### **Annual Integrity Report to Council 2015-2016**

The mission of the University of Cambridge is to contribute to society through the pursuit of education, learning, and research at the highest international levels of excellence. The University recognises that the pursuit of excellent research and the fulfilment of our responsibilities to participants in research, research users and the wider community require the maintenance of the highest standards of integrity and ethics. As such the University supports and is committed to upholding the Universities UK *Concordat to Support Research Integrity*.

This statement has been made to the University's Council to demonstrate that measures are being taken to sustain and further enhance the integrity of the research undertaken at the University. It is in fulfilment of recommendations made by the *Concordat* for annual reporting on research integrity to the University's governing body and covers the academic year 2015-16. As recommended by the *Concordat* this statement will be made publically available online.

This annual report has been designed to be a stand-alone document that does not require readers to consult previous years' reports. The report therefore repeats text from previous reports where this relates to structural aspects of the University's research integrity procedures and processes, as well as developments made in previous years that have continued to be important during 2015-16.

## Governance of Research Integrity at the University of Cambridge

The University of Cambridge recognises that supporting and strengthening the understanding and application of research integrity issues requires clear senior leadership. To ensure that research integrity is governed at a high level within the University, the Pro-Vice-Chancellor for Research (PVC-R) was appointed as the senior academic lead on research integrity matters within the University in October 2013. The PVC-R is responsible for providing academic leadership on research integrity and acts as the first point of contact for anyone with comments, concerns or questions regarding research integrity at Cambridge, fulfilling a recommendation under Commitment 3 of the *Concordat*.

The PVC-R is supported by the University's Research Strategy Office (RSO), from whom he receives reports on research integrity matters. A full-time Research Governance and Integrity Officer (RGIO) manages the RSO's responsibilities in this area. The RGIO supports the PVC-R, Head of the Research Office and University Research Ethics Committee (UREC) to oversee the University's research ethics and governance systems, foster a culture of research integrity across the institution and support the implementation of the University's Misconduct in Research policy. The RGIO is tasked with ensuring that actions are taken to embed the commitments of the Concordat into the University's research environment and ensuring that systems, practices and processes across the University are periodically reviewed so that they remain fit for purpose and reflect best practice in research integrity. The RGIO also provides researchers and staff with a clear point of contact for advice, support and guidance on research integrity, research ethics, legal requirements, and professional obligations and standards. The RGIO works with other administrative teams, including the Legal Services Office and Research Operations Office, to ensure that new ethical, legal and regulatory requirements are communicated and implemented effectively.

This is a permanent position and is central to the University's ongoing commitment to strengthen research integrity at Cambridge.

The UREC has also been given responsibility to 'advise the Pro-Vice-Chancellor (Research) on the development and implementation of policies and procedures relating to research integrity', particularly in relation to Commitment 2 of the *Concordat*. All changes to research integrity policies and procedures are commented on by the UREC before decisions are made by the University's central committees. To facilitate a joined up approach to research governance, the PVC-R and the UREC receive reports on research integrity matters from the RSO.

The UREC has responsibility for the co-ordination of the continual development and dissemination of the University's research ethics policies (excluding animal research) and has oversight of local and School-level Research Ethics Committees (RECs). Ethical review is primarily provided by local and School-level RECs. The UREC provides review to projects that are beyond the expertise of School-level RECs and hears appeals against local and School level RECs. The University's RECs report annually to the UREC so that potential concerns can be identified and addressed. The UREC undertakes continuous review and monitoring of the University's ethics system to ensure that it meets best practice standards and provides a streamlined and effective service for researchers. The UREC is also responsible for monitoring the implementation of the University's ethics policies, which is carried out primarily through their monitoring of local ethics committees and surveys of and consultations with departments. The UREC provides the University's RECs with advice and guidance; this includes an annual formal advice document and guidance documents based on specific issues. The UREC reports annually to the General Board and Research Policy Committee (RPC).

The PVC-R is Chair of the RPC. The RPC receives the minutes of the UREC and major issues or new policies relating to research integrity are referred to the RPC for consideration and approval. The RPC also refers research integrity matters to the General Board where necessary.

