Research Ethics Committee Summary Report

January 2014 – December 2015

Prepared by the Office of Research Ethics
All queries to research.ethics@ucd.ie

Foreword

University College Dublin is committed to delivering excellence in research and innovation. Central to this is the application of best practice in research ethics and research integrity.

This is supported within UCD by the UCD Research Ethics Committee, its sub-committees, and the Office of Research Ethics. This report describes the activities of the committees and of the office. These activities are notable for their scale and diversity, and for the vital role they play in ensuring the highest standard of ethical practice in research across the university.

I am deeply grateful to the members of the Research Ethics Committee and its sub-committees, and to the staff of the Office of Research Ethics. They have given generously of their time and their expertise to deliver the many activities described here. In doing so, they show their commitment to their colleagues, to the university, and to the application of the highest ethical standards in research.

Finally, I wish to pay particular tribute to Professor Alan Baird, outgoing Chair of the Research Ethics Committee, who has guided the work of the committee with wisdom and judgement. His commitment to the area of research ethics and integrity is well known, and shines through every aspect of the work described here. Research at University College Dublin has been greatly strengthened by his guiding hand.

Professor Orla Feely

UCD Vice President for Research, Innovation and Impact

Chair's Review

Having served the Research Ethics Committees and Sub-Committees over almost fifteen years I have no doubts of the extraordinary contributions my colleagues have made over the years to the functioning of the University. This includes, but is not limited to, the protection of UCD investigators, research subjects and, of course, animals which are used in research and teaching. The scale and diversity of activities is reflected in this Annual Report. Recent changes include alignment with new legislation and formation of Animal Welfare Committees which has reported to and continues to work with the Animal Research Ethics Committee.

In 2014 a *National Policy Statement on Ensuring Research Integrity in Ireland* was launched. The Registrar of UCD, Professor Mark Rogers is the University's Research Integrity Officer. As part of its service to the research community the REC web page (http://www.ucd.ie/researchethics/) developed sections on Resources & Training, Horizon 2020 & Ethics and Research Integrity. For example, our online Research Integrity Portfolio can be used by any UCD academic or researcher. Similarly, the COPE guidelines for authorship are hosted here. They provide guidelines for authors and reviewers in the different disciplines which often have quite varied traditions and practices regarding authorship.

Jan Stokes and Maciek Szydlowski have been wonderful colleagues, running an efficient and pro-active Office, dealing with a broad range of activities, including dealing with innumerable inquiries as well as drafting the updates of the REC Policy Documents. Their tireless professionalism and good humour has made Chairmanship of the Committee a real joy. Academics from within and beyond UCD have been more than generous in devoting time and effort to the work of the Committees. I can only hope they have learned as much from Ethics Committee membership as I have.

Professor Alan Baird
Outgoing Chair

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Executive Summary:

From January 2014 to December 2015:

- A total of **981 submissions** for full ethical review or exemption processed;

- There are on average **54 M**e**mbers** of the Research Ethics Committees;

- There are a **number of vacancies for membership** of the REC to be appointed;

- There are **20 Schools** represented (71% members from the sciences);

- A total of **70 Research Ethics Committee meetings** were held;

- The HREC have processed **85 Student Access Requests**;

- There have been a number of significant **changes made to the operation of the AREC** which has aligned its processes with the statutory requirements of the HPRA;

- Under the period of this review the AREC continued to act as the statutory UCD Animal Welfare Body (AWB);

- The **4 REC Core Policy documents** were revised and approved by the UMT;

- The office of Research Ethics provided **68 Ethics Advisory Consultations**;

- There were **10 workshops and seminars** provided on research ethics;

- Research Ethics Website Resources provides **newly created Ethics Self-Assessment Tool;**

- UCD became an associate member of the UK Research Integrity Office (UKRIO);

