University of Dundee

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

26 February 2019

Academic Year 2017/18

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 2017/18 academic year. Membership 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 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. Professor Margaret Smith and Dr Morag Martin stepped down from the Sub-Committee in the reporting period and were thanked for their long service and helpful contributions, whilst Dr Paul Davies (MRC PPU Unit Manager), Dr Sharon King (Tayside Biorepository Manager) and Professor Cameron Ross (co-Research Integrity Lead for the School of Social Sciences) were welcomed as new members.

4. This report summarises the activities of the Sub-Committee, and associated research integrity initiatives, during academic year 2017/18.

Summary of Sub-Committee Business

Policy Development and Review

5. Consistent with the commitment of the Sub-Committee to regularly review institutional research policies, the Committee considered whether the following policies required revision:

    5.1 **Policy to Govern the Acceptance of External Funding**: Following review of the policy a minor revision was agreed to avoid misinterpretation of the wording relating to research funding terminology.

    5.2 **Policy to Govern the Management of Research Data**: The review of the policy initiated in academic year 2016/17 was concluded in the reporting period. Revisions included making it clear that the University subscribes to the Concordat on Open Research Data and strengthening the sections relating to the use of personal data sets[1] and the length of time data should be stored for. New sections were added relating to the management of research data gathered by students; selection of an appropriate license under which data will be made available; and requirements for registration of, and posting summary results data from, clinical trials (see paragraph 13). The revised policy also included two new appendices containing detailed guidance notes to assist researchers in the practical management of research data.

6. The Sub-Committee further considered the development of the following putative policies during the reporting period:

    6.1 **Policy on the Use of Human Tissue**: Significant progress was made on the development of a potential policy to strengthen the University's governance of human tissue to encompass non-NHS human tissue samples stored outwith the Medical and Dental Schools (first proposed in academic year 2016/17). The aim of the policy is to provide support for researchers to embed best practice, building on the expertise developed through the Tayside Biorepository. Additional work was needed in relation to clarifying what tissue was covered by the policy ('relevant human tissue'), ethical approval routes, human volunteers, new data protection legislation and registration of tissue samples. This would be further progressed by the Tayside Biorepository Manager in conjunction with the Health Informatics Centre (HIC) in academic year 2018/19.

    6.2 **Research Publications Policy**: The development of an overarching *Policy to Govern the Publication of Research*, proposed in academic year 2016/17, was put on hold due to the rapidly evolving external environment in relation to scholarly communications and open access. Individual policies on good practice in research, open access and guest authorship and ghostwriting remain in place.

Concordat to Support Research Integrity[2]

7. The activities reported below aim to support the development of a research environment that nurtures good practice and creates a culture of research integrity (consistent with commitment 3 of the Concordat).

[1] Consistent with the implementation of the General Data Protection Regulation ((EU) 2016/679) and the UK Data Protection Act (2018).
[2] The Concordat to Support Research Integrity: http://www.universitiesuk.ac.uk/policy-and-analysis/reports/Pages/research-concordat.aspx

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 is supplemented by annual face-to face workshops for staff and postgraduate research students provided by the external consultant who developed the online training in partnership with the University.

9. During the reporting period, the Sub-Committee approved a procedure for maintenance of the online training through annual review, and provision for refresher training, to take account of any significant changes to the research landscape. A review of the training was initiated in the reporting period and resultant updates, for example to take account of changes to data protection legislation, will be completed in the 2018/19 academic session.

10. Nine other higher education institutions are currently using the resource under license from the University of Dundee and will also receive the updates once completed.