The University also has management procedures to ensure that consideration of the 3Rs (the Replacement, Refinement and Reduction of Animals in Research) are embedded into all aspects of our strategic operation management and a well-developed governance system for animal welfare. The <u>Animal Welfare and Ethical Review Body (AWERB)</u>, currently chaired by the Establishment Licence Holder, has regular meetings with the University's three Named Veterinary Surgeons and Named Animal Care and Welfare Officers and actively/directly oversees the management of governance. University Policies developed by the AWERB are implemented in all research facilities.

In any work involving animals of protected species, the policy of the University of Cambridge is to adhere to high standards of humane care and treatment of those animals. Research and teaching activities at the University involving animals considered to be sentient are governed by a range of legislation, including the Animals (Scientific Procedures) Act, 1986 and, in the case of teaching to veterinary students, the Veterinary Surgeons Act 1966. Compliance of research involving these species is monitored by University staff, including the Named Veterinary Surgeons, and by the Home Office through its inspectors. All members of the University carrying out procedures regulated under the Act must by law

have prior training, relevant experience, and authority from the Home Office. All projects affecting such animals are subject to prior formal ethical review within the University. Further details on animal welfare at the University are available here:

http://www.cam.ac.uk/research/research-at-cambridge/animal-research/our-policies/animal-welfare.

Heads of Department and Faculty are responsible for research integrity and ethics matters in their institution, including the implementation of the University's research ethics and integrity policies and procedures at a local level and taking initial responsibility for actions under the *Misconduct in Research* policy.

# Policies and procedures for supporting research integrity

Under Commitments 2 and 3 of the *Concordat*, the University is required to have clear policies and procedures to support research integrity.

The University's commitment to upholding the principles of the Concordat is set out in its *Statement on Research Integrity*, which is publically available on the University's Research Integrity website. The Statement explains the ways in which the University will support researchers to maintain the highest standards of integrity in research and publically highlights the role of the PVC-R as first point of contact for anyone with comments, concerns or questions regarding research integrity at Cambridge.

The Statement on Research Integrity has been designed to complement existing University policies and guidelines for supporting the highest standards in research. The University's Guidelines on Good Research Practice sets out principles of good conduct that all those engaged in research at the University are expected to follow. They cover a range of issues including openness, supervision, training, intellectual property, the use of data and equipment, the publication of research results, and ethical practice. The Guidelines provide a more comprehensive introduction to good research practice at Cambridge than the Statement on Research Integrity and highlight links to further guidance on key issues.

The Guidelines have also been developed into a *Research Integrity and Good Research Practice Checklist*, which is designed to help supervisors to provide research students with an introduction to issues of research integrity and encourage broader dialogue about good research practice. The *Checklist* is available as a <u>webpage</u> and downloadable document.

The University's approach to the governance of the ethics of research and the ethical review process are set out in the *Policy on the Ethics of Research involving Human Participants and Personal Data.* This policy provides guidance on the University's expectations of ethical practice in research, setting out guiding principles by which all research activities undertaken by University employees, or on University premises, must abide. It also offers clear guidance for those seeking and those undertaking ethical review of a project and the governance arrangements for the University's ethical review process. Heads of Department and Chairmen of Faculty Boards are responsible for implementing the policy at a local level and individual researchers and supervisors of research students are expected to familiarise themselves with their responsibilities.

The University also recognises that its position globally as a centre of research excellence comes with the associated responsibility of ensuring that all research with animals is

undertaken with a priority in achieving the highest welfare standards. This underpins the University Animal Welfare Policy.

As required by the *Concordat*, the University's policies are subject to periodic review to ensure that they remain 'fit for purpose'. During 2015-16 the University's *Policy on the Ethics of Research Involving Human Participants and Personal Data* underwent a review by the UREC. The review recommended a number of changes that were agreed by the General Board at their 4 November 2015 meeting. These changes included:

- Clarity that the policy applied to research undertaken by University employees outside the University and overseas;
- Reference to the University's *Guidelines on Good Research Practice* and *Research Integrity Statement* to ensure better policy integration;
- New guidance on research involving vulnerable groups;
- A new requirement for research ethics committees to provide clear guidelines on timetable for ethical review;
- Clarity that research ethics committee may also advise, where appropriate, on wider ethical issues raised by research projects and their outcomes.