- **Forthcoming for 2016:**

  o February: Epigeum Research Integrity Workshop with Professor Nick Steneck, Director of the Research Ethics and Integrity Program of the Michigan Institute for Clinical and Health Research

  o March/April: AREC Workshop with Mr David Anderson (LASA, UK)

  o April: Research Ethics for Academic Supervisors Workshop

Introduction

The *Research Ethics Summary Report 2014-2015* provides an overview of the activities of the UCD Research Ethics Committee (REC), its sub-committees, and the Office of Research Ethics. Research Ethics in UCD assists researchers in an environment that is committed to ensuring they adhere to high ethical standards. As would be expected from a leading University, UCD provides a well-supported platform for research, locally, nationally and internationally whether funded or unfunded, and research ethics does the same. Research Ethics in UCD continues to grow and strives to provide solutions for researchers as the nature of their research, and regulatory environment changes, bringing new challenges. Increasingly this growing need the processes have evolved too. So many researchers in UCD are aware, and are becoming more aware, that research ethics can, and does, enhance research for the better.

From January 2014 to December 2015, Research Ethics in UCD underwent a number of significant changes signifying a steady growth in awareness of, and engagement with, research ethics and research integrity by researchers. Through an increased use of the Research Ethics Management System (REMS) for submissions and reviews, through the Research Ethics Approvals System (REAS) and through the through the engagement with the processes, UCD researchers have reaped the benefits for their research. All ethics reviews are carried out by the Research Ethics sub-committees and are conducted in accordance with internationally accepted best practice and ethical norms.[1]

The Committees are committed to ensuring that the research activities in UCD are carried out to the highest standards and in a way which respects the dignity, rights, and welfare of subjects, and which minimises risk to subjects, researchers, third parties, and to the University itself. It is a formal requirement of UCD that all research involving humans or animals conducted within UCD, or other locations, by UCD staff or students, requires the individual researcher and/or teams of researchers to obtain ethical approval or exemption.

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[1] The UCD Research Ethics Approvals System historically follows an internationally recognized system of ethical review recommended in *The Operational Procedures for Research Ethics Committees: Guidance 2004* published by The Irish Council for Bioethics.

The range and diversity of the research studies that require ethical approval or exemption is broad and often ethically challenging but the systems for ethical review in place in UCD maintain standards of excellence and continue to meet international standards of best practice in ethical research.

This Summary Report reflects the current levels of activity and developments for the both the REC and the Office of Research Ethics, and illustrates our response to change within, and beyond, the University.

PART I: UCD RESEARCH ETHICS COMMITTEES

It is the purpose of the UCD REC and its sub-committees to ensure that all research in UCD is conducted according to best ethical practice. To realize this aim the committees are strongly committed to:

- raising awareness and encouraging research integrity;
- maintaining ethical standards of practice in research;
- ensuring researchers are fully aware of regulatory changes through information, education, training and clear processes;
- ensuring that researchers are made fully aware of their legal obligations and ethical responsibilities in the collection, use, storage and future use of data;
- protecting human subjects of research from risk and to preserve subjects' rights;
- encouraging the implementation of the 3Rs (Reduction, Refinement and Replacement) in research and teaching involving the use of animals;
- ensuring that the requirement of fully informed consent is properly observed;
- providing reassurance to the public and outside bodies that all the above are being done;
- safeguard the reputation of UCD, its researchers and their research.

The REC and its sub-committees provide services that adhere to international best practice and provide aims to protect the researchers, their work, their participants (human or animal) and the university[2]. Both the Animal Research Ethics Committee (AREC) and the Human Research Ethics Committees (HRECs) are responsible for reviewing all submissions for full ethical approval.[3] In addition to providing the university with a robust research ethics reviewing system the REC continues to inform all staff and researchers as to the benefits of research ethics and integrity for their research through workshops, consultations and the Office website. From the recruitment of human participants through to the publication of their research the continued adherence to standards of best practice in research ethics has benefited the research community campus-wide. This not only ensures that UCD researchers maintain and enhance a solid professional reputation but that they also retain public and professional support and trust.

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[2] Ibid.,
[3] All research conducted within UCD or in other locations by UCD staff/students involving human or animal subjects requires the individual researcher and/or teams of researchers to obtain ethical approval or exemption from full ethical review.

