

***REC ANNUAL REPORTS***

***September – August 2007-08***

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***September – August 2008-09***

*Approved by the Research Ethics Committee: December 2009*



## Executive Summary

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- **Research Ethics Committees 2007 - 2008:** There are currently 7 Research Ethics Committees
- **There were a total of 95 Committee meetings held from September 2007-August 2009** [not including Undergraduate REC meetings]
- **There were a total of 323 Protocols reviewed since September 2007**
- **Provision of Training for Committee Members:** A training day specifically for the Animal Research Ethics Committee was held on October 23<sup>rd</sup> 2007. The second training day for all Research Ethics Committee members was held on November 22<sup>nd</sup> 2007.
- **The first REC Forum was held in December 2007:** The first REC Forum was held on December 12<sup>th</sup> 2007.
- **HREC Members' Schools Presentations on Research Ethics:** each HREC member made presentations to their committee on how research ethics was dealt with in their school and made recommendations for their specific requirements.
- **Undergraduate Research Ethics Committee (UREC):** two new URECs were established for the School of Psychology and the School of Medicine and Medical Science
- **Research Ethics Workshops for Supervisors:** two half-day workshops were provided specifically for supervisors – September 30<sup>th</sup> 2008 and January 29<sup>th</sup> 2009.
- **Graduate Research Ethics Workshops Series:** the HREC Chairs provided six lunch-time workshops for the College of Human Sciences Graduate School in 2008-09.
- **Website for Research Ethics:** The Office of Research Ethics created a new UCD website for Research Ethics.

**Contents:**

|  | <i>Page</i> |
|--|-------------|
| <b>Executive Summary</b>   | 2           |
| <b>Introduction</b>  | 4           |
| <b>Section 1: UCD Research Ethics Committees – Overview</b>  | 5 – 7       |
| <ul style="list-style-type: none"> <li>• <i>Research Ethics Committee Structure</i></li> <li>• <i>Research Ethics Committee Meetings</i></li> <li>• <i>Committee Membership</i></li> <li>• <i>Research Ethics Approvals System</i></li> <li>• <i>Policy &amp; Guidelines Approved</i></li> <li>• <i>Appeals Process</i></li> </ul>   |             |
| <b>Section 2: Human Research Ethics Committees</b>   | 8 – 9       |
| <ul style="list-style-type: none"> <li>• <i>Undergraduate Research Ethics Committees (URECs)</i></li> <li>• <i>HREC Documentation</i></li> <li>• <i>HREC &amp; Insurance</i></li> <li>• <i>HREC Schools Presentations on Research Ethics</i></li> </ul>  |             |
| <b>Section 3: Animal Research Ethics Committee</b>   | 10          |
| <ul style="list-style-type: none"> <li>• <i>Training &amp; Education in Animal Research</i></li> <li>• <i>AREC Sponsored Education Seminars/Presentations</i></li> <li>• <i>AREC Policies ratified by REC</i></li> </ul>   |             |
| <b>Section 4: Research Ethics Development</b>  | 11 - 12     |
| <ul style="list-style-type: none"> <li>• <i>Research Ethics Committees Forum</i></li> <li>• <i>Research Ethics Development Plan Report</i></li> </ul>  |             |
| <b>Section 5: Research Ethics in Education/Training in UCD</b>   | 13 – 15     |
| <ul style="list-style-type: none"> <li>• <i>Training for Research Ethics Committee Members</i></li> <li>• <i>Training for AREC Members</i></li> <li>• <i>Education in Research Ethics for UCD Students</i></li> <li>• <i>Presentations/Seminars on Human Research Ethics</i></li> <li>• <i>Presentations/Seminars on Animal Research Ethics</i></li> <li>• <i>Supervisors' Workshops</i></li> <li>• <i>Graduate Research Ethics Workshop Series</i></li> </ul> |             |
| <b>Section 6: Research Ethics for UCD</b>  | 16 – 17     |
| <ul style="list-style-type: none"> <li>• <i>Research Ethics Website</i></li> <li>• <i>Research Ethics and External Organisations</i></li> <li>• <i>Federalwide Assurance (FWA) for UCD Human Research Ethics</i></li> </ul>  |             |
| <b>Section 7: Action Required by UCD Academic Council</b>  | 18          |

