

UCD RESEARCH ETHICS COMMITTEE

Annual Report

September 2005 – August 2007

Approved by the Research Ethics Committee: October 2007



Executive Summary

- ***Research Ethics Committees Workload Increased 2006 - 2007:***

There are currently **6** Research Ethics Committees and 4 of these were established in 2007. The Human Research Ethics Committee (HREC) was split into two due to the increase of applications for review. The School of Psychology established a pilot committee to review undergraduate applications, and another committee was established for the Chairs of the committees.

1. Research Ethics Committee (REC)
2. Animal Research Ethics Committee (AREC)
3. Human Research Ethics Committee – Life Sciences (HREC-LS)
4. Human Research Ethics Committee – Human Sciences (HREC-HS)
5. Chairs REC (Executive Committee)
6. School of Psychology Undergraduate Research Ethics Committee (SPUREC)

- ***There were a total of 46 Committee meetings since September 2005***

- ***There were a total of 461 Protocols reviewed since September 2005***

- ***Provision of Training for Committee Members:***

The first training day for all Research Ethics Committee members was held on June 12th 2007. There are two more ethics training days scheduled for later in 2007, one of which is specifically for Animal Research Ethics Committee members.

The Research Ethics Committee continues to promote the ethical use of human and animal subjects in research throughout UCD in accordance with internationally accepted ethical norms that focus on the welfare of the study participants. The UCD Research Ethics Approval System is well established now and has made a valuable contribution to the University's overall research-intensive programme. Since September 2004 there have been over 400 protocols submitted to both the Human Research Ethics Committees (HREC) and the Animal Research Ethics Committee (AREC) and this is a reflection of the growing awareness of the requirement for, and the benefits of ethical review.

The Research Ethics Committee (REC) met 14 times, approximately every two months since September 2005.

There are three sub-committees that report to the REC and the following is an update on the main aspects of their work:

UCD Research Ethics Approval System

The total number of submissions for ethical review from September 2004 to August 2007 is detailed in the table below:

PROTOCOLS SUBMITTED TO HREC & AREC (September '04 – August '06)			
	HREC	AREC	Totals
Sept 04 – Aug 05	53	50	103
Sept 05 – Aug 06	79	57	136
Sept 06 – Aug 07	149	73	222
Totals	281	180	461

Human Research Ethics Committee Update

The Human Research Ethics Committees examine the ethics of using humans in research. The HREC met 12 times since September 2005.

Establishment of second HREC:

Due to the increase in the numbers of UCD research projects applying for ethical review and the small membership of HREC, the creation of a second Committee was agreed and approved by the Research Ethics Committee.

The two HREC Committees report separately and equally to the Research Ethics Committee. Each Committee is be made up of approximately 50% of the existing HREC in order to ensure that expertise is maintained and includes interdisciplinary members from across the University. Although both Committees include members from a wide range of UCD Schools, each Committee has a specific focus – one deals with the Colleges (2) of Life Sciences and Engineering, Mathematics & Physical Sciences, and the other with the Colleges (3) of Human Sciences, Arts & Celtic Studies, and Business & Law. The Committees are known as HREC-Sciences and HREC-Humanities.

A letter to all Heads of Schools was sent out in February 2007 requesting nominations for membership.

Dr Michelle Butler and Dr William Watson were appointed as the Chairs and Dr Teresa Burke and Dr Joan Tiernan as Vice-Chairs of the two new Committees.

Also as a consequence of the rise in applications being submitted to the HREC for ethical review, it was agreed that both committees would increase the number of meetings per year. There are now 12 meetings scheduled for each year. A specific day has been assigned to each Committee (HREC-Sciences: 1st Wednesday of every month; HREC –Humanities: 2nd Thursday of every month). Each Committee met 4 times from May to August 2007.

School of Psychology Undergraduate Research Committee (SPUREC):

Both the REC and HREC agreed to the creation of an Research Ethics Committee within the School of Psychology (SPUREC) to specifically review undergraduate applications due to the number and nature of undergraduate research protocols requiring approval in that school. The Committee will include two HREC representatives who will provide reports to HREC-Humanities. Nominations to this School committee will be agreed by both HREC and REC. The School of Psychology Undergraduate Research Ethics Committee will run as a pilot for one year and a report will be submitted to REC at the end of the year.

