

# University of Edinburgh

## Annual Research Ethics and Integrity Report to University of Edinburgh's Risk Management Committee

**Submitted by:** Research Policy Group (RPG)

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### Executive Summary

The University of Edinburgh is committed to ensuring that all its research is conducted in accordance with Universities UK Concordat to support Research Integrity (2012). This concordat is supported by all the key public funders of research, such as the Scottish Funding Council and Research Councils UK and major UK charities that fund research. Edinburgh was one of the first Universities to sign up to this UUK concordat.

The Annual report draws on information from the three College annual Research Ethics and Integrity reports. As the first report of this type it outlines the University's Research ethics and integrity policies and processes as well as the governance and monitoring arrangements at University, College and School level.

Subsequent annual reports will not reiterate information provided in this report but outline the outcome of reviews of research integrity policies and procedures, any changes made and good practice shared. A key feature of this report is the internal audit of research ethics procedures commissioned by the College of Arts, Humanities and Social Sciences. The internal audit report is being closely studied by the other two Colleges to maximise the lessons that can be learnt. The Annual Research Ethics and Integrity report also serves as a means of formally reporting incidents of research misconduct and subsequent learning points. Within the period covered (April 2014 - March 2015) the monitoring systems identified no such incidents. The report concludes by outlining any external activity that has been undertaken by University staff or is planned to support and strengthen understanding of research integrity issues. Of these activities, the most notable is that the University was asked to host the 13<sup>th</sup> World Congress of Bioethics.

The Annual Research Ethics and Integrity report has been approved for submission to Risk Management Committee by the University's Research Policy Group. RPG has oversight over all matters of Research policy. Through the Research Ethics and Integrity Review Group, which is a subgroup of RPG, it monitors compliance with the UUK Concordat. REIRG also ensures information on all aspects of research ethics and ethics and governance is up to date and promotes good practice.

As this is the first University Research Ethics and Integrity report, the scope of the report includes the governance of research under the aegis of the Animal Welfare and Ethical Review Body and the NHS Lothian Research Ethics Committee to give a complete picture. It is acknowledged that these bodies report separately through the University's governance structures but it was felt that on this occasion it would be helpful to include this material as the UUK Concordat is inclusive of research involving animals, human participants and tissue thereof.

After the report has been considered by the Risk Management Committee a copy will be uploaded to the University's Research Integrity website, which can be seen by anyone visiting the University's website.

## 1. Introduction

The University of Edinburgh is committed to ensuring that all its research is conducted in accordance with the five commitments set out in the [Universities UK Concordat to support Research Integrity \(2012\)](#). The UUK Concordat has the support of the four national Research Bodies as well as Research Councils UK, the NHS National Institute for Health Research and the Wellcome Trust. The Concordat is underpinned by the [RCUK Policy and Guidelines on Governance of Good Research Conduct](#) and the [UK Research Integrity Office's Code of Practice for Research](#). Edinburgh was one of the first UK universities to adopt this code of practice).

The UUK Concordat recommends that a short annual statement should be presented to University's governing body and made publicly available thereafter. This report is intended to serve that purpose. The report was approved by the Research Policy Group (RPG) following endorsement by the Research Ethics and Integrity Review Group (REIRG).

The Report illustrates the University's commitment to high quality and ethical research by declaring the practical measures taken to support research integrity. It is intended to drive internal review and catalyse further activity. The report is structured in accordance with recommendations set out in the UK Research Integrity Office's *Self-Assessment Tool for the Concordat to Support Research Integrity* (version 1.0, 2014). The scope of the UUK concordat covers staff and research postgraduates, however it is intended that there should be a gradual extension to cover all students not just research postgraduates. This is consistent with the [University's Strategic Vision 2025](#), which encourages "the Edinburgh offer" to see 'all of our undergraduates developed as student/ researchers with clear and, supported pathways through to Masters and PhD'.

