

UCD Research Ethics Summary Report September 2011 – December 2012

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UCD Research Ethics 10-Year Review

Approved by the UCD Research Ethics Committee on December 13th, 2012

Noted by the UCD Governing Authority on February 19th, 2013



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Foreword

The 2012 report by the UCD Research Ethics Committee reflects the growth of the research activity and complexity over the past 10 years. Fifty-five members of staff and external experts provide an invaluable service in reviewing nearly 500 applications annually and in leading the development of our institutional review and ethical oversight of research. Two full-time staff supports the ethics committees and have created an on-line system to facilitate the academic community's submissions and ongoing review.



The Research Ethics Committee continuously evolves its function to reflect the rapid changes in research, including the use of stem cells and the analysis of large-scale web data. This year, there has been a change in the national system for overseeing animal research, with the Irish Medicines Board assuming authority from the Departments of Health and Children and Agriculture and Food. The IMB will also provide ethical oversight in a process that will evolve over the next 3 years. The university will need to consider whether it will continue to provide ethical approval or will move to an Institutional Review Board model where it is responsible for good practice in animal research within UCD. 2013 also sees the completion of an extensive national review of research integrity following on several well-publicised failures of oversight in other jurisdictions. It is hoped that all of the research bodies and universities will sign up to the proposed national system, which will include a national committee for referral of difficult issues. UCD will appoint a Research Integrity Officer to implement good practice and training of researchers, and to assist in addressing complaints. I would like to thank the Chair, Professor Alan Baird, and all of the members of the research ethics committees for giving so generously of their time and expertise. I would also like to thank the research community for their commitment to best practice in research and in their professionalism in managing the complex demands of research oversight.

Des Fitzgerald,
Vice President for Research



RESEARCH ETHICS 10 YEAR REVIEW

In November 2012 the UCD Research Ethics Committee celebrated its first 10 years in existence and the following briefly highlights achievements for that period.

2002

- UCD Research Ethics Committee Established

2003

- Human Research Ethics Committee (HREC) and Animal Research Ethics Committee (AREC) begin first reviews
- Total Submissions received for review: **24** (excluding AREC)

2004

- UCD Research Ethics Approvals System Launched
- Total Submissions received for review: **43**

2005

- REC establishes Working Group on Regenerative Medicine
- Part-time Research Ethics Administrator Appointed
- Total Submissions received for review: **127**

2006

- REC Working Group on Regenerative Medicine produce Report
- Full-time Research Ethics Administrator Appointed in June
- A new record-keeping system for Research Ethics begins in September
- UCD Human Research Ethics Committee registers for US Federalwide Assurance
- New Undergraduate REC established in School of Psychology (UREC-SPsy)
- REC Chair, Professor Peter Wilson, receives UCD Research Service Award
- Total Submissions received for review: **146**

2007

- HREC splits into two committees – HREC-Sciences and HREC-Humanities
- 1st Research Ethics Committees Forum held in December
- New Policy on Expenses & Incentives
- Full-time Research Ethics Administrator Appointed as permanent member of staff
- Total Submissions received for review: **258**

2008

- New Policy on Access to UCD Students
- New Policy on Data Storage & Retention (Protection)
- New Appeals Procedure Policy
- New Insurance/Indemnity Guidelines
- New Undergraduate REC established in School of Medicine & Medical Science (UREC-SMMS)
- The Office of Research Ethics expands to two full-time members of staff
- New Research Ethics Website created
- Total Submissions received for review: **352**

2009

- New Policy on HREC Amendments/Extensions
- Research Ethics Application Advisory Service launched
- Consultation to Irish Universities Graduate Skills (IUA)
- Total Submissions received for review: **404**

2010

- New Taught Masters REC established in School of Education (TMREC-SE)
- New undergraduate Research Committee established in School of Public Health, Physiotherapy & Population Science (UREC-SPHPPS)
- Total Submissions received for review: **498**

2011

- New Taught Masters REC established in School of Applied Social Science (TMREC-SASS)
- New Taught Masters Research Committee established in School of Psychology (TMREC-SPsy)
- Research Ethics Compliance Review Pilot begins
- Total Submissions received for review: **520**

2012

- New Taught Masters Research Committee established in School of Law (TMREC-Law)
- New Research Ethics Advisory Consultation replaces Applications Advisory Service
- New Research Ethics Website goes live
- REC Corporate members of the Universities Federation of Animal Welfare (UFAW)
- Contribution to Consultation on Policy Statement on Ensuring Research Integrity in Ireland (IUA)
- Total Submissions received for review: **444**

THE RESEARCH ETHICS SUMMARY REPORT SEPTEMBER 2011 – DECEMBER 2012

❖ INTRODUCTION

This Research Ethics Summary Report is intended to present the activities of both UCD's Research Ethics Committees and the Office of Research Ethics from September 2011 to December 2012. It demonstrates that not only do the research ethics committees and administrative staff oversee and maintain the Research Ethics Approvals System but also provide education, information and advice to staff and students on research ethics.