It is the intention of UCD Research Ethics to ensure that all researchers are treated equally and fairly in both the reviewing processes and the information and guidance being provided. The high standard of applications for full ethical review and exemptions reflect the quality of information, assistance and education being provided by the REC, the sub-committees and the Office of Research Ethics. This is a demonstration of how UCD Research Ethics systems work and how well attuned UCD researchers are with the widely accepted global principles for best research practice.

REC Organization & Management

The UCD Research Ethics Committee (REC) oversees, and advises on policy and guidelines regarding, the work carried out by the three sub-committees.[4] The REC reports to the Governing Authority and also provides a report for noting to the Academic Council.

Administrative support for the REC, HREC and AREC is provided by the staff in the Office of Research Ethics who report directly to the UCD SIRC (Safety, Insurance, Operational Risk, & Compliance) Office. They are responsible for the management and coordination of the Research Ethics Approvals System, the Research Ethics Management Systems and provide advice, consultations, information and training to the research community.

Research Ethics Committees: Membership

The term of office for members of the REC and the sub-Committees is three years, renewable. Each Committee has a Chair and Vice-Chair and as many members as are required to fulfill the terms of reference in the REC *Operating Procedures*. Members are drawn principally from the Academic Community within UCD but also include external members in accordance with the specific requirements of each committee.

Nominations for membership to the sub-committees are considered and approved by the REC. Nominations to the REC are in the gift of the President or designate. In 2015 it was noted that the Vice-President for Research Impact and Innovation (VPRII) was named as the designate who would

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[4] See Appendix I for an organizational chart

appoint members to the REC. The membership constitution in the *REC Operating Procedures* is currently under review by the VPRII and the membership requirements may change.

Since January 2014 many of the long serving members (some founding members) have come to the end of their term of office on the REC and currently there are a number of vacancies. The REC Chair's terms of office came to an end in September 2015 and he had agreed to continue as chair until a replacement was appointed.

Table 1: *Research Ethics Committee Membership*

Per Year (except)*	REC	AREC	HREC-Humanities	HREC-Sciences	Total
September 2009 – August 2010	*16*	*12*	*19*	*20*	*60**
September 2010 – August 2011	*19*	*14*	*19*	*18*	*63**
September 2011 – December 2012	*17*	*12*	*17*	*16*	*55**
January – December 2013	*16*	*15*	*18*	*15*	*57**
January – December 2014	**11**	**15**	**15**	**14**	**55***
January – December 2015	**11**	**15**	**12**	**16**	**54***

*Seven REC members are also members (Chairs & Vice-Chairs) of one of the sub-committees and therefore not counted twice.

The REC meets on average 6 times a year while the sub-committees meet once a month except in August or when there are no submissions for full ethical review.

Table 2: *Meetings held by Research Ethics Committees September 2004 – December 2013*

Per year	REC	Chairs (REC pre-meetings)	AREC	HREC	Total
Sept 2008 – Aug 2009	*6*	*7*	*11*	*21*	*45*
Sept 2009 – Aug 2010	*6*	*4*	*11*	*21*	*42*
Sept 2010 – Dec 2011	*4*	*3*	*10*	*19*	*36*
Jan 2012 – Dec 2012	*9*	*4*	*11*	*21*	*45*
Jan 2013 – Dec 2013	*5*	*4*	*11*	*21*	*41*
January – December 2014	4	0	10	20	34
January – December 2015	4	0	11	21	36

(Excludes meetings held by URECs or TMRECs)

Table 3: *Schools Representation in Research Ethics Membership*
(REC members are not counted twice where they also serve on one of the sub-committees)*

