Audit Committee Agenda 23 June 2016

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 2015 to 30 May 2016.*

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: 21 May 2015, 22 October 2015 and 23 February 2016. They will continue to meet termly with the next meeting to take place on 28 June 2016. Terms of reference and constitution have been discussed and agreed and are available on the Research Governance and Integrity's section of the website. A report to Senate was made on 7 June 2015.

2. Policies and Procedures

The Research Governance Committee has updated Good Research Practice policy (formerly a guideline) which was reviewed by Senate on 7 June 2016. Minor revisions will be made and forwarded to SLT for formal adoption. The policy will be circulated to all staff during the summer of 2016.

The procedures for investigating allegations of scientific misconduct has been amended and will be reviewed by the RGC at the meeting on 28 June 2016.

The RGC agreed that the guideline on working with the private sector, including the statement on working with the tobacco industry, should be discussed at SLT as the ramifications are wider than just research.

3. Inspections

3.1 Human Tissue Authority (HTA) inspection

A routine, regulatory inspection by the HTA was conducted on 19 May 2015. The final Corrective and Preventive Action (CAPA) plan devised by the Quality and Governance Manager, and reviewed at the Laboratory Safety Committee meeting in September 2016 was accepted by the lead inspector on 6 April 2016 and the inspection is now considered closed.

3.2 Medicines and Healthcare products Regulatory Agency (MHRA) inspection

A triggered MHRA inspection took place on 5-6 October 2015 following two confirmed serious breaches at NHS sites. These breaches were of a similar nature; they both involved the dosing of patients with trial drug when they should have received the standard stock drug. Both patients are fine and doing well. In addition to the Sponsor inspection, eight site assessments were conducted by the MHRA across the UK. The MHRA accepted the proposed CAPA plan devised by the Quality and Governance Manager in discussion with the trial team and closed the inspection on 4 March 2016.

As a result of the inspection, the trial has updated several procedures since the breaches, namely that they have requested the full risk assessment from each NHS site for holding the trial drugs outside of the pharmacy department. This is necessary as the group run emergency trials which need access to the trial drugs at all times.

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

9 June 2016