### **The Report is intended to address the five commitments of the UUK concordat:**

- *We are committed to maintaining the highest standards of rigour and integrity in all aspects of research*
- *We are committed to ensuring that research is conducted according to appropriate ethical, legal and professional frameworks, obligations and standards*
- *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*
- *We are committed to using transparent, robust and fair processes to deal with allegations of research misconduct should they arise.*
- *We are committed to working together to strengthen the integrity of research and to reviewing progress regularly and openly.*

## 2. Supporting and strengthening research integrity

### **2.1 Outline of policies and processes in place in order to meet the UUK concordat and associated governance arrangements**

#### **2.1i Governance at the University level**

The Research Ethics and Integrity Review Group (REIRG) was established by the University's Research Policy Group (RPG) in autumn 2014 to ensure that research integrity and governance has a strong profile at Edinburgh and is firmly embedded in the University's ethos and culture.

REIRG is chaired by the Head of Research Support Office in Corporate Services Group (formerly the Research Office at Edinburgh Research and Innovation<sup>1</sup>), and its membership comprises the Head of

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<sup>1</sup> Since February 2016 the Research Support functions and staff of Edinburgh Research and Innovation have become the Research Support Office in Corporate Services Group

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Strategic Performance and Research Policy, the three College Research Officers, a representative of the University's Academic and Clinical Central Office for Research and Development (ACCORD), two senior members of academic staff and the University Data Protection Officer. Representatives from the University's Institute of Academic Development (IAD) attend on request. The University is developing a connected community of integrity professionals with key named individuals, through the coordinated actions of the Colleges and REIRG.

RPG has oversight of all aspects of Research Policy and, through REIRG, it both monitors compliance with the UUK *Concordat to support research integrity* and ensures that information on all aspects of integrity, ethics and governance is visible and up to date. REIRG identifies gaps in policy and procedure which it acts on directly or via a recommendation for action to RPG. It is intended that REIRG will, with support from IAD and the Colleges, plan a programme of events and workshops and facilitate the provision of online learning and development materials that promote awareness of good practice in regard to research integrity and ethics as well. IAD and REIRG members recognise that any new materials developed or adopted from other HEI bodies must reflect the differing needs of the diversity of academic disciplines represented at the University.

REIRG also acts as the University's point of contact with the UK Research Integrity Office (UKRIO) and ensures compliance with internal and statutory reporting requirements. Through annual reports from Colleges, it monitors the processes in place so that staff and research students know about the University's research and integrity policies and how to implement them. These annual reports also provide a record of any formal investigations of research misconduct. The reporting protocol satisfies the requirements placed upon the University by RCUK, the Scottish Funding Council and Wellcome Trust. The protocol is regularly reviewed to ensure it is up to date and continues to meet the requirements of funders.

The UUK Concordat is inclusive of research involving animals, human participants and tissue thereof. These two aspects of the Concordat are subject to governance arrangements that are outside the scope of RPG. Such activities are covered by specific Acts of Parliament and are monitored by the University Animal Welfare and Ethical Review Body and the NHS Research Ethics Committee, respectively. These Committees report separately to the Risk Management Committee. As this is the first Annual University Research Ethics and Integrity report, it does on this occasion extend to include the governance of research that is within the scope of the Animal Welfare and Ethical Review Body and the NHS Research Ethics Committee to give a complete picture.

### 2.1.ii Governance at a College Level

The majority of human research carried out by the College of Medicine and Veterinary Medicine (CMVM) relates to human participants, their data or tissues, and falls under the scope of the NHS Research Ethics Committee (REC) Review. The Research Governance Office and the Academic and Clinical Office for Research and Development (ACCORD) provide support to all researchers undertaking research is within the scope of the NHS REC so that ensure they are aware of all relevant ethics and regulatory requirements and that proposals comply with the relevant regulatory framework. The scope of ACCORD also extends to clinical trials of investigational medicinal products that fall under the Medicines for Human Use (Clinical Trials) regulations, and the department is regularly inspected by the Medicines and Healthcare products Regulatory Agency (MHRA) to ensure a high standard of regulatory compliance.

