University of Dundee

University Court
Research Governance & Policy Sub-Committee: Annual Report

22 June 2020

Academic Year 2018/19

Introduction

1. The primary objective of the Research Governance & Policy Sub-Committee is to ensure that the governance and policy context for the undertaking of research within the University is optimal. More specifically, the Sub-Committee is responsible for:

    1.1 reviewing governance processes and associated research and related policy extant at both University and the local level, and identifying need for improvement and development including the involvement of external stakeholders;
    1.2 establishing systems which accommodate the needs of good institutional governance, that are externally accountable, and which take into account the diversity of the institution's research activities;
    1.3 ensuring that institutional research governance processes are transparent and are well communicated throughout the University;
    1.4 promoting "buy-in" by facilitating dialogue and dissemination of good and consistent practice across the schools;
    1.5 attempting to minimize the burden of governance and policy demands on research staff commensurate with achieving high levels of internal and external confidence in the University's processes.

2. The Sub-Committee was chaired by Professor Alan Fairlamb, School of Life Sciences, in the 2018/19 academic year. Membership of the Sub-Committee includes staff from across the Schools and the primary areas of research governance activity within the institution, including the Health, Safety and Welfare Committee, Tayside Medical Science Centre (TASC) Research Governance Committee, the University Research Ethics Committee (UREC) and the Welfare and Ethical Use of Animals Committee. The Sub-Committee normally meets three times during each academic year and reports to the University Research & Knowledge Exchange Committee (RKEC) with the minutes of its meetings included with RKEC papers.

3. This report summarises the activities of the Sub-Committee, and associated research integrity initiatives, during academic year 2018/19.

Summary of Sub-Committee Business

4. The Sub-Committee considered a range of issues in the reporting period including: the San Francisco Declaration on Research Assessment; the House of Commons Science and Technology Committee Research Integrity report; the consultation on revisions to the Concordat to Support Research Integrity; the reporting of clinical trials; potential errors or misconduct in research highlighted through PubPeer; potential refinements to the University's research misconduct policy; record keeping for biological agents; open access to the results of publicly-funded research; policies governing the use of human tissue; and business transformation in relation to a proposed new online ethics review system. A number of these areas are expanded on below along with actions and activities that support the

University's commitment to the Concordat to Support Research Integrity and a summary of the annual reports from the areas of research governance across the University that report to the Sub-Committee.

San Francisco Declaration on Research Assessment

5. The San Francisco Declaration on Research Assessment (DORA) comprises a set of recommendations designed to improve how the output of research is evaluated by funders, academic institutions and other parties. By adding their names to the Declaration, signatories indicate their support for the adoption of the recommendations. These include avoiding the use of journal-based metrics, such as Journal Impact Factors, as a surrogate measure of the quality of individual research articles, in assessing an individual scientist's contributions, or in hiring, promotion, or funding decisions. In other words, the content of a publication is more important than publication metrics or the identity of the journal in which it was published. Funders, such as the Wellcome Trust, are increasingly adopting these principles when assessing research outputs for funding decisions and asking funded-organisations to commit to the principles.

6. The former College of Life Sciences (now School of Life Sciences) had previously signed and implemented the Declaration but the University as an institution had not. In January 2019, the Sub-Committee agreed that the University should indicate its support for the principles in the Declaration by becoming a signatory and recommended this course of action to the Research and Knowledge Exchange Committee (RKEC). RKEC agreed the University should endorse the Declaration in February 2019 and this was subsequently endorsed by Senate. The Vice-Principal for Research, Knowledge Exchange and Wider Impact signed the Declaration on behalf of the University in June 2019. Consistent with the University's position as a signatory, REF Groups involved in the selection of outputs were instructed not to use journal impact factors or any hierarchy of journals in their assessment of outputs in the University's REF 2021 Code of Practice. Further work on implementing the principles of the Declaration will start in academic year 2019/20.

Concordat to Support Research Integrity

7. The actions and activities reported below aim to facilitate the development of 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 (consistent with commitment 3 of the Concordat).

8. **Researcher Training:** The University provides online research integrity training, *Responsible and Ethical Practice in Research and Publication*, for both staff and students. All postgraduate research students registered from 1 August 2016 onwards are required to complete the training prior to their upgrade review. The training underwent further review in the 2018/19 academic session with a significant revision of the section on data protection to incorporate new legislation and other minor updates started, including re-recording of a few small areas in response to the changing external environment. The updates will be released in the 2019/20 session to enable them to be aligned to the requirements of the revised version of the Concordat to Support Research Integrity (published late 2019). The training is supplemented by annual face-to face workshops for staff and postgraduate research students provided by an external consultant and School-level activities led by Research Integrity Leads and Advisors (see below).