UCD School of	REC	AREC	HREC-Sciences	HREC Humanities	Total
College of Humanities & Arts					**2**
Languages, Cultures & Linguistics (formerly Irish, Celtic Studies & Folklore)				1	1
History & Archives				1	1
College of Business					**2**
Business	(1)	1		1	2
College of Engineering & Architecture					**2**
Electrical & Electronic Engineering			2		2
College of Health & Agricultural Sciences					**19**
Agriculture & Food Science			1	1	2
Medicine	1	2	2		5
Nursing, Midwifery & Health Systems			2	2	4
Physiotherapy & Sports Sciences		1	2		3
Veterinary Medicine	1 (1)	4			5
College of Science					**10**
Biology & Environmental Science		2			2
Biomolecular & Biomedical Science	(2)	2	1		3
Computer Science			1	1	2
Mathematical Sciences & Statistics		2			2
Physics			1		1
College of Social Sciences & Law					**9**
Applied Social Science				2	2
Archaeology				1	1
Education				1	1
Law, Sutherland School of	(1)		1		1
Psychology	(1)		1	1	2
Social Policy, Social Work & Social Justice			2		2

Note: the numbers exclude the schools where there is no representation on any of the committees, the 5 members from UCD Units and the one external member

Table 3 demonstrates the wide range of expertise available to research ethics through its membership. Members participate in reviewing applications, policy and form revisions, and working groups on behalf of their committees but also provide advice and guidance on research ethics issues relating to their own discipline within their own schools.

Undergraduate Research Ethics Committees and Taught Masters Research Ethics Committees

The Undergraduate Research Ethics Committees (UREC) and Taught Masters Research Ethics Committees (TMREC) are REC Approved school committees that report directly to the relevant HREC as illustrated in the organization chart in Appendix I.

Table 4: *Current Undergraduate and Taught Masters research ethics committees*

Dated Approved by REC	UCD School	Committee Type	Reports to	Applications Processed for 2014 *
Mar 2007	Psychology	UREC	HREC-Humanities	89
Sept 2008	Medicine & Medical Science	UREC	HREC-Sciences	31
Jan 2010	Education	TMREC	HREC-Humanities	53
Apr 2010	Public Health, Physiotherapy & Population Science	UREC	HREC-Sciences	10
Apr 2011	Social Policy, Social Work & Social Justice (formerly Applied Social Science)	TMREC	HREC-Humanities	No Reviews
Oct 2011	Psychology	TMREC	HREC-Humanities	20
Aug 2012	Law	TMREC	HREC-Humanities	9
Nov 2015	Nursing, Midwifery & Health Systems	TMREC	HREC – Sciences	n/a

*According to the UREC/TMREC Annual Reports received and not including resubmissions.

The URECs and TMRECs are required to attend an annual meeting with the HREC Chairs and provide an annual report. The members are due to meet in early January 2016 to discuss a range of issues such as streamlining the processing of insurance and requests to access students.

PART II: Research Ethics Review – ongoing developments

The Office of Research Ethics consists of two full-time members of staff who co-ordinate administrative support for the Research Ethics Committee Chairs and members in delivering the approvals process. They also provide support to all researchers who require advice, information, workshops and education. The following selection highlights some of the developments and progress for the past two years.

Animal Research Ethics Committee

There have been number of significant changes made to the operation of the AREC since January 2014. The AREC continues to align its processes with the statutory requirements of the Health Products Regulatory Authority (HPRA) in order to promote best ethical standards and practice in animal research and contribute to the successful statutory authorization of UCD research projects. These key changes can be summarized as follows:

- New AREC application forms were launched to reflect the different types of research and teaching activities[5] and their corresponding statutory requirements. Also, a separate exemption from full review process was introduced for projects, which either fall outside the scope of statutory regulations or have been fully reviewed and approved by an external ethics committee recognized by AREC and the HPRA.

- AREC submission processes were streamlined and all (except exemptions) types of submissions were made available online via UCD Infohub/SISweb.

- AREC forms were standardized and coded and each was accompanied with a set of short guidelines regarding their corresponding statutory requirements on AREC Intranet.

- AREC Intranet was further developed to include core information regarding statutory compliance in UCD.

- AREC protocols were aligned with HPRA Project Authorizations in terms of scopes of projects and their timeframes (one AREC protocol – one HPRA authorization).