The services described above are also accessible to the College of Humanities and Social Sciences (CHSS) which employ a Research Governance Co-ordinator (0.5 FTE for the period of the period – to be increased to 1.0FTE as a result of a report described below). The post holder works closely with the CMVM team and reviews CHSS research ethics applications that require NHS REC review.

ACCORD works closely with the NHS Lothian REC service and oversees submissions for research legally requiring NHS REC review. Research involving any of the following potential activities legally requires NHS REC review (whether NHS patients or healthy volunteers are recruited):

Investigational medicinal products (IMP)	Midwives conducting a clinical trial
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Non CE-marked medical devices or CE-marked medical devices that have been modified or being used for a new purpose	Material consisting of or containing human cells, which has been taken from the living or the deceased
Exposure to ionising radiation	Analysis of DNA where there is no explicit consent in place
People who lack (or lose) the capacity to give informed consent	Processing of confidential patient information without consent

The NHS Lothian REC also considers proposals that involved prisoners either as NHS patients or healthy volunteers and has the authority to consider those relating to if required xenotransplantation<sup>2</sup>

Thanks to successful negotiation between ACCORD and NHS Lothian REC, a separate committee was established in 2014 to review CMVM projects (ACCORD Medical REC) involving healthy volunteers not falling under the categories above. These include research involving:

- administration of a substance that is not considered to be an IMP (defined as ‘any substance being administered by a doctor on his direct personal responsibility in order to investigate physiology or pathology in the context of medical science/research and not for the therapeutic or diagnostic benefit of the participants in the research’).
- CE marked medical devices
- Imaging studies involving volunteers for MRI
- Blood or other tissue sampling for lab based projects.

The use of student volunteers for experimental work is monitored by the CMVM Student Advisory Committee. For the most part experimental applications tend to be covered by a self-certification ethical review process with the committee itself considering requests to study the teaching and learning process within CMVM. This review process will be rolled out to each CMVM Schools carrying out research involving student volunteers and this will cover any projects not otherwise covered by existing ethical review procedures.

The Colleges of Humanities and Social Sciences (CHSS) and Science and Engineering (CSE) each have a Research Ethics and Integrity Committee, which is a sub-committee of their respective Research Committees. Each College’s Research Ethics and Integrity committee is chaired by their Dean of Research and have a membership drawn from senior academic staff from each school in the College in question. The CHSS committee meets once per semester. The CSE committee has a standing commitment to meet annually and other meetings of the CSE committee are arranged as needed. The responsibilities of the College Research Ethics and Integrity committees include rigorously examining Schools’ responses to the [RCUK Research Integrity Assurance questions](#). The RCUK questions are used to show that the Schools’ ethical procedures are consistent with the standards that RCUK expects of research organisations to which it awards funding. The collated answers from all three College to RCUK questions will enable the University to show to RCUK that it has procedures for governing good research practice and for investigating and reporting unacceptable research conduct that meet the UUK Concordat and RCUK *Guidelines on the Governance of Good Research Conduct*.

The Schools’ responses to the RCUK Research Integrity Assurance questions form the basis of the College reports for CHSS and CSE. The CMVM report is prepared by the College Research Office and outlines all research ethics monitoring activity with College.

Regarding research animal ethics, Central Bioresearch Services (CBS) within Corporate Services Group (CSG) is responsible for the day-to-day management and operation of all laboratory animal Biomedical Research Facilities (BRFs) The highest standards of animal welfare are adhered to under the guidance of the University’s Veterinary Services, which provide expert veterinary advice and direct Home Office liaison. A CBS Management Committee (CBSMC), reporting to CMVM, is made-up of key members of the research community and College administrators supporting the Director of CBS. Each BRF has unique design

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<sup>2</sup> The NHS Research Ethics Committee designated as the Gene Therapy Advisory Committee for Scotland and thus able to consider and approve research proposals involving gene therapy, embryonic stem cell therapy, therapeutic use of genetically modified stem cells or therapeutic xenotransplantation maps onto the NHS Lothian REC.

features matched to the research being conducted and has been built to the highest construction quality. All are served by High Volume Air Conditioning to maintain controlled temperatures and relative humidity at optimal environmental conditions for breeding.

