R

R

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)

4ÈÅ 2 ') / ŏÔ Í ÁÉÎ ÏÂÊÅÃÔÉÖÅ ÉÓ ÔÏ ÐÒÏ Í ÏÛÅ Á Û1ÕÁÌÉÔÙ 2ÅÓÅÁÒÃÈ #ÕÌÔÕÒÅ ÁÔ ,3 (4 - ŋ Å Î ÓÕÒÉÇ ÔÈÁÔ × Å ÓÕÐÐÏÒÔ 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

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:

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 undergo871 0 595 ii1 0 0 1il

TERMS OF REFERENCE

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

To oversee the work of School bodAgA7(s)-4(w[wd)10(ter)1h.(Ag8 1u5(c)-4(the w)4(or)11(37.1)8F1 8.03J2)-5(4(.