

UNIVERSITY OF LEICESTER

COUNCIL

1 OCTOBER 2019

Annual Report on Research Integrity 2018-19

Purpose of this report

1. 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 umbrella body reported to by the Research Councils.
2. The *Concordat* recommends that all Universities should present a short annual statement to their governing body (i.e. Council) and that this report should include a summary of actions and activities that have been undertaken to support and strengthen understanding and application of research integrity issues.
3. This report forms the 2019 statement for the University of Leicester, covering August 2018 to July 2019, and supports Commitment 5 of the *Concordat*.

Background

4. The *Concordat to Support Research Integrity* was launched in 2012 with support from the Government, HEFCE (now Research England) and major research funders such as RCUK (now part of UKRI) and the Wellcome Trust. The University has publicly stated its commitment to the provisions of the *Concordat*.

Commitments

5. The key provisions of the *Concordat* are enshrined in five commitments:
 - i. We are committed to maintaining the highest standards of rigour and integrity in all aspects of research.
 - ii. We are committed to ensuring that research is conducted according to appropriate ethical, legal and professional frameworks, obligations and standards.
 - iii. 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.
 - iv. We are committed to using transparent, robust and fair processes to deal with allegations of research misconduct should they arise.
 - v. We are committed to working together to strengthen the integrity of research and to reviewing progress regularly and openly.
6. In line with the *Concordat*, this report will be made publicly available on the University website once approved. This report has also been considered by the University Ethics and Integrity Committee and the Research and Enterprise Committee as well as Council.
7. A Research Integrity Working Group (RIWG - Membership and Terms of Reference in Appendix 1) was set up in February 2019, as a successor to the Research Ethics and Integrity Training Group (REITG), to continue work on research integrity. RIWG reports directly to the University Ethics and Integrity Committee.
8. During the 2018-19 academic year, RIWG and REITG carried out activities in the areas listed below, which are summarised later in this report:

- i. Responded to the consultation by Universities UK (UUK) on a revised *Concordat for Research Integrity*;
- ii. Oversaw roll-out of mandatory online research integrity training for all postgraduate research (PGR) students starting from October 2018 onwards;
- iii. Obtained funding from the University for renewal of the licence for online training;
- iv. Attended external research integrity events;
- v. Worked with Human Resources (HR) and Research and Enterprise Division (RED) to draft a process for the smoother management of research misconduct cases;
- vi. Prepared responses to the UKRI assurance questionnaire for the audit in July 2019;
- vii. Supported HR, RED and the Pro-Vice-Chancellor (Research and Enterprise) in managing allegations of research misconduct;
- viii. Wrote the 2019 Annual Report on the implementation of the *Concordat* for Council.

Research Councils UK Integrity Assurance

9. 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, to meet the requirements set out in the *Concordat* and the UKRI Policy and Guidelines on the Governance of Good Research Conduct. At the University of Leicester these are embodied in the Research Code of Conduct.
10. In July 2019, the UKRI will visit the University for the regular, three-yearly audit, the first since 2016. As part of the audit process, universities are expected to provide responses to questions on research integrity and misconduct. Our responses for the 2019 audit are given in Appendix 2.

The Work of the Research Integrity Working group in 2018-19

11. RIWG responded to a consultation, led by UUK on behalf of research funders, about revisions to the *Concordat on Research Integrity*. Whilst we were generally supportive of the proposed changes and the need to refresh the *Concordat* after seven years of operation, we were concerned about the implications of some proposals for HEIs, especially those related to training. The revised *Concordat* proposes that research integrity training be made mandatory for all researchers. We argued for a phased implementation of some of the requirements to allow HEIs time to develop suitable training and processes. The proposed revisions were also discussed at the annual UK Research Integrity Organisation (UKRIO) Conference, where our representative was able to highlight our concerns in more detail directly to UUK and UKRI (Commitments ii and v).
12. In mid-2016, the University funded 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, and a post-course questionnaire. RIWG ensured that the content was customised and also that the PGR regulations for completion of probation were updated to include completion and passing of this course. The course is available to all PGRs and those who start their courses from October 2018 onwards must complete and pass the relevant module by the end of their first year (second year for part-time PGRs) in order to pass probation (Commitments ii, iii and v).
13. The University has funded a further 3-year licence for the Epigeum modules, ensuring that PGR training will continue. The modules are being refreshed and updated (Commitments ii, iii and v).
14. Dr Bailey attended the UKRIO annual conference to learn about best practice and new developments in research integrity. The University is a member of UKRIO (Commitments i and iii).
15. Although the Research Code of Conduct outlines how allegations of research misconduct will be dealt with, recent cases have identified areas where processes could be improved. In particular, they highlighted how HR and RED could work together more smoothly, particularly in more complex cases. In addition, a recent case involving staff at multiple HEIs illustrated how work across HEIs might be

facilitated. As a result of these experiences, a process and flowchart have been prepared for use by RED and HR in future cases (Commitment iv).