CBS has the capability and expertise to oversee the husbandry and research needs for a number of laboratory animal species and each BRF is complemented with suites of specialist procedure rooms e.g. sterile surgeries, recovery rooms and observation rooms for behavioural phenotyping suites. CBS services include: Quarantine barrier rules and information on barrier control systems and observing quarantine; staff development and training; a wide range of technical services; specialist services, e.g. embryo import and export; computing regulations that refer to CBS; support to assist with common financial issues, etc.

The University's Animal Welfare and Ethical Review Board oversees all aspects of the ethical review process as defined by the (Scientific Procedures) Act 1986 as amended by the Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012, incorporating changes brought in by the European Directive (2010/63/EU) on the protection of animals used for scientific purposes. The Roslin Institute functions under a separate Establishment licence under the terms of the above Act and has similar review systems to ensure compliance. In addition to the Animal Welfare Board, Veterinary Medicine operates the R (D) SVS Veterinary Ethical Review Committee that serves the purpose of regulating all veterinary biomedical research by staff and supervised students involving animals that lies outwith the above-named Act.

The University was recently commended for its open approach to providing online information about its animal research by [Speaking of Research](#) – an international advocacy group that exist to present an accurate picture of the importance of animal research in medical and veterinary science. The University is one of only eleven Universities in the world to receive full marks.

### 2.1.iii. School Level processes

Each school in CHSS has a Research Ethics committee or subcommittee of its Research Committee. These committees are responsible for ensuring that ethical reviews of all research proposals are considered in a manner consistent with the UKRIO's *Code of Practice for Research*. The approval process followed depends on the nature of the research processes and can vary from a Level 1 self-assessment process to proposals at Level 2, 3 and 4<sup>3</sup>, which are considered either by a full meeting of Schools research ethics committee or members of that group as required. Some research within CHSS requires ethical approval by external bodies such as the NHS Research Ethics Committee and is referred accordingly. The expectation is that research in CHSS must comply with whatever is the most rigorous relevant ethical framework.

All CHSS Schools have a named individual who is responsible for dealing with allegations of research misconduct, publicly accessible websites hold information about the Schools' ethics and integrity policy including process for giving ethical approval for research proposals. Each School's process for reviewing research proposals is described in outline in the annual College report. The College report also states the arrangement each school has for the review of its ethics and integrity policies.

CSE Schools have similar processes to CHSS Schools. Research proposals that go beyond a Level 1 self-assessment are considered either by a standing Schools Research Ethics and Integrity Committee; an *ad hoc* Ethics committee with membership drawn from senior staff in the School; or the Research Committee of the School in question, reconvened as an Ethics Committee. Research conducted by staff of the School of Biological Sciences that involves animals or NHS patients or tissues thereof are referred to Animal Welfare and Ethical Review Board or the NHS Research Ethics Committee as appropriate.

Information about the Central and School level arrangements for dissemination and training are given below.

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<sup>3</sup> REIRG is developing a generic Research Ethics and Integrity form and is likely to follow UKRIO advice to have three levels for the assessment of issues of research ethics and integrity instead of four.

## **2.2 Introduction or revision of research integrity policies and procedures, requirements, process reviews or support mechanisms.**

REIRG undertakes a continuous review of the University's policies pertaining to research ethics and integrity and their practical application in order to identify good practices as well as gaps in knowledge and practice. At its meeting on 21 March 2016, REIRG considered the findings of an internal audit of the College of Humanities and Social Sciences Research Ethics and Integrity procedures, which is described in outline below.

At its October 2015 meeting, RPG agreed to adopt the UUK recommendations for ensuring compliance with those aspects of the '[Prevent duty](#)' that apply to the conduct of research. RPG has delegated to REIRG the responsibility for ensuring that schools amend their Research Ethics and Integrity procedures in accordance with the UUK recommendations for compliance. This activity is being monitored by REIRG with assistance from the secretary to RPG. In January 2016 the Deputy Secretary (Student Experience) held a 'Prevent' workshop for academic staff and research administrators to raise awareness of the implications of the Prevent duty in the context of research.

