the School to strengthen integrity of research.

1. Research Governance Committee (RGC)

The Research Governance Committee (RGC) has met three times: 28 June 2016, 8 November 2016 and 7 March 2017. They will continue to meet termly with the next meeting to take place on 25 May 2017. The Research Governance Committee reports to Senate; the most recent report was submitted for the 6 December 2016 meeting.

2. Policies and Procedures

The RGC have amended and reviewed the following policies/guidelines:

Good Research Practice policy

- Senate approved policy on 7 June 2016
- The policy was circulated to all staff and is on the Research Governance and Integrity Office (RGIO) webpage

Investigating allegations of misconduct

- Significant changes were required to update the procedure to comply with standardised practices
- Approved by the RGC in November 2016 and approved by Senate on 6 December 2016
- On the RGIO webpage

Confidentiality and Anonymisation of Research Data

- It was noted that there is an increasing number of funders and journals who now require that data be put in the public domain following publication. This document provides LSHTM guidelines and procedures for how to handle and share data.
- Reviewed and approved by the RGC on 7 March 2017
- On the RGIO procedures page on the intranet

3. Fraud & Misconduct

Two protocol violations were submitted to the ethics committee (ref 6326) for fraud discovered in two countries on the study. LSHTM is not the legal sponsor for the trial, thus the RGC and RGIO were not involved in the investigation nor management of the incidents. The PI was invited to attend the RGC

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meeting held 8 November 2016 to provide further details regarding these incidents and share their experiences of the incidents encountered during their study to date and how they were managed.

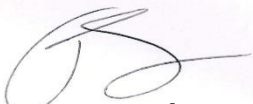
In both sites, site staff hired to undertake specific functions in the community fabricated data. It was confirmed that thorough data verification was conducted and any data that could not be verified will not be included in the analysis of the trial.

Following the investigation, corrective and preventive actions were implemented by the local study teams. Further investigations by an independent team were carried out on behalf of the Research Integrity Officer (RIO) appointed by the university in one of the countries. The RIO provided a set of recommendations, which have been accepted by the study team.

One of the possible reasons why the community staff fabricated data is due to incentives provided to encourage staff to complete work in a timely fashion. These are not necessarily financial, but through recruitment targets, with the incentive being continuing employment if targets are reached. The PIs believe that it was this strong incentive that led to the falsification of data.

The RGC were reassured by the discussion with the PIs. The LSHTM sponsor Standard Operating Procedures (SOPs) cover the issues discussed, including for central monitoring which details how to review data between and within sites to check for data inliers and outliers, which could help in identifying fraudulent data.

The Audit and Risk Committee is asked to NOTE the foregoing report.



Patricia Henley

3 May 2017