The UCD Research Ethics Committee (REC) continues to oversee the general ethical conduct of all research undertaken in UCD which is in keeping with international best practice in research. The Animal Research Ethics Committee (AREC) and the Human Research Ethics Committees (HRECs) are responsible for reviewing all submissions for ethical approval. 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. The Research Ethics process is designed to assist researchers in an environment that is committed to ensuring its researchers adhere to high ethical standards.

This Report is self-explanatory. It reflects current levels of activity as well as historic developments. It illustrates how REC committees, through their dedicated membership, have been responsive to change within and beyond the University. Future challenges will be met with the same spirit of collegiality and professional administrative support. Ethical behaviour and research integrity is universal. So it should remain.

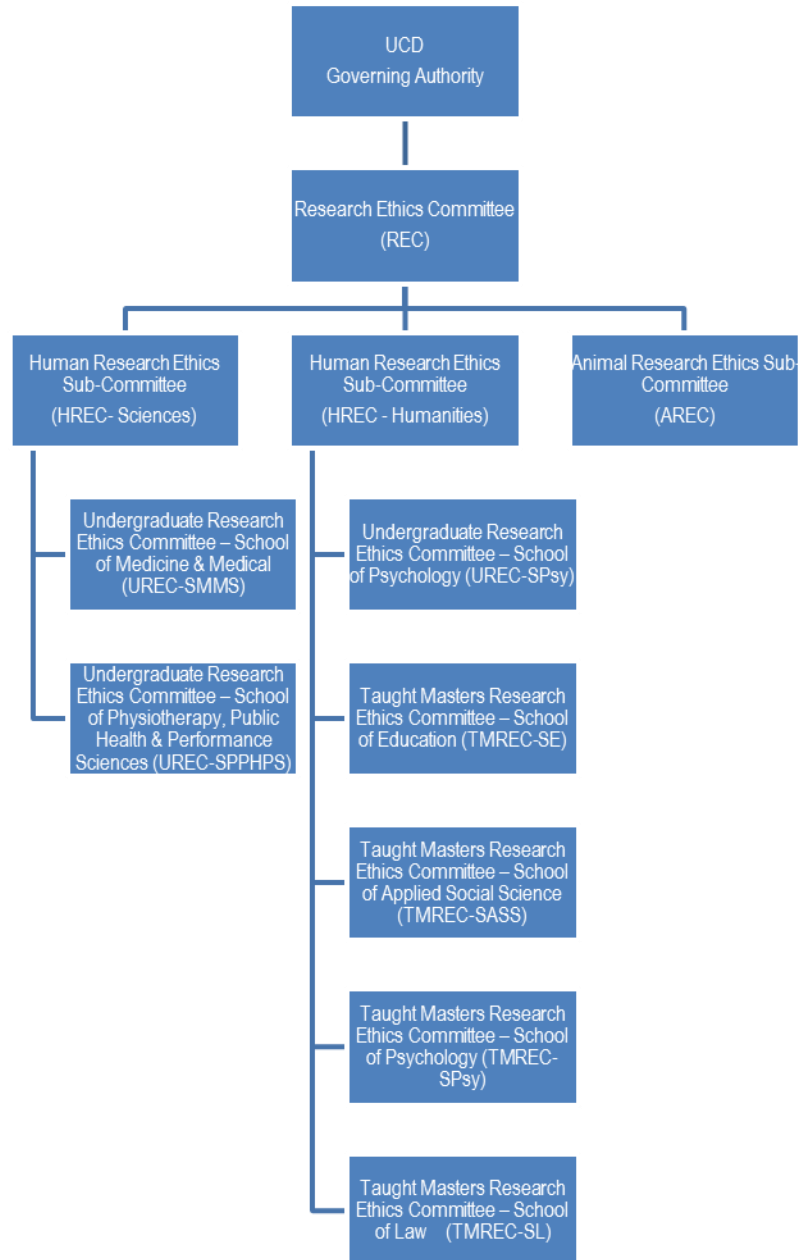
Executive Summary:

Since September 2011 there have been:

- **57** Research Ethics Committee meetings held;
- **682** Submissions/Requests processed;
- **33** Ethics Advisory Consultations provided;
- **23** Student Access requests processed for the Registrar;
- A new Research Ethics website created.

SECTION 1

❖ UCD RESEARCH ETHICS COMMITTEES ORGANISATIONAL STRUCTURE



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

SECTION 1

▪ The UCD 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 fulfil the terms of reference in the REC *Operating Procedures* (sections: 3., 4., and 5). Members are drawn principally from the Academic Community within UCD but also include external members in accordance with the specific requirements of a committee. Nominations for the sub-committees are considered and approved by the REC.

