



UNIVERSITY *of* LIMERICK  
OLLSCOIL LUIMNIGH

**University of Limerick Animal Ethics Committee  
(ULAEC)**

**Use of Live Animals in Research**

**Code of Practice**

## **1. Animal Ethics at UL**

The code of practice of using animals in research is carried out in addition to the Academic Integrity in Research code of conduct [1], and the Academic Regulations of the University of Limerick. It expects all members of the University using protected animals in research to observe the 3 R's : Reduction, Refinement, and Replacement of Animal experiments of which much of the legislation controlling the use of live animals for research is based. Reduction is achieved by using methods which minimise animal use and enable researchers to optimise the levels of information from fewer animals or to obtain more information from the same number of animals, thereby, reducing future use of animals. Refinement refers to improvements to scientific procedures and husbandry which minimise actual or potential pain, suffering, distress or lasting harm and/or improve animal welfare in situations where the use of protected animals is unavoidable. It applies to the lifetime experience of the animal. Replacement refers to methods that avoid or replace the use of animals defined in an area where they would otherwise have been used.

The University of Limerick does not have an animal facility; however, all UL personnel carrying out procedures on live protected animals, elsewhere, must do so in accordance with protocols which have been approved by UL Animal Ethics Committee (ULAEC). Where research involving animals is conducted by University of Limerick researchers outside of the University, it is the researcher's responsibility to ensure ethical approval is sought from the institution responsible for the care of the animals.

## **2. Definitions**

The European council directive 31986L0609[2] give the following definitions for protected animals, experiment, and competent persons. Other definitions can be found in the directive.

### **2.1 Definition of a 'Protected Animal'**

'Protected animals', unless otherwise qualified, are those which have the capacity to experience pain, suffering, distress or lasting harm as a result of procedures which may be carried out in the course of research. Based on expert opinion for the EU Commission (EFSA Journal (2005) 292, 1-46) this includes all non-human vertebrates, cyclostomes (lampreys and hagfish), cephalopods (octopods, squid, cuttlefish and nautiloids) and

decapod crustaceans (lobsters, crabs and prawns). Larval stages of fish and above invertebrates are judged to be capable of experiencing pain, suffering or distress once they are capable of feeding independently. Vertebrates are judged to have this capacity from the beginning of the last third of development within the egg or mother. However, the principles of care and use as outlined later apply to all animals used in research, including those that fall outside the definition of protected animals

## **2.2 Definition of an ‘Experiment’**

'experiment' means any use of an animal for experimental or other scientific purposes which may cause it pain, suffering, distress or lasting harm, including any course of action intended, or liable, to result in the birth of an animal in any such condition, but excluding the least painful methods accepted in modern practice (i.e. 'humane' methods) of killing or marking an animal; an experiment starts when an animal is first prepared for use and ends when no further observations are to be made for that experiment; the elimination of pain, suffering, distress or lasting harm by the successful use of anaesthesia or analgesia or other methods does not place the use of an animal outside the scope of this definition.

## **2.3 Definition of a ‘Competent Person’**

'competent person' means any person who is considered by a Member State to be competent to perform the relevant function. This is defined in SI566 [4] as “suitably qualified person’ means a person qualified to provide advice or treatment, or both, relating to the health and welfare of experimental animals”. The term competent has not been well defined, an explanation is given by Federation of European Laboratory Animal Science Associations (FELASA) [6], and Norwegian ethics definition [7].

## **3. General Care and Husbandry of Animals**

The following points are summarised from European Council directive 31986L0609, and Duke University animal Programme code of Ethics [3].

- 3.1 When live animals are used in research or biological testing, there must be a reasonable expectation that such utilization will contribute to the enhancement of human or animal health, the advancement of knowledge, or the good of society. The relative value of the study is a particularly important consideration in potentially painful experiments where there is an ethical imperative that the benefits of the research clearly outweigh any pain, discomfort, and distress that might be experienced by the animals.
- 3.2 All animals shall be provided with housing, an environment, at least some freedom of movement, food water and care which are appropriate to their health and well being, which must be inspected on a daily basis
- 3.3 Researchers shall as far as possible recognize the validity of data generated by animal experiments carried out in at other institutions.
- 3.4 It is recognized that in many research protocols there is simply no alternative to the use of live animals. Despite this social imperative for animal experimentation, all investigators have an ethical obligation to explore ways in which animals can be partially or totally replaced by other biological or mathematical/computer systems. When a research question can be pursued using reasonably available non-animal or *in vitro* models and still result in sound scientific conclusions, the investigator should choose these alternatives.
- 3.5 Selection of an appropriate animal model is an important consideration, particularly at a time when alternative models for animal research are being emphasized. It is the investigator's responsibility, therefore, to select the optimal species for a particular project. In addition, the number of animals utilized in a protocol should be minimized consistent with sound scientific and statistical standards. It is also the investigator's responsibility to consider the source of the animal and ensure that all animals used for experimental purposes are lawfully acquired as defined in Section 2 of SI566/2002 [4] or subsequent updates.
- 3.6 When animals are used in a research project the investigator has an ethical obligation to seek the least painful techniques feasible that will allow the protocol objective(s) to be pursued adequately. If a procedure has associated pain, discomfort, or distress, it is imperative that the investigator estimate the probable