### **2.2.i Revision of related institutional systems (e.g. financial audit process or whistleblowing policy)**

During session 2014/15, the College of Humanities and Social Sciences (CHSS) commissioned an internal audit of the College's research ethics and integrity procedures and their application by staff within its 11 Schools. The audit considered the ethical approval processes followed by a sample of research conducted in a selection of HSS schools. In order to spread the examples of good practice and the learning points, CHSS agreed to share the findings and recommendations with other Colleges via REIRG and RPG.

The audit revealed the need for changes in some aspects of CHSS' processes and practices relating to research ethics and integrity and, in particular, the need to raise awareness. In general researchers in CHSS do consider ethical issues carefully. However the audit suggested that there was scope for further improvement by sharing the examples of best practice and that a programme of cross College awareness-raising and training activities would be beneficial. It is worth noting that the inconsistencies identified by the internal audit were most apparent as they related to research projects undertaken by undergraduates and those on taught postgraduate programmes rather than staff. There is an intention that all students at the University are gradually brought within the range of the University's undertaking to meet the commitments of the *UUK Concordat*, however it should be noted that currently only research postgraduates are within scope. The *UKRIO Code of Practice* does offer suggestions to those HEIs that wish to apply the Code to all their students.

CHSS senior management have not only accepted the audit's recommendations but have already started to act on them. The CHSS College Office has agreed to make a two-year 0.2 FTE appointment (with effect from August 2016) to provide leadership in this area and has increased the time allocated to the CHSS research governance coordinator from 0.5 FTE to full time. REIRG commends CHSS for the actions it has taken and those that are planned, which should take CHSS beyond simple compliance with regulatory frameworks to demonstrating thoughtful and responsible practice relating to ethics and integrity in across its research.

Several of the audit recommendations have University-wide relevance and the HSS internal audit report is being studied by both CSE and MVM.

### **2.2.ii Inclusion of relevant external requirements and guidance into institutional processes.**

As RPG has given outline agreement to bringing the University's research misconduct policy into line with the UKRIO procedure, The Convenor of REIRG and the secretary to RPG are working with central HR and Academic Services to put this agreement into effect. HR has agreed to develop a high level overview of the UKRIO procedure so that, in the event that an allegation is made which requires formal investigation, there is a clear pathway.

## **2.3. Dissemination and awareness-raising activities that you have undertaken.**

### **2.3.i Face to Face events - Central**

The majority of activities and events to raise awareness and disseminate information about the University's Research Ethics and Integrity procedures take place at the level of the School. REIRG works at a local level across the University through the College representatives who report back to their respective College Committees and Schools.

### **2.3.ii Face to Face Events - Colleges and Schools**

The Schools use their websites and intranets as well as induction programmes to make staff and students aware that the University is committed to the *UUK Concordat to support Research Integrity* and expects its staff to put the *UKRIO Code of Practice* into action either directly through their own actions or indirectly by teaching and supervising students.

Rather than list activity within each School, outlined below are a few examples of good practice in regard to face-to-face activity to disseminate information about the research ethics and integrity procedures. As the University is reviewing its centralised Research Ethics and Integrity training requirements for staff – an undertaking that the above-mentioned CHSS member of staff will be closely involved with on appointment most of the examples relate to support for students.

History, Classics and Archaeology: A talk on research ethics has been added to the briefing meeting that is held for all undergraduate students at the beginning of year four (shortly before they submit their dissertation proposal), which also entails the completion of ethics questionnaires.

Health in Social Sciences: Now has a requirement that Ethics status is included as a part of the PGR review board and is formally noted. It is also part of the PGR induction sessions and has a section within the PGR handbook.

Biological Sciences: the Graduate School runs an annual 'Research Ethics and Integrity' training day for postgraduate students, which largely focusses on misconduct and integrity issues. Other graduate development seminars in Biological Sciences deal with issues such as authorship and confidentiality.

Geosciences: Graduate School runs a research ethics and integrity module as a part of the Planning and Management course for postgraduate students.

