COUNCIL *AND* RESEARCH AND ENTERPRISE COMMITTEE *AND*

UNIVERSITY ETHICS AND INTEGRITY COMMITTEE

June 2020

2020 report on Research Integrity from the Research Integrity Working Group (RIWG)

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 2020 statement for the University of Leicester, covering July 2019 – June 2020, 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 concordat was updated in 2019. 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. The revised Concordat builds on these commitments, providing clarification on specific areas to support researchers and employers to discharge their responsibilities.

7. In line with the Concordat, this report will be made publicly available on the University of Leicester website once approved. This report is being considered by the University Ethics and Integrity Committee and the Research and Enterprise Committee as well as Council.

8. 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.

9. During the 2019-20 academic year, 50% of formal meetings (up to the time of this report) were cancelled due to strike action. Members of the group met separately to drive forward activities in the areas listed below, which are summarised in the next section.

   I.   Liaised with United Kingdom Research Integrity Office (UKRIO) on the revised concordat to understand the implications for the University
   II. Built on the work undertaken in 2018-19 to introduce mandatory online research integrity training, by undertaking a training needs analysis for all researchers;
   III. Attended external research integrity events;
   IV. Prepared responses to the consultation by the Dignity and Respect Group on the internal Personal Relationships Policy;
   V.   Supported HR, Research and Enterprise Division (RED) and the Pro Vice Chancellor (Research and Enterprise) in managing allegations of research misconduct;
   VI. Wrote the 2020 Annual Report on the implementation of the Concordat for Council.

Research Councils UK Integrity Assurance

10. 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.

11. In July 2019, the UKRI visited the University for the regular, three-yearly audit, the first since 2016. The UKRI Funding Assurance Report was issued late 2019 with a positive finding. The Report used the responses provided and made reference to the University Research Integrity and Ethics policies and procedures. The Report also noted the workings and initiatives of the University Ethics and Integrity Committee together with its reporting structure. The Report did not make any recommendations or findings relating to research integrity and ethics. The recommendations in the Report, as expected, referred to minor improvements to costs charged to research grants. These were accepted by the University and improvement actions implemented.

Work of RIWG

12. The Chair of the RIWG consulted with UKRIO on the revised Concordat. It was noted that the University were meeting many of the updated commitments already due to previous work undertaken by the RIWG. Several actions were identified, the main action was to ensure appropriate research integrity training is provided for all researchers. (Commitments 1, 2, 3).

13. In mid-2016, the University funded a three-year licence for online training courses in ethics, integrity and intellectual property, supplied by Epigeum. 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. Members of RIWG met to understand if this training could be rolled out to all researchers to meet criteria in the revised concordat. It was identified that the online modules were not suitable for all

researchers. A training needs analysis and training material review is underway to support this requirement consulting with key stakeholders, including students. (Commitments 1, 2, 3).

14. Shaun Monkman, Ethics and Integrity Manager, attended the *Westminster Higher Education Forum Keynote Seminar: Next steps for protecting research integrity in the UK* to learn about changes to the research integrity landscape. In addition, Shaun represented the RIWG at a Universities UK round table discussion on the creation of a new national research integrity committee. The consultation was in response to recommendations made by the Commons Science and Technology Committee. (Commitments 1, 2, 5).

15. RIWG provided input and advice regarding the University of Leicester's Personal Relationships Policy from an integrity perspective. The RIWG were represented at the policy working group. The key recommendation from the RIWG was to map out existing policy and regulation that addressed relationships to ensure that the policy was consistent and did not raise any unnecessary discrimination issues.

16. We received one research misconduct allegation over the period of this report, which despite significant effort, the person making the allegations has not been able to provide any details to investigate. Should further details be provided then the complaint will be reopened. This is a similar number of formal allegations compared to the previous reporting year. With further mandatory training planned and general awareness of research integrity improving, we may see an increase in the coming year. (Commitments 4, 5).