9. Nine other higher education institutions were using the resource under license from the University of Dundee in the 2018/19 academic year and will also receive the updates once completed.

10. **Research Integrity Leads and Advisors:** At University-level, the member of staff with responsibility for overseeing research integrity is the Convener of the Research Governance & Policy Sub-Committee. At School level, the system of Research Integrity Leads and Advisors introduced in the 2017/18 academic session became further embedded with a second interactive full-day training session taking place in March 2019. This provided an opportunity for new and existing Leads/Advisors to receive an update on research integrity and publication ethics; engage in case study group activity to inform training at a local level; explore different ways to use and adapt case studies; and discuss the research integrity landscape from the perspectives of different disciplines. Research Integrity Leads and Advisors come together as a University-wide Research Integrity Group about three times a year to discuss their experiences and share best practice.

11. Research Integrity Leads and Advisors are not intended to be a substitute for Line Managers, supervisors and colleagues in the promotion of good research practice but rather to provide an independent point of contact and source of advice for staff and students who would rather speak, at least in the first instance, to someone outside their immediate research environment. The aim is to create a supportive environment for staff and students to obtain impartial advice on the responsible conduct of research and any issues concerning them, including the reporting of potential research misconduct. Should a member of staff or student perceive that the Research Integrity Lead/Advisors from their own School have a conflict of interest in the matter they wish to discuss, they may instead approach a Research Integrity Lead or Advisor from another School.

12. **Research Ethics Procedures:** Following an ongoing review of the non-clinical research ethics procedures introduced in August 2016, a significant enhancement to the application and guidance materials was completed and made available to staff and students online between January and April 2019. In addition to revisions to existing checklists, forms and guidance, the following new materials were introduced: guidance for researchers on which activities do and do not require ethical approval (to supplement the existing checklist); additional guidance on data management (incorporating the requirements of the General Data Protection Regulation); procedure for best practice in ethical review and approval of research projects involving the use of human tissue from healthy volunteers; reviewer checklists for both low risk and medium/high risk projects; procedures for post-approval requests for amendments or extensions; procedures for appeals against decisions made by a School Research Ethics Committee (SREC) or the University Research Ethics Committee (UREC); and participant information sheet and consent form templates/guidance[1].

13. **Research Governance and Policy Handbook:** The Research Governance and Policy Handbook is designed to assist staff and students in identifying and locating the correct policy and governance procedures to ensure the responsible conduct of proposed research within the University. The handbook includes: a policy roadmap that details the policies that should be read and understood before undertaking a research project; research ethics procedures; information on the Concordat to Support Research Integrity; information on and contacts for Research Integrity Leads and research integrity training; and policies governing research misconduct and whistleblowing. The previously separate UREC website was integrated into the handbook in the reporting period. A 'Governance and Policy' panel was also included as one of six key areas on the University's research landing page during the reporting period to increase the visibility of this area both internally and externally; this links directly to the Research Governance and Policy Handbook.

14. **Scottish Research Integrity Network (SRIN):** During the reporting period the University of Dundee and the University of Edinburgh began collaboration on an initiative to set up a Scottish Research Integrity

[1] The full set of application and guidance materials are available from the Research Governance and Policy Handbook.

Network to share knowledge and best practice, including drafting a remit for the network and liaising with colleagues in other Scottish institutions to gauge interest. The initiative attracted significant interest from other institutions, culminating in the first meeting of the network being scheduled for November 2019 (further information on this will be provided in the report for academic year 2019/20).

15. The University provided a response to the consultation on the revised Concordat to Support Research Integrity in April 2019.

Reporting of Clinical Trials Results

16. The report for academic year 2017/18 detailed actions taken to rectify the backlog in reporting of clinical trials results. Led by the Director of R&D (NHS Tayside), a Professor of Cardiovascular Medicine & Therapeutics in the School of Medicine and a member of the Sub-Committee, this included the appointment of a Trials Registry Officer. These actions were reflected in a key paper on compliance with the requirement to report results on the EU Clinical Trials Register in the British Medical Journal[2] which listed the University of Dundee as the university with the highest proportion of trials reported (82%), whilst reporting that non-commercial trials sponsors such as universities have particularly low reporting rates overall. This relatively high compliance rate was also reported in the subsequent House of Commons Science and Technology Committee report on clinical trials transparency. The Director of R&D (NHS Tayside) was invited to give presentations on increasing clinical trials transparency and compliance at the Universities UK Research Integrity Forum in April 2019 and the UK Research Integrity Office (UKRIO) conference in May 2019 and featured in the Health Research Authority's 'Make It Public' campaign to help increase public access to research findings.