Medicine: The Wellcome Trust Clinical Research Facility has run the Edinburgh Education Programme since 2003. It delivers over 70 training sessions each year and works to meet the changing requirements of clinical researchers locally and across Scotland. In addition to face-to-face teaching, it also uses web streaming to increase accessibility to the education programme.

The Wellcome Trust Clinical Research Facility offers courses, workshops, seminars, bespoke training; MSc/Dip/Cert in Clinical Trials by online learning; the Patient & Public Involvement Advisory Service; an Event Management Service; and National Clinical Research Training Database. Of particular note, the following courses cover aspects of understanding the forms of research misconduct including fabrication and falsification of data, plagiarism and improper attribution, and/or the consequences of poor practice and misconduct: Good Clinical Practice; Understanding Randomised Controlled Trials; Applying for Research Approvals using the Integrated research Application System; Research Data and Confidentiality; Legal and Ethical Issues in Consent; Data Management; Thinking Like a Researcher. ACCORD staff attend regular ongoing training to ensure they can support and advise researchers in the planning and conduct of their clinical research. ACCORD also delivers regular training sessions to the research community when ACCORD policies or Standard operating Procedures are updated.

### **2.3.iii Online - Central**

REIRG webpages are housed with the research pages of University's Governance and Strategic Planning (GaSP) unit. REIRG webpages are currently maintained by GaSP and there is a link to these pages from the recently established RPG wiki that is accessible to staff and students.

The REIRG webpages link to the UUK *Concordat to Support Research Integrity* and the UK Research Integrity Office's *Code of Practice for Research*. In addition, there are links to the following research funding bodies' codes of conduct: European Commission; The Wellcome Trust; The Leverhulme Trust; the National Institute for Health Research, and Research Councils UK. The REIRG webpages also provide links to relevant University material such as University's policies on Special Areas of Study (Human and Animal); the University's Research Data Management Policy; Procurement; Intellectual Property, Health & Safety and Research Misconduct.

The REIRG website is a repository for online training resources that are freely available for staff and students such as the Universitas21 Global Research Ethics and Integrity course and a MOOC on Research Ethics and integrity run by the University of Auckland. Other relevant material is available on the IAD website which is linked to the REIRG website. The IAD website also links to the Universitas21 course mentioned above reflecting the fact that those enquiring about training and development opportunities are more likely to access the IAD webpages. REIRG is working with IAD to review the centralised training requirements for staff and students.

GaSP intends to carry out a major review and update of its web pages once the migration to EdWeb is complete. The Convenor of REIRG and secretary to RPG will work together to update the REIRG webpages during this review and update period.

### **2.3.iv Online – Colleges and Schools**

All three Colleges have Research Ethics and Integrity webpages which provide information about the governance of Research Ethics and Integrity within each Colleges as well as access to relevant guidance documentation. The CHSS research integrity webpages and HSS Schools will be revised accordingly to take forward some of findings of the HSS research ethics and integrity internal review.

The Schools in CHSS and CSE have Research Ethics and Integrity websites or intranets which provide information about school specific procedures that researchers – staff, students or visitors - are required to follow. Each School website lists the name(s) of those who can provide information, advice and guidance about ethical issues relating to research proposals as well as showing how proposals that need more formal consideration are dealt with. Many of the Schools have links to the online training material mentioned above and staff and students are actively encouraged to make use of these resources. CSE are appointing a summer intern in 2016 who will be looking at how the Schools Research Ethics and Integrity policies and practices are reflected in their websites. The CSE Social Media and Web Developer will take forward the recommendations that the intern's report generates.

For CMVM information about research ethics and integrity procedures that must be followed are presented on the main College webpages reflecting the different structure of this College. ACCORD provides a website delivering guidance on all aspects of clinical research, with links to ACCORD Standard Operating Procedures (SOPs), policies and guidance documents relating to research involving human participants, their data or tissue.

Schools conducting research with animals are directed to the Animal Welfare and Ethical Review Body within CMVM which has sole responsibility for approving proposals that come within the scope of the *Animals (Scientific Procedures) Act 1986*.

