

HRB Policy on the Use of Animals in Research

Version 2.1

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1 Purpose

The HRB funds research that uses animals where it is legal, ethical and scientifically justified and no viable non-animal alternatives exist. This policy outlines the conditions required for funding this type of research.

2 Background

Research involving animals helps to enhance our understanding of human, animal and environmental health and biology. It raises many complex issues for example, ethics, animal welfare, transparency, reproducibility, and translation.

The <u>European Union Directive 2010/63/EU</u> on the protection of animals used for scientific purposes was issued to ensure harmonised standards of animal welfare across the EU, whilst maintaining Europe's place as a world leader in scientific research. This legislation was transposed into Irish law by <u>SI No 543/2012</u> and is implemented by the <u>Health Products Regulatory Authority</u> (HPRA), the competent authority in Ireland responsible for the protection of animals used for scientific purposes.

It is important to ensure the principles embedded in the legal text are implemented in practice. In particular, the Directive imposes a clear and explicit obligation on licensed researchers to ensure that the opportunities for replacement, reduction and refinement of animal involvement (See <u>principles</u> of the 3Rs - Replacement, Reduction and Refinement) are intrinsic to their work.

3 HRB Requirements

All animal work funded by the HRB must:

- meet the 3Rs standards
- have HPRA Authorisations for use of animals in research
- have research ethics committee approval

To ensure that the 3Rs are being implemented appropriately, the HRB recommends that any related systematically identified, appraised, synthesised and interpreted evidence is considered and/or such evidence synthesis is performed where possible before deciding to progress to animal studies. Guidance and training on systematic reviews in pre-clinical and toxicological research can be found at syrcle.network and reviews of available non-animal models can be found at the EU Reference Laboratory for alternatives to animal testing EURL ECVAM.

Researchers are advised to consult the <u>PREPARE guidelines</u> for planning research and experimental procedures developed by Norway's National Consensus Platform for the advancement of "the 3 Rs" (<u>Norecopa</u>) and The Royal Society for the Prevention of Cruelty to Animals (<u>RSPCA</u>) and the <u>ARRIVE guidelines 2.0</u> produced by the UK National Centre for the Replacement, Reduction & Refinement of Animals in Research (NC3Rs).

Applicants to the HRB, whose research proposals include the use of animals, must fully justify the experimental design and its suitability to address the research questions posed in the appropriate section of their application. Applicants must provide detailed justification for their choice of design, intervention and numbers of animals to be used. Sufficient information concerning methodological issues must be provided. In line with the HRB policy on Gender in Research Funding, researchers should outline how sex and/or gender analysis will be integrated in the design, implementation, evaluation, interpretation and dissemination of the results of the research proposal. Researchers should plan to include both sexes in research involving animals unless scientifically justified otherwise. The Experimental Design Assistant provides guidance for using animals of both sexes in a study.

If any research is to be carried out in a third country, the Research Body must ensure that research involving the use of animals is carried out in the spirit of Irish legislation and complies at all times with the relevant laws and regulations in the host country. These requirements apply whether or not the animals are to be purchased with funds requested within the proposal itself.

4 Implementation

Where the HRB funds research that use animals, Principal Investigators are required to confirm receipt of a HPRA Authorisation for use of animals in research and ethical approval prior to commencement of this work. Date of receipt and licence/reference number must be supplied. Award payments will be withheld until provided.