HREC Policies Ratified by the REC

The **Policy on Expenses and Compensation for Human Subjects in Research** was ratified by the REC on 26th April 2007.

Ethical issues arise with the use of Incentives and Rewards as mechanisms to increase subject enrolment, especially when employed in situations where the subject is in a dependency relationship with the researcher, where risks are high, the research is degrading or where participants may have an aversion to a study. The UCD HREC adopted a policy to provide guidance on the appropriate use of expenses and compensations and to ensure that subjects consent voluntarily to research participation and that they are not coerced or unduly influenced or pressurised into participation.

Animal Research Ethics Committee Update

The Animal Research Ethics Committee examines the ethics of using of live animals in research and teaching programmes and actively promotes use of animals in accordance with the 3 Rs policy (reduction, refinement, replacement). The Committee now meets regularly on the first Wednesday of every month and has met 17 times since September 2005.

AREC Policies ratified by REC:

The **Policy on Post Mortem Tissue** was adopted by the REC in February 2007. Protocol applications to AREC involving live animals usually require an animal licence from the Department of Health and Children whereas the use of post-mortem (PM) tissue from the same or different animals does not require a licence. Therefore this policy is intended to ensure good practice regarding the safety and welfare issues in relation to the use of PM tissue.

The **Policy on the Breeding and Maintenance of Genetically Modified Laboratory Animals** was adopted by the REC in August 2006. Both policies are posted on the Research Ethics Website www.ucd.ie/research/ethics

AREC Audits of UCD Animal Facilities:

There have been 4 audits of animal facilities carried out since 2005:

- 1) A one-day external audit was conducted in July 2005 to assess the housing and handling facilities and management of farm animals used for research and teaching purposes at UCD Lyons Research Farm;
- 2) This was followed by a second audit six months later in March 2006 which was to review the winter housing for the animals;
- 3) An external audit of the research animal facilities on UCD campus was carried out in October 2005 (UCD Biomedical Facility, Conway Institute Biological Services Unit and Veterinary Sciences Centre Class 3 unit). The auditors' report was positive overall but recommended refurbishment of the Heating Ventilation and Air Conditioning (HVAC) system in UCD Biomedical Facility. Because of the substantial costs involved the option of building a new unit is being discussed with the Vice-President for Research. In the interim, alternative measures have been taken to control varying levels of humidity in affected rooms;
- 4) Another animal welfare audit was carried out at Lyons Research Farm on 26 March 2007 to assess the housing and handling facilities and management of farm animals used for research purposes and to ensure that best practice is being followed.

AREC Education Seminars/Presentations:

September 2006:

- Dr Harald Schmidt, Assistant Director, Nuffield Council on Bioethics gave a presentation on research involving animals (hosted by the College of Life Sciences). *

October 2006:

- The Chair of AREC presented a 1-hour lecture on Animal Ethics to the incoming College of Life Science and Conway Institute postgraduates as part of a 3-day orientation.

November 2006:

- The Chair of AREC, along with the Chair of HREC and Stephanie Dycke (Irish Council for Bioethics) presented a joint 3-hour workshop “Ethics: Scientific Integrity and Responsibility, Ethics in Biomedical and Animal Research” to the incoming College of Life Science and Conway Institute postgraduates.
- Dr Mark Prescott – UK National Council of the 3Rs gave a presentation on “Replacing, Reducing and Refining the Use of Animals in Research” *

December 2006:

- The Chair of AREC presented a 30-minute overview on UCD Ethics to the Library and Information Group.

January 2007:

- Professor Peter Sandoe of KVL (Copenhagen University Veterinary Sciences Centre) presented a lunch-time talk on “Animal Experimentation – can we find an ethical balance between costs to animals and benefits to humans?” *

May 2007:

- Professor John Webster was the plenary speaker at the Animal Welfare Seminar and presented a presentation on “Concepts in Animal Welfare”. This

seminar was one of a series of lectures for different sections of the animal welfare organizations. *

* These presentations are available on the Research Ethics web site

www.ucd.ie/research/ethics

Ongoing training:

The UCD Biomedical Facility Director and Biomedical Named Veterinary Surgeon for small animals is a joint organiser of and contributor to a two-day training course for new postgraduate students and researchers whose work involves research on live animals. The course is held three times each year, in UCD in March, TCD in October and UCC in December. It aims to optimise the welfare of research animals by reinforcing the principles of reduction, refinement and replacement and by approaching the ethics of animal research from a variety of different perspectives. Participants are encouraged to confront the issues through lectures and practical exercises. The course culminates in a debate with speakers from the Irish Anti-vivisection Society and occasionally from UK groups such as the British Union for the Abolition of Vivisection. This opportunity to engage in open discussion has been welcomed by both speakers and researchers and helps engender a mutual respect for opposing but strongly held moral viewpoints whilst identifying the shared objectives of replacement of animal research with non-sentient alternatives.

