UNIVERSITY OF DUNDEE

RESEARCH GOVERNANCE & POLICY SUB-COMMITTEE

ANNUAL REPORT TO COURT

Academic Year 2016/17

1. **Introduction**

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:

- 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;
- 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;
- ensuring that institutional research governance processes are transparent and are well communicated throughout the University;
- promoting "buy-in" by facilitating dialogue and dissemination of good and consistent practice across the schools;
- 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.

The Sub-Committee was chaired by Professor Alan Fairlamb, School of Life Sciences, in the 2016/17 academic year (with Professor Margaret Smith deputising for the first meeting). 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.

This report summarises the activities of the Sub-Committee during academic year 2016/17.

2. **Summary of Sub-Committee Business**

2.1 Policy Development and Review

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

Policy and Procedures for Investigating and Resolving Allegations of Misconduct in Research: The update to RCUK's *Policy and Guidelines on Governance of Good Research Conduct*[1] introduced the

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[1] RCUK Policy and Guidelines on Governance of Good Research Conduct:
http://www.rcuk.ac.uk/publications/researchers/grc/

requirement for organizations to notify RCUK of allegations of research misconduct at the stage it is decided to undertake an informal inquiry as opposed to the previous requirement to notify RCUK at the later stage of deciding to undertake a formal investigation. The Wellcome Trust similarly introduced a requirement to inform the Trust at the point a decision is made to conduct a preliminary investigation[2].

The Sub-Committee agreed that the informal inquiry/preliminary investigation stage referred to by RCUK and the Wellcome Trust was broadly equivalent to the stage at which an 'initial assessment' is taken by the Dean of School in the University's *Policy and Procedures for Investigating and Resolving Allegations of Misconduct in Research*[3]. In order to comply with the new requirements it was decided that, where a funder requires the University to notify it of allegations of research misconduct at the informal inquiry/preliminary investigation stage, the Dean of School should inform the University Secretary and Research Policy Manager that an initial assessment is being undertaken along with the name of the individual, the link to the funder and the nature of the allegation(s). The University Secretary and/or Research Policy Manager will then notify the relevant funder(s). The University's policy was updated accordingly.

Policy to Govern the Management of Research Data: This policy was subject to ongoing review during the reporting period against a backdrop of the external development of a Concordat on Open Research Data which proposed a series of principles for working with research data in a rapidly evolving area. Proposed revisions to the policy resulting from this ongoing review will be incorporated into an updated version of the policy in academic year 2017/18.

The Sub-Committee also considered the development of the following putative policies during the reporting period:

Policy on the Use of Human Tissue: A potential policy to strengthen the University's governance of human tissue was drafted for discussion. The University has strong governance of surplus tissue derived from NHS patients and non-NHS tissue samples in the Medical and Dental Schools through the Tayside Biorepository but may benefit from incorporating best practice developed by the Biorepository in the governance of non-NHS human tissue samples stored in other Schools. The Sub-Committee supported the further development of this policy, to be taken forward in academic year 2017/18.

Research Publications Policy: A draft *Policy to Govern the Publication of Research* was developed by the end of the reporting period. The Sub-Committee agreed that the University's *Policy on Guest Authorship and Ghostwriting* should be condensed and incorporated into the new policy and suggested defining the responsibilities of authors and the provision of standard formats/templates for ethical statements for research involving animal and human (non-clinical/clinical) subjects. The policy will be further developed in academic year 2017/18, taking into account any developments around the UK Scholarly Communications Licence (an open access policy mechanism)[4].

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[2] Wellcome Trust Research Misconduct Statement: https://wellcome.ac.uk/funding/managing-grant/research-misconduct
[3] University of Dundee Policy and Procedures for Investigating and Resolving Allegations of Misconduct in Research: https://www.dundee.ac.uk/research/governance-policy/misconduct-whistleblowing/#!faq-0
[4] UK Scholarly Communications Licence and Model Policy: http://ukscl.ac.uk/

2.2 Concordat to Support Research Integrity[5]

Framework for Ethical Review and Approval of Non-Clinical Research: Research should be conducted according to appropriate ethical, legal and professional frameworks, obligations and standards (commitment 2 of the Concordat). In academic year 2014/15 the Sub-Committee recognized the need to reform the framework for ethical review and approval of non-clinical research involving human participants by devolving greater responsibility to School-level sub-committees with the University Research Ethics Committee (UREC) acting as an oversight committee. The structure of the School committees was agreed in academic year 2015/16, during which the remits of the committees were developed along with the processes to be used by researchers and reviewers.

The new committee structure and processes came into effect on 1st August 2016. Six School Research Ethics Committees (SRECs) were formed, three of which were joint committees covering two Schools:

- Art & Design
- Dentistry/Nursing & Health Sciences
- Education & Social Work
- Humanities/Social Sciences
- Medicine/Life Sciences
- Science and Engineering

The new processes incorporated a checklist to route applications submitted for review down either a 'low' or 'medium/high' risk route so that the review procedures used are proportionate to the risk.

Researcher Training: Provision of training in research integrity is a key element of a research environment that nurtures good practice and creates a culture of research integrity (commitment 3 of the Concordat). The development of online training in research integrity, overseen by the Sub-Committee, in conjunction with the University's Organisational and Professional Development Unit and an external expert, came to fruition in the reporting period. The final version of the resource, *Responsible and Ethical Practice in Research and Publication*, comprised a video, quiz and case studies on each of the following sub-topics:

- Introduction to research integrity and the responsible and ethical conduct of research
- Ethical approval and practice
- Plagiarism and recycling of text and research outputs
- Authorship
- Collaborative research and data management and integrity
- Peer review and publication ethics

The resource is hosted on the University's Virtual Learning Environment (VLE), with separate sites for staff and postgraduate research students. A compendium of the case studies and notes for moderators was also produced for supervisors and senior academics, to support face-to-face training at School level.