Table 1: *Research Ethics Committee Membership*

	REC	AREC	HREC-Humanities	HREC-Sciences	Total
<i>September 2009 – August 2010</i>	16*	12	19	20	60
<i>September 2010 – August 2011</i>	19*	14	19	18	63
<i>September 2011 – December 2012</i>	17*	12	17	16	55

*Seven of the REC members are also members (Chair & Vice-Chair) of one of the sub-committees.

There are currently three external members: one serves the REC only, one serves the HREC-Sciences only, and one serves both HREC-Sciences and REC. The REC will be seeking additional members in 2013 and will seek approval for new nominees from the President.

In September 2011 the Chair of the REC, Professor Peter Wilson, stepped down after 10 years of valued and committed service to the REC. The role of REC Chair was temporarily filled by Professor Maurice Boland until April 2012. Professor Alan Baird is currently the Chair of the REC.

SECTION 1

▪ **Undergraduate Research Ethics Committees and Taught Masters Research Ethics Committees**

The Undergraduate Research Ethics Committees (UREC) and Taught Masters Research Ethics Committees (TMREC) report directly to the relevant HREC as illustrated above. The Research Ethics Committee approved the establishment of three Undergraduate RECs and four Taught Masters RECs as follows:

Table 2: *Current Undergraduate and Taught Masters research ethics committees*

Approved by REC*	UCD School	Committee Type	For Specific Module or School Reviews	Reports to	Applications Processed for 2011-2012 **
March 2007	Psychology	UREC	Core module of BA	HREC- Humanities	86
September 2008	Medicine & Medical Science	UREC	RDGY30090 - Research: Radiography Thesis	HREC- Sciences	30
January 2010	Education	TMREC	All Taught Masters Progs	HREC- Humanities	53
April 2010	Public Health, Physiotherapy & Population Science	UREC	BSc Physiotherapy only	HREC- Sciences	19
April 2011	Applied Social Science	TMREC	Core module of M.Soc.Sc.SW	HREC- Humanities	20
October 2011	Psychology	TMREC	Core module of M.Psych.Sc	HREC- Humanities	22
August 2012	Law	TMREC	Taught LLM and MSc	HREC- Humanities	n/a

*Each School REC is approved initially on a pilot-basis for one-year.

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

The REC approved Terms of Reference for both the URECs and the TMRECs require that each of the committees includes at least four members and one of them should be a member of a UCD HREC. Since January 2012 the URECs and TMRECs are required to attend an annual meeting with the HREC Chairs and provide an annual report. The next meeting will take place in February 2013.

SECTION 2

❖ UCD RESEARCH ETHICS APPROVALS SYSTEM

The current UCD Research Ethics Approvals System was established in 2004 and is an internationally recognised system for reviewing research involving human participants and animals. All ethical reviews are conducted using this system. The ethical reviews are carried out by the UCD Research Ethics Committees and are conducted in accordance with internationally accepted best practice and ethical norms. 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 an exemption from full review. Each submission for ethical approval is reviewed by either the AREC or one of the HRECs. All submissions for full ethical review are discussed at the monthly meetings. All submissions, exemptions, decisions, responses, amendments, extensions, resubmissions and approvals are processed by the Office of Research Ethics.

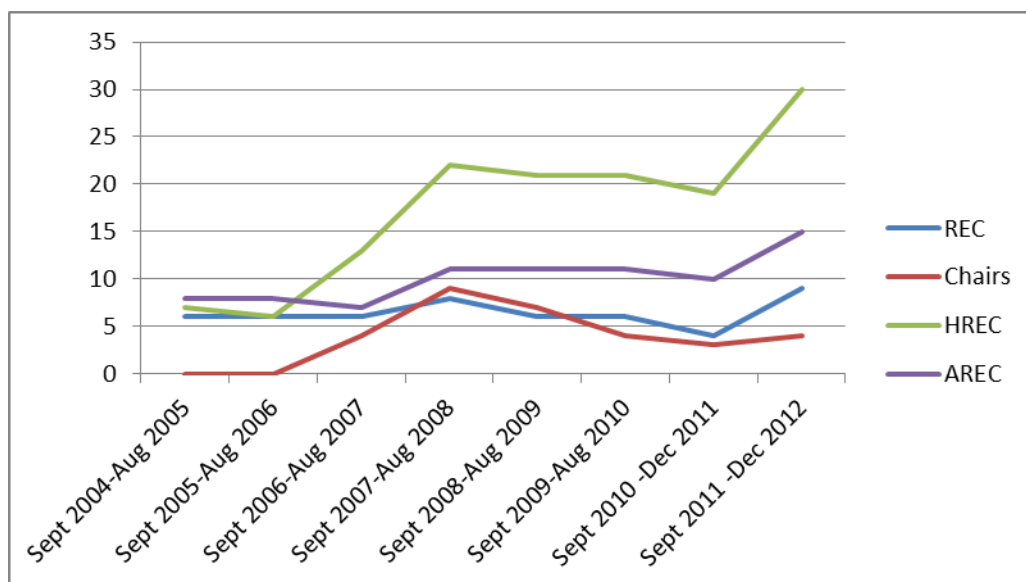


Fig 1: Meetings held by Research Ethics Committees September 2004 – December 2012