## **Introduction**

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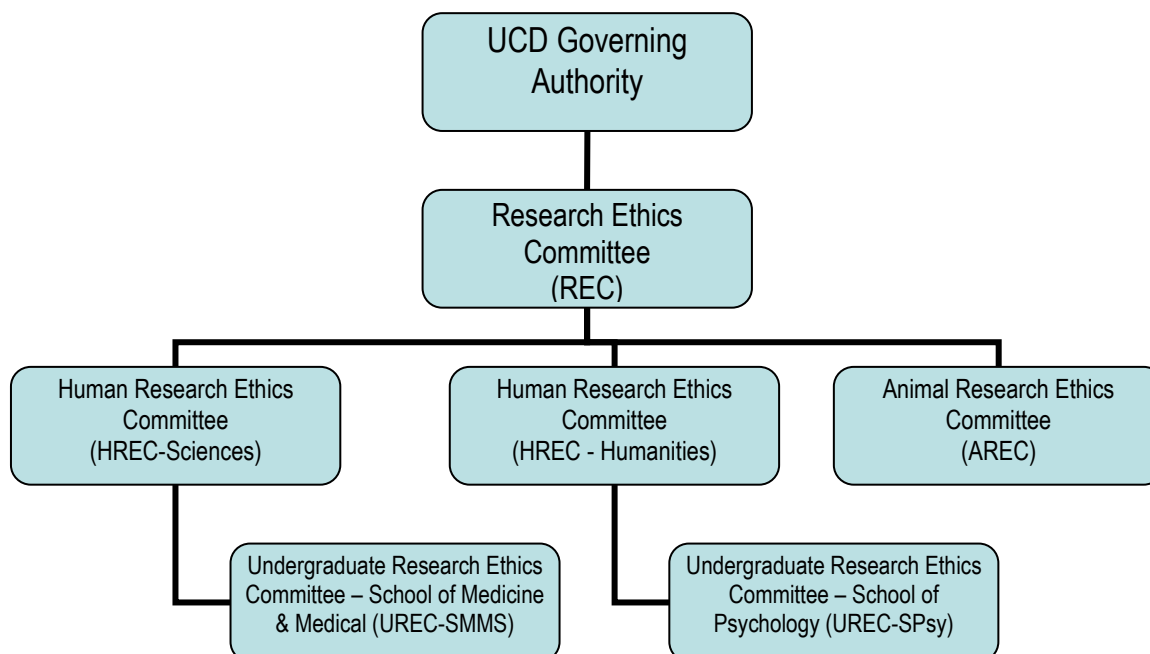
The Research Ethics Committee continues to promote the ethical use of human and animal subjects in research throughout UCD in accordance with internationally accepted ethical norms that focus on the welfare of the study participants. The UCD Research Ethics Approval System is making a valuable contribution to the University's overall research-intensive programme. Since September 2004 there have been over 1,000 protocols submitted to both the Human Research Ethics Committees (HREC) and the Animal Research Ethics Committee (AREC). Awareness of the requirement for Research Ethics continues to grow and the benefits of either an ethical review or exemption are being noted.

The Research Ethics Committee (REC) met 14 times - approximately every two months. The REC receives reports from the sub-committees and discusses all matters of concern with each committee, approves nominations for membership, ratifies policies and hears appeals.

There is one committee called the Chairs Committee and its membership is made up of all the Chairs vice-Chairs for the REC and the sub-committees. There are three sub-committees that report to the REC and the sections below provide an update on the main aspects of their work.

## SECTION 1: UCD Research Ethics Committees - Overview

### UCD Research Ethics Committees reporting structure:



There were 95 research ethics committee meetings for 2007-09 as indicated in **red** below (not including URECs):

| NUMBER OF MEETINGS HELD BY RESEARCH ETHICS COMMITTEES<br>(September '04 – August '09) |           |           |           |           |            |
|---|-----------|-----------|-----------|-----------|------------|
|   | REC       | CHAIRS    | HREC      | AREC      | Totals     |
| Sept 04 – Aug 05  | 6         | none      | 7         | 8         | 21         |
| Sept 05 – Aug 06  | 6         | none      | 6         | 8         | 20         |
| Sept 06 – Aug 07  | 6         | 4         | 13        | 7         | 30         |
| <b>Sept 07 – Aug 08</b>   | <b>8</b>  | <b>9</b>  | <b>22</b> | <b>11</b> | <b>50</b>  |
| <b>Sept 08 – Aug 09</b>   | <b>6</b>  | <b>7</b>  | <b>21</b> | <b>11</b> | <b>45</b>  |
| <b>Totals</b>   | <b>32</b> | <b>20</b> | <b>69</b> | <b>45</b> | <b>166</b> |