17. RIWG prepared this annual report (Commitment 5).

Related Developments

18. 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 here.

   a. **Research and Enterprise Division**

   i. Creation of a new Ethics and Integrity Manager post

   It was reported to Council last year that there were significant risks to the University from loss of expertise in ethics and integrity due to staff departures, with impacts on support for integrity allegations, ethics reviews etc.

   The response to this risk was the creation of a new *Ethics and Integrity Manager* post, which was appointed to in October 2019 for a period of 1 year. The post oversees Ethics and Integrity central policy and processes, with a specific aim to ensure a joined-up approach. (Commitments 1, 2, 3, 4 and 5)

   To facilitate this collaborative approach the post holder inputs into the following meetings:

   - Research Integrity Working Group – Secretary
   - University Ethics and Integrity Committee – Secretary
   - Animal Welfare Ethical Review Body (AWERB) – Member
   - Human Tissue Act Committee – Member
   - Research Sponsorship Operational Management Group (NHS Research) – Member

It is of note that the post holder was appointed after a period of absence of previous staff who undertook similar work. In addition, during the past 18 months significant changes to legislation and guidance affecting research activity have occurred. There is a significant amount of work to be undertaken to update policy and processes as well as develop systems to implement these mandated changes.

ii.   Creation of a joint Research Ethics, Governance and Integrity Office (REGI)

The Ethics and Integrity Manager post was created as part of a small restructure in RED, the Research Governance Office was expanded to include Ethics and Integrity. The restructure concentrated on the creation of an integrated office which can drive real improvements in research conduct across the University. Previously, governance, processes, and advice were disjointed due to NHS and non-NHS research being managed in different ways. The aim of the new office is to create a "one stop shop" for researchers no matter what area their project falls under and will provide a firm foundation to allow changes to processes policy and guidance. (Commitments 2, 3)

iii.   Creation of a new website combining Ethics, Integrity and Research Governance guidance and process

The new REGI Office is creating a brand new website to support researchers, it is being completely re-written with the researcher at the heart. The driver of this project is the need to provide researchers with clarity on what they need to do to deliver high quality, robust, transparent research fit for the 21st century. (Commitment 2, 3)

iv.   Review of current ethics and governance processes

The REGI office are reviewing all current processes to ensure they are fit for purpose and clear to researchers. As part of this, members of the office are reviewing existing systems. Working with colleagues from other institutions to identify best practice. A plan will be formed to implement improvement changes to ethical and sponsorship approvals. This will build on the previous work undertaken to restructure the Ethics Committees. (Commitment 2, 3)

b. **University Ethics and Integrity Committee**

i.   The University Ethics and Integrity Committee (UEIC) oversees research processes to facilitate projects through a robust ethical framework with strong reporting procedures, and strategies designed to minimise the potential for harm. It provides an ethics training framework for supervisors and researchers so they are able to 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.   An annual report was prepared and presented to the Research and Enterprise Committee and to Senate. (Commitment 2, 3).

iii.   UEIC have an away day planned for all members of research ethics committees, this will include workshops by UKRIO and local experts in research data, human tissue and contracts. This will be held in the new academic year due to COVID-19. (Commitment 1,2,3).

c.   **Research Governance Office (RGO)**

i.   The RGO (now REGI) 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 Research Authority (HRA) and Medicines and Healthcare Regulatory Agency (MHRA) approval, and providing oversight of current studies, 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 1, 2, 3, 4).

ii.   REGI delivered researcher training covering all applicable legislation and guidance including Good Clinical Practice (GCP R2) as well as organisational policy. The training sets 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 1, 2, 3).

iii.   An annual report on sponsored research activity was prepared and presented to Research and Enterprise Committee and Senate (Commitments 2, 3).