occurrence, magnitude, and duration of the pain, discomfort, or distress in order to adequately plan for the treatment of pain.

- 3.7 In potentially painful procedures the investigator must take all necessary steps to assess and monitor pain as well as discomfort and distress. In assessing pain the investigator should use behavioural signs based on the normal behaviour pattern of the species under study. In some circumstances, physiological parameters may be used (e.g., plasma cortisol, catecholamines, white blood cell counts, and cardiovascular parameters).
- 3.8 If a procedure will cause more than momentary slight pain or distress to the animal, the pain must be minimized both in intensity and duration through the administration of appropriate anaesthetics, analgesics, and tranquilizers consistent with acceptable standards of veterinary medicine. It should be emphasized that the requirement for the alleviation/reduction of pain applies not only at the time the procedure is being conducted but also following the procedure until such time when the pain is either alleviated or reduced to an acceptable tolerance level.
- 3.9 In no case should potentially painful experiments be conducted on an awake animal while under the influence of a paralytic or curarizing drug without the concomitant use of an appropriate anaesthetic.
- 3.10 Research in which painful stimuli are used should be so designed as to provide a means of escape from that pain by the animal.
- 3.11 It is recognized that in certain research protocols the administration of appropriate anaesthetics and/or analgesics will compromise the scientific validity of the experiment. Such experiments must be justifiable in terms of scientific design and value, and the deletion of these drugs should be based on referenced scientific fact or experimental data and not intuition. In addition, pain, discomfort, and distress levels should be carefully monitored. There is a limitation on the pain to which an experimental animal may be exposed. Investigators should choose the earliest possible end-point in order to minimize pain and discomfort. An animal that is observed to be in a state of severe pain that cannot be alleviated or reduced to an acceptable tolerance level should be immediately euthanized.

- 3.12 No animal should be subjected to multiple survival surgeries, except when they are interrelated and essential to the primary research objective.
- 3.13 Physical restraint procedures should be used on awake animals only after alternative procedures have been considered and found to be inadequate. When restraint is utilized the animal should be trained or conditioned to the restraining device, using positive reinforcement, prior to the beginning of the experiment. The restraining device should provide the minimum restraint consistent with the maximum security and comfort of the animal. In addition, the restraining device should provide the animal with the greatest possible opportunity to assume its normal postural adjustments. Awake animals should not be subjected to prolonged physical restraint.
- 3.14 It is the responsibility of the investigator to ensure that adequate post-surgical/procedural care is provided to all animals. This care must meet acceptable standards in veterinary medicine and be provided as long as necessary, including during non-duty hours.
- 3.15 Euthanasia is the act of inducing painless death. The decision to perform this act must be taken by a competent person, preferably a veterinary. The sacrifice of an animal will be carried out by a competent person in line with current national guidelines. If an animal will not be subjected to euthanasia at the completion of a research protocol, it is the responsibility of the investigator to ensure that the final disposition of the animal is both humane and acceptable.
- 3.16 Procedures involving the use of animals should be performed by or under the immediate supervision of an individual with the appropriate qualifications and experience relative to the procedures to be carried out on live animals. People carrying out the procedure should have an adequate level of competence.
- 3.17 Records shall be kept of all animals used. In particular, these records shall show the number and species of all animals acquired, from whom they were acquired and the date of their arrival. Such records shall be kept for a minimum of three years.
- 3.18 Ensure that any outsourcing of animal research adheres to the European/Irish regulations

#### 4.0 Exemption from full review

Ethical approval with exemption from full review is granted in very few cases for the use of animals for Research. However, at the discretion of the Committee, exemption from full review may be granted in certain circumstances, some of which may be:

- 1) Approval by a recognised Animal Research Ethics Committee already exists. If this is the case please attach the approval to your application to the ULAEC.
- 2) The study involves the use of certain invertebrate animals. See section 2.1 above
- 3) The study involves animals which are not exposed to any procedure which would cause pain or distress to the animal that is greater than would be during their normal lives eg non experimental, agricultural, clinical veterinary practices
- 4) Other situations as justified by the applicant.