### **Committee Membership**

Membership is drawn principally from the Academic Community within UCD but also includes external membership in accordance with the specific requirement of a committee. Members agree to serve three years and have the option to continue after that time if approved by the REC. The membership composition of each committee is in accordance with the REC *Operating Procedures*.

| <b>REC</b> | <b>AREC</b> | <b>HREC-LS</b> | <b>HREC-HS</b> | <b>Total<br/>Membership</b> |
|------------|-------------|----------------|----------------|-----------------------------|
| 17         | 12          | 17             | 18             | 64                          |

### **UCD Research Ethics Approval System:**

Due to the revisions of the AREC and HREC guidelines, applications forms and the new website, the Approvals Systems is more streamlined and efficient. A number of changes to the Decision letters have allowed resubmissions and responses to be dealt with more efficiently and lessen the turn-around time for each submission. Applicants usually receive confirmation of the Committees' Decisions 2-3 days following their review, despite the provision of 5 working days.

The total number of submissions for ethical review (including exemptions from review) for the period September 2007 to August 2009 is detailed in the table below in **red**:

| <b>PROTOCOLS SUBMITTED TO HREC &amp; AREC<br/>(September '04 – August '09)</b> |             |             |               |
|--|-------------|-------------|---------------|
|  | <b>HREC</b> | <b>AREC</b> | <b>Totals</b> |
| <i>Sept 04 – Aug 05</i>  | 53          | 50          | 103           |
| <i>Sept 05 – Aug 06</i>  | 79          | 57          | 136           |
| <i>Sept 06 – Aug 07</i>  | 149         | 73          | 222           |
| <b>Sept 07 – Aug 08</b>  | <b>224</b>  | <b>82</b>   | <b>306</b>    |
| <b>Sept 08 – Aug -09</b>   | <b>251</b>  | <b>72</b>   | <b>323</b>    |
| <b>Totals</b>  | <b>756</b>  | <b>334</b>  | <b>1,090</b>  |

***Policies & Guidelines Approved by the REC:***

- REC Membership Policy
- REC Appeals Procedure Policy
- Guidelines for Appealing a Research Ethics Decision
- HREC Docs 10 – 12 (see Section 2 below)
- UCD Research Ethics Insurance/Indemnity Guidelines
- UCD Research Data Storage and Retention of Research Guidelines
- AREC Policy Document on Education and Training of Persons Carrying out Research on Animals

***Appeals Process:***

The REC received its first Appeal from an applicant who had received ethical approval in June 2007. The applicant wrote to the HREC-Sciences to request a change to the conditions of the approval. The HREC-Sciences Decision was that the conditions could not be waived. This Decision was appealed and the REC upheld the Decision in February 2008.

## SECTION 2: Human Research Ethics Sub-Committees

There are two Human Research Ethics Committees that examine the ethics of using humans in research – HREC-Sciences (LS) and HREC-Humanities (HS). These committees meet regularly every month – where possible the LS on the second Wednesday and the HS on the second Thursday of every month.

### ***Undergraduate Research Ethics Committees (URECs):***

The School of Psychology Undergraduate Research Ethics Committee (UREC-SPsy) completed its one-year pilot during 2007-2008. This Committee had two meetings and reviewed 78 applications in total. A report was submitted to the HREC-Humanities and the REC in September 2008. It was agreed that the pilot programme was a success and the Committee was formalised for 2008-2009. The Committee reviewed 83 applications for the 2008-2009 academic year and will report to the HREC-Humanities and the REC in September 2009.

The School of Medicine & Medical Science Undergraduate Research Ethics Committee (UREC-SMMS) was approved by the REC in October 2008. The UREC-SMMS Committee met to review the research ethics applications of 4<sup>th</sup> year BSc radiography students in the School of Medicine and Medical Science on 29th October 2008. The Committee reviewed thirty-three applications and a report was submitted to the HREC-Sciences.