## **2.4 A summary of your education and training provision, including the audiences that have been reached and any new activities.**

### **2.4.i Centre**

REIRG intends to hold a cross-College Good Practice event with external speakers, probably from UKRIO, in October 2016. A small group of members of REIRG are currently planning the content of the event.

### **2.4.ii School and College**

Relevant programmes of study available to external applicants: The University offers three taught Postgraduate programmes that have a particular focus on ethics. These are the LLM in Medical Law and Ethics offered by the School of Law, the MSc in International Animal Welfare, Ethics and Law offered by the



R(D)SVS and the MSc in Clinical Trials by Online Learning offered by jointly by Edinburgh Medical School and the Deanery of Molecular, Genetic and Population Health Sciences.

The internal training examples outlined below are drawn from the Colleges' reports and are considered good practice.

Geosciences: The Chair of the School's Research Ethics and Integrity Committee has produced research ethics and integrity teaching material that can be used across all the disciplines within the School (30 minute presentation with PowerPoint slides, suggested reading and a discussion-based tutorial with scenarios) which are being made available across all the School's undergraduate programmes.

Geosciences have also introduced a series of drop-in sessions across the academic year (four in total) when the Chair and Administrator of the School's Research Ethics and Integrity Committee are available to answers questions relating to the School's research ethics and integrity procedures and more general queries about research ethics. These sessions have been advertised to staff and students (particularly those contemplating research across all levels across the School).

Law: The School's research Ethics and integrity Committee is planning dedicated training sessions and an enhanced and increased web presence. It is intended that these enhancements will be in place by the end of the current academic session.

The School of Law has ensured that the requirements for ethical research are built into research training for students, and there is a separate student research ethics officer in place to scrutinise the ethical approval forms of every undergraduate and postgraduate student.

Medicine: The [Wellcome Trust Clinical Research Facility Education programme](#) offers a wide range of training. Examples of relevant short courses available to students, staff (University and NHS) and from industry include: the Edinburgh Clinical Trials Management Course 2016; 'Recipes for Success': Standard Operating Procedure (SOP) Writing Workshop; Applying for Research Approvals in Lothian - Using the Integrated Research Applications System (IRAS); Research Data and Confidentiality: What you really need to know; and Understanding the Basics of Randomised Controlled Trials.

### 3. Addressing research misconduct

#### 3.1 Confirm that University of Edinburgh has a processes for the reporting and investigating of allegations of research misconduct.

The University has a current research misconduct policy, but progress is underway to adopt the UKRIO Research Misconduct Procedure as outlined at section 2.2.ii.

ACCORD follows regulatory requirements to identify and manage serious breaches of Good Clinical Practice and/or trial protocols.

#### 3.2 Confirm that the process has appropriate principles and mechanisms to ensure that investigations are thorough and fair, carried out in a transparent and timely manner, and protected by appropriate confidentiality.

The CHSS and CSE Annual Research Ethics and Integrity reports give details of the person(s) in each School who are responsible for dealing with allegations of research misconduct as well as a web-link to these policies.

#### ACCORD SOPs to identify and manage serious breaches stipulates strict timelines and procedures for carrying out investigations.3.3 Provide brief, anonymised summary data on any formal investigations conducted by your institution into allegations of research misconduct.

3.3.i Number of formal investigations undertaken in the past year, including:

How many allegations were upheld in full or in part?	None
How many allegations were dismissed?	None
The number of ongoing investigations.	None

3.3.ii A breakdown of the number of formal investigations undertaken in the past year: *None*  
By discipline. *None*  
By the broad type of misconduct that was alleged. *None*

3.3.iii For allegations that were externally funded, a breakdown by funding body. *None*

### **3.4 Summary of Key Learning Points and Outcomes from concluded investigations and Actions Taken**

None required.

It is anticipated that some of the findings from the CHSS Internal Audit of its Research Ethics and Integrity processes and policies have a wider relevance beyond CHSS.

## **4. External Engagement**

### **4.1 Collaborations with external organisations to support and strengthen understanding and application of research integrity issues, whether UK-based institutions or those from other countries.**

Edinburgh will be hosting the [13<sup>th</sup> World Congress of Bioethics in June](#).

