Audit Committee Agenda 24 June 2015

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 May 2014 to 30 April 2015.*

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. The concordat sets out five commitments (Appendix 1) that will provide assurances to government, the wider public and the international community that research in the UK continues to be underpinned by the highest standards of rigour and integrity.

1. Research Governance Committee (RGC)

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.

The newly convened Research Governance Committee met on 21 May 2015 for the first meeting. The Constitution and Terms of Reference were discussed and agreed. The RGC will meet once per term.

A report to Council was made on 9 June 2015 (Appendix 2).

2. Policies and Procedures

The Research Governance Committee has prioritised the following policies to be reviewed at the October 2015 meeting:

a. Policy and procedures for investigating allegations of scientific misconduct (concerning staff and for students)

b. Good Research Practice policy

c. Policy on working with the public sector, including statement on tobacco industry

In addition, the RGC has delegated the production and authorisation of Standard Operating Procedures (SOPs) to the Research Governance and Integrity Office, with the Quality and Governance Manager responsible for signing them. SOP production will continue, with an aim to completing the suite of SOPs by September 2015.

All policies and procedures will be written in compliance with the Research Integrity Concordat, ie to ensure highest standards of best practice; systems to promote research integrity; and transparent, robust and fair processes to investigate alleged research misconduct. These will be shared with staff and made available on the LSHTM web page which is currently being reviewed and improved.

3. Clinical Trials Sub-Committee

Council agreed on 9 June 2015 to dissolve the clinical trials sub-committee, recognising that the Terms of Reference for this committee were included within those for the Research Governance Committee.

4. 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

16 June 2015

Appendix 1: Five Commitments of the Research Integrity Concordat

1. We are committed to maintaining the highest standards of rigour and integrity in all aspects of research.
2. We are committed to ensuring that research is conducted according to appropriate ethical, legal and professional frameworks, obligations and standards.
3. We are committed to supporting a research environment that is underpinned by a culture of integrity and based on good governance, best practice and support for the development of researchers.
4. We are committed to using transparent, robust and fair processes to deal with allegations of research misconduct should they arise.
5. We are committed to working together to strengthen the integrity of research and to reviewing progress regularly and openly.

Appendix 2: Report to Council 9 June 2015

1. Research Governance & Integrity Office (RGIO)

The RGIO's main objective is to promote a 'Quality Research Culture' at LSHTM; ensuring that we support and promote high quality research and are consistently striving to the best possible standards, as well as to develop and implement best practice as required.

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.

The staff list is listed in Appendix 1.

1.1 Research Governance

The procedures directing research governance in the UK are found in the Research Governance Framework for Health and Social Care (2005) which sets out the principles and responsibilities to be complied with for all health-related research in the UK. At LSHTM, it is expected that all researchers comply with the Guidelines on Good Research Practice. From 2013-14 it is a condition of HEFCE funding that institutions confirm that they comply with the Concordat for Research Integrity produced by Universities UK, with the research councils and the Wellcome Trust.

The Research Governance Committee will have oversight, with the Constitution and Terms of Reference (ToR) found in Appendix 2.

1.2 Clinical Trials

The RGIO are responsible for assessing clinical trials for sponsorship, conducting a risk assessment and ensuring that the current insurance policies will cover the trial in the relevant countries. The clinical trials sub-committee have an oversight role and will comment on a trial should the need arise. Further discussion of the clinical trials sub-committee is in section 3.1. The current terms of reference for the sub-committee are in Appendix 3.

The RGIO is also responsible for providing the quality assurance for clinical trials via its auditing function. Further details are in section 2.4.

1.3 Human Tissue

The Human Tissue Act 2004 (HTA) regulates the removal, storage and use of human tissue, from both the living and deceased, for Scheduled Purposes (including research). All human tissue stored at LSHTM under the research licence must comply with the HTA, and the Quality & Governance Manager is responsible for this as the Designated Individual on the licence.

There is a standing item on the agenda at Laboratory Safety Committee for any issues with human tissue governed by the Human Tissue Act.

2. Activities

This report covers activities from 1 May 2014 to 30 April 2015.

2.1 LSHTM sponsorship of clinical trials

The RGIO reviewed 33 trials for sponsorship in the above timeframe. The trials can be broken down into the following types of study:

Clinical Trial of an Investigational Medicinal Product (IMP) (eg drug)	7
Clinical Trial of a non-IMP (vitamins etc)	1
Clinical Trial of a public health intervention (eg health management, training)	14
Clinical Trial - other	4
Clinical Trial - Device	7

Number of trials by Faculty and Department:

Faculty of Epidemiology and Population Health	**6**
DPH: Dept of Population Health	1
IDE: Infectious Disease Epidemiology	5
Faculty of Infectious and Tropical Diseases	**25**
CR: Clinical Research	10
DC: Disease Control	13
II: Immunology & Infection	2
Faculty of Public Health and Policy	**2**
SEHR: Social and Environmental Health Research	1
GHD: Global Health and Development	1

In total, the School is the sponsor of **89** active studies. Please see Appendix 4 for details.

2.2 LSHTM sponsorship of other research

In addition to trials, the RGIO is responsible for the oversight of other types of studies for which LSHTM is sponsor under the Research Governance Framework. During this period, the office

reviewed and agreed sponsorship for 12 studies, mainly qualitative projects within the NHS, including student projects.