***HREC Documentation:*** The REC approved the revision of all the current HREC Guidelines and Application forms and also approved the following:

- Request to Amend/Extend Form (HREC Doc 10)
- Unexpected Adverse Events Report Form (HREC Doc 11)
- End of Study Report Form (HREC Doc 12 )
- UCD Research Ethics Insurance/Indemnity Guidelines
- UCD Research Data Storage and Retention of Research Guidelines



**HREC & Insurance:** The REC approved the set-up of another Group on UCD Connect to allow the Safety Office access to the HREC submissions from the School of Medicine & Medical Science, School of Physiotherapy & Performance Science and the School of Nursing, Midwifery & Health Sciences.

**HREC Schools Presentation on Research Ethics:** The Schools Presentation on Research Ethics ran from February to July 2008. Each HREC member was invited to give a short presentation to their Committee (either HREC-Humanities or HREC-Sciences) which was intended to assist the HRECs in understanding how research ethics and the work of the Committees was being perceived by their School and how the HREC could develop a positive interface with the UCD research community.

Each Presentation included 3 specific areas: an introduction as to what the School does and how research ethics was addressed; the perception with the school of what research ethics is: and how HREC members could represent their school with the HREC and how they could represent the HREC within their school.

| <b>Schools</b> | <b>Comments on what each school requires from Research Ethics</b>   |
|----------------|---|
| SPsy           | <ul style="list-style-type: none"> <li>• Ethics are taught throughout the School</li> </ul>   |
| SMMS           | <ul style="list-style-type: none"> <li>• Ethics Liaison Office - with clearly defined role</li> <li>• Training and education</li> <li>• Website should have as much information on current policies etc</li> <li>• Teaching Ethics Committee</li> </ul>   |
| SNMHS          | <ul style="list-style-type: none"> <li>• Annual Workshops, information sessions, seminars</li> <li>• Streamlining processes where ethical approval required from more than one institution</li> <li>• Ethics Liaison Officers – 2 members of staff on REC</li> <li>• What type of monitoring is there?</li> </ul>   |
| SBBS           | <ul style="list-style-type: none"> <li>• Exemption procedures clarified</li> </ul>  |
| SPPS           | <ul style="list-style-type: none"> <li>• SPPS undergraduate committee?</li> <li>• Direct communication between Ethics Committee and Safety Office</li> <li>• Researchers available to answer questions directly at the Committee meetings</li> <li>• Exemption from Ethical Review Application signed by research supervisor and not Head of School.</li> </ul> |
| SICSIFL        | <ul style="list-style-type: none"> <li>• Clarity on when research is exempt</li> </ul>  |
| SHA            | <ul style="list-style-type: none"> <li>• Website should be broken down in a discipline specific manner - It applies more to sciences than humanities</li> </ul>   |
| SS             | <ul style="list-style-type: none"> <li>• Information, advice, training &amp; feedback</li> </ul>  |
| SL             | <ul style="list-style-type: none"> <li>• Monitoring compliance with ethics</li> <li>• Is there appropriate expertise available to HREC</li> </ul>   |
| SCSI           | <ul style="list-style-type: none"> <li>• Need for the increase in awareness of researcher responsibility &amp; ethical sensitivity.</li> <li>• School would welcome the establishment of an in-house committee to review all local proposals &amp; sort them into 'exempt' or 'review' classes</li> </ul>   |
| SP             | <ul style="list-style-type: none"> <li>• Need clear information on research ethics</li> </ul>   |
| SELLL          | <ul style="list-style-type: none"> <li>• Ethics approval mechanism can influence type of research been undertaken particularly for minor thesis – would like in-house approval with external monitoring</li> </ul>  |
| SASS           | <ul style="list-style-type: none"> <li>• Development is needed in training, feedback, advice, information</li> <li>• Responsibility of supervisor to monitor ethical issues</li> </ul>  |

## SECTION 3: Animal Research Ethics Committee

The Animal Research Ethics Committee examines the ethics of using 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 meets regularly on the first Wednesday of every month – there have been 21 meetings between September 2007 and August 2009.

### ***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 (see page 15 below). 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.