17. The Sub-Committee agreed that, following this encouraging progress, the target would be to reach 100% compliance (whilst noting that this was complicated by legacy issues for trials involving investigators who had left the University 10 – 15 years ago). In this respect, a new Standard Operating Procedure for Registering and Reporting Research in a Publicly Accessible Database was developed and implemented in the reporting period. This describes the processes that must be followed to ensure compliance. The University's clinical trials reporting can be tracked via the EU Trials Tracker website.

PubPeer

18. PubPeer is an online platform for post-publication peer review by the research community. Through PubPeer, scientists can comment on the quality and integrity of published papers. Comments are frequently used to highlight potential research misconduct, particularly suspected image manipulation. However, the PubPeer database did not allow articles with comments to be searched by institution name, thereby making it difficult for institutions to monitor and respond to comments in a timely manner. During the reporting period the Convener liaised with PubPeer on this issue and was granted a trial of a new system under development that incorporates an alert system to inform institutions of any new postings relating to that institution. Following a successful trial in conjunction with members of the School of Life Sciences Research Integrity Group (SLS RIG) the University was one of the first institutions to take out an annual institutional subscription to the new service. Given that alerts usually relate to potential image manipulation, the response to alerts is managed through the SLS RIG, contacting Research Integrity Leads in other Schools or external authors as necessary. This enables the University to be proactive in maintaining the integrity of the scientific record (through pursuing

[2] Goldacre, B., *et al.* "Compliance with requirement to report results on the EU Clinical Trials Register: cohort study and web resource", BMJ 2018;362:k3218 http://dx.doi.org/10.1136/bmj.k3218.

publication of corrections or retractions where necessary) and initiating investigations of research misconduct where there is evidence of intent rather than honest mistakes.

Research Misconduct

19. One formal investigation of potential research misconduct by a member of staff was completed in academic year 2018/19. Following an appeal, a member of staff was found to have committed research misconduct. The member of staff was subsequently admonished; required to undergo a period of mentoring and supervision of their research activities; and to undertake research integrity training.

20. Another formal investigation of potential research misconduct by a member of staff was initiated at the end of the 2018/19 academic year; the findings will be included in the report for 2019/20.

21. The current Code of Policy and Procedures for Investigating and Resolving Allegations of Misconduct in Research provides a transparent, fair and robust operational framework for investigating allegations of research misconduct. Following recent investigations, the Sub-Committee considered a number of potential refinements to the Code and lessons learned in relation to research misconduct. These included: the need for early preservation of data in research misconduct investigations (for example, through processes for implementing temporary litigation holds on e-mail accounts); potential revision of the timetable to allow more time for complex investigations; potential reduction in the size of the Investigating Committee to increase efficiency; and potential changes to the format for appeals following a finding of research misconduct. In addition to considering these potential refinements, a future review of the Code will be informed by the revised version (expected 2021) of the UKRIO Misconduct Investigation Procedure (originally published in 2008) and the updated definition of research misconduct in the revised Concordat to Support Research Integrity, along with other available policies, procedures, external expectations and advice with respect to research misconduct.

Reporting to the Sub-Committee

22. The Sub-Committee's remit does not require it to capture detailed information on activities at the local level but rather to satisfy itself, by reviewing higher level evidence, that sufficient rigour exists in the policies and processes operated by the institution. The Sub-Committee therefore receives and considers annual reports from the various areas of research governance operating across the University to ensure that the appropriate policies and processes are in place. Reports (both written and oral) for calendar year 2018 were received from the University Health, Safety and Welfare Committee; Tayside Medical Science Centre (TASC) Research Governance Committee; University Research Ethics Committee; and the Welfare and Ethical Use of Animals Committee:

    22.1 **Health, Safety and Welfare Committee**: As part of its remit, the Health, Safety and Welfare Committee covers health and safety issues arising from all research activities undertaken by the University and reports to the People and Organisational Development Committee. The main Health and Safety Policy and Arrangements and the Estates & Campus Services' Out of Hours policy had been reviewed and updated in the reporting period. Two new policies had been created, a Working and Assistance Animals Policy and an Unmanned Aerial Vehicles (Drones) Safety Management Policy. The Head of Safety Services noted that it is difficult to keep the 62 policies the Committee is responsible for up-to-date, as the process and consultation involved can be time consuming. They were looking at whether it would be possible to consolidate some individual policies into single policies to reduce the overall number. The Sub-Committee accepted the report.

22.2 **Tayside Medical Science Centre (TASC) Research Governance Committee**: The TASC Research Governance Committee provides oversight of the systems and processes that exist in clinical research to ensure that the required standards are met. The Committee is responsible for providing assurance to the NHS Tayside Clinical Care & Governance Committee that clinical research is undertaken in a manner that shows evidence of accountability, responsibility, compliance with standards and management of risk.