(Does not include meetings held by URECs or TMRECs)

SECTION 2

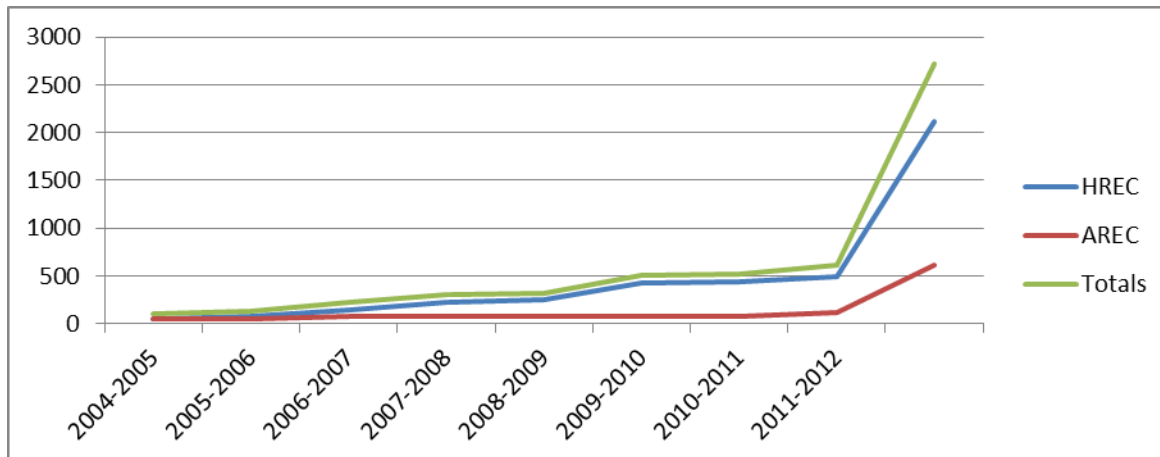


Fig 2: Submissions to the HREC and the AREC = 2,726 (not including URECs or TMRECs)

Table 3: Breakdown of 682 submissions processed from September 2011 – December 2012

	AREC	HREC- Humanities	HREC- Sciences	Totals
New Submissions for full review	79	49	68	196
Exemptions from full review*	n/a	141	145	286
Amendment or Extension Requests Received for Chairs approval	90	37	25	152
Adverse Events Reports Received	5	2	3	10
End of Study Reports Received	n/a	5	5	10
External Requests for exemption	n/a	4		4
Internal non-academic Requests for Exemption	n/a	1		1
Requests to Access UCD Students	n/a			23

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

SECTION 3

❖ COMMISSIONED REPORTS

The following reports were commissioned by the Vice-President of Research.

▪ ***REC Working Group on Regenerative Medicine & Research Report***

The REC Working Group on Regenerative Medicine and Research was reconstituted and the membership was restructured by the REC in December 2008. The Working Group met five times during 2010 and 2011 to discuss and revise the 2006 *REC Report on Regenerative Medicine and Research*. The revised Report was approved by the REC in September 2011 for submission to the Academic Council for their meeting in December 2011 and in October 2012. The Report was then submitted to the Governing Authority in December 2012.

The REC Working Group requested that the UCD Governing Authority would consider a number of recommendations including but not exclusively as follows:

- The Group understands that the Governing Authority wishes to consult widely in the university on this policy document. In particular, the Group recommends that the Academic Council be consulted on the issue of research involving human embryonic stem cells (hESC) or stem cell lines derived therefrom.
- The Group is of the view that the REC should recommend that the Academic Council promote discussion of the issue of human embryonic stem cell research throughout the University with a view to considering one of the following options:
 - 1) Prohibit any research involving human embryonic stem cells and/or human embryonic stem cell lines.
 - 2) Permit research on human embryonic stem cell lines under strict regulation by the University.
- The Group recommends that, in the event that UCD does formulate a policy, including strict regulation, permitting the use of human embryonic stem cells or human embryonic stem cell lines in accordance with option 2), applications for such research should be reviewed by the HREC –Sciences Committee, which would seek the additional specific expertise required to carry out such a review.