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[5] (1) Conducting scientific procedures on live animals, (2) Breeding of GM animals, (3) Euthanasia for post-mortem tissue sourcing, (4) Use of live animals in teaching and training.

- UCD *Policy on the Use of Animals in Research and Teaching* was approved by the UMT in October 2015 and is due to be reviewed by the Governing Authority in 2016.

- The *Compliance Governance Structure Policy Document* was approved by the UMT in October 2015.

- Throughout 2014 and 2015, the AREC continued to act as the statutory UCD Animal Welfare Body (AWB) until the formal establishment of UCD Compliance Committee and reconstitution of the AWB sub-committees in Belfield and Lyons Estate as Animal Welfare Sub-Committees (AWSCs) in December 2015.

Human Research Ethics Committee

- The HREC continues to act on behalf of the UCD Registrar to process request from researchers to access UCD students. There were 85 requests to access UCD Students processed in the period under review. There were 3 requests to carry out campus-wide surveys with students and these were reviewed by the University Student Survey Board (USSB). All three requests were approved.

- The HREC-Humanities Chair continues to oversee the co-ordination of the processes involved with the Undergraduate (UREC) and Taught Masters (TMEREC) RECs. Both the HREC Humanities and Sciences Chairs process the UREC and TMREC Annual Reports for noting by the REC.

- The HREC Guideline documents are due for a review in 2016.

Research Ethics Integrity

There have been a number of developments which are described in detail in **Part III below**.

Research Ethics Policy Review

The four REC Core policy documents (see below) were approved by the REC in June 2014 and were subsequently passed by the UMT in October 2015. These four documents underpin the UCD Research Ethics Approvals System, and all of the approved Research Ethics Committee (REC) policies and guidelines. The approvals system is the process by which all submissions to the Office of Research Ethics for ethical review and/or exemption, and all reviews, decisions and approvals are carried out on behalf of the university. It is overseen by the UCD Research Ethics Committee which derives its operating authority from the UCD Governing Authority. The Research Ethics Committee oversees and advises on policy regarding the work carried out by the sub-committees The Research Ethics Committee facilitates and promotes research in UCD based on internationally accepted ethical norms and with attention to the welfare of study participants.

The Code of Good Practice in Research: establishes and maintains standards of best practice in research for all researchers in UCD who are engaged in research with human or animal subjects. UCD is fully committed to the advancement of high quality academic research and to ensuring that all research activities undertaken by University employees, or on University premises, that involve human or animal subjects or personal data are undertaken in a way that safeguards the dignity, rights, health, safety, and privacy of those involved. This commitment extends to all researchers (staff and students), participants, and third parties.

The UCD _Research Ethics Policy:_ presents an overview on how research ethics is managed University-wide. It provides the basic principles of best practice in research for all research involving human and animal subjects in research. The Policy is applicable to all UCD researchers, (staff, students and postdoctoral researchers) and should be read in tandem with the UCD *Code of Good Practice in Research* and the REC *Operating Procedures*.

REC Operating Procedures: defines the ethical standards required for the professional conduct of all research within UCD carried out by UCD researchers.

Policy on the Use of Animals for Research and Teaching: UCD is committed to ensuring that all staff and students involved in the use of animals for any purposes treat those animals with respect and consideration. Animals form a valuable part of the research and teaching activity of the university.

The use of animals for research makes a valuable contribution to the understanding and development of therapies for both human and animal health problems and to improvements/efficiencies in animal production systems. The principles of the 3Rs (Replacement, Reduction and Refinement) underpin all animal related work carried out at the University, thereby ensuring that the number of animals used is appropriate to the study and that procedures and care are refined and regularly reviewed to maximise animal welfare.

The REC also approved the following documents:

AREC Summary of Committee Guidelines & Requirements: defines the ethical standards required for the professional conduct of all <u>animal</u> research within UCD carried out by UCD researchers.