4. Risk factors

19.   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
Failure to have appropriate integrity and ethics systems and training has potential for reputational and financial damage.	RWIG is working to identify or create suitable training. REGI are reviewing all ethics, governance and integrity processes to ensure fitness for purposes.	High	Medium
Failure to have suitable systems for ethical review in place for both NHS and other projects, or failure to adhere to procedures, regulations and Codes is both a reputational and financial risk. It has been identified that the current process and systems for Ethical approval and monitoring of research &	REGI, the RIWG and UEIC are working together to review IT solutions and updated policies and procedures to address this issue.	High	Medium

enterprise activity within the University of Leicester are lacking robust features to support the effective and efficient oversight of projects. The COVID-19 pandemic demonstrated that these systems had lagged behind the needs of the University as it was impossible to get a clear picture of the University's research activity from the current system.			
The Ethics and Integrity Manager post has been appointed in a time of unpreceded change. The post is critical to mitigating the risks presented in this report as well as implementing the required changes to policy, procedure and IT solutions to ensure that the University's research & enterprise activity is appropriately approved, overseen and conducted with integrity. Failure to ensure appropriate approval and oversight processes will have a significant impact on funding opportunities. The UEIC and RIWG have always had ongoing secretarial support which is critical to university business, this post also serves to cover this work. The post is fixed term until October 2020.	The Head of Research Ethics, Governance and Integrity is working to address this. This may be challenging given the current COVID-19 financial situation.	High	Medium
Failure to investigate allegations of research misconduct fairly, and to deal appropriately and promptly with the findings has potential for reputational and financial damage.	Research Code of Conduct sets out what misconduct is and how it will be investigated. Underpinned by Disciplinary Ordinance and new process flowchart.	Medium	Low
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 adhere to any of the five principles of the Concordat, which the University has publicly 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

5. Conclusions

20. The last 18 months has been an unprecedented time for changes in legislation, guidance and funder requirements, all of which are increasing the requirement for the University to have robust processes and procedures in place for approval and oversight of research & enterprise activity.

21. Due to the significant changes detailed in 20 above, current processes and IT systems are no longer fit for purpose and require work to update or replace.

22. There has been a period of reduced activity in relation to the above, and loss of institutional memory, due to staff leaving. However, the creation of the Ethics and Integrity Manager post and restructure of the REGI Office provides an optimal position for the University to drive compliance with the Concordat, streamline process and provide timely and accurate advice and guidance to researchers. This needs to be maintained going forward. Failure to comply with the Concordat would lead to reputational damage and withdrawal of research funding opportunities.

23. Significant work is required over a period of years to update, implement and embed revised Ethics and Integrity policy and procedures (and IT an integrated solutions) to ensure compliance, this position is consistent with other institutions.

24. RIWG, UEIC and REGI and the wider RED team are working together 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.

25. The review of training and implementation of new training modules will directly support Commitment 5 of the Concordat (*working together to strengthen the integrity of research and to reviewing progress regularly and openly*).

6. Recommendations

26. That this report be approved as the University's 2020 annual report on research integrity and be made publicly available on the external integrity website.

7. Actions required of the Committee

27. The Committee is asked to note the work of the RIWG and approve the report as the 2020 annual report.

Lead Authors: Dr Michelle O'Reilly, Chair

                        Shaun Monkman, Member and Secretary

With contributions from all RIWG members.

Date of report to UEIC: 27 April 2019
Date of Report to REC:
Date of Report to Council:

This report will be updated with any misconduct allegations reported during the time it take to pass through the committees.

Appendix 1: Research Integrity Working Group

Membership and Terms of Reference

Membership:

    Dr Michelle O'Reilly (Chair: CLS & CSSAH)

    Prof. Mark Jobling (CLS, Genetics & Genome Sciences)

    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 Genevofa Kefalidou (CSE, Informatics)

    Dr Alex Goddard (RED, Doctoral College)

    Mr Shaun Monkman (Research Governance Office)

    Dr Michelle Muessel (Research Governance Office)

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 Code of Conduct for research;
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 and 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).

Approved by RIWG: 26/02/2019 v2