The full Report from the REC Working Group on Regenerative Medicine (revised 2011) is available on the Research Ethics Website.

SECTION 3

▪ **Participant Consent Working Group Report**

The Vice-President for Research, attended the REC meeting on 15th December 2011, to highlight issues related to developing trends of online research. He requested that the REC consider what, if any, set of guidelines could be established within UCD to assist researchers in how best to address the issue of obtaining informed consent and at the same time facilitate online research. The REC established a Working Group to examine and report on the topic.

The group reviewed available documentation and available best practice guidelines. While copious documentation is available on conducting research on the internet, the bulk of this report is focussed on experience in Social Sciences and Humanities research. The report highlights some of the important publications on the topic and provides broad guidance in the area. In its deliberations the Working Group identified key aspects of (a) ensuring informed consent and (b) verification of the identity of participants. These issues are dealt with in detail and recommendations and guidelines are provided in how such issues should be addressed by researchers.

The Report was approved by the REC in September 2012 and the Report was submitted to the Vice-President of Research in October 2012.

SECTION 4

❖ CORPORATE MEMBERSHIPS

▪ **University Federation of Animal Welfare (UFAW) UK**

The Universities Federation for Animal Welfare is an independent registered charity that works to develop and promote improvements in the welfare of all animals through scientific and educational activity worldwide. The UCD REC acquired corporate membership in November 2012 to avail of the many benefits that include:

- Promotes and supports developments in the science and technology that underpin advances in animal welfare;
- Promotes education in animal care and welfare;
- Provides information, organises symposia, conferences and meetings, publishes books, videos, technical reports and the international quarterly scientific journal *Animal Welfare*.

▪ **Association of Research Ethics Committees (AREC) UK**

AREC UK is an independent, self-governing body of Research Ethics Committees, local and multi-centre, including their members and administrators. Its aims are to foster excellence in research involving human participants that will enhance human health or well-being. Universities now form the core of AREC membership, and AREC is committed to continuously adapting to the changing needs and requirements of members. The UCD REC is currently in the process of acquiring corporate membership and plan to avail of the many benefits that include:

- Provide training via tailored, in-house workshops and regional seminars which may be undertaken jointly with local organisations;
- Produce up to date information for subscribers and research participants through the quarterly Journal 'Research Ethics' and information sheets.



SECTION 5

❖ OFFICE OF RESEARCH ETHICS ACTIVITIES

Research Ethics interfaces with many areas in UCD and the Office of Research Ethics ensure that the Research Ethics Approval System is a smooth-running process for both researchers and committee members. The Office of Research Ethics has 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 items demonstrate the range of activities that the Office of Research Ethics is engaged with both internally and externally.

1) *Research Ethics Advisory Consultations*

The Office of Research Ethics successfully launched a new Application Advisory Service in September 2009 which was revised in 2012 and renamed the Research Ethics Advisory Consultation. It continues to provide a one-to-one session for UCD students and staff who require assistance with submissions to the Human Research Ethics Committees (HREC) for ethical review and exemption from full review. The advice provided by the administrative staff (advisors) from the Office of Research Ethics is specifically aimed to guide the staff and students on how to submit their documentation for review using the relevant documents and guidelines available on the research ethics website. The overall aim of the service is to improve the quality of the submissions to the HREC which would lead to a shorter/faster approval time.

Both of the HRECs acknowledged that these advisory sessions have made a significant difference to the calibre of applications being submitted to the Committee for review.

The Office of Research Ethics have provided to date **104** one-to-one sessions for researchers seeking assistance. From September 2011 to December there have been **33** sessions provided.

SECTION 5

2) Requests to Access UCD Students

In June 2009 the REC and Registrar approved the UCD Policy and Request Form for requests to access UCD students. It was agreed that all requests would be processed through the Office of Research Ethics. Research by UCD staff and students, and external organisations that involves accessing the students of University College Dublin requires both appropriate ethical approval and the permission of either the Registrar (where multiple groups of students are involved) or the relevant Head of School (where students in one School are involved).

This includes non-Academic staff and students. External Individuals and Organisations whose research utilises UCD facilities or takes place on UCD premises are expected to comply with these policies and procedures. The Registrar has the right to refuse any request and may seek advice from the UCD Research Ethics Committee.

Since September 2011 there were **23** requests processed for the Registrar approval.

3) The University Student Survey Board (USSB)

The USSB was approved by the Academic Council in 2011 to ensure that a co-ordinated approach is taken across the university to surveying student opinion, regardless of where the survey originates. Co-ordination of the student survey process permits creation of an institutional database that includes data from University-wide surveys. Consolidation of the data provides a central source that can be consulted and further analysed as required by interested members of University staff, which can facilitate strategic planning and be used to assist in external reporting requirements.

