

**COUNCIL AND RESEARCH STRATEGY, POLICY & PERFORMANCE
COMMITTEE AND ETHICS COMMITTEE**

June 2018

2018 report on Research Integrity

1. Purpose of this report

This report outlines the requirements placed on the University under the Concordat to Support Research Integrity (*the Concordat*) and the UK Research and Innovation Research Integrity Assurance questionnaire (*UKRI Questionnaire*). UKRI is the new umbrella body – from 1 April 2018 - to which the Research Councils now report and has taken over integrity matters from Research Councils UK. Research England replaced the research section of HEFCE in April 2018.

The Concordat recommends that the University should present a short annual statement to its governing body (i.e. Council) that includes a summary of actions and activities that have been undertaken to support and strengthen understanding and application of research integrity issues.

This report forms the 2018 report, covering July 2017 – June 2018, and supports Commitment 5 of the Concordat.

2. Background

Concordat to Support Research Integrity

The Concordat was launched in 2012 with support from the Government, HEFCE (now Research England) and major research funders such as RCUK and the Wellcome Trust. The University has publicly stated its support for the Concordat.

The key provisions of the Concordat are enshrined in five commitments:

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.

In line with the Concordat, this report will be made publicly available on the University website once approved. This report is being considered by the University Ethics Committee and Research Strategy, Policy and Performance Committee as well as Council.

Research Ethics and Integrity Training Group

REITG (Membership and Terms of Reference in Appendix 1) was set up in February 2016 as a successor to the Research Integrity Working Group, to take forward the work begun by RIWG. REITG reports to the University Ethics Committee and has a two-year plan of work. This will finish in July 2018 following which its work will be continued by a sub-group of the University Ethics Committee.

During the 2017-18 academic year, REITG carried out activities in the areas listed below, which are summarised in the next section.

1. Reviewed and updated the Research Code of Conduct;
2. Updated the Research integrity website;
3. Oversaw completion of customisation of online training and piloted it with a group of postgraduate research students with a view to mandatory roll-out for all postgraduate research students from October 2018;
4. Assisted in responding to external requests for information;
5. Attended external Research Integrity events;
6. Wrote the 2018 Annual Report on the implementation of the Concordat for Council;
7. Prepared responses to the RCUK assurance questionnaire.

Research Councils UK Integrity Assurance

Research Organisations in receipt of UKRI funding are required to have procedures for governing good research practice, and for investigating and reporting unacceptable research conduct, so as to meet the requirements set out in the Concordat and the UKRI Policy and Guidelines on the Governance of Good Research Conduct.

As part of the current UKRI assurance process, universities are expected to provide responses to six questions. Responses for 2018 are given in Appendix 2. UKRI have indicated that the current processes will be reviewed and may change.

3. Work of REITG

1. REITG were responsible for a major review of the Research Code of Conduct which will be sent to Senate for approval in June 2018. There were significant changes to the sections on NHS-related research, and data use and data protection to bring the Code into line with the new EU-wide General Data Protection Regulation. In addition, there were numerous smaller changes such as updating Committee names and many of the weblinks (Commitments 1,2,4).
2. Following approval, the revised Code will be made available as a publically-available downloadable pdf document on the research integrity website. In addition the web-based version will be updated: <http://www2.le.ac.uk/offices/researchsupport/policyandstrategy/research-code-of-conduct-and-ethics-1/research-code-of-conduct-and-ethics> (Commitments 1,2,4).
3. In mid-2016, funding was released by the University for a three-year licence for online training courses in ethics, integrity and intellectual property, supplied by Epigeum. The research integrity course includes five subject-oriented modules. During 2017-18, all five modules were reviewed by group members and agreement reached on how to streamline and customise the content. All five have now been customised and were piloted with a group of postgraduate students in February 2018. Completion of the modules is currently optional, but it is hoped to make the modules mandatory from 2018-19. Roll out of the modules to other groups (e.g. research staff and early career researchers) will be the responsibility of the new group, reporting to the University Ethics Committee (Commitments 2,3,5).
4. In November 2017, the Rt. Hon. Norman Lamb MP wrote to all UK HEIs in his capacity as Chair of the House of Commons Science and Technology Committee, asking for information on the publication of annual reports and for information on whom to contact for either general information on research integrity or to raise a matter of concern in relation to research integrity. A letter asking for similar information was received from Professor Paul Boyle in his capacity as Chair of the Universities UK Research Policy Network later the same month. REITG assisted in compiling the response to both letters. We were able to supply all the requested information and confirm that we met the three stated commitments of the Concordat.