16. UKRI will be visiting the University in July 2019 for their regular audit; they visit every HEI about once every three years. As part of the preparations, RIWG, RED and HR completed the UKRI assurance questions relating to Ethics and Integrity (Commitment v).
17. The UKRI audit questionnaire requires that we report on all cases of research misconduct involving staff or PGRs with UKRI funding that were completed in the last three years (Appendix 2). As the UKRI reporting requirements have changed recently and the report covers three years rather than one, the number of cases reported is different to that seen in previous annual reports to Council. In this three year period, there was one case which did not proceed to a formal investigation and four which did. Of these, one was not determined as the member of staff left, one allegation was not upheld and two were upheld in part. We also had our first case where a member of our staff was assisted to take forward a case involving collaborators from another HEI, with a satisfactory outcome. (This is not reported in Appendix 2 as this reflects only allegations against our staff.) RIWG worked with HR, RED and the PVC (Research and Enterprise) to support the investigation and management of all these cases (Commitment iv).
18. We received more research misconduct allegations over the last 18 months than in the previous 18, but this does not mean that misconduct is becoming more common. Rather, as acknowledged by UKRI and other research funders, a rise in cases would be expected as awareness increases of what good research conduct entails and researchers become clearer about how to report allegations. Awareness has been increased also recently following reports in both scientific and popular media of a number of high profile cases. It is too early to say if this increase will be sustained or results from random fluctuation, but, over time, as understanding of good practice grows and becomes embedded, we would hope to see a decline in both allegations made and upheld.
19. RIWG prepared this annual report (Commitment v).

Related Developments

20. The current report has concentrated on the work of RIWG, but other groups have also carried out work relevant to research integrity. These developments are reported briefly below.
 - a. University Ethics and Integrity Committee
 - i. The University Ethics and Integrity Committee (UEIC) oversees the processes to ensure good research is facilitated through a robust ethical framework with strong reporting procedures, and strategies designed to minimise the potential for harm. It provides a training framework for ethics for supervisors and researchers so they can map their strategy and work onto the broader ethical objectives of the Institution. The work of the UEIC promotes the understanding that ethics often operates in a risky and uncertain environment, and hence must conform to key principles, provide safeguards and be responsive to risk. A key objective is to safeguard the reputation of the University, participants involved in research projects at all levels (UG, PGT, PGR and staff), and the research teams. This activity maps on to all of the five key commitments.
 - ii. UEIC carried out a light-touch review of the Ethics Code of Practice to update names, weblinks, etc. A full review is planned for 2019-20 (Commitments i, ii and iii).
 - iii. An annual report was prepared and presented to Research and Enterprise Committee and Senate (Commitments ii and iii).
 - iv. UEIC oversaw the commissioning, development and deployment of a range of improvements to the online ethical review system, which included a robust procedure for reviewing and

auditing research projects to ensure compliance with our ethics and integrity code of conduct (Commitments i, ii and iii).

- v. UEIC held an away day for all members of research ethics committees to launch the developments in the online system and to discuss changes to the external landscape. Topics covered included the Prevent Duty, GDPR regulations and specific issues caused by the increasing amount of international research carried out, particularly the ODA agenda (Commitments i, ii and iii).

a. Research Governance

- i. The Research Governance Office (RGO) oversees the processes by which the University ensures all NHS-related research complies with relevant legislation. Their work contributed to the first four commitments of the Concordat. All research activity taking place in the NHS requires a sponsor, and the Office oversaw all projects where the University is acting as sponsor. It supports researchers in obtaining ethics and Health Regulatory Authority and Medicines and Healthcare Regulatory Agency 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 and Integrity Committee as required by the HRA (Commitments i, ii and iii).
- ii. RGO delivered researcher training covering all applicable legislation and guidance including Good Clinical Practice (GCP R2) as well as organisational policy. The training set expectations for researcher conduct. This training was available to all researchers conducting research in the NHS. The Team also provided an advice phone line for researchers should they have any queries regarding research (Commitments i, ii and iii).
- iii. During 2018-19, the first annual report on RGO activity was prepared and presented to Research and Enterprise Committee and Senate (Commitments ii and iii).

Risk factors

21. A number of integrity-related risks have been identified, many of which could have serious consequences for the University, should they arise. The table below sets out:

- The key risks and potential consequences;
- Identified mitigations;
- Risk before mitigation (high / medium / low : red / amber / green);
- Residual risk after mitigation.