### ***AREC Sponsored Education Seminars/Presentations:***

| Date     | Organisation  | Title of Presentation                         | Venue            |
|----------|---|---|------------------|
| 2/10/07  | Dr Simon Festing, Research Defence Society, UK                            | Safeguarding the future of Animal Research    | Conway Institute |
| 24/04/08 | Dr Jens Linge, European Centre for the Validation of Alternative Medicine | 3Rs and the Validation of alternative methods | Conway Institute |

### ***AREC Documentation:***

The REC ratified the following AREC Document:

- AREC Policy Document on Education and Training of Persons Carrying out Research on Animals

## SECTION 4: Research Ethics Development

### ***Research Ethics Committees Forum:***

The UCD Research Ethics Committee (REC) held their first REC Forum on Wednesday, December 12<sup>th</sup> 2007. All of the members of the REC, the Human Research Ethics Committees (HREC) and the Animal Research Ethics Committee (AREC) were invited to attend. The REC Chair, Dr Peter Wilson, opened the Forum by welcoming everyone to the meeting and introduced the Research Ethics Committees' Development Plan as a method for the membership to determine the purpose and objectives of the committees and determine how Research Ethics in UCD might develop.

There were four areas considered for further development:

1. Visibility & Perception of REC
2. Professor/Director/Vice-President of Ethics
3. Training/Education – teaching research Ethics:
4. Development of Research Ethics – Remit & Policy

The points raised under these four areas at the REC forum were later considered at a Special REC Meeting on April 3<sup>rd</sup> 2008 which was held to discuss the Research Ethics Committees' Development Plan.

### ***Research Ethics Committees Development Plan:***

It was agreed that the points raised in the REC Development Plan Report (April 2008) regarding the REC Remit & Policy and the establishment of a Centre for Professional Ethics should be brought to the attention of the Registrar. The four areas identified at the REC Forum were discussed and the following actions were agreed at a special meeting of the REC (03/04/08):

#### *Visibility & Perception of REC*

It was agreed by the REC that there should be an impact assessment by UCD on where and how research ethics assists the reputation of the University. The following actions were put forward:

1. Publication of the Annual Report for general distribution around the University, once it is approved by the Academic Council as required in the *REC Operating Procedures and Policies*
2. Presentations need to be made to individual schools and research Institutes outlining the principles of ethics, the role of the committees and application process:
  - a one-page guideline will be prepared for each school based on the findings from the current HREC programme of Schools Requirements Presentations.
  - a panel of speakers/presenters from the membership should be established to deliver lectures on research ethics.
3. Graduate students and new staff members need to be informed about research ethics at the time they start.
4. Higher profile for the “UCD Research Ethics Website” either as a separate site to “UCD Research” or included in the front page of the “UCD Research” website.

### Training & Education

The REC is aware that issues of training and education extend across three levels:

1. Ensuring appropriate training for members of the REC and its subcommittees;
2. Promoting continuing education and development on research ethics among UCD staff members;
3. Promoting education on research ethics among UCD students.

There should be a provision of training days that are delivered by experienced committee members to include workshops, presentations and an annual forum.

It was also proposed that a review should be carried out on how the Scientific Community and Undergraduates are educated and trained in research ethics.

## SECTION 5: Research Ethics in Education/Training in UCD

**Training for members of Research Ethics Committees:** The second Ethics Training Day was held on 22<sup>nd</sup> November 2007 and 12 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).

**Training in Research Ethics for members of AREC:** There was a specifically structured training day for Animal Research Ethics on October 23<sup>rd</sup> 2007. David Morton, Professor of Biomedical Science & Ethics from the University of Birmingham jointly facilitated on the day.

**Research Ethics Workshops for Supervisors:** There were two half-day workshops provided by the HREC Chairs specifically for UCD supervisors on September 30<sup>th</sup> 2008 and January 29<sup>th</sup> 2009. Heads of School were invited to nominate someone from their School who would benefit from a workshop that would assist them with students seeking ethical review or exemption from review. The HREC Chairs intended to demystify research ethics by explaining the Submission Process – guidelines, policies & forms; Information Sheets, Informed Consent & other supporting documentation; and Exemptions. Approximately 33 supervisors availed of the opportunity to attend. The REC approved the HREC proposal to conduct two half-day workshops annually.