As part of its regular consideration of research ethics practice in the University, the UREC has proposed further revisions to the policy, which will be brought to the General Board for consideration during 2016-17.

The regulatory/operational framework governing animal research underwent a review, concluding in August 2014, details of which are <u>available online</u>. The *Statement on Research Integrity* and *Guidelines on Good Research Practice* are due for review in 2017.

The policies listed above, together with other policies relevant to research integrity, are freely available online. Up to date links to these policies will be published as part of each Annual Research Integrity Report:

- Statement on Research Integrity: <a href="http://www.research-integrity-statement">http://www.research-integrity-statement</a>
  <a href="mailto:integrity-statement">integrity-statement</a>
- Guidelines on Good Research Practice: <a href="http://www.research-integrity.admin.cam.ac.uk/research-integrity/good-research-practice">http://www.research-integrity/good-research-practice</a>
- Policy on the Ethics of Research involving Human Participants and Personal Data: http://www.research-integrity.admin.cam.ac.uk/research-ethics
- Animal welfare policies: <a href="http://www.cam.ac.uk/research/research-at-cambridge/animal-research/our-policies">http://www.cam.ac.uk/research/research-at-cambridge/animal-research/our-policies</a>
- University Financial Regulations: http://www.admin.cam.ac.uk/offices/finance/regulations/
- Whistleblowing' Policy: http://www.admin.cam.ac.uk/offices/hr/policy/whistleblowing.html
- Policy Against Bribery and Corruption: <a href="http://www.admin.cam.ac.uk/offices/secretariat/bac/">http://www.admin.cam.ac.uk/offices/secretariat/bac/</a>
- Children and Vulnerable Adults Safeguarding Policy: <a href="http://www.hr.admin.cam.ac.uk/policies-procedures/children-and-vulnerable-adults-safeguarding-policy">http://www.hr.admin.cam.ac.uk/policies-procedures/children-and-vulnerable-adults-safeguarding-policy</a>

 Research Data Management Policy Framework: http://www.data.cam.ac.uk/university-policy

## **Cultivating best practice**

The University is committed to continually improving the way in which it works to sustain and enhance the integrity of research undertaken at the University. To achieve this, the University has taken the following actions during 2015-16.

In May 2016, following approval by the UREC and the RPC, the University subscribed to the UK Research Integrity Office (UKRIO). UKRIO is an independent charity, funded by subscriptions, that seeks to support researchers and research organisations in relation to matters of research integrity, research ethics and research misconduct. Joining UKRIO has given the University access to additional training assistance from UKRIO, UKRIO guidance documents and assistance, a register of UKRIO advisors for misconduct investigations, and assistance in developing and enhancing our guidelines, procedures and training. In addition, by subscribing, the University is supporting the UKRIO's advice service, which is available to anyone in need of assistance of advice with issues relating to research integrity. The University intends to utilise membership of UKRIO to enhance its support for research integrity, particularly through improved training. The University's membership of UKRIO is advertised on the research integrity website.

It was also agreed during 2015-16 to add a requirement for supervisors to "ensure that [graduate students] are aware of the University's expectations in respect of research integrity and good practice" to the <u>Code of Practice for Graduate Students</u>. This new text, together with a link to the *Research Integrity and Good Research Practice Checklist* will be included in the Code from 2016-17 onwards.

During 2015-16 the University undertook a major revision of its processes for supporting researchers to meet their obligations under Export Control law. A new export control policy, including a new process to manage applications for licences, was approved by the Research Policy Committee in June 2016 and the Head of the Research Office was formally appointed as Export Control Director. During summer 2016, the Research Governance and Integrity Officer has developed a new export control website, which is due to be launched in Michaelmas Term 2016-17 to support efforts to disseminate information on the new policy and export control legislation across the University.

The University has also taken steps to develop its processes for ensuring compliance with the Nagoya Protocol and the Regulation that implements it within the EU. During 2015-16 the Research Office has been consulting with a roundtable group drawn from relevant departments and administrative offices to develop advice and guidance on compliance with the Protocol. This will be considered by the RPC in Michaelmas 2016 with the view to launching the guidance and developing local compliance systems during 2016-17.

