Audit Committee Agenda 3 June 2014

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 Committee is asked to note the report covering activities from 1 June 2013 – 23 May 2014.

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.

1. Research Governance

Research governance is defined as the broad range of regulations, principles and standards of good practice that exist to achieve, and continuously improve, research quality across all aspects of healthcare in the UK and worldwide.

1.1 Research Governance Committee

It was agreed by the Senior Leadership Team in May 2014 to establish a Research Governance Committee to oversee the work of research governance, including the clinical trials sub-committee, research data management and information security and coordinate future developments across the School.

Draft terms of reference and the proposed constitution of the new committee are attached as Appendix 1, to be reviewed at Senate on 2 June 2014. The draft is based on a review of terms of reference for research, governance and ethics committees in a sample of other research-intensive universities. They also reflect the wording of the Code of Practice on university governance published by the Committee of University Chairs (CUC).

The CUC Code is currently being updated and a revised version will be published over the next few months. Although the Code is voluntary, our Financial Memorandum with HEFCE stipulates that we have to include a declaration in our financial statements either that we fully comply with the Code or an explanation of how and why we do not. The revised Code is likely to state that[1]:

- "The governing body must protect institutional reputation by ensuring clear ethical standards, policies and procedures are in place"
- "In supporting academic freedom, the governing body should ensure the highest standards of ethics in the conduct of academic affairs. Some aspects of research governance raise particular sensitivities (eg animal experimentation) and well established codes of practice exist where compliance is required"
- "The governing body should approve and review the implementation of a policy on ethics and reputational risk which should apply throughout the institution"
- "As part of its overall responsibility for risk management, the governing body should ensure risk management includes academic risks such as those involving partnerships and collaboration, recruitment and retention, data provision, quality assurance, and research integrity. It should have oversight of all major academic partnerships involving significant risk".

[1] This wording is taken from the final draft Code issued for consultation in February 2014

It is proposed that the Ethics Committee should continue to report directly to Council. This reflects the spirit of the CUC Code, but also provides an additional layer of external scrutiny and challenge for ethical judgements regarding our research; which seems appropriate, rather than having the Ethics Committee reporting to a staff-only body.

1.2 Policies and Standard Operating Procedures (SOPs)

The Research Governance Committee will be asked to prioritise from the following list of policies:

a. procedures for investigating allegations of scientific misconduct (concerning staff and for students)
b. update Good Research Practice guidelines
c. update all Standard Operating Procedures. SOPs are in the process of being amalgamated with the LSHTM CTU SOPs to create an overarching set of procedures for all research types.
d. revising policy for handling potentially controversial results
e. revising policy on contact with the tobacco industry
f. update policy on use of audio and video in research
g. developing guidance on conflicts of interest
h. developing guidance on peer review
i. developing guidance on research with children
j. developing guidance on informed consent
k. developing guidance on clinical trials in India
l. developing guidance on risk assessments in research
m. developing guidance on publishing research to include open-access journals
n. developing guidance on use of social media in research

2. Clinical Trials Sub-Committee

The clinical trials sub-committee is responsible for activities governing sponsorship of trials at LSHTM. The sub-committee reviewed 35 trials for LSHTM sponsorship in the above-stated timeframe, and agreed sponsorship for 31 trials. One trial did not meet regulatory requirements and sponsorship was refused until requested amendments are actioned. Three trials are awaiting further documentation to be provided by the Chief Investigator.

The trials can be broken down into the following types of study:

Clinical Trial of an Investigational Medicinal Product (IMP) (eg drug)	5
Clinical Trial of a non-IMP (vitamins etc)	2
Clinical Trial of a public health intervention (eg health management, training)	19
Clinical Trial - other	9

Number of trials by Faculty and Department:

EPH	
DPH: Dept of Population Health	10
IDE: Infectious Disease Epidemiology	2
NCDE: Non-Communicable Disease Epidemiology	1
ITD	
CR: Clinical Research	3
DC: Disease Control	19

In total, the School is the sponsor of **88** active studies. Please see Appendix 2 for details.

2.1 Inspection by the Medicines and Healthcare products Regulatory Agency (MHRA)

A routine, regulatory inspection by the MHRA was conducted on 19-21 March 2013, with full report submitted to LSHTM on 17 July 2013. The MHRA closed the inspection on 5 December 2013 following the LSHTM response (available if required).

2.2 Quality Assurance

Trials are selected through for an audit via two channels: as a result of the risk assessment conducted during the sponsorship assessment, or due to a site-reported incident. A total of 9 audits were undertaken, covering 3 clinical trials.

3. Research Ethics

There are three ethics committees at LSHTM: Interventions, Observational and MSc. From October 2013, applications to the ethics committee have been submitted via an online system: http://leo.lshtm.ac.uk. The system allows the committee to edit the application form, FAQs and the help section without the use of an intermediary. The system assures compliance with key international ethical and research guidelines, for example the Declaration of Helsinki and ICH GCP, through a "smart" form which enables only relevant questions for a study type and ensures that all documents are uploaded prior to submission. The system also tracks applications and approvals and prompts the user to submit annual reports.

Committee	Number of applications
MSc *	368
Interventions	62
Observational	147

**Numbers from 2012-2013 academic year as submissions are ongoing for the 2013-2014 academic year.*

5. Fraud & Misconduct

There have been no formal allegations or proven incidents of scientific misconduct at the School during the last year.

The Audit Committee is asked to NOTE the foregoing report.

Patricia Henley
27 May 2014

Appendix 1: Research Governance Committee

CONSTITUTION

Vice Director (Chair)	x1
Chair of Ethics Committee	x1
Chair of Clinical Trials Committee	x1
Three senior members of academic staff appointed from Senate	x3
Secretary & Director of Resources & Planning	x1
Quality and Governance Manager	x1
Head of Library & Archives Service	x1
Head of IT Security, IT Audit and Compliance	x1
Research Operations Manager	x1
Head of Legal Services	x1

TERMS OF REFERENCE

To have oversight of research governance matters across the School.

To oversee the work of School bodies with particular responsibility for research governance matters, including the Ethics and Clinical Trials Committees, Research Data Management, and the Information Security Working Group.

To consider any appeals relating to decisions by the Ethics or Clinical Trials Committees.

To monitor, review and where necessary update policies and procedures relating to research governance, to ensure that the School continues to comply with relevant regulatory requirements, the Concordat for Research Integrity and best practice.

To promote best practice and encourage consistency in matters of research governance across the School.

To monitor compliance with School policies and procedures relating to research governance and external regulatory requirements.

To manage allegations of research misconduct and provide guidance on questions of research integrity.

To manage research governance audits or inspections of the School by external bodies, including the Medicine and Healthcare Products Regulatory Authority and the Human Tissue Authority.

Appendix 2: LSHTM sponsored-trials

Overall, LSHTM is sponsor for 88 active trials (in set-up, in recruitment, in follow-up):

Clinical Trial of an Investigational Medicinal Product	30
Clinical Trial of a Public Health Intervention (eg health management, training)	33
Clinical Trial of surgery	1
Other Clinical Trial	13
CT - non-IMP (vitamins etc)	7
Clinical Trial of a device	4

Total numbers by Faculty and Department:

EPH	**30**
DPH: Dept of Population Health	16
IDE: Infectious Disease Epidemiology	8
NCDE: Non-Communicable Disease Epidemiology	6
ITD	**54**
CR: Clinical Research	18
DC: Disease Control	34
II: Immunology & Infection	2
PHP	**4**
GHD: Global Health and Development	4