HREC Summary of Committee Guidelines & Requirements: defines the ethical standards required for the professional conduct of all <u>human</u> research within UCD carried out by UCD researchers.

The REC approved documents are available on the Research Ethics Website.

Research Ethics Management System (REMS)

The Research Ethics Management System has been running for three years and has contributed enormously to the efficient running of the Research Ethics Approvals System in general. The researchers, Heads of Schools and reviewers have engaged with the new system from the start and have continued to ensure that the submission process is fast and efficient for all. In time it is envisaged that the system will include the HREC Exemption Submission process too.

Processed Submissions

Table 5 below provides a breakdown of the variety of submissions being processed by the Office of Research Ethics. It does not account for the number of queries both internal and external that are dealt with on a daily basis by the administrative team, and it does not reflect the number of consultations and ad hoc meetings provided for researchers.

Table 5: *Submissions processed from January 2014 – December 2015*

Type of Submissions received	AREC	HREC-Humanities	HREC-Sciences	Totals
New Submissions for full ethical review	124	130	145	**399****
*Exemptions from full ethical review**	(27)**	270	311	**581***
Amendment, Extension or New Researcher Requests	153	71	87	**311**
Unforeseen or Adverse Events Reports	47	1	1	**49**
End of Study Reports	19	9	16	**44**
External Requests for exemption	0	6	3	**9**
Requests to Access UCD Students	n/a	85		**85**
Total Submissions & Requests Received and Processed				**1,478**

* All HREC exemptions from full review are notified to the Office of Research Ethics.
**All AREC exemptions are reviewed by Committee members and therefore included in total for full review.

Key Points for noting

- Committee Chairs have indicated that it can take up to **5 man hours** (in total) to process and review a new application from submission through to approval.

- The Committee members have indicated that it can take up to **3 hours to review one submission** (including pre-meeting review and post-meeting responses). For a meeting with an average of 5 submissions for review that means 15 hours per member. For complex reviews the number hours can be greater.

- Following full ethical reviews by members there were **27 submissions did not respond** at all to the committee review decision or withdrew their application.

- **It takes on average from 21 to 24 working days to obtain approval** for a submission for full ethical review. The turnaround time is determined by the quality of the original submission and requests for clarification, and by how quickly and clearly a researcher responds to the committee decision letter.

Research Ethics Advisory Consultations

Over the past two years the volume and nature of the queries and consultation requests (HREC only) have changed. Increasingly the queries are related to Horizon 2020 (see below) requirements for ethics and as such some research teams have called upon the expertise within the Office of Research Ethics to assist on an ongoing basis as and when the need arises. In addition the staff members are now called upon to provide assistance to working groups and committees such as most recently providing assistance to the INSIGHT Centre for Data Analytics and the Systems Biology Ireland – UCD TopMed10 Fellowship Programme Management Committee.

The frequency and nature of general queries has also changed to reflect an increased awareness of ethical requirements. Researchers are less inclined to need assistance with general information about the submission process but increasingly aware of discipline-specific issues arising from their projects. Topics range from the use of ancient weapons, publishing ethics and authorship, overseas concerns, and specific queries on Integrity and misconduct, Garda vetting, data ownership, online platforms and social meeting, surveys and vulnerable groups.

The Office of Research Ethics continues to provide a one-to-one session for UCD students and staff with the aim of raising awareness of ethical issues as well as improving the standard of submission for both full ethical approval and exemptions. As a testament to the research community engaging with the process the quality of the submissions has improved resulting in a faster review and approval time. There were **68 pre-submission advisory consultations provided** in the period under review.

Horizon 2020

The Office of Research Ethics assists UCD researchers in completing the ethics component of their Horizon 2020 and other grant applications, in particular with the Ethical Issues Table and the Ethics Self-Assessment. The Office of Research Ethics provides an Ethics Self-Assessment template to assist researchers in describing how their proposal meets national legislative and ethical best practice requirements of the country or countries where the research is to be carried out.

