



## Use of Animals for Research & Teaching Policy

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## 1. Purpose

At Atlantic Technological University (ATU), research involving animals plays an important role in advancing knowledge in animal and human health, animal biology and ecology, and improving welfare and efficiencies in animal production systems. Such research may also inform measures designed to protect animals and their habitats. Recognising the importance of this research, ATU is committed to ensuring that any use of animals for research or teaching is conducted with respect and consideration for animal welfare. The policy is guided by established principles of *Replacement, Reduction, and Refinement* (the 3Rs).

This policy seeks to provide a comprehensive framework for governing and managing procedures conducted on animal subjects within the scope of research and teaching at ATU. It does so in the context of statutory and institutional requirements for the ethical use of protected live animals, as defined within the scope of statutory instruments and directives.

## 2. Scope

This policy applies to all ATU personnel, including staff and students, engaged in research or teaching involving protected live animals on any ATU campus or on behalf of ATU at any location. Research not involving live animals is governed by the ATU Research Ethics Policy.

## 3. External Reference Documents

ATU's research and teaching activities involving protected live animals are subject to *Directive 2010/63/EU* and its transposing legislation, *Statutory Instrument No. 543 of 2012* as amended (with exclusions for animal husbandry, clinical veterinary, and agricultural practices).

- *Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes.*
- *Statutory Instrument No. 543/2012 - European Union (Protection of Animals used for Scientific Purposes) Regulations 2012*

## 4. Policy

### 4.1 Guiding Principles

The principles of *Replacement*, *Reduction*, and *Refinement* (the 3Rs) inform all animal-related research and teaching at ATU.

#### 4.1.1 Principle of Replacement

Animals may only be used where no suitable alternative to *in vitro*, *in silico* or literature-based alternative exists.

*In vitro* alternatives refer to and could include studies on, for example, cell cultures, bacterial cultures, or biological molecules.

*In silico* alternatives refer to computer-aided experiments, analysis, models or simulations used to predict (for example) how drugs, chemicals, or diseases might behave in a living organism.

Literature-based alternatives may involve the use of existing research, literature reviews, analyses, and databases to gather necessary information without conducting new experiments involving animals.

Applications for animal research ethical approval must first satisfy the University's *Animal Research Ethics Committee (AREC)* of the intrinsic value of the proposed activity. All applicants must engage in the pursuit of alternatives to the use of live animals, including research to develop and promote the adoption of such alternatives.

#### 4.1.2 Principle of Reduction

This principle mandates reducing the number of animals used in research and teaching to the absolute minimum necessary to achieve the objectives of a study or educational programme. Each proposal involving the use of animals must include a detailed justification for the number of animals required. This justification should be supported by a carefully designed experimental approach, incorporating robust statistical analyses to ensure that the smallest possible number of animals is used without compromising the scientific integrity or educational value of the work.

#### 4.1.3 Principle of Refinement

This principle underscores the importance of prioritising animal welfare in all aspects of research and teaching that involves live animals. It requires that every procedure, from

design to execution, is conducted with the highest standards of care and ethical consideration. This is facilitated by adherence to approved standard operating procedures, appropriate training, and carefully considered authorisation to conduct approved procedures. Central to this is the requirement to adhere to statutory standards of training and education for all personnel involved. All procedures are subject to review and refinement by the Animal Welfare Body and the Health Products Regulatory Authority.

ATU is committed to ensuring that staff and students adhere to the guidelines, SOPs, and policies of the University's *Animal Research Ethics Committee (AREC)*, the *Animal Welfare Body*, and the Designated Veterinarian(s).

## **4.2 Ethical Requirements / Animal Research Ethics Committee**

The University's *Animal Research Ethics Committee (AREC)* will evaluate proposals to conduct procedures on live animals for research or teaching and determine whether the use of animals is justified within ethical considerations. This committee's primary role is to evaluate if the proposed use of animals aligns with established ethical standards.

All ATU teaching and research activity involving the use of live animals that come under *S.I. 543/2012* must have prior ethical approval from the AREC. Where the research or teaching requires the conduct of a procedure, as defined by *S.I. 543/2012*, it also requires an *Individual Authorisation* and *Project Authorisation* issued by the Health Products Regulatory Authority (HPRA).

### **4.2.1 Terms of Reference of University Animal Research Ethics Committee (AREC)**

1. Ensure ATU operates in line with international best practice or standards on the use of animals for scientific purposes.
2. Facilitate implementation and compliance with legislation concerning the use of animals for scientific purposes.
3. Promote the application of the principles of *Refinement, Reduction* and *Replacement* (3Rs) in relation to the use of live animals in research or teaching.
4. Ensure ATU adheres to appropriate standards of animal welfare, housing, and husbandry.
5. Examine research proposals in order to consider and decide on ethical issues arising from the use of animals and/or their organs and tissues and ascertain whether or not each individual proposal is acceptable.
6. In the context of an institutional acceptance that the use of animals must be avoided unless no valid or practical alternatives are available, it is the responsibility of the AREC to consider the following during evaluation of each application:
  - i. Scientific validity and novelty of the proposed research

- ii. Welfare implications or costs to animals being used
- iii. Proposed benefits of the work
- iv. Wider social acceptability of the proposed projects

#### **4.2.2 Composition of AREC**

Composition of the Animal Research Ethics Committee is informed by national and international best practice. Membership of the committee is ratified by the Vice President for Research and Innovation in ATU and comprises:

- Chairperson (Animal Research Compliance Officer)
- Designated Veterinarian(s)
- Animal Care and Welfare Officer(s)
- Representative(s) of the research community in ATU
- Person(s) with statistical expertise
- Independent / lay person not engaged in research

All persons must declare potential conflicts of interest in relation to direct or indirect involvement with project(s) under review. Where such potential or actual conflict of interest arises, such individuals must not be involved in the review.