In consultation with the Office of Research Ethics and the Chair of the REC it was agreed that the web pages containing policy and forms for the USSB would be hosted by Research Ethics website. A new page is currently being created for the USSB.

SECTION 5

4) Workshops, Presentations, Seminars & Talks

The Research Ethics Committees are committed to providing a series of workshops and presentations each year. The committee members also attend talks and presentations on ethics.

In response to specific requests the following presentations were provided:

a) For UCD Graduates:

- School of Information & Library Studies [September & October 2011]
- School of Business [October 2011]
- Conway Institute (*lab-based biological scientists*) [October 2011] College of Human Sciences [December 2011]
- Graduate Studies Transferable Skills Course [December 2011]
- Conway Institute (*lab-based biological scientists*) [October 2011]
- School of Public Health, Physiotherapy & Population Science [December 2012]

b) For UCD Academic Staff:

1st Annual Winter Workshop on *Data Management & Protection* [January 2012]

Invited Speakers:

- Mr Gary Davis (Data Protection Office)
- Mr Asim Sheikh (UCD)
- Dr Jane Gray (NUI Maynooth – IQDA)
- Dr James McBride (ISSDA)

c) Training & Development for Office of Research Ethics Staff September 2011 – December 2012:

- E-Procurement Training
- Information Protection & Insurance (IT Security)
- CMS (web) training
- Access Core Skills
- Introduction to Project Management
- PowerPoint Presentation
- MA in Ethics – funded by UCD
- MSc in Healthcare Ethics & Law (*ongoing*) – funded by UCD

d) External Conferences, Workshops & Seminar

- *Hospital Approvals of Clinical Trials* (Institute of Molecular Medicine)
- *Collecting Oral Narratives –Ethics Best Practice & the Law* (Oral History Network of Ireland)
- *Publication of Research Ethics in Print* (UK Association of Research Ethics Committees).

SECTION 5

5) Research Ethics Compliance Review

The Research Ethics Committee (REC) approved a new Research Ethics Compliance Review in March 2011 with an aim to ensure that all research carried out in UCD that involves humans or animals is compliant with state legislation and international best practice in research. The review was identified in conjunction with the REC and the objective was to get assurance that research was conducted in accordance with the ethical approval granted by the REC.

This Review intends to provide a post ethical approval monitoring programme in association with the UCD Internal Audit who agreed to incorporate a research ethics component in their process which currently looks at risks, controls, policies, procedures and data protection as well as financial and compliance issues. This is in line with compliance reviews in other institutions and with legislation.

The Research Ethics Compliance Review piloted between September 2011 and May 2012. This involved the random selection of approved applications from a number of different schools. The UCD Internal Audit randomly selected 15 approved applications to carry out the pilot which was performed as part of the Internal Audit work programme. The audit consisted of reviewing the documentation for a sample of research ethics approvals and completing a short questionnaire with the researchers (PIs or students). Separate questionnaires were used for animal research projects and human research projects as there are different requirements in the respective research ethical approval processes.

This review, by its nature, focused on the identification of exceptions and weaknesses to facilitate corrective action. It did not give equal emphasis to the areas that operate in accordance with policies and procedures.

The Head of UCD Internal Audit provided a report of his findings for the REC in June 2012 which included the three observations below.

SECTION 5

a) Policies & Guidelines: In general, applicants had a good understanding of the policies and guidelines in place for both human research and animal research studies. A number of the PIs in the sample selected were current or former members of the REC or its sub-committees and were therefore very familiar with the policies and guidelines. PIs submitting their first application to the HREC sub-committees (for human research in both sciences and humanities) in particular noted the assistance of the Office of Research Ethics in providing one-to-one workshops to explain the approval process and the requirements to be complied with. There were two issues which require some further attention:

- Applicants seeking approval from the HREC sub-committees are required to have read the UCD Data Protection Policy and the Data Protection Guidelines on Research in the Health Sector issued by the Data Protection Commissioner in 2007 (the latter document being relevant to only some research projects). It was not clear that all PIs were aware that these were two separate documents.
- Applicants seeking approval from the HREC sub-committees are required to have read the relevant policies and guidelines in preparing their applications and to confirm that they have read the most recent versions on the UCD website. Policies and guidelines are revised and updated from time to time and it may not be possible to confirm which version applicants have read at the time they received approval.

Recommendation

The research ethics application form should capture the details of the version of the policies and guidelines signed-up to by applicants. This recommendation can be facilitated when the online research ethics application system is put in place.

b) End of Study Reports: The HREC ethical approvals process requires PIs to submit an *End of Study Report* when their study is completed. None had been submitted for any of the projects in the sample selected although a number of PIs noted that the research project was not yet complete. This requirement is generally given a low priority and is widely overlooked. Some PIs advised that the issuing of a reminder about this requirement would be helpful.