**Graduate Research Ethics Workshops Series:** Members of the HRECs provided six lunch-time workshops for the College of Human Sciences Graduate School. Workshops covering various topics concerning ethical review procedures were scheduled for the academic year 2008-09. These workshops explained the basic ethical responsibilities of researchers working with human subjects and outlined the procedures by which the University’s ethics committees ensure that those responsibilities are met. The following workshops were provided:

- *Ethics Application Process* – Introductory seminar on the submissions process, privacy and recruitment and includes templates used in the process.
- *Ethics and Health Issues*

- *Ethics & Vulnerable Groups Part 1: Children & the Elderly*
- *Ethics & Vulnerable Groups Part 2: Refugees, Asylum Seekers, the disabled*
- *Ethical Dilemmas: a discussion of research design, methodologies and exemptions.*
- *Ethical Approval-What Next?: procedures following approval: requests for amendments and extensions and reporting adverse events.*

Some of these presentations are available on the Research Ethics Website.

***Education in Research Ethics for UCD Students:*** The Committee members of both AREC and the two HRECs provide presentations and seminars for UCD staff and students on Research Ethics throughout the academic year. The following two tables are just some examples of the type of presentations/seminars that were held from September 2007 to August 2009.

### **Presentations/Seminars on Human Research Ethics**

| <b>Date</b>           | <b>Presentation/Seminar</b>   | <b>Attendees</b>   | <b>Venue</b>                          |
|-----------------------|---|--|---------------------------------------|
| Sep 2007-<br>May 2008 | Research Methods Training Module  | MA in Educational Psychology & MEd in Special Education Needs  | School of Education                   |
| Sep 2007-<br>May 2008 | Research Methods and Dissertation 1 Tutorials   | 2 <sup>nd</sup> year students from 3 Masters progs: MA in Ed Psych, Med in Sen, MEd, MA                    | School of Education                   |
| Sep 2007-<br>May 2008 | Core Research Skills  | (CNWY40080)  | School of Medicine & Medical Science  |
| Sep 2007-<br>May 2008 | Advanced Research Skills  | Biological Scientists (CNWY40060)  | School of Medicine & Medical Science  |
| 23/04/08              | Research Methods and Dissertation 1 module  | Year 3 BSc Physiotherapy students  | School of Physiotherapy               |
| 13/05/08              | Presentation on Research Ethics   | PG College of Human Sciences   | UCD Newman                            |
| Jul 2008, Sep 2008    | 'Integrity in Research'   | Molecular Medicine Ireland Clinician Researchers   | School of Medicine & Medical Science  |
| Apr 2008              | Advanced Research Skills Module   | PG College of Life Sciences  | Conway Institute                      |
| 2008-09               | Online Research Skills: Ethics- Good Research Practice & Ethics – Use of human subjects | 50 CLS & EMPS students<br>Online Research Skills Grad (ANSC50020) (CSI50050) –                             | UCD                                   |
| 20/01/09              | Ethics Presentation   | Graduate Research Skills Seminar   | School of History & Archives, UCD     |
| 25/02/09              | Research Ethics   | Research Methods & Dissertation PHTY30120 – BSc Physiotherapy & BSc Health & Performance Sciences students | UCD                                   |
| 19/03/09              | Ethics Presentation   | Research & Innovation Committee  | College of Arts & Celtic Studies, UCD |

### Presentations/Seminars on Animal Research Ethics

| <b>Date</b>   | <b>Presentation/Seminar</b>   | <b>Attendees</b>   | <b>Venue</b>                         |
|---------------|---|--|--------------------------------------|
| 4/10/07       | Ethics in Animal Research   | PG module: Introduction of Core Research Skills (CNWY50020)                                      | Conway Institute                     |
| 4/10/07       | UCD Seminar Series on Animal Welfare sponsored by the Veterinary Council of Ireland | 4 presentations  |                                      |
| Oct 2007      | Animal Ethics   | PG Orientations  | Campus Wide                          |
| 8 & 9/10/07   | LAST-Ireland 2 day training course in animal welfare, ethics and legislation        | Researchers who use live animals   | TCD                                  |
| 24/10/07      | Animal Ethics training day in association with Prof. David Morton.                  | AREC Committee Members   | UCD Nova                             |
| 14 & 15/01/08 | LAST-Ireland 2 day training course in animal welfare, ethics and legislation        | Researchers who use live animals   | UCD                                  |
| 28 & 29/01/08 | LAST-Ireland 2 day training course in animal welfare, ethics and legislation        | Researchers who use live animals   | UCC                                  |
| 5/03/08       | Animal Research Ethics  | UCD Science Medicine and Society undergraduate module (MDSA10210)                                | School of Medicine & Medical Science |
| 11/06/08      | The Ethics of Animal Research Ethics  | PG module on Research Ethics   | Trinity College Dublin               |
| 23 & 24/06/08 | LAST-Ireland 2 day training course in animal welfare, ethics and legislation        | Researchers who use live animals   | NUI Galway                           |
| 29 & 30/09/08 | LAST – Ireland 2 day training course in animal welfare, ethics and legislation      | Researchers who use live animals   | TCD                                  |
| 04/03/09      | Animals in Research   | Science, Medicine & Society Module :MDSA10210  | UCD                                  |
| 09/03/09      | LAST – Ireland 2 day training course in animal welfare, ethics and legislation      | Researchers who use live animals   | UCD                                  |
| 24/03/09      | 'Integrity in Research'   | Molecular Medicine Ireland CSFP course for Physician Scientist (MD/PhD candidates, 19 students). | Conway Institute                     |

