RCSI Guidance for Pre-clinical Research

INTRODUCTION

Animal studies at RCSI are conducted only when they contribute to the advancement of knowledge that is likely to lead to the improvement of the health and welfare of animals and human beings. They must have well-defined scientific objectives and due consideration must be given to the welfare of the animals. Where possible, the use of animal tissue or in vitro models should always be preferred to live animal models.
Scientists in RCSI are required to demonstrate that there are no alternatives available before the ethical review process will permit the procedures.
Any RCSI led animal research carried out in a third country should be conducted in accordance with international best research practice, local regulatory and ethical requirements, which should be aligned with those in Ireland (including animal welfare requirements).

LEGAL REQUIREMENTS

RCSI's policy concerning the use of animals in research is informed by European legislation outlined in **Directive 2010/63/EU**. This legislation was transposed into Irish law in December 2012 by **SI No 543 of 2012** and is implemented by the Health Products Regulatory Authority (HPRA).
The HPRA is the competent authority in Ireland responsible for the protection of animals used for scientific purposes.

In compliance with the above, RCSI has designated persons fulfilling the following roles for the care of the animals and legal compliance respectively: **Designated Veterinarian** (DV), **Animal Care and Welfare Officer** (ACWO), **Information Officer** (IO), **Compliance Officer** (CO).

REFERENCES

1 https://www.hpra.ie/homepage/veterinary/scientific-animal-protection
2 https://norecopa.no/prepare
3 https://norecopa.no/media/kctfpwb3/prepare_guidelines_norecopa.pdf
4 https://www.nc3rs.org.uk/arrive-guidelines

APPLICATION PROCESS AND REVIEW OF PROPOSALS

RCSI aims to improve the welfare of animals used for scientific purposes and to promote the principles of the **3Rs - Replacement, Reduction and Refinement** (See Figure 1).

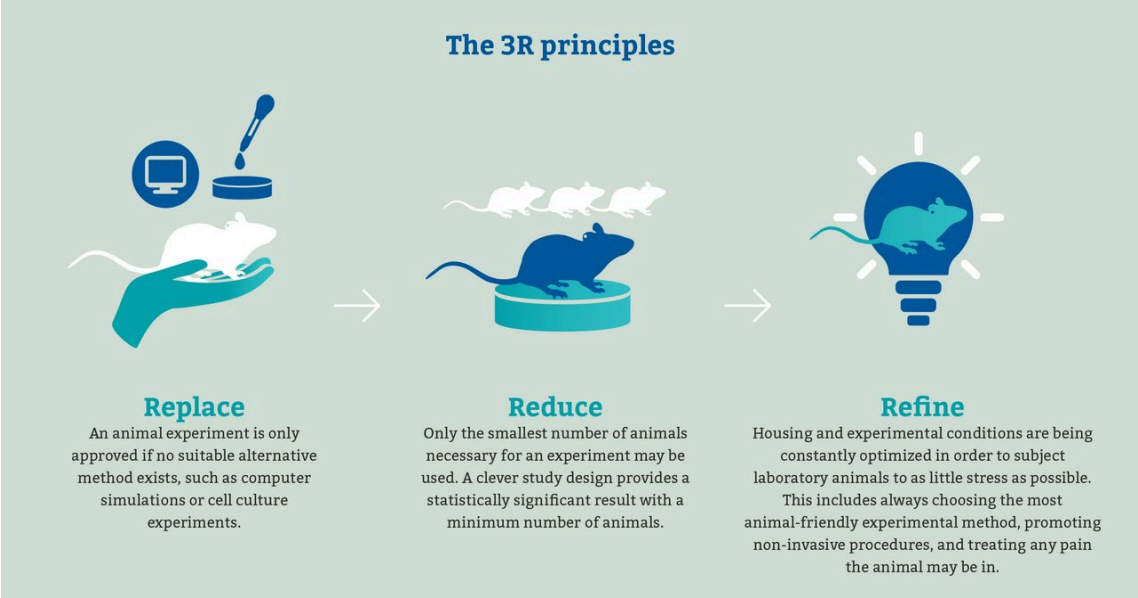

Fig. 1. The 3Rs principles.

RCSI applications for project authorizations where laboratory animals are used, are expected to adhere to the general principles and best practice outlined in the **guidance provided by the HPRA**[1], and are advised to consult the **PREPARE guidelines**[2] (Animal Research: guidelines for planning experiments) and **checklist**[3]; and **ARRIVE guidelines**[4] (Animal Research: Reporting In Vivo Experiments).

The **Project Authorization holder** must ensure that, before the research commences, and for the full award duration of the project, all the necessary ethical, legal and regulatory requirements in order to conduct the research are met, and all the necessary licences and approvals have been obtained.

REFERENCES

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Where research projects involve the use of animals, the following requirements must be met:

- **Institutional ethical approval**. Wherever possible, researchers must adopt procedures and techniques that avoid the use of animals by the use of alternative approaches to address the principles of the 3R's (replacement, reduction, refinement).
  Where this is not possible, the research should be designed to conform to recognised best practice.

  The Animal Research Ethics Committee (**AREC)** review all applications for animal studies to be delivered at RCSI. These proposals must fully justify its suitability to address the research questions and harm-benefit analysis by outlining the following, prior to submission of the application to the HPRA for approval:

  - ✓ The overall purpose and specific objectives of the project.
  - ✓ The scientific benefit of the project.
  - ✓ Alternatives to animal use considered.
  - ✓ The experimental design.
  - ✓ The choice of species.
  - ✓ The numbers of animals required, including power calculations where appropriate.
  - ✓ Animal Welfare monitoring arrangements.
  - ✓ Animal details (acquisition of animals from approved suppliers).

- **HPRA authorization approval**

  - ✓ RCSI, as an Establishment Authorization holder for the breeding, supply and use of laboratory animals for scientific purposes, complies with the legal requirements outlined in the legislation for animal husbandry (e.g. environmental parameters, non-aversive methods of animal handling, etc.) of the different species hosted.
  - ✓ Project Authorization holders and project managers must apply for **an individual and project authorization,** and get approval from the HPRA before any work can commence. Individuals performing procedures or conducting euthanasia in those studies must hold an **individual authorization** too.

- **Training and competency**

  - ✓ Individual authorization holders must attend an induction for the relevant animal facility, for the provision of an introductory seminar, facility walk around, Standard Operational Procedures (SOPs) revision and basic practical training related to the species of interest.

  - ✓ Trained individual authorization holders must be signed off by the Training Officer on the relevant techniques/procedures involving live animal use before working unsupervised.

REFERENCES

1 https://www.hpra.ie/homepage/veterinary/scientific-animal-protection
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3 https://norecopa.no/media/kctfpwb3/prepare_guidelines_norecopa.pdf
4 https://www.nc3rs.org.uk/arrive-guidelines

- **Animal Welfare Monitoring arrangements**.
  - ✓ **Individual authorization holders** under a specific HPRA project authorization are responsible for conducting **project specific welfare checks** on the experimental animals.
  - ✓ The **DV** will provide support and monitor the care and welfare, husbandry practices and health monitoring of the animals at the facilities, ensuring a system of veterinary care for the animals 24h/365 days.
  - ✓ Trained **technical staff** are also available to care for the animals and perform daily welfare checks.

- The **Animal Welfare Body (AWB)** will supervise and assess protocol deviations, unexpected adverse events and end-of-project reports on completion of studies. The AWB will revert to the AREC relevant information to be considered for the assessment of new applications.

REFERENCES

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