Risk and consequences	Mitigation	Initial risk	Remaining risk
Loss of expertise in ethics and integrity due to staff departures impacts on support for integrity allegations, ethics review etc.	A replacement has been appointed to cover these areas, but it will take some time until they are fully up to speed.	High	Medium
Failure to have appropriate integrity and ethics systems and training in has potential for reputational and financial damage.	Online integrity training compulsory for PGRs from October 2018. Ethics training required for researchers and ethics officers. Systems and processes regularly reviewed.	High	Medium
Failure to investigate allegations of research misconduct fairly, and to deal appropriately and promptly with the findings has potential for reputational	Research Code of Conduct sets out what misconduct is and how it will be investigated. Underpinned by Disciplinary Ordinance and also new process	Medium	Low

and financial damage.	flowchart.		
Failure to provide adequate responses to assurance questions risks reputational damage with key funding bodies and, in the extreme, removal of funding.	Work across professional services and with Colleges to ensure prompt and accurate responses to audits etc.	Medium	Low
Failure to have suitable systems for ethical review in place for both NHS and other projects, or fail to adhere to procedures, regulations and Codes is both a reputational and financial risk	UEIC and RIWG work together to ensure systems and processes are fit for purpose, updated regularly and non-compliance dealt with. Codes and processes disseminated widely to ensure awareness amongst researchers.	High	Low
Failure to adhere to any of the five principles of the Concordat, which the University has publically endorsed, is a reputational risk.	The publication of this report, along with the activities outlined, above provide assurance of commitment to the Concordat.	Medium	Low

Conclusions

22. RIWG 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.
23. The launch of the online training modules directly supports Commitment v of the Concordat (*working together to strengthen the integrity of research and to reviewing progress regularly and openly*) but this is still an area where much work is required. Expansion of our training to all researchers and relevant corporate services staff is a key next step which will require significant commitment of time and resources.
24. The updates to the research Ethics Code of Practice underline the University's commitment to *ensuring that research is conducted according to appropriate ethical, legal and professional frameworks, obligations and standards* (Commitment ii). The annual reports from RIWG, UEIC and RGO all underpin the same commitment.

Recommendations

25. That this report be approved as the University's 2019 annual report on research integrity and be made publicly available on the external integrity website.

Action required

26. Council is asked to note the work of the RIWG and approve this report as the 2018-2019 annual report on research integrity.

Lead Authors: Dr Michelle O'Reilly, Chair of the RIWG
Dr Juliet Bailey, Member and Secretary of the RIWG

With contributions from all RIWG members.

Date of report: 29 July 2019

Appendix 1: Membership and Terms of Reference

Research Integrity Working Group 2018-19

Membership:

Dr Michelle O'Reilly (Chair: CLS & CSSAH)
Prof Mark Jobling (CLS, Genetics & Genome Biology)
Prof Jonathan Barratt (CLS, Cardiovascular Sciences)
Prof Elizabeth Hurren (CSSAH, History Politics and International Relations)
Dr Chris Grocott (CSSAH, Business)
Prof Paul Cullis (CSE, Chemistry)
Dr Genovefa Kefalidou (CSE, Informatics)
Dr Alex Goddard (RED, Doctoral College)
Dr Shaun Monkman (RED, Research Governance)
Dr Michelle Muessel (RED, Research Governance)
Dr Juliet Bailey (RED, Research Strategy & Policy Team)

Reports to: University Ethics and Integrity Committee

Terms of Reference:

- a) To monitor sector developments, responding to consultations and similar exercises and ensure that these are reflected in the University's codes and procedures;
- b) To regularly review and update the University's Research Code of Conduct;
- c) To ensure suitable research integrity training is available for all researchers;
- d) To communicate the Group's work broadly across the University;
- e) To provide an annual report to Council on the actions of the Group and the implementation of the Concordat, ensuring this is externally and internally accessible on the web;
- f) 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: UKRI Audit Response on Research Integrity allegations

A	B	C	D	E	F	G	H							I						
Case Ref	Date first aware of allegation(s)	Date of decision to hold informal investigation	Date informal investigation completed	Only complete if a formal investigation held			UKRI Research Council							Type of Research Misconduct						
				Date of decision to hold formal investigation	Date formal investigation completed	Outcome of formal investigation	AHRC	BBSRC	ESRC	EPSRC	MRC	NERC	STFC	Fabrication	Falsification	Plagiarism	Misinterpretation	Breach of duty of care	Improper dealing with allegations of misconduct	Other
CLS/01/2016	12/10/2016	24/10/2016	23/01/2017								X						X			
CLS/01/2017	24/10/2017			21/12/2017	22/02/2018	Allegation not upheld					X									X
CLS/02/2017	14/12/2017			11/04/2018	18/12/2018	Allegation partially upheld		X									X			
CLS/03/2017	05/09/2017			18/09/2017	05/10/2017	Undetermined				X										X
CSE/01/2018	15/05/2018			04/07/2018	27/07/2018	Allegation partially upheld			X								X			