## SECTION 6: Research Ethics for UCD

Apart from providing reviews, exemptions and training/education, the Research Ethics Committee members are also engaged in a variety of ways, such as contributing to the design and content for the new website, and streamlining the guideline documentation continually. Not only do the members assist the staff and students of UCD they also provide information and assistance to external bodies when requested.

**Research Ethics Website:** Following on from the recommendations at the REC Forum a new and autonomous Research Ethics Website was created and developed, which went live in September 2008. All of the Committees are represented on the site including all of the revised documentation – approved policies, guidelines and application forms. The administrative staff in the Office of Research Ethics received training in web authoring. The new website allows the Committees to update and amend on a daily basis.

**Research Ethics Assisting External Organisations:** Upon occasion the Research Ethics Committees are approached for advice, guidance and assistance by external organisations who see UCD Research Ethics as providing a best practice model for ethical reviews. In light of the Innovation Alliance the REC is looking forward to a mutually beneficial dialogue with the research ethics committees in Trinity College Dublin. The REC is currently seeking to establish a working link with the TCD research ethics administration to ensure that the approval systems are in alignment.

| Date     | External Organisation   | Meeting with   | Purpose of Meeting   |
|----------|---|----------------|--|
| 07/12/07 | Heike Felzmann, NUI Galway  | CHAIRS         | NUIG gathering information regarding the organisation and the experiences of the UCD REC as part of a larger review of RECs in Ireland. Also conducted a review on behalf of the HSE and the Office of the Minister for Children |
| 21/05/08 | Dr Justine Horgan<br>Cosc - The National Office for the Prevention of Domestic, Sexual and Gender-based Violence,<br>Department of Justice, Equality and Law Reform | HREC<br>Chairs | Seeking Advice on establishing and setting up an ethical review system for applications to carry out funded projects. Requested permission to use current HREC documentation as template.  |



***Access to UCD Students Policy:***

In February 2008 the Registrar's office requested assistance with devising a formal procedure that would deal with external requests from other organisations who wished to access students to conduct research. The HREC Chairs liaised with the Registrar's Office in the development of a policy document, an application form and a submissions procedure for such requests. The REC agreed that submissions would be processed by the Office of Research Ethics in accordance with the guidelines agreed by the REC and upon the condition that there would be no undue burden for the Office of Research Ethics.

***Working Group on Regenerative Medicine:***

The Working Group on Regenerative Medicine was reconstituted at the REC meeting on December 2008 and a meeting of the Working Group with Dr Deirdre Madden UCC took place on November 28<sup>th</sup>. It was agreed that the Working Group would write to ethics committee of Irish Medical Council, in light of recent high court judgement on Roche v Roche and the UCC and UCD press releases. A letter and a copy of the Working Group for Regenerative Medicine Report (2006) was sent to Dr Madden on December 8<sup>th</sup> suggesting that the Medical Council might review their ethical guidelines in light of the recent UCC decision and earlier publication by the Irish Council for Bioethics. Professor William Watson (HREC-Sciences Chair) replaced Dr Michelle Butler on the Working Group.

***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 approval for Federalwide Assurance in January 2009 and 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.

## Section 7: Action Required by UCD Governing Authority

### Action Required:

1. Adopt REC Annual Reports 2007-2008 and 2008-2009
2. Approve Revised REC Operating Procedures (attached)
3. Note REC Approved Policy Documents (attached)

Professor Peter Wilson  
Chair, Research Ethics Committee

31<sup>st</sup> August 2009

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