5. Dr Bailey attended the UK Research Integrity Organisation annual conference to learn about best practice and new developments in research integrity, including the implications of the new data protection regulations, which fed into revisions to the Research Code of Conduct. The University is a member of UKRIO (Commitments 1,3).
6. REITG have prepared this report as the annual report for the University on research integrity issues (Commitment 5).
7. REITG completed the UKRI assurance questions relating to Ethics and Integrity. These are shown in Appendix 2 (Commitment 5).

4. Related Developments

The current report has concentrated on the work of REITG but other groups have carried out work relevant to research integrity. These developments are reported briefly here.

University Ethics Committee

- The Committee has revised the structure of its sub-committees, following several departmental mergers, to adapt to changes in University structure. As a result, a number of new departmental ethics officers and administrative assistants have been appointed (Commitment 2,3).
- A need for additional external lay members for the main and sub-committees was identified, to ensure external representation meets funders' guidance. Some additional members have been appointed and recruitment for the rest is ongoing (Commitment 2,3).
- The University Ethics Committee has overseen a programme of improvements to the online ethics review system. These included changes to the internal reporting structure to reflect the new sub-committee structure, new functionality to allow completion and review of final reports on projects, and minor bug fixes (Commitment 2).
- The University Ethics Committee held an away day for all members of ethics committees to bring them up to date with developments in the online system and latest external issues as well as giving them an opportunity to share local policy and practice. Topics covered included the Prevent Duty, GDPR regulations and specific issues raised in the context of increased research in international contexts (Commitment 3).
- The University Ethics Committee has agreed to assume responsibility for research integrity and the Prevent Duty from October 2018. Some training and information-sharing will be required beforehand to ensure that this is accomplished successfully and the membership and structure may need amending.

Research Governance

- The Research Governance team oversees the processes by which the University ensures all NHS-related research complies with relevant legislation. The five member team used to be part of the College of Life Sciences but is now part of Research and Enterprise Division. Their work contributes to the first four commitments of the Concordat.
- All research activity taking place in the NHS requires a Sponsor, and the Team oversees all projects where the University is acting as sponsor. It supports researchers in obtaining ethics and Health Regulatory Authority approval, as well as assisting with planning projects and undertaking ongoing monitoring. Ethical review of such research is undertaken by the NHS Research Ethics Committee based in the NHS, rather than the University Ethics Committee.

- During 2017-18, the reporting line for the Research Sponsorship Committee – which oversees cases of research misconduct relating to projects where the University is Sponsor – has been strengthened. The Committee now sends minutes and annual reports to the Research Strategy, Policy and Performance Committee. In addition, the links to the Research Code of Conduct, the reporting of research misconduct in this area and the links to the University’s discipline ordinance have been clarified (Commitments 1,2,3).

5. Resource implications

Funding has already been secured for the licence for the online training module and the upgrades to the online ethics review system.

6. Risk factors

There are potentially major reputational risks to the University if an incident of research misconduct were to take place and the University were perceived not to have appropriate systems and training in place, or failed to report this appropriately. The University has publically endorsed the Concordat and to be seen not to be adhering to the five principles would constitute a reputational risk.

Under the RCUK assurance requirements, failure to provide adequate responses to the assurance questions risks reputational damage with key funding bodies and, in the extreme, removal of funding. Any block on access to research funding would have very serious financial and reputational implications.

The University must also be seen to investigate allegations of research misconduct fairly, and to deal appropriately and promptly with the findings.

The work undertaken this year has highlighted that ethics, integrity and Prevent – all key areas in research compliance – are under-supported.

7. Equality implications

Throughout its work REITG has sought to ensure that all those whom the Code covers are treated equally by its provisions.

8. Conclusions

REITG has continued to work to ensure that the University has the required procedures and policies in place to comply with the commitments of the Concordat, and that researchers are helped to understand what it means to carry out research with integrity, and the standards the University expects of them.

