Code	QA501
Title	Code of Good Practice in Animal Research
Policy Owner	VP Research & Innovation/Director of Research
Date	February 2024
Approved By	Academic Council

1. Purpose

Rules and guidelines for ensuring that animal care and research conducted at the University of Galway is carried out in a scientifically refined, ethical, rigorous, respectful and sensitive manner, and in compliance with legal requirements.

2. Description

There is general consensus in our society that, until satisfactory alternatives have been developed, the use of animals in research is necessary for medical and scientific progress. Animal research under certain constraints and conditions is facilitated by legislation.

The Health Products Regulatory Authority (HPRA), on behalf of the Department of Health, is the competent authority responsible for the implementation of Directive 2010/63/EU and SI No 543, as amended, on the protection of animals used for scientific purposes in Ireland. Establishment, Project and Individual authorisations will be assessed by the HPRA and these authorisations must be in place prior to the commencement of any research work involving animals. All scientific work involving animals must receive ethical approval before the project commences. All research involving animals conducted within the university must receive ethical approval from the University's Animal Care and Research Ethics Committee (ACREC). For research involving animals conducted outside of the university, the principal investigator is responsible for ensuring that ethical approval for the project has been granted from the relevant body prior to project commencement.

The policy of the University of Galway is to facilitate the implementation of the legislation and to actively promote the application of the "3 Rs" to the use of animals for scientific purposes[1]. The "3 Rs" are:

- ***Refinement*** or improvement of husbandry and procedures to minimise the degree of pain, suffering/distress and/or long-lasting harm and to enhance animal well-being.
- ***Reduction*** of the number of animals used in research to the minimum necessary to achieve meaningful results.
- **Replacement** of live animals by non-animal alternatives where possible2

The University of Galway, through the Animal Care Research Ethics Committee (ACREC) and Animal Welfare Body (AWB), actively supports the implementation of the 3Rs and monitoring that animal research at the University is conducted in an ethically approved manner and to the highest welfare standards.

[1] *http://www.nc3rs.org.uk/ (UK National Centre for the Replacement, Refinement, and Reduction of Animals in Research)*

3. Rules and Guidelines

- Research/teaching involving live animals and/or their organs or tissues cannot proceed without ethical approval from the ACREC and/or HPRA
- AWB review and HPRA approval is required for research involving procedures on live animals - *i.e.* Project authorisation
- In all studies involving live animals, the potential benefits or gains of the proposed research/teaching application must outweigh the pain/distress inflicted on the animals, known as the Harm/Benefit analysis.
- Applicants shall apply the Principles of Replacement, Refinement and Reduction where possible in their research proposals.
- Students, researchers, staff, and visitors working with laboratory animals must attend and pass the accredited training as outlined in the EU Education and Training Framework Document published by the EU. A list of accredited providers is available on the HPRA website.
- Students, researchers, staff and visitors working with live animals must adhere to professional and legal requirements, including HPRA individual authorisations (*i.e.* Authorisation Holders).
- All workers must comply with all relevant Health and Safety standards for the environment and premises in which they work.
- Authorisation holders can only perform work at the premises designated on their HPRA project authorization.
- Authorisation holders/researchers must strictly adhere to all conditions of their ACREC and/or HPRA project authorisation including experimental procedures and types and numbers of animals used.
- Authorisation holders/project manager shall make themselves aware and comply with the terms and conditions of the project authorisation.
- Authorisation holders/project managers must maintain records of animals used, procedures performed, results obtained, drugs used, and fate of the animals for a minimum period of 5 years; these records must be available to HPRA upon request.
- The ACWO/Designated Veterinarian/AWB must be informed if there is any deviation from approved end-points or if any animals experience ill-health in line with the conditions of a Project Authorisation and its distress scoring sheet.
- Authorisation holders/project managers are encouraged to self-report any non-compliance that might accidentally occur to the HPRA within 3 working days of the occurrence being detected or immediately if animal welfare was affected
- Authorisation holders/Project managers are responsible for the animals for the duration of the study and must provide out-of-hours contact details in case of emergencies.
- Housing and husbandry is provided by fully-trained personnel in line with best practice.
- Designated premises must maintain complete records of all animal activity at the university for a minimum of five years.
- Licensees must furnish end-of-year returns to the HPRA regarding the use of animals.
- Authorisation holders/Project managers must provide an end of project report to the AWB as outlined in the terms and conditions of approval.
- All projects classified as severe must provide a retrospective evaluation to the HPRA or as outlined in the terms and conditions of the project authorisation.

4. Responsibilities

Name	Responsibility
Director of Research	• Policy Owner and Compliance Officer
Research and Innovation Committee	• Execution and oversight of good practice
Animal Care Research Ethics Committee (ACREC)	• Ethically review and approve all animal research conducted at University.
Animal Care and Welfare Officer (ACWO)	• Overseeing animal welfare according to Section 45 Part 7 of Dir 10/63 EU
Designated Veterinarian (DV)	• Advisory duties in relation to wellbeing and treatment of animals, according to Section 48-Part 7 of Dir. 10/63 EU
Project Manager	• Overall implementation of research projects and compliance with the project authorisation
Principal Investigator/ Authorisation Holder	• Ensure research projects are performed only at the establishment(s) specified and that all procedures of the project are carried out within the terms of the authorisation
Researchers	• Ensure compliance with the terms of the project authorisation
Animal Welfare Body (AWB)	• Ensuring the welfare of animals in the establishment and promoting the 3Rs (reduction, replacement and refinement)

5. Related Documents

QA500 Animal Care Research Ethics Committee Policy

QA502 Animal Welfare Body

Standard Operating Procedure for ACREC Review of Ethical Applications