During November 2015 the University was subject to a Funding Assurance audit by RCUK, which included audit of the University's research ethics and integrity processes. A response to the audit questions was prepared by the RGIO. The report of the audit has been received and the RCUK note that "there is good evidence of very effective processes around...

Research Integrity and Ethics" and that "Research Ethics and Integrity procedures have been significantly enhanced since our last visit".

# Supporting and strengthening the understanding and application of research integrity issues

The *Concordat* requires institutions to take actions to maintain awareness among researchers of, and help them to comply with, institutional policies and processes relating to research integrity and ethical approval and the wider funder, professional and legal standards expected of them.

# Advice and guidance

Expert support and guidance on research integrity is offered throughout the University. Centrally the RGIO and the Clinical School's Research Governance Officer support researchers to understand and meet to expected standards of research ethics and integrity, as well as legal, professional, regulatory and funder obligations. Additional support and guidance on specific issues can be found throughout the central administrative offices, including the Research Office, University Biomedical Support Services, Health and Safety, Human Resources, the Information Compliance Office, Office of Scholarly Communications, and the Legal Office. Department and Faculty research ethics committees provide an additional source of support for researchers. Guidance can also be sought from School-level research ethics committees and the UREC.

The dissemination of research ethics and integrity policies and procedures has been identified as a key focus for strengthening the understanding and application of research integrity issues at Cambridge. Central to the University's awareness raising efforts is the maintenance of the <u>University research integrity website</u>. The website provides guidance on research ethics and research integrity, including the University's ethical review process for research. The site also provides links to the University *Misconduct in Research* policy and information on research ethics and research integrity training.

The site is managed and developed by the RGIO and is regularly updated with new policies and guidance, as well as links to external sources of support. The main addition to the website during 2015-16 has been the development of a new set of pages focusing on <a href="extension-ethics">ethics</a> application guidance. These pages have been developed in response to requests for better central guidance on research ethics approval, which has previously been provided at the local level. They seek to provide high-level, universal guidance that applies across the University's departments and faculties and are approved by the UREC before posting online. The initial pages focus on basic principles and consent forms and information sheets. Guidance on conflicts of interest and ethical review for research overseas are planned for 2016-17.

The University's *Statement on Research Integrity* has also been developed as a means of building awareness of research integrity. The *Statement* has been designed to act as a brief introduction to research integrity for new staff at Cambridge. It sets out the standards by which the University expects all its researchers, research students and visiting researchers to abide and provides links to other University policies that relate to research integrity. The *Statement* has been made into a leaflet, which is <u>available online</u> so that it can be integrated

into departmental and faculty training and induction. The leaflet is provided by the RGIO at central inductions for new postdoctoral staff and as part of centrally run training.

The research integrity website is also designed to act as a hub for anyone seeking information and guidance on research integrity issues at Cambridge; as such it provides links to guidance offered by Schools, departments, local research ethics committees and relevant administrative offices. Of particular importance is the University's guidance on animal welfare issues, which is provided on the <u>University's Animal Research webpages</u> and by the <u>University Biomedical Support Services (UBSS)</u>. Notable examples of online guidance provided elsewhere in the University include the clinical governance information provided on the <u>Clinical School website</u> and the detailed <u>guidance for research involving human participants in technology research</u> developed by the Schools of Technology and Physical Sciences.

Good data management practice is crucial for both the verification of research findings and to maintain the integrity of the research. In addition, <u>funders now require</u> that research data is properly managed during the research lifecycle and is made available at the end of research project/at time of publication. One of the key roles of the Research Data Management (RDM) Facility at the University of Cambridge is to create support services for research data management and sharing at Cambridge. In line with this, the RDM Facility conducts constant outreach and engagement with the research community, running information sessions, workshops and training on research data management, and organising <u>high level debates on research data management and sharing issues</u>. Since January 2015 the team have spoken with over <u>1800 academics</u>. In addition the Facility runs a Twitter feed (<u>@CamOpenData</u>) with over 1000 followers and sends out a <u>regular newsletter</u> to over 1700 recipients.