The Chair and five out of the eight members of the organising Committee for the International Association of Bioethics' annual committee are staff at University (Prof Graeme Laurie (Chair); Elisabeth Pope Barlow; Karen Baston; Shawn Harmon, Martyn Pickersgill; Nayha Sethi).

In addition to hosting the above international conference, the University has a number of staff who play key external roles in collaborative activities to support and strengthen understanding and application of research integrity issues. A short list of examples of collaborative activity is given below:

Business: Professor Richard Harrison (Chair in Entrepreneurship and Innovation) was a member of the Advisory Board for the 2015 Sustainability, Ethics and Entrepreneurship Academic Research Conference, held at University of Denver, Colorado.

Law: Professor Graeme Laurie (Professor of Medical Jurisprudence) is the Programme Director of the LLM Medical Law and Ethics and was a member of the Council of Europe's Expert Group on the revision of Recommendation 2006(4) on research on biological materials of human origin.

Social and Political Sciences During 2015-16 Professor Joyce Tait CBE FRSE (Director of Innogen Institute) was a member of the US National Academy of Sciences/ Natural Research Council Committee on Re-programming Non-Human Populations using "Gene Drives": Recommendations for Responsible Conduct of Research.

### **4.2 Public engagement activities conducted by your institution, particularly involving research participants or patients, which included coverage of research integrity.**

Listed below are some examples of relevant public engagement activity:

[Sarah Cunningham-Burley's video](#) on social issues in relation to new technologies and health and public engagement in medical sciences.

[Steve Yearley's video](#) about how the media and public view scientific research, especially those with bio ethical implications.

[Graeme Laurie's video](#) on how we can protect patient privacy in health-related research and also promote benefits for all.

### **4.3 External conferences, workshops or other events on research integrity to which your institution has contributed.**

Hamish Macandrew, Convenor of REIRG, attended the UKRIO conference in May 2015. A UKRIO event held in Glasgow also in spring 2015 was attended by College Research Officers.

**4.4 Membership of, or collaborations with, organisations with a particular interest in research integrity and related issues. For example, the Association for Research Ethics, the Committee on Publication Ethics or UKRIO.**

The University has a several senior members of national or international organisations with a particular interest in research Integrity and related issues. A list, which is not exhaustive, is given below:

Divinity: Professor Mona Siddiqui OBE (Chair of Islamic and Interreligious Studies and Assistant Principal for Religions and Society) is a member of the Nuffield Council of Bioethics and sits on its Membership Sub-Group.

Law: Professor Graeme Laurie was a member of the Nuffield Council of Bioethics from 2009 until 2015

Centre for Medical Education: Professor Kenneth Boyd (Professor Emeritus of Medical Ethics) is a member of the Board of the Institute of Medical Ethics and one of five Honorary Vice-Presidents.

Social and Political Sciences: Jane Calvert is a member of the Nuffield Council of Bioethics Working Party on Emerging Biotechnologies.

REIRG: The Convenor of REIRG, Hamish Macandrew, is a member of the UK Research Integrity Office.

## **5. Funder-Specific Activities**

### **5.1 A summary of any actions taken to safeguard and support research integrity relating to researchers and projects supported by particular funding bodies.**

*Please note that you may prefer to list funder-specific activities as subsets of relevant general activities instead of listing them in a separate section. For example, a description of your 'generic' training and development activities could be followed by a summary of training provided for researchers supported by a particular funder.*

The Wellcome Trust has supported the University's Clinical Research Facility Education Programme since 2003. Further details of the provision supported by the Trust is given in previous sections.

The Animals (Scientific Procedures) Act requires that personal and project licences for research involving the use of animals are awarded only to individuals who have had appropriate education and training, including attending an accredited training course. ScotPIL is a consortium of Scottish Universities, which offers accredited training courses throughout the year. The University of Edinburgh, through ScotPIL, runs Module 1-4 Training for small animals three times a year, and large animal and zebrafish twice a year.