22.3 There were six policies under the remit of TASC during the reporting period, underpinned by several Standard Operating Procedures (SOPs), with scheduled review dates set for those not reviewed and updated in the last 12 months. A risk register is updated three times per year, prior to each Research Governance Committee meeting, by a sub-group of the Committee. The Committee had reviewed two of its policies in the reporting period: Clinical Research Quality Management System; and Good Clinical Practice Training Policy for Personnel Involved in Clinical Research. A new policy (Clinical Research Computer System Validation) had also been developed. Another new TASC policy (Clinical Research Projects Involving Human Tissue) came into effect in January 2019, shortly after the end of the reporting period for the Committee, bringing the total to seven.

22.4 An outcome of Good Clinical Practice audit findings was that all breaches are now reported directly to the TASC Research Governance Office rather than just those breaches categorised as serious by the Trial Manager. The TASC Research Governance team would assess each report to determine seriousness, providing an early detection opportunity for prevention of recurrent minor breaches which, by way of their cumulative nature, could become serious over time. No serious breaches affecting patient safety or data integrity were identified during any audits. TASC was commended for its internal reciprocal auditing plan for 2019, between the TASC and Institute for Medical Science and Technology (IMSaT) Quality Assurance Managers, noting that instead of bringing in costly external auditors, internal experienced auditors would undertake this work through the sharing of best practice. The Sub-Committee accepted the report.

22.5 The oversight of registration and reporting of clinical trials had been taken forward by the Director of R&D (NHS Tayside) and their team (see paragraph 16 for further details).

22.6 **University Research Ethics Committee (UREC)**:

22.7 The University Research Ethics Committee (UREC) is responsible for upholding the ethical standards of practice in non-clinical research involving human participants in the University in order to protect participants and researchers from harm, preserve participants' rights, and to provide reassurance to the public and funders regarding the ethical conduct of research at the University. It provides oversight, monitoring and guidance to the six School Research Ethics Committees (SRECs), three of which are joint committees covering two Schools, and acts as the first point of contact for the review and approval of proposals to access and use security-sensitive material.

22.8 The revision of procedures, forms and guidance that had started in the previous reporting period was completed and the UREC website updated in early 2019 (see paragraph 12). The remit for UREC had also been updated in early 2019 (to incorporate ethical review of cases referred to UREC where the SREC could not reach a decision, for instance due to complexity or conflicts of interest). Following a minor review of the University's Code of Practice for Non-Clinical Research Ethics on Human Participation a working group had been established to undertake a more comprehensive review. Whilst there was still work to do with respect to

security-sensitive research and the monitoring of standards for ethical review, and it would be desirable to appoint a Deputy Convener for UREC, the Convener of the Sub-Committee noted that there had been a transformation of UREC over the past few years. The Sub-Committee accepted the report.

22.9 **Welfare and Ethical Use of Animals Committee**: The Welfare and Ethical Use of Animals Committee (WEAC) acts on behalf of the University Court in ensuring that the University meets its obligations under the Animals (Scientific Procedures) Act 1986 (amended 2012 to comply with Directive 2010/63/EU) to discharge the functions of an Animal Welfare and Ethical Review Body as required under that Act, and to determine policy on all matters relating to animals on University premises. Two new independent members were recruited to the Committee from January 2019. For the approval of applications for Home Office project licences and major amendments to existing licences a quorum comprising the Convener (the Director of Biological Services), the University Veterinary Surgeon, at least one Named Animal Care and Welfare Officer, at least two scientists and at least one independent member is required. The Committee reports to Court after each of its quarterly meetings. The Director of Biological Services and the University Veterinary Surgeon also meet with the University Secretary on a quarterly basis.

22.10 The WEAC's Terms of Reference and the Code of Practice for the Use of Animals in Teaching and Research are reviewed at least once a year by the Director of Biological Services and amendments are discussed and formally approved by the Committee prior to submission to Court for approval.

22.11 There is a cycle for review of Home Office project licences as they last five years. The WEAC had spent a considerable amount of time in 2018 reviewing project licenses in the reporting period but it was anticipated that there would be fewer review applications the following year. There were processes in place for dealing with non-compliance and the Home Office Inspector commented favourably on the composition and activities of the Committee at their most recent annual “risk profiling” meeting with the Establishment Licence-Holder. With regular external audits from the Home Office, the Convener noted that the Sub-Committee has confidence that the area of research governance is working efficiently. The Sub-Committee accepted the report.

Changes to the Reporting Cycle

23. The Sub-Committee has agreed to change the annual reporting cycle for the areas of research governance from calendar years to academic years. This will align the reporting period with that used by other committees and Court and make reports more timely. The next report to Court will therefore be transitional to account for the overlap that will occur in the transition from reporting by calendar year to academic year.

Professor Alan Fairlamb
Convener
14 June 2020