The launch of the online training modules directly supports Commitment 5 of the Concordat (*working together to strengthen the integrity of research and to reviewing progress regularly and openly*) which was identified previously as the one where most work still needed to be done.

The changes to the University Ethics Committee structure and approval systems underline the University’s commitment to *ensuring that research is conducted according to appropriate ethical, legal and professional frameworks, obligations and standards* (Commitment 2). The same applies to the changes to research governance reporting.

9. Recommendations

That this report be approved as the University’s 2018 annual report on research integrity and be made publically available.

10. Actions required of the Committee

The Committee is asked to note the work of the REITG and approve the report as the 2018 annual report.

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Dr Juliet Bailey, Member and Secretary, REITG & Head of Research Strategy & Policy, Research and Enterprise Division

With contributions from all REITG members.

Date of report: 6 June 2018

Appendix 1: Membership and Terms of Reference

Membership:

- Prof. Mark Jobling (Chair: CMBSP, Genetics & Genome Sciences)
- Prof. Jo Brewis (CSSAH; until April 2018, Business)
- Prof. Paul Cullis (CSE, Chemistry)
- Prof Jose Miola (CSSAH, law)
- Dr Meera Warriar (RED: Doctoral College)
- Ms Lynne Parsons (RED: Research Strategy & Policy Team)
- Mr Peter Alfano (RED: Doctoral College)
- Mr Howard Taylor and later Mr Edward Matts (IT Services)
- Dr Juliet Bailey (also Secretary; RED: Research Strategy & Policy Team)

Reports to: University Ethics Committee

Terms of Reference:

- a) To ensure the University's Code of Conduct for research is up to date;
- b) To ensure suitable training is available for all researchers on ethics, integrity and intellectual property;
- c) To communicate the Group's work broadly across the University;
- d) To report to Council on the implementation of the Concordat;
- e) To consider and record the potential equal opportunity impacts of decisions made by the Group (in accordance with the 'due regard' provisions of the Equality Act 2010).

Appendix 2: RCUK Assurance Questions: Research Ethics & Integrity

Research Organisations are required to have procedures for governing good research practice, and for investigating and reporting unacceptable research conduct that meet the requirements set out in the Concordat to Support Research Integrity (2012)¹ and the Research Councils' Code of Conduct and Policy on the Governance of Good Research Conduct (2009)² and any subsequent amendments. The reasons for collecting the information are:-

- *Primarily to provide assurance to the RCs that HEIs are complying with RCUK Policy and Guidelines on the Governance of Good Research Conduct:*
- *But also, to feed in to RCUK's narrative statement in meeting the requirements of the Concordat; and*
- *To allow RCUK to compare the data it receives from HEIs as part of the assurance programme with other information about research misconduct received by other routes, either from HEIs or from elsewhere.*

RCUK plans to make public annually:

- *Numbers of HEIs where the Assurance programme has received that the HEI has and has not complied with RCUK guidelines on statements/processes/name responsible persons*
- *Numbers of formal investigations of research misconduct that have been undertaken in the past three years which relate to researchers funded by or responsible for funding from Research Councils (including Supervisors or postgraduate awards (Q11.5)*
- *Trend data on the above (following year one)*

No HEI will be named. It is recognised that numbers will need careful explanation as increases may be 'good' as they may reflect better reporting.

NB: The RCUK Policy and Guidelines requires Research Organisations to keep the relevant Research Council(s) informed of all allegations of research misconduct – at the time the allegation progresses to the formal investigation stage – whether the case concerns individuals and/or research awards funded by the Council(s).

We expect that the format and timing of this report may change in future years as RCUK has been replaced by UKRI.