2.3 Studies involving human tissue

77 applications (26%) involving the use of human tissue were submitted to the LSHTM ethics committee which are included on the database and reviewed regularly to ensure compliance with the HTA.

2.4 LSHTM audit programme

A total of 8 audits were undertaken, covering 4 clinical trials.

2.5 Training

The Research Facilitator (RF) is responsible for the in-house teaching of Good Clinical Practice, as well as specialist courses such as monitoring, data management and informed consent. The RF has also developed an online GCP course which is on moodle and is currently undergoing final testing and piloting with an expected launch date of mid-June 2015. An online course in Good Clinical Laboratory Practice (GCLP) incorporating the Human Tissue Act will be developed over the next year.

2.6 Inspection by the Human Tissue Authority

A routine, regulatory inspection by the HTA was conducted on 19 May 2015. A report will be issued in due course, after which the RGIO will respond with the corrective and preventive action plan.

2.7 Procedures and policies

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. Policies within Research Governance are to be drafted for review at the next Research Governance Committee meeting.

3. Items for discussion

3.1 Clinical Trials Sub-committee

The clinical trials sub-committee was convened in 2008 and has met on an irregular basis (as needs arose) until its last meeting on 3 September 2013, where the Chair announced he was stepping down. There has been limited response to emails suggesting another meeting. The RGIO manage all sponsorship responsibilities, and the ToR is incorporated within the Quality and Governance Manager's job description. With the convening of the Research Governance Committee in May 2015, Council are asked to dissolve the Clinical Trials Sub-Committee, with oversight of clinical trials to become the remit of the Research Governance Committee.

3.2 Research Governance Committee constitution

Council are asked whether an external member should sit on the Research Governance Committee (current membership and ToR in Appendix 2), and for suggestions.

Patricia Henley
2 June 2015

Appendix 1: Staff in RGIO

Patricia Henley, Quality & Governance Manager

Naomi Tranter, Research Facilitator

Rebecca Carter, Research Governance Coordinator

Appendix 2: Research Governance Committee constitution and ToR

CONSTITUTION

Members

Deputy Director and Provost (Chair)	x1
Chair of Ethics Committee	x1
Chair of Animal Welfare and Ethical Review Board	x1
Three senior members of academic staff appointed by their Dean	x3
Secretary & Director of Resources & Planning	x1
Quality and Governance Manager	x1
Head of Legal Services	x1
External	x1

To Attend on Request

Head of Library & Archives Service	x1
Head of IT Security, IT Audit and Compliance	x1
Research Operations Manager	x1
Academic Registrar	x1
Pro-Director, or nominate	x1

Secretariat

To be provided by the Office of the Quality & Governance Manager

Quorum

The Committee's quorum will be six members in attendance, at least three of whom must be academic members of staff (including the Chair).

Frequency of meetings

The committee will meet once per term.

REPORTING

The Committee will report on its activities to Senate, usually via Senate Executive Group (an advisory group of Senate). The Chair of the Research Governance Committee will use his or her judgement to determine whether the Committee can approve minor changes to regulations and other processes and procedures, or, whether these should be escalated to Senate Executive Group for consideration and potential acceleration to Senate.

To facilitate the governance structure outlined above, the Committee will produce a brief report after each meeting for submission to Senate Executive Group.

TERMS OF REFERENCE

To have oversight of research governance matters across the School, including Chariot Innovations.

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

To consider and adjudicate on any appeals relating to decisions by the Research Ethics Committees.

To oversee the development of 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 ensure that effective monitoring and reporting arrangements are in place to investigate any allegations of research misconduct.

To receive reports of research governance audits or inspections of the School by external bodies, including the Medicine and Healthcare products Regulatory Authority and the Human Tissue Authority, to receive regular reports from AWERB based on Home Office inspections, and to consider the School's response to any findings arising from these reviews, including monitor the outcome of any associated action points.

Appendix 3: Terms of Reference of the Clinical Trials Sub-Committee (December 2012)

The CTSC is responsible to Council for:

1. Ensuring that LSHTM meets its obligations as a sponsor of clinical trials, wherever they are undertaken;
2. Monitoring compliance of the School (as Sponsor) and of individual trials, with relevant Clinical Trials Regulations;
3. Approving the trials for which the School will act as Sponsor;

The CTSC will meet as required and report to Council annually on compliance and its work. On behalf of Council, SLT will receive regular feedback on the work of the CTSC.

Appendix 4: Total number of active LSHTM-sponsored trials (n=89)

4.1 By Type of Trial:

Clinical Trial of an Investigational Medicinal Product (IMP) (eg drug)	27
Clinical Trial of a non-IMP (vitamins etc)	5
Clinical Trial of a public health intervention (eg health management, training)	41
Clinical Trial - other	7
Clinical Trial - Device	9

4.2 By Department and Faculty:

Faculty of Epidemiology and Population Health	**31**
DPH: Dept of Population Health	17
IDE: Infectious Disease Epidemiology	11
NCDE: Non-Communicable Disease Epidemiology	3
Faculty of Infectious and Tropical Diseases	**51**
CR: Clinical Research	22
DC: Disease Control	24
II: Immunology & Infection	5
Faculty of Public Health and Policy	**7**
SEHR: Social and Environmental Health Research	2
GHD: Global Health and Development	5