Working Group on Regenerative Medicine

A Working Group was established in January 2005 to prepare a report on the possible UCD approaches to the conduct of all aspects of regenerative medicine, stem cell research and assisted human reproduction and the social, ethical and legal factors to be taken into account in determining UCD policy in this area. The Group reviewed the report of the Government-appointed Commission on Assisted Human Reproduction as it applied to UCD. The report from the Working Group was presented to the Vice-President for Research in April 2006 and subsequently submitted to the Senior Management Team in June 2006.

Irish Council for Bioethics and Federalwide Assurance

The REC maintains close liaison with the Irish Council for Bioethics (ICB) which is the collaborative and advisory body for all research ethics committees in Ireland. The ICB recommends that each REC issues an annual report.

UCD obtained Federalwide Assurance in July 2006. Federalwide Assurance (FWA) is an assurance of compliance with the US federal regulations for the protection of human subjects in research. It is approved by the Office for Human Research Protections (OHRP) for all human subjects research conducted or supported by the U.S Department of Health and Human Services (HHS). The FWA is also 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.

Training Needs Assessment for Research Ethics Committees

The training needs of the Research Ethics Committees has been assessed and discussed by all committee members. Professional training in ethics for all members was assessed with a view to achieving the following:

- 1) training for trainers;
- 2) provide seminars/workshops on ethics to other UCD academic staff
- 3) contribute/participate in the modularised elements for 4th level postgraduates.

The first Ethics Training Day was held on 12th June 2007 and 20 members from all of the Research Ethics Committees attended. A one-day programme "Introduction to Research Ethics in a Higher Education Context" was provided by the Professional Ethics unit from Keele University (UK). The training day was widely viewed as a valuable exercise and a second day of the same one-day programme has been scheduled for November 22nd for the members who could not attend in June.

The Chairs of the HRECs met with UCD Human Resources and the Centre for Teaching & Learning to discuss the issue of training for trainers within UCD, the possibility of accreditation, and Continuing Professional Development.

As the training provided by Keele University deals with research in human subjects the AREC agreed to devise their own tailored made training day.

Training in Ethics for AREC:

The Committee are attending a specifically structured training day for Animal Research Ethics on October 23rd 2007. David Morton, Professor of Biomedical Science & Ethics from the University of Birmingham has agreed to be the facilitator for the day.

Online applications and UCD Research Interface

Both of the HRECs and AREC are developing online applications and it is envisaged that both of these applications will be up and running in early 2008 following a pilot period.

Research Ethics Website

It was agreed that the members of AREC would not be named on the website as some members of AREC felt that there could be personal safety issues for those involved with designated facilities. For consistency, it was decided that HREC members would likewise not be named, but that the main REC would. Naming committee members is in line with best practice for the running of Ethics Committees as recommended by the Irish Council for Bioethics.

The Research Ethics web pages are no longer restricted and are now available to the public. However, the UCD Research web pages are currently undergoing a content and structure audit, which may determine a relocation of some of the information onto a more internally-focused intranet or portal. The membership of the REC is included on the website.

Vice-President's Award

In December 2006 at the Winter Celebration of Research, the Vice-President for Research, Professor Des Fitzgerald, presented Dr Peter Wilson with the Research Service award for his contribution to research in UCD and as Chair of the Research Ethics Committee since 2002.

Action required:

1. Adopt Annual Report 2005 – 2007
2. Note Revised Operating Procedures to be submitted at a later date
3. Note Research Ethics Committee Membership (attached)

Professor Peter Wilson
Chair, Research Ethics Committee

Mr John Coman
Corporate and Legal Affairs Secretary
(Research Ethics Committee Secretary)

25th October 2007