**The following checklist may be used to determine if Full Animal Ethical Approval is Required**

	YES	No
<b>Does the Research Involve any of the following</b>		
<b>Pain or distress to the animal that is greater than would be during their normal lives</b>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Confinement of the animal</b>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Changes to the diet which will cause pain or distress</b>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Surgery</b>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Removal of tissues/organs</b>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Isolation of organs</b>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Drug Testing/Manufacture</b>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Fitting Prosthesis</b>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Sedation</b>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Narcosis</b>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Analgesia</b>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Muscle Relaxation</b>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Genetically Modified Organisms/Microorganisms</b>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Any procedure which the animal would not normally be exposed to during its life outside of research scenario</b>	<input type="checkbox"/>	<input type="checkbox"/>
<p>If you have answered <b>Yes</b> to any of the above questions, you will need to complete <u>the full</u> ULAEC application form and submit it to the ULAEC for review</p>		

#### 5. Legal Liability and Insurance Policy

It is the sole responsibility of the applicant to follow European Guidelines on animal experimental procedures, as indicated in the European council directive 31986L0609 [2],

or its subsequent updates and the cruelty to animals act 1876 as amended by the European Regulations 2002, and its application to Ireland under SI566/2002 [4], SI613/2005[5]. Where applicable, the applicant should have a licence from the Department of Health and Children.

It should be noted that under these guidelines one or more of the following licenses may be required

1. Project License
  - Required where procedures which are not part of normal husbandry practices are performed on animals
2. An establishment License
  - Required where research is taking place on a premises which is not licensed as a research facility.
3. Clinical Trial License

## **6. UL Animal Ethics Committee operating procedures**

- 6.1 All procedures involving live animals (both protected and invertebrates) by UL personnel, including staff and students must be approved by the ULAEC.
- 6.2 Those applying for an Exemption from Full Review do not need to complete Sections 8 to 13 inclusive of the ULAEC application form.
- 6.2 Applications should be submitted using the standardised ULAEC Application to Dr Seán Fair, Room SR2-005, Department of Life Sciences
- 6.3 The ULAEC will meet in the first week of each month except August. If there are no applications, the ULAEC will not meet.
- 6.4 Applications must be submitted no later than the 20<sup>th</sup> day of the month to be considered at the subsequent monthly meeting eg If submitted on March 19<sup>th</sup> then the application will be reviewed at the April meeting.
- 6.5 Applications will be circulated to ULAEC members via email prior to the meeting
- 6.6 Application will either be approved, approved subject to certain alterations, or rejected.

## **6. Misconduct and Consequences of Misconduct**

The primary responsibility for handling research misconduct rests with the University and/or employer. Misconduct and consequences of misconduct in research is defined in

the document ACADEMIC INTEGRITY IN RESEARCH code of conduct [1]. Non compliance with the code may give rise to allegations of misconduct and in turn misconduct in research may be grounds for disciplinary action, and/or action under the terms of SI566. Further to this misconduct in the treatment of animals in research shall be dealt with in a thorough, fair and confidential manner. Misconduct deemed to be within the bounds of Section 5(E) of SI566/2002, will be dealt with through the appropriate legal routes.

7. Complete application forms should be sent directly to the ULAEC Chairman, Dr Seán Fair, Room SR2-005, Department of Life Sciences, UL email: [sean.fair@ul.ie](mailto:sean.fair@ul.ie)

## 7. References

- 1 ACADEMIC INTEGRITY IN RESEARCH code of conduct currently in draft format
- 2 Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31986L0609:en:NOT>
3. The Duke Animal code of ethics : available at [http://vetmed.duhs.duke.edu/policy\\_code\\_on\\_ethics.htm](http://vetmed.duhs.duke.edu/policy_code_on_ethics.htm)
4. Statutory Instrument European Communities (Amendment of Cruelty to Animals Act 1876) Regulations 2002 (SI566) available at <http://www.irishstatutebook.ie/2002/en/si/0566.html>
5. Statutory Instrument European Communities (Amendment of Cruelty to Animals Act 1876) Regulations 2005 (SI613) available at [http://www.dohc.ie/other\\_health\\_issues/uaeosp/si2005613.pdf?direct=1](http://www.dohc.ie/other_health_issues/uaeosp/si2005613.pdf?direct=1)
6. T. Nevalainen et al Federation of European Laboratory animal science associations, FELASA guidelines for education of specialists in laboratory animal science (Category D) <http://www.felasa.eu/recommendations/guidelines/guidelines-for-education-of-specialists-in-las-category-d/>
7. Regulation on Animal Experimentation unofficial translation of Norwegian Ministry of Agriculture guidelines. <http://oslovet.veths.no/statute.html>