### **4.3 Compliance and Authorisation**

Compliance with statutory requirements for the use of animals under *S.I. 543/2012* is a shared responsibility of all university members engaged in research and teaching involving protected live animals.

#### **4.3.1 Designated Statutory Roles**

The University has made appointments to specific statutory roles to monitor and ensure compliance with legislative requirements. These are:

- *Animal Ethics Compliance Officer (CO)*: Oversees general compliance with animal use regulations.
- *Designated Veterinarians (DVs)*: Provide veterinary oversight and animal welfare expertise.
- *Animal Care and Welfare Officers (ACWOs)*: Oversees the day-to-day welfare of the animals.

- *Training Officer*: Ensures appropriate training of and for University members involved in animal research and teaching.
- *Information Officer*: Manages and disseminates relevant information within the university.

#### **4.3.2 Animal Welfare Body (AWB)**

The persons holding the designated statutory roles in 4.3.1 above collectively form the University's *Animal Welfare Body (AWB)*. The AWB has a statutory responsibility to ensure the welfare of animals used in research and teaching. Detailed terms of reference for the AWB are available in Appendix II of the university's *Site Master File*.

#### **4.3.3 Project Authorisation Process**

Applications for Project Authorisation to the Health Products Regulatory Authority (HPRA) can only be submitted by staff members holding an Individual Authorisation from the HPRA.

Any individual performing a procedure on a live animal protected by *S.I. 543/2012* requires the following:

- a. Ethical approval from the University's Animal Research Ethics Committee (AREC)
- b. A valid Individual Authorisation issued by the HPRA (which must include authorisation for the proposed procedure(s)) along with a valid Project Authorisation issued by the HPRA.
- c. Evidence that relevant training deemed acceptable by the Compliance Officer has been completed.
- d. A training record certifying the demonstration of procedural competency.

#### **4.3.4 Obligations when Practising under an Authorised Project**

All individuals must adhere to the conditions of their Project Authorisation.

The University's AWB has the authority to instruct individuals to cease their projects immediately if non-compliance is observed. Repeated non-compliance may lead to recommendations by the AWB for AREC to deny the approval of ethics applications and / or for HPRA to revoke an individual's authorisation to use animals.

#### **4.3.5 Monitoring and Auditing**

All research or teaching involving protected live animals is subject to reporting and audits by the Health Products Regulatory Authority (HPRA). Activities must align with the Establishment Authorisation issued to the University by the HPRA.

## 4.4 Responsibilities

### 4.4.1 Statutory Roles & Responsibilities

The relevant designated statutory roles pertaining to this policy, along with the outline responsibilities for those holding these role(s) is defined in section 4.3.1. (above) of this policy.

### 4.4.2 Responsibilities of Individuals Involved in Animal Research

Permission to use live animals for research or teaching is granted under a strict ethical and legal framework that comes with personal, ethical and legal responsibilities.

- All members of the University permitted to work with live animals must always treat the animals with care and respect.
- All members of the University permitted to work with live animals must comply with the legal and ethical requirements placed upon them, including:
  - Conditions and duration of their ethical permission, and/or their individual, and project authorisation.
  - AWB and AREC approved SOPs.
  - Training requirements / training record demonstrating competence approved by the Training Officer for all procedure/s or euthanasia methods they will conduct.
- Where an individual believes they may not be in compliance with any of the above, they must inform the Animal Ethics Compliance Officer (CO) without delay. Failure to inform the CO in a timely manner is a non-compliance under the terms of the University's Establishment Authorisation and must be reported to the HPRA.
- Individuals are required to provide appropriate husbandry and care, monitor animal welfare, and notify the ACWOs, CO, or DV (see section 4.3.1) without delay should issues affecting the welfare of the animals arise.
- Where directed to by any of the aforementioned individuals, a member of the university using live animals for research or teaching must use the Standard Operating Procedures (SOPs)<sup>1</sup> for reporting issues affecting animal welfare to the Animal Welfare Body. Failure to notify ACWOs, CO, or DV of issues animal welfare in a timely manner is a non-compliance under the terms of the University's Establishment Authorisation and must be reported to the HPRA.

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<sup>1</sup> All references to SOPs in this policy document refer to *Standard Operating Procedures* of the Health Products Regulatory Authority (HPRA)



#### 4.4.3 Responsibilities of Other University Members

Any member of the university that has any concern about any observed aspect of the use of animals should report these to one of the Animal Care and Welfare Officers or to one of the Designated Veterinarians.

### 5. Documents Associated with this Policy

- *Animal Research Ethics Application Form*
- *ATU (Animal Welfare) Establishment Authorisation Site Master File and its Appendices, as approved by the HPRA.*
- *Establishment Authorisation Standard Operating Procedures as approved by the HPRA.*

### 6. Revision History

Revision No	Description of Change	Approval Date
000	New Policy	05 Feb 2024