The resource was piloted with a small number of postgraduate research students in August 2016 and, following good feedback, the student site was launched for new postgraduate research students, in conjunction with research integrity workshops delivered by the external expert, in October 2016; it was subsequently made available to all postgraduate research students in March 2017. The parallel staff site (the configuration of which is slightly different to the student site) was made available in May 2017.

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[5] The Concordat to Support Research Integrity: http://www.universitiesuk.ac.uk/policy-and-analysis/reports/Pages/research-concordat.aspx

Consistent with the Sub-Committee's recommendation in April 2016 (endorsed by the University's Research & Knowledge Exchange Committee in May 2016), all new postgraduate research students registered from 1 August 2016 onwards are required to complete the training prior to their upgrade review.

Six other higher education institutions are currently using the resource under licence from the University of Dundee.

2.3 Research Misconduct

One formal investigation of potential research misconduct was concluded within the 2016/17 academic year; a member of staff was found to have committed serious research misconduct and subsequently resigned from the University. The University issued a short statement about the case in December 2016 (https://www.dundee.ac.uk/research/governance-policy/misconduct-whistleblowing/).

One formal investigation of potential research misconduct by a member of staff was initiated within the 2016/17 academic year. The investigation continued into the subsequent academic year and hence the outcome will be included in the report for 2017/18.

2.4 Reporting to the Sub-Committee

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 2016 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:

Health, Safety and Welfare Committee: The annual report included the report of an internal audit conducted in January 2016 as an appendix. All controls were assessed either as 'Yellow' (no major weaknesses in control but scope for improvement) or 'Green' (adequate and effective controls which are operating satisfactorily). The Sub-Committee noted that virtually all of the actions highlighted in the audit report had been completed. Health and Safety policies had gone live for each School and Health and Safety Advisors were being appointed within each School. Mandatory induction training had been achieving about 80% completion, but this was being pursued with help from the School Health and Safety Advisors, Deans and School Managers. Four policies had been updated during the reporting period: Uranium and Thorium Safety Management; Laser Safety Management; Protection Against Ionising Radiation; and Travelling on University Work Overseas. A better centralised online database for risk assessment/management was being sought, but there were concerns about how such a database would be maintained. The Sub-Committee approved the report.

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 had been reformed, and the role and remit refreshed, in 2016, ensuring adequate lay, NHS Tayside and University of Dundee representation.

Following a Medicines and Healthcare products Regulatory Agency (MHRA) inspection in the summer of 2016 there were no concerns about safety and the MHRA had been impressed with the way large complex multi-centre clinical trials were run. There were three major findings (non-critical) with

staggered completion dates dependent on the complexity of the task. In this respect, the inspection highlighted that there should be an increase in staff recruited to both the data management and trial monitoring teams in order to provide robust trial management by the Sponsor (University of Dundee). The report also highlighted that processes needed to be better documented (there was confidence in the process but the documentation of the process itself required improvement). Resultant actions which were required by December 2016 had been completed, and TASC was on schedule to meet the deadlines for further actions. It was noted that cross-border research collaborations with sites in England were subject to delays compared to Scotland-only studies due to teething problems with newly instituted Health Research Authority (HRA) systems. The Sub-Committee approved the report.

University Research Ethics Committee (UREC): The newly constituted 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 new School Research Ethics Committees (SRECs), three of which are joint committees covering two Schools. The new committee structure and processes for ethical review and approval of non-clinical research involving human participants came into effect on 1st August 2016 (see section 2.2 above for details). UREC was welcoming feedback on the new processes from SREC Conveners and others; this will inform revisions to the processes in academic year 2017/18 and ongoing discussions on the development and implementation of an online system for ethical review and approval of non-clinical research as part of the OneUniversity Business Transformation project.

Training for reviewers had been provided by an external expert using case studies and would be revisited based on feedback. The University's *Code of Practice for Research Ethics on Human Participants*[6] had been updated to reflect the new School structure and would be subject to further review by UREC in the 2017/18 academic year. At the time of reporting, it was noted that a Deputy Convener and lay member of UREC were still to be appointed; the lay member was appointed in April 2017. The Sub-Committee approved the report.

Welfare and Ethical Use of Animals Committee: The Welfare and Ethical Use of Animals Committee 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.

It had broadly been business as usual for the Committee in 2017. The *Code of Practice for the Use of Animals in Teaching and Research*[7] had been reviewed and updated in the reporting period and a new Convener had been appointed. The Committee also had two lay members and an external member. The Committee would be reviewing mouse breeding and how it exerts its own oversight in the coming year. The Sub-Committee approved the report.

Professor Alan Fairlamb
Convener
09 February, 2018

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[6] Code of Practice for Research Ethics on Human Participants:
https://www.dundee.ac.uk/research/ethics/applicationprocedure/
[7] Code of Practice for the Use of Animals in Teaching and Research:
https://www.dundee.ac.uk/media/dundeewebsite/ethics/documents/Code-of-Practice-for-the-Use-of-Animals-in-Teaching-and-Research-16.pdf