Recommendation

The low level of compliance with the requirement to submit an *End of Study Report* needs to be addressed. An online research ethics application system would facilitate the sending of an automatic e-mail reminder to the researcher when the End of Study report is due.

c) Encryption of Laptops: Laptops holding personal data are required to be encrypted. It was outside the scope of the review to confirm that this was done, however it is UCD policy.

Recommendation

The guidance regarding the requirement for laptops to be encrypted needs to be reinforced.

SECTION 5

6) *Federalwide Assurance (FWA) for UCD Human Research Ethics*

The Human Research Ethics Committee updated its registration with the US Office for Human Research Protections (OHRP) which was first registered in August 2006.

The HREC received further approval for Federalwide Assurance in January 2009 and again in February 2012 UCD continues to be internationally recognised as having a Human Research Ethics Committee that is compliant with US Federal regulation thus allowing the smooth transition for any funding between US organisations and UCD. The FWA is approved by OHRP for federalwide use, which means that other U.S. federal departments and agencies that have adopted the U.S. Federal Policy for the Protection of Human Subjects (also known as the Common Rule) may rely upon the FWA for the research that they conduct or support.

7) *Human Resource Strategy for Researchers (HRS4R)*

The European Charter and the Code of Conduct for the Recruitment of Researchers are best practice guidelines for the employment and development of researchers. In order to facilitate the implementation of the Charter and Code the European Commission can award the “HR Excellence in Research Award”. This logo is awarded to research institutions and funding agencies that have made significant progress in implementing the Charter and Code.

The process for obtaining the award involved conducting an internal analysis of how the university is performing against the four areas outlined in the Charter:

- Ethical and Professional
- Recruitment
- Working Conditions & Social Security
- Training

The Office of Research Ethics were invited to join a taskforce set up by UCD Research to provide an analysis and identify gaps. An Action Plan to address the gaps in meeting the practices was outlined under each of the principles of the Charter. Following the submission by UCD of the action plan to the European Commission (EC) in July 2012, the EC approved the use of the HR Excellence Award logo.

SECTION 5

The Action Plan recommended the following under the title 'Ethical and Professional Aspects':

UCD will continue to contribute to the discussion on National Protocols and facilitate the implementation of the National Protocols for Research Integrity as published by Royal Irish Academy and the Irish Universities Association.

UCD Research will facilitate the establishment of a Working Group on Research Integrity and Research Ethics including researchers at all levels of the research career path, staff representatives from UCD Office of Research Ethics Committee, UCD Corporate and Legal Affairs Office, UCD Graduate Studies Office, UCD Teaching and Learning, UCD Library, UCD Research etc.

The Working Group will develop mechanisms for embedding good research practice into the culture of all scholarship and promote awareness of research integrity and research ethics issues, including supports to promote good research practice to undergraduates, graduates and staff engaged in research. Specifically, it is suggested that a common module, workshop or staff programme on research integrity principles and ethical practices be developed and applied as part of undergraduate, postgraduate and researcher training.

The Task Force discussed several specific actions which the Working Group may consider in order to ensure that appropriate research practices are embedding into the culture of UCD and researchers at all stages of their career including, for example:

- Develop workshops on research integrity and research ethics
- Best practice in data management and storage
- Establishment of Research Ethics officer at School level
- Establishment of Research Integrity Officer as Institutional level
- Raise awareness of research integrity and research ethics across campus
- Design and dissemination of handbook on research integrity and research ethics for new researchers in UCD



SECTION 5

8) Research Ethics Website

From April to August 2012 the staff of the Office of Research Ethics scoped, developed and populated a new website for Research Ethics using CMS and discontinued the Dreamweaver site. The new website is designed with the researcher in mind and is intended to facilitate easier access to application forms and guidelines. It is intended that when an online application management system is in place that the approval system will become more effective and streamlined. There are a number of new features including an AREC Intranet, a new 'Information for Participants' page, an online booking form for ethics consultations, and a regular 'news' section on the home page. The website will also hosts a webpage for the University Students Survey Board (USSB).

The new website was developed by the staff of the Office of Research Ethics at no extra cost to UCD. All web-authoring for this site is carried out by the staff of this office. The website went live on October 1st 2012: www.ucd.ie/researchethics

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NEWS HEADLINES

AREC Update
 The Animal Research Ethics Committee introduced a number of changes intended to improve its operations and assist researchers with more efficiency. These changes include the introduction of the AREC Intranet as well as some modifications to the Approvals System.