QUESTION	RESPONSE
i) Please confirm that you have policies and procedures in place that meet Research Integrity and	<p>We confirm that the University of Leicester has policies and procedures in place that meet Research Integrity and Ethics requirements, including processes for dealing with allegations of misconduct.</p> <p>The University's Code of Conduct for Research sets out the University's commitment to integrity in research. It is underpinned by a range of other codes, each of which lay out in more detail the specific responsibilities of researchers in</p>

¹ www.universitiesuk.ac.uk/highereducation/Documents/2012/TheConcordatToSupportResearchIntegrity.pdf

² www.rcuk.ac.uk/RCUK-prod/assets/documents/reviews/grc/RCUKPolicyandGuidelinesonGovernanceofGoodResearchPracticeFebruary2013.pdf

<p>Ethics requirements, including processes for dealing with allegations of misconduct. How often are these reviewed and when were they last reviewed?</p>	<p>these areas (e.g. ethics codes, intellectual property policy, sensitive research policy, etc.). The Code of Conduct for Research underwent major revision in 2011 and again in October 2014 and June 2018, with minor updates in between, approximately annually.</p> <p>The University's processes for dealing with research misconduct by staff form part of the Discipline Ordinances which were extensively rewritten in 2011. They are based on the UK Research Integrity Office procedure. The Discipline Ordinances were reviewed by Human Resources at the same time as revisions to the Research Code of Conduct and found to still meet internal and external requirements.</p> <p>The University's academic regulations for students make provision for the handling of cases of research misconduct under Senate Regulation 11: Regulations covering student discipline (http://www2.le.ac.uk/offices/sas2/regulations/documents/Senatereg11-discipline.pdf). This was last updated in August 2017.</p> <p>The Standard Operating Procedure for dealing with allegations of research misconduct in clinical trials sponsored by the University was updated in 2018, and the reporting lines for the Sponsorship Committee were amended.</p>
<p>ii) Please provide the publicly accessible web links to these policies and the name of the senior officer responsible for dealing with cases of misconduct.</p>	<p>The weblink to the Research Code of Conduct is http://www2.le.ac.uk/offices/researchsupport/policyandstrategy/research-code-of-conduct-and-ethics.</p> <p>The Senior Officer responsible is the Pro Vice Chancellor (Research and Enterprise) Professor Iain Gillespie, who is also Chair of the Research Strategy, Policy & Performance Committee.</p> <p>The Ethics Code of Practice can be found at https://www2.le.ac.uk/institution/ethics/code.</p>
<p>iii) How are these policies disseminated to staff? Please indicate if any special provision is made for new employees (including post-graduate students) and also how staff awareness is maintained.</p>	<p>Policy updates, and general updates on ethics and integrity, are disseminated through the University Ethics Committee which has representation from ethics sub-committees and is the key link to staff and students based in our three Colleges. They are also reported at the main Research Strategy, Policy and Performance Committee and amended policies are approved via Senate.</p> <p>The Research Sponsorship Committee oversees procedures and monitoring of University-sponsored clinical trials, and disseminates updates more widely through its members. From March 2018, this provides regular reports to the Research Strategy, Policy and Performance Committee.</p> <p>A quick link to the Research Code of Conduct is available via University website A-Z to assist colleagues in finding information on integrity.</p> <p>PDF versions of a booklet on research integrity are emailed to students - masters and doctoral, both campus-based and distance learning – as part of the new starters' packs. The online induction resources for PGRs also point to the research integrity pages.</p> <p>In February 2018 we launched online training for postgraduate research students, comprising five subject-specific modules covering all aspects of research integrity.</p>