11. **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. In order to embed support for research integrity at a local level, the Research & Knowledge Exchange Committee agreed in May 2017 that all Schools would nominate a member of academic staff to act as the local lead for research integrity, building on work in the School of Life Sciences to establish a Research Integrity Group consisting of a lead and advisors. Research Integrity Leads (RILs) were appointed for all Schools in the 2017/18 academic session[3]. The appointment of Deputy RILs and Research Integrity Advisors (RIAs) was also encouraged to ensure that there is an alternative person who can be contacted if the Lead is away or has an actual or potential conflict of interest. The School of Life Sciences paper *Supporting and Promoting a Culture of Research Integrity*, which included a process map highlighting workflow and responsibilities, was commended by the Sub-Committee as providing an example of best practice which could be adapted by other Schools establishing a Research Integrity Group.

12. Whilst RILs and RIAs are new roles that will evolve with experience, it is expected that they will play a key role in promoting a culture of research integrity in Schools through promoting and delivering training and providing a sounding board for staff and students who are seeking confidential and impartial advice on matters such as the responsible conduct of research, potential issues of research integrity or making an allegation of research misconduct. In this respect, fourteen RILs and RIAs attended a highly interactive full-day 'train the trainer' research integrity training session in the reporting period which allowed for wide-ranging and in-depth discussion of a range of research integrity issues and included group activities designed to enhance participants' ability to moderate face-to-face discussions of case studies associated with the online training. This lead to the formation of a Research Integrity Leads Group to allow members to discuss their experiences and share best practice. A second training day for RILs and RIAs is planned for academic session 2018/19.

Reporting of Clinical Trials Results

13. The Sub-Committee considered Alltrials and TranspariMed reports that showed a significant deficiency in the posting of clinical trial results to publicly accessible registries by institutions conducting clinical trials, particularly universities. The University had a significant backlog of trials for which the results had not been posted. The Sub-Committee agreed that the University should follow best practice in the

[3] https://www.dundee.ac.uk/research/governance-policy/leads/

reporting of clinical trials, that there was a need for rapid progress in resolving this backlog, and that the Sub-Committee would monitor progress towards compliance. The Director of R&D (NHS Tayside), a member of the Sub-Committee, took the lead on pursuing compliance and recommended and sought the appointment of a temporary Trials Registry Officer to help rectify the backlog and ensure the University's Registry entries were up to date and complete. The resulting significant improvement in the University's posting of clinical trials results will be detailed in the annual report for academic year 2018/19.

14. The revisions to the *Policy to Govern the Management of Research Data* (see paragraph 5.2) included the addition of the following clause: "All clinical trials sponsored by the University of Dundee must be registered on an appropriate publicly accessible research register within 6 weeks of first participant recruitment in the UK. Summary results data from clinical trials must be made publicly accessible in an appropriate format within 12 months from trial completion." This was consistent with the addition to the *TASC Publication Policy* of a requirement to upload study results to public registers, which was implemented earlier in the reporting period[4].

House of Commons Science and Technology Committee Inquiry into Research Integrity

15. During the reporting period, the House of Commons Science and Technology Committee held an inquiry into research integrity, demonstrating the importance attributed to research integrity at the highest levels of government. The Sub-Committee noted the University's positive response to a request from the Chair of the Science and Technology Committee to confirm that the University as an employer complied with specific recommendations from the Concordat to Support Research Integrity. The recommendations of the Science and Technology Committee's report, published in July 2018, include a strengthening of the Concordat and a timetable for reaching 100% compliance with the strengthened version within the next year. The outcomes from these recommendations are likely to be key areas for consideration by the Sub-Committee in academic sessions 2018/19 and 2019/20.

Research Misconduct

16. One formal investigation of potential research misconduct by a member of staff, initiated in the 2016/17 academic year, was completed within the 2017/18 academic year; the findings are subject to appeal and will therefore be included in the report for 2018/19.

Reporting to the Sub-Committee

17. 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 2017 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:

    17.1 **Health, Safety and Welfare Committee**: The annual report was presented by the newly appointed Head of Safety Services. As part of its remit, the Health, Safety and Welfare

[4] TASC Publication Policy: Guidance for Investigators: https://www.ahspartnership.org.uk/admin/js/libs/tiny_mce/plugins/moxiemanager/data/files/Policy%2006%20v7.pdf

Committee covers health and safety issues arising from all research activities undertaken by the University. Two policies (relating to first aid and catering) had been reviewed and updated in the reporting period. No new policies had been created; to reduce burden the Committee further developed existing policies rather than creating new ones. Future areas for consideration included the use of the HASMAP auditing tool and the introduction of refresher training, although this would involve a high administrative burden. The Sub-Committee approved the report.