Research Ethics Workshops & Seminars

In addition to the advisory consultations which are requested on a weekly basis, the Research Ethics Committee members also provide guidance and advice for their schools. In addition they provide a series of workshops and presentations each year on research ethics, some of which are listed below:

- *Introduction to Research Ethics* (Staff Development Training): [Dec 2015]

- *Introduction to Research Ethics* (Staff Development Training): [Nov 2015]

- College of Human Sciences, *Graduate Workshop on Research Ethics* [Nov 2015]

- *Research Ethics for Academic Supervisors* (Staff Development Training): [Dec 2014]

- College of Human Sciences, *Graduate Workshop on Research Ethics* [Mar2015]

- *Research Ethics for Academic Supervisors* (Staff Development Training): [Dec 2014]

- College of Human Sciences, *Graduate Workshop on Research Ethics* [Nov 2014]

- *Introduction to Research Ethics* (Staff Development Training): [Nov 2014]

- REC Information Workshop [Sept 2014]: Dr Peter Lennon (Dept of Health) on the *Health Information Bill 2014:* 'Research Ethics Approval Framework' & Dr Patricia Clarke (HRB) on the *EU Data Protection Regulation 2012/0011(COD):* 'The Irish Position'.

- *Ethical Issues in Data Management* [Feb 2014]

Research Ethics Website

For many researchers, both internal and external, information on research ethics in UCD is accessed via the website.

The website provides staff and students with a Resources page, which includes links to external documents relating to international law and ethical best practice, and specific areas of research ethics (research with children, persons with disabilities, other vulnerable groups, etc.). Increasingly researchers are seeking guidance on authorship issues and publishing ethics and the website provides links to COPE (Committee of Publication Ethics). Also researchers require

discipline specific guidance ranging from stem cell research to oral history research and much more. The Ethical Best Practice and Information Pack continues to expand

All web-authoring for this site is carried out by the Office of Research Ethics daily: www.ucd.ie/researchethics

Stakeholders

Both the committee Chairs and administrative staff are often called upon to attend meetings with a variety of units on campus that have an interest in working with Research Ethics to improve the quality of information they provide for Staff and Students. Apart from the majority of UCD Schools and Institutes, the following list provides a sample of the range of stakeholder units throughout the university and beyond that interact with research ethics:

- ❖ HPRA (Health Products Regulatory Authority) formerly the Irish Medicines Board
- ❖ INSIGHT Centre for Data Analytics
- ❖ Royal College of Surgeons/Beaumont Hospital REC
- ❖ SIRC (Safety, Insurance, Risk, Operational Compliance) Office
- ❖ Systems Biology Ireland – UCD TopMed10 Fellowship Programme
- ❖ UCD Biomedical Facility & Designated Veterinary Surgeon
- ❖ UCD Bursar's Office
- ❖ UCD Internal Audit
- ❖ UCD IT Management Services
- ❖ UCD IT Web Development
- ❖ UCD Legal Affairs Office
- ❖ UCD Library Academic Services
- ❖ UCD Lyons Research Farm & Designated Veterinary Surgeon
- ❖ UCD Registrar's Office
- ❖ UCD Research
- ❖ University Student Survey Board (USSB) & UCD Institutional Research

PART III: Research Integrity in UCD

Research Ethics & Research Integrity

Research Ethics in UCD strives to safeguard the researcher, the research, the participants, and the university**,** but the essential prerequisite for ethical research is the integrity of the researcher. Through raising awareness about research ethics and providing information and training both the Office of Research Ethics and the Research Ethics Committees are also engaged in promoting research integrity. As required by any leading university, UCD is committed to providing clear procedures for research integrity for researchers following the recent publication of a National Policy Statement on *Ensuring Research Integrity in Ireland,* provided by the Irish Universities Association (IUA) and its sponsors.[6] This statement was intended to provide a research integrity framework for Ireland, and was significantly influenced by the *UK Concordat on Research Integrity* (2012).[7]

The Office of Research Ethics and the REC are committed to ensuring that research is being conducted according to established rules, regulations, guidelines and professional codes. Both continue to advise and assist on a wide range of issues that go beyond the ethical review such as authorship and publication, conflict of interest, data management practices, collaborative research issues, and the provision of training in good research practices.[8]

In furthering our interest in recognizing that research integrity has been central in the provision of research ethics to UCD researchers we sought to embrace it further and to explore how other universities compared to UCD.   In May of 2015 a representative from the Office of Research Ethics and UCD research attended the UK Research Integrity Office (UKRIO) annual conference on Research Integrity in London.