	<p>These are available via the virtual learning environment to both campus-based and distance learning students, and completion of these will be made mandatory beginning with cohorts starting in October 2018.</p> <p>Research methods and design training, including understanding ethics and ethical review processes and questionnaire design, are a major part of introductory modules for PhD research in relevant subjects.</p>
<p>iv) Please outline any actions and activities that have been undertaken to support and strengthen understanding and application of research integrity issues (for example, postgraduate and researcher training, or process reviews).</p>	<p>The Research Ethics and Integrity Training Group (REITG) reports via the University Ethics Committee to the University's Research Strategy, Policy & Performance Committee. REITG has been active, in various forms, since the start of 2014, but after July 2018 its work will be taken over by a sub-group of the University Ethics Committee. Oversight of reviews of research impacted by the Prevent agenda will also fall under the University Ethics Committee from next academic year.</p> <p>REITG includes representatives from each of the three Colleges with expertise in relevant areas, alongside professional services colleagues with specialist knowledge. The group calls upon additional expertise when required.</p> <p>During the last 12 months, extensive work has been undertaken to customise the five subject-orientated modules on integrity within the Epigeum online training courses, funded by the University in 2016. All modules have now been rolled out to post-graduate research students on a voluntary basis, but completion will become mandatory from October 2018.</p> <p>Colleges and departments have continued to offer their regular courses in aspects of research integrity such as plagiarism and authorship, data storage, intellectual property, etc. The Library also supports students and staff with workshops and online material on open access, authorship etc.</p> <p>The formation of the new Doctoral College (DC) in October 2017 brought together support for research students and early career research staff in one place. The DC have already begun incorporating integrity elements into the ethics training for research students, particularly in relation to data integrity, and publication ethics, and linking it also to data management practices. The Epigeum modules are to be made mandatory (with pass/fail mandated through a test at the end of the course) from cohorts starting from October 2018. Also integral has been the use of case studies (e.g. The Lab simulation exercise is done with cohorts on the NERC doctoral training partnership to good effect). The DC is also rolling out work with research staff and ECRs in each College to increase awareness of good practice around research integrity, data management and open access, and to help researchers understand the connections, and appreciate what it means for their research.</p>
<p>v) The Research Councils expect that the research they support will be carried out to a high ethical standard. Please explain the arrangements</p>	<p>Oversight of University ethical review and ethics policies lies with the University Ethics Committee.</p> <p>When making an application for external funding, staff are required to indicate on their internal application approval form whether or not ethical review is required for their project, and whether approval would come from the University or NHS ethics committee. For projects falling within the remit of NHS ethics review, the University's Research Governance Office, which also sits within RED, provides dedicated expertise and has close links to the local NHS trusts and ethics committees.</p>

<p>you have in place for reviewing that any research funded by the Councils is planned and conducted in accordance with such ethical standards.</p>	<p>An online ethics review system is used for all non-NHS research. All staff and PGR ethics applications must be submitted via this system for consideration by one of six research ethics committees. Where an undergraduate or taught postgraduate research project is deemed risky, this may be escalated to the relevant research ethics committee for consideration. The system provides online video tutorials to take applicants through the questions and the ethical issues they need to consider under each section. This system was comprehensively updated during 2017-18.</p> <p>The committee can approve the application without change, or request amendments to, for example, protocols or questionnaires. It can also request mid-point reviews or updates if it feels a project merits additional oversight. Any changes to the research design have to be communicated through the system with either an amendment to the online application, or a new application where there are significant changes to the original design.</p> <p>All ethics committees are required to include lay members who are independent from the University. A number of new lay members have been appointed in the current period and additional new members are being sought.</p> <p>All staff with responsibility for approving the ethics applications of undergraduate and taught Master’s students, as well as those sitting on ethics committees, must attend a training session prior to being able to authorise any ethics application.</p> <p>Research support staff will only allow externally-funded projects requiring ethical approval to proceed from award to activation stage once the PI has supplied the ethics approval code and the approval date. These are recorded as part of the project details within the finance system.</p> <p>Following changes to departmental structures within the University, UEC reviewed the structure of ethics sub-committees and the new structure came into operation in October 2017.</p>
<p>vi) How many investigations of research misconduct have been undertaken in the past three years which relate to researchers funded by or responsible for funding from Research Councils (including supervisors of postgraduate awards)?</p>	<ul style="list-style-type: none"> • <i>“The relevant date should be when the investigation <u>is completed</u>”</i> • <i>By completing Annex 1, please give by academic year (1 Oct – 30 Sept), for the past three completed academic years (starting with the most recent completed year), the number of completed investigations</i> <i>And for <u>each</u> instance:</i> <ul style="list-style-type: none"> ○ <i>Whether it was fabrication, falsification, plagiarism, misrepresentation, breach of duty of care or improper dealing with allegations of misconduct (as defined in the RCUK policy pages 6-7), or other (if other, please explain briefly); and</i> ○ <i>Whether the allegation was upheld (in whole or in part). If in part, please give brief details in the final row</i> • <i>Names of individuals are <u>not</u> required</i> • <i>In terms of overall numbers, there are no ‘right’ or ‘wrong’ answers</i> <p>There are no investigations relating to RCUK grant holders or researchers to report for the period 1 October 2016 – 30 September 2017, or for the previous two years. This is the most recent full academic year for which figures are available.</p>