The RDM Facility provides researchers with <u>seven core services</u>: online information, advocacy and outreach, training, consultancy on data management, policy development and discussions with funders, data management plan support and data repository. Thanks to the intense programme of advocacy and training in data management and sharing delivered by the RDM Facility, the number of data submissions received by the University repository is continuously growing, with Cambridge holding more datasets in the institutional repository than any other UK university. A recent <u>Primary Research Group report</u> recognised Cambridge as having "particularly admirable data curation services". The Graduate School of Life Sciences in Cambridge responded to the overwhelmingly positive feedback on the research data management workshops by requesting to add the workshop to their compulsory core competencies training for first year students in 2016/2017.

The research community benefits from good research data management practice in terms of efficiency within their own research programmes, increased recognition for data that is shared through the ability to cite data that has a DOI allocated to it, and the ability to use other datasets made available. The University benefits from being recognised as a world leader in the development of research data management practices. The community benefits through a more cost effective use of research funds because work does not need to be duplicated.

Training, mentoring and events

Training has also been identified as a priority for the University's work to support research integrity. Face-to-face research integrity training has been available centrally since 2014. The course is open to all research staff and research students and aims to familiarise attendees with the University's policies and procedures for research integrity, ethics and misconduct. The course also uses case studies and discussion to explore key research integrity issues. During 2015-16 the number of sessions offered was increased due to demand.

The RGIO also offers bespoke training for departments, faculties and Schools where this is requested. During 2015-16 this included: training for all new PhD students in the School of Clinical Medicine, Department of Chemistry and Department of History of Art. All these courses will be repeated in 2016-17 and more developed on request. In addition to research ethics and integrity training, the RGIO provided an initial introductory session on the Nagoya Protocol for Biological Safety Officers on 17 May 2016.

Centrally the University also provides online or face-to-face training in areas such as good research practice, working with human subjects, data protection and health and safety. Training is provided by the University Biomedical Support Services for those seeking Home Office Licences. The RGIO also provides training to administrators on the University's ethical approval system so that they can better support researchers within their departments. This training was revised for 2015-16 so that it provided a more in-depth introduction to ethics and integrity, including case studies specifically designed to train administrators. Two new sessions specifically designed to help University librarians understand research ethics and integrity were also delivered in June 2016 as part of the Office of Scholarly Communication's Research Support Ambassadors scheme, which aims to help library staff better deliver front-line support to researchers.

Online research integrity training is in development and externally provided online training is promoted through the <u>research integrity website</u> and the Clinical School's <u>Research Governance website</u>.

Since 2015 departments and faculties have been expected to integrate the *Concordat* and all relevant University statements and policies, including the *Misconduct in Research* policy, into faculty or department inductions for new academic staff and PhD students. In addition to this, many of the University's departments and Schools offer subject-specific training in research integrity issues. The approach taken to this varies locally: it includes training that has been integrated into Departmental research skills courses; stand-alone lectures or workshops; School-level support, such as research ethics training offered by the Social Sciences' Research Methods Centre; and courses arranged with external providers, such as training sessions offered at the School of Clinical Medicine by the Human Research Authority. The School of Clinical Medicine also offered sessions on good practice in the use of research data, run by the MRC, and research integrity, provided by an external contractor.

Induction events for postdoctoral staff are run by the University's Office of Postdoctoral Affairs. The RGIO attends all such inductions to provide a brief introduction to research integrity and research ethics and to answer questions from attendees.

Mentoring plays a key role in building awareness and understanding of policies and procedures at Cambridge. The University formally requires that all its institutions make

arrangements for the mentoring of newly appointed staff and runs schemes for peer and developmental mentoring.

The University is also committed to raising the profile of research integrity matters through hosting relevant talks and events. On 13 June 2016 the UREC hosted its second Research Ethics Workshop. This is an annual event designed to raise awareness of research ethics issues and the ethical approval process. It consists of a series of talks relating to a specific theme (the 2016 theme was 'Interdisciplinary Research Ethics') followed by an extended question and answer session with members of the UREC. The event is aimed at training and supporting members of local research ethics committees and to raise awareness of ethical review and research ethics and integrity issues across the University.