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[6] See The National Policy Statement on *Ensuring Research Integrity in Ireland (2014)* https://www.ria.ie/about/our-work/policy/research/research-integrity.aspx.
[7] *The Concordat to Supporting Research Integrity (*2012)
http://www.universitiesuk.ac.uk/highereducation/Documents/2012/TheConcordatToSupportResearchIntegrity
[8] *See also the European Code of Conduct for Research Integrity (March 2011)*
http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf *European Science Foundation and ALLEA (All European Academies).*

UK Research Integrity Office (RIO)

UCD also became an associate member of the UKRIO in May 2015. The UKRIO is an advisory body whose publications has been endorsed by UK funding bodies and learned societies, and is used by many leading UK research organisations, including over 50 universities.

UKRIO was established in 2006 to provide support on research integrity to the UK research community and the public. With expertise rooted in legal, ethical and other structures under which research is conducted in the UK, UKRIO do the following:

- promote and support good research practice and assist with resolving concerns about poor practice and outright misconduct;
- cover all disciplines and give advice on research wherever it is carried out, in universities, the NHS, private sector bodies and charities;
- provide support that is appropriate, practical and proportionate, rather than burdensome and bureaucratic;
- promote common approaches to common situations and provide specialist, subject-specific expertise whenever necessary.

The UK *Concordat to Support Research Integrity* was developed with the assistance of UKRIO, and it is recognised as a key source of support for research institutions and researchers.

Epigeum: online tool for Research Integrity

UCD continues its association as a Group Development Member contributing to the development of an online tool for research integrity. Epigeum is available for all researchers in UCD and a link is provided on the Research Ethics website and the Office of Research Ethics provides UCD academic staff with a password to access the course programmes. There are 5 faculty versions on research integrity with 5 hours of online training and 23 – 32 hours of offline training per version to avail of.

Epigeum will jointly host with the UCD Research Ethics Committee a workshop on Research Integrity for early February 2016. Epigeum launched its Research Integrity Impact Programme at the end of 2015 and one aspect of the workshop is to discuss creating an Irish version. The guest speaker will be Professor Nick Steneck, Director of the Research Ethics and Integrity Program of the Michigan Institute for Clinical and Health Research, Professor Emeritus of History at the University of Michigan, and consultant to the Federal Office of Research Integrity, HHS.

Epigeum: online tool for Research Integrity

CONCLUSION

All improvements and developments within the Research Ethics Approvals System and the training and advice provided by the Office of Research Ethics and the Research Ethics Committees are steered not only by international best practice but also by the researchers and their research. Each study has its own set of unique elements that raises issues and concerns and presents challenges to both the researcher and the committee reviewer alike. The majority of the committee membership and the submissions come from the sciences both for the AREC and the HREC-Sciences and there is a steady flow of activity on a daily basis between researchers and the Office of Research Ethics. It is interesting to note that many of the submissions to the HREC-Humanities present such a wide range of studies and provide the Office and the Committee with wonderful variations that allow us to improve our guidelines and seek ethical solutions that protect the research, the participant, the researcher and the institution.

The REC and the Office of Research Ethics continue to provide an enormous range of expertise for researchers to access. However, it requires a continuing and ongoing programme of raising awareness on research ethics within the research and teaching community in UCD. This is demonstrated by the fact that the committee members still encounter research submissions which show a limited understanding of research ethics despite the fact that both the committees and the Office of Research Ethics provide a wide range of information to facilitate the researchers and their research.

Appendix I: UCD Research Ethics Reporting Structure