17.2 **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. The new Dean of the School of Nursing and Health Sciences had been appointed as Chair of the Committee following the retirement of the previous Dean.

17.3 The Committee had reviewed four policies in the reporting period covering good clinical practice training for personnel involved in clinical research, publication guidance for trialists, negotiation and signatures of agreements of investigator-led clinical trials, and commercial research services. Where appropriate, policies had been combined into standard operating procedures (SOPs) to provide clearer processes. In this context, three policies had been discontinued as their contents were covered in the TASC safety and pharmacovigilance SOPs.

17.4 All laboratories that provided services to clinical trials were required to respond (via a questionnaire) to a Medicine and Healthcare Regulatory Agency (MHRA) inspection of laboratories that offer clinical trials services in the reporting period and this had been completed. There is also an internal audit programme in TASC to ensure continued Good Clinical Practice (GCP) compliance and to identify situations that may arise that require quality improvements. These included study-specific audits, a rolling programme of GCP process and facility audits and audits of the Tayside Biorepository and selected University of Dundee clinical research laboratories. Audit findings were being addressed by the Quality Assurance Manager working with relevant staff to implement improvements to processes. Six study-specific audits were conducted in 2017 to ensure GCP compliance and future MHRA inspection readiness for Clinical Trials of Investigational Medicinal Products (CTIMPs). It was explained that the reason for missing documents representing nearly half of the study-specific audit findings was that studies were live at the time of audit and some documents were therefore awaiting filing in the Master File at Ninewells Hospital because they were in practical use at other sites. Overall, no serious breaches affecting patient safety or integrity of data were identified during any of these audits.

17.5 The Sub-Committee noted that the oversight of registration and reporting of clinical trials required resolution and that this would be taken forward with the TASC Research Governance Office by the Director of R&D (NHS Tayside) (see paragraph 13 for further details). The Sub-Committee approved the report.

17.6 **University Research Ethics Committee (UREC)**: 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.

17.7 The governance arrangements established in August 2016 had been subject to review during the reporting period to take account of feedback from SRECs and users on the new forms and processes. This review was taking place in the context of a planned migration of the current system for review and approval of ethics applications to an online system as part of the OneUniversity business transformation project, but the planned transition to the online system had been delayed. The Terms of Reference for UREC and SREC had been revised and updated with responsibility for training for reviewers now predominantly resting with SRECs, to take account of disciplinary differences, but maintaining oversight from UREC. Revision of forms and processes in response to feedback was well underway and due to be completed in the next reporting period. A review of the Code of Practice for Research Ethics on Human Participants was also due to be completed in the next reporting period. UREC would also be considering whether a cost effective solution to monitoring compliance with the Code can be found. The Sub-Committee approved the report subject to minor amendments to the membership list, and reference to compliance monitoring, being added to the written report (both completed).

17.8 **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.

17.9 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. The Code of Practice provides a statement of required behaviours of every user of animals or tissue derived from animals; any deviation from the Code can result in disciplinary action. The latest version of the Code had been provided to a previous meeting of the Sub-Committee for information and comment.

17.10 The WEAC has vigorous internal monitoring and had recruited a former Home Office inspector with extensive experience of animal welfare and ethical review bodies, both in the UK and the wider EU, as an independent member. The Home Office inspector visits the animal facilities regularly and unannounced. When time permits, the inspector also attends WEAC meetings as an observer (about once a year) and has commented favourably on its composition and activities. The Sub-Committee approved the report subject to a short narrative on the controls that were in place being added to the written report (completed).

Professor Alan Fairlamb
Convener
13 February, 2019