The University also benefits from the work of the Ethics of Big Data research group at the Centre for Research in the Arts, Social Sciences and Humanities. This group provides fortnightly talks on issues relating to Big Data ethics (including research ethics) that are open to all. Details of their 2015-16 programme are available here.

The University is committed to the continuing and ongoing improvement of its processes for supporting and strengthening the understanding of research integrity at Cambridge and future efforts will be reported on in subsequent annual reports.

# Addressing research misconduct

As required under Commitment 4 of the *Concordat*, the University has a *Misconduct in Research* policy and procedure that sets out a transparent, robust, confidential and fair process for dealing with allegations of research misconduct. The policy provides a clear definition of research misconduct and the responsibility of members to report incidents of misconduct, whether these have been witnessed or are suspected.

The investigation procedure sets out a thorough process through which allegations are investigated by individuals with appropriate authority, qualifications and experience and no conflict of interest in the case. The procedure is clearly linked to disciplinary procedures contained within the University's Statutes and Ordinances to ensure that appropriate action can be taken when concerns are upheld. The procedure also ensures that allegations are investigated in an appropriately confidential manner.

The University is committed to ensuring that it meets all obligations to provide information on investigations of research misconduct to funders of research and professional and/or statutory bodies as required by conditions of grant and other legal, professional and statutory obligations, and will support researchers to do the same.

The *Misconduct in Research* policy, including details of the relevant contacts and procedures, is available on the <u>University HR website</u>. It is also highlighted on the <u>University research integrity website</u>, as part of research integrity training, within the *Good Research Practice Guidelines* and accompanying checklist, and in the research integrity leaflet.

Individuals seeking advice on the University's misconduct procedure are able to contact the PVC-R, the Academic Secretary, the RGIO, their Head of Institution and/or the relevant HR Advisor for the institution concerned.

The policy is appropriate to the needs of the University. To ensure that this continues to be the case, the policy is currently under review. A revised version of the policy has been approved by the UREC and is currently in discussion with various stakeholders before being considered by the RPC, Human Resources Committee and General Board.

Whistleblowers receive specific protections under the University's 'Whistleblowing' policy. Under the 'Whistleblowing' policy disclosures may be made to the Academic Secretary (in the case of Institutions under the supervision of the General Board) or the Registrary (in the case of all other University Institutions).

The University's *Misconduct in Research* policy sets out a two stage investigation process. Allegations are initially considered through a preliminary investigation and will progress to a formal investigation if a *prima facie* case that requires further investigation is identified at the preliminary stage. The *Concordat* requires that the University provide a high-level report on any formal investigations of research misconduct that have been undertaken during each academic year and to include it in this public statement. In the interests of transparency, the University has decided to also report on any preliminary investigations of research misconduct undertaken. The table below provides this report for the 2015-16 academic year.

Table 1: Investigations carried out under the University of Cambridge Misconduct in Research policy, 2015-16.

Type of allegation	Stage reached	Investigation result
Fabrication	Formal Investigation	Ongoing

#### **External engagement**

The *Concordat* recognises that a key part of successfully supporting a culture of research integrity in universities is for institutions to learn from each other and disseminate good practice. The sector has responded to this impetus and Cambridge has actively engaged with the resulting collaboration and sharing of good practice.

During 2015-16 the RGIO, Head of Research Office and Clinical School Governance Officer have been active participants in conferences and workshops organised by bodies such as the UK Research Integrity Office, Human Research Authority, MRC, Export Control Organisation, Regulatory Delivery (for issues relating to the Nagoya Protocol) and the Russell Group.

The RGIO is also a member of the Russell Group's Research Integrity Working Group, which has been established to ensure that good practice is shared and to support shared efforts to foster a research environment that nurtures research integrity. The RGIO is one of the organisers and presenters for the 2016 Russell Group Research Integrity Workshop, which will focus on 'Building a Culture of Research Integrity. The RGIO is also a member of the League of European Research University's Research Integrity Expert Group. In this role he has contributed towards the organisation of LERU research integrity activities and responses to European-wide consultations on research integrity issues.