Deadline Dates
 Deadlines for next submissions are as follows: HREC - Sciences (LS): February 25th HREC - Humanities (HS): February 26th AREC: February 22nd

UCD Connect Login
 Username
 Password
 LOG IN

hr
 HR EXCELLENCE IN RESEARCH
 Links

SECTION 5

9) Online Application Management System

The Office of Research Ethics is currently liaising with UCD IT Management Services to develop a system that will enable a speedier and more effective submissions process. This is an application management system that will assist the office with record keeping and assist the researcher with managing their multiple submissions. This is not an online application form. The new system will be piloted for the HREC in early 2013.

10) Meetings with Internal Units and External Organisations

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. The following list provides a sample of the range of stakeholder units throughout the university that interface with research ethics:

- UCD Research [*for both HRS4R and the Marie Curie COFUND*]
- UCD Library Academic Services
- Biomedical Facility & Named Veterinary Surgeon
- Lyons Research Farm & Named Veterinary Surgeon
- University Student Survey Board (USSB) & UCD Institutional Research
- The Office of the Registrar
- Graduate Studies
- Corporate & Legal Affairs Office
- Safety Office
- UCD Internal Audit

UCD Research Ethics is generally considered to possess an effective robust reviewing system in place and from time to time external organisations request advice on how to proceed, or request permission to use our guideline documents as templates.

SECTION 5

- *The Irish Medicines Board (IMB)*

As of January 2013, the EU Directive 2010/63 on the protection of animals used for scientific purposes came into law, with the IMB being the new Competent Authority. The UCD AREC Chair and the UCD Named Veterinary Surgeon have met with the IMB on a number of occasions in 2012 to assess what the new arrangement will mean for researchers, the AREC and UCD. The IMB have also liaised with the staff of the Office of Research Ethics to discuss the current approvals system. The IMB have acknowledged that the UCD Approval System is rigorous and thorough and they have noted our processes with interest for the development of their system. However, notwithstanding these early communications between UCD and the IMB, this legislation introduces a newly created requirement on researchers to adhere to certain procedures in order to obtain approval for their research from the IMB. This newly created set of legal requirements around the use of animals for research and the approval of same by the IMB will, it is expected, place an increased burden on the AREC and the Office of Research Ethics.

11) International Collaboration

UCD has been part of an international collaboration with world-class authors and universities and Epigeum (a spin-out company of Imperial College, London) to develop online learning packages to support all aspects of research from project management and presentation skills to collaboration and career management. Most recently, a new venture in research integrity has been published (2012). This internationally-developed programme is designed to provide researchers with a better understanding of their obligations and responsibilities, along with practical advice on how to deal with the complex situations in which they may find themselves. In partnership with UCD Graduate Studies, these transferable skills components are offered to postgraduates, early stage researchers and research supervisors.

❖ CONCLUSION

The Research Ethics Committee (REC) encourage researchers to appreciate that the ethical aspects of all research carried out by UCD staff and students are addressed in a professional manner, comply with UCD's ethical standards, and abide by any or all relevant regulatory requirements. As this Summary Report demonstrates the REC supports this through the ethical approval, advisory and review processes. The sub-committees have, over the ten years since REC's establishment, processed in excess of 2,800 applications from UCD Researchers across all Colleges and Institutes. Researchers are further supported by relevant Policies and Guidelines which are updated regularly.

There are currently 55 members of the research ethics committees drawn from a variety of academic and administrative areas, each committing and giving their time freely. They ensure that research ethics in UCD is applied according to international standards of best practice and they facilitate a vast array of funded and non-funded research. The confidence of funding authorities during grant application review is enhanced by the support offered to researchers by the REC.

The Office of Research Ethics provides support for all researchers via email and the website and through the Ethics Advisory Consultation and Research Ethics Training across a broad range of disciplines. There are two full-time members of staff who ensure that the approvals system is maintained to a high standard, and that the daily management of the office runs smoothly despite a confined space and the absence of a permanent location. Their commitment to research ethics is evident by their personal dedication to study and development with one MA in Ethics conferred in November 2012 and an MSc in Healthcare Ethics & Law currently ongoing.

Forthcoming for 2013:

- The REC is developing a new programme of educational events which will begin with the 2nd REC Annual Workshop on *Research with Children & Young People* on March 21st. The speakers will include Emily Logan, the Ombudsman for Children, Geoffrey Shannon, Special Rapporteur to the Government on Child Protection, and Dr Colm O'Donnell, Consultant Neonatologist and Director of the Clinical Research Unit in Our Ladies Children's Hospital Crumlin.
- A new Applications Management System will be piloted for HREC submissions in the Spring and will be available to all staff and students in September 2013.
- The REC is committed to the revision of research ethics policy documents and will engage with the Academic Secretariat to develop policies in accordance with Policy Framework Guidelines.¹
- The Office of Research Ethics is to be re-located again – the 4th time in six years.

¹ A full listing of all current REC approved policies and guidelines are available on the Research Ethics website:
http://www.ucd.ie/researchethics/information_for_researchers/policies_guidelines/

