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POLICY ON THE USE OF SMALL ANIMALS IN RESEARCH

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1 INTRODUCTION

Velindre University NHS Trust (the Trust) is responsible for the provision of non-surgical tertiary oncology services to the population of South-East Wales. These services are delivered at a specialist treatment, teaching, research and development centre – Velindre Cancer Centre.

The Trust is committed to the delivery of a varied portfolio of research into new ways to prevent, diagnose and treat cancer, and to optimise the effectiveness of existing cancer treatment.

In the pursuit of developing new treatments, the Trust recognises that animal research remains part of understanding disease processes and ensuring medicines are safe for patients.

In the UK, the use of animals in experiments and testing is regulated under the Animals (Scientific Procedures) Act 1986 (ASPA), as amended¹. The implementation of this Act regulated by the Home Office in England, Scotland, and Wales and by the Department for Health, Social Security and Public Safety in Northern Ireland.

Under the Animals (Scientific Procedures) Act 1986, as amended, the principles of the 3Rs (replacement, reduction, and refinement) provide a framework for conducting humane animal research and promote the use of alternative methods to reduce the number of animals used.

The Trust recognises the principles of replacement, reduction, and refinement of animals in research, and actively supports their implementation.

2 OBJECTIVES

This policy covers:

- Trust statement of policy on the use of animals in medical research.
- Legal controls on animal use.
- How the Trust implements this policy and support the principles of the 3Rs.

The policy does not aim to be comprehensive. However, it sets out principles for good practice and refers to other publications that provide advice or instruction on specific aspects, including statutory requirements.

3 SCOPE

This policy is intended to provide general guidance on the use of small animal research. However, for completeness references are made to specially protected species (SPS) including pigs.

¹ As amended by the following UK Statutory Instruments:

The Animals (Scientific Procedures) Act 1986 (Amendment) Regulations 1998. (SI1998/1974).

The Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012. (SI2012/3039).

The Animals (Scientific Procedures) Act 1986 (EU Exit) Regulations 2019. (SI2019/72).

It sets out the expectations of the Trust for animal research and is therefore useful for Trust researchers, staff, and Board and Committee members involved in reviewing proposals to the Trust that may support the conduct of animal research projects.

4 STATEMENT OF POLICY

The Trust does not take the decision to provide its support to animal research lightly.

The Trust does not conduct animal research within its premises.

The Trust commits to provide its support only to the conduct of high-quality animal research by other organisations, which will ultimately be of benefit to the Trust's patient population.

The Trust is committed to the 3Rs of reduction, replacement, and refinement, as basic principles of humane animal research. Any animal research requesting Trust support must follow these principles to improve animal welfare.

The Trust will only provide its support to animal research where the Trust is satisfied that:

- a. The animal research is sponsored by an organisation who is a signatory of the Concordat of Openness on Animal Research in the UK [\[https://concordatopenness.org.uk/\]](https://concordatopenness.org.uk/).
- b. The animal research study design is scientifically robust, and the animal model is appropriate and relevant to the research question being asked.
- c. There are no feasible alternatives to using an animal model.
- d. All reasonable efforts have been made to address the principles of the 3Rs.
 - **Replacement** – methods which avoid or replace the use of animals in research that has the potential to cause them harm.
 - **Refinement** – improvements to 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 animals is unavoidable.
 - **Reduction** – methods which minimise animal use and enable researchers to obtain comparable levels of information from fewer animals or to obtain more information from the same number of animals, thereby reducing future use of animals.
- e. All animal research will be done in strict compliance with:
 - Applicable law including, in the UK, the Animals (Scientific Procedures) Act 1986, as amended.
 - Ethics Committee requirements, in the UK, the Animal Welfare and Ethical Review Body.
 - All applicable standards, guidance and codes of conduct relevant to animal research listed on the Home Office [\[https://www.gov.uk/guidance/research-and-testing-using-animals\]](https://www.gov.uk/guidance/research-and-testing-using-animals) and Department for Environment, Food & Rural Affairs (Defra) [\[https://www.gov.uk/government/organisations/department-for-environment-food-rural-affairs\]](https://www.gov.uk/government/organisations/department-for-environment-food-rural-affairs) websites.

- f. Welfare standards are consistent with the principles of UK legislation, and the relevant standards, guidance and codes of conduct laid down by the Home Office and Defra, above, are applied and maintained. This also applies to any animal research that is to be performed outside the UK.
- g. The animal research has been successfully independently peer reviewed by appropriate expert reviewers, and that the researchers have adequately responded to any concerns those expert reviewers have raised.
- h. The animal research involving the use of SPS or pigs, includes an appropriate independent review by the National Centre for the Replacement, Refinement and Reduction in Research (NC3Rs) and that the researchers have adequately responded to any concerns those expert reviewers have raised.

The Trust recognises that horses, cats, dogs, and non-human primates (NHPs) are designated SPS under the Animal (Scientific Procedures) Act 1986, as amended, due to public concerns regarding their use in research and their additional welfare needs. The Trust will only support the use of these species in animal research in the limited circumstances for toxicology and safety pharmacology studies where required for safety or regulatory purposes. The Trust expects researchers to take every possible measure to avoid the use of SPS.

5 LEGAL CONTROLS ON ANIMAL USE

The Trust will only support animal research on the basis that the researchers, those organisations sponsoring the research, and the bodies funding the research comply with the UK's legal provisions, plus any related standards, guidance, and codes of conduct issued by government departments and the specific conditions of licences.

UK legislation, standards, guidance and codes of conduct applicable to animal research are listed on the Home Office [<https://www.gov.uk/guidance/research-and-testing-using-animals>] and Department for Environment, Food & Rural Affairs (Defra) [<https://www.gov.uk/government/organisations/department-for-environment-food-rural-affairs>] websites.

Support for any animal research involving regulated procedures under the ASPA is on the absolute condition that no work can commence until the licence authorisations required under the Act have been granted and that it will be terminated if such authorisations are subsequently withdrawn.

6 POLICY IMPLEMENTATION AND SUPPORTING THE 3RS

The Trust is committed to ensuring that the policy on animal research is implemented effectively, particularly with respect to the 3Rs.

This is important in reducing animal use in research, improving welfare standards and for ensuring appropriate animal models for scientific benefit are used, and that experiments are scientifically robust and reproducible.

The Trust supports the 3Rs through a variety of mechanisms:

- a. **Research that supports the 3Rs** – the Trust’s strategy focuses on donor and patient research. The Trust is committed to the endeavours of cancer-relevant initiatives and projects that replace or reduce the need for animals in cancer research in the future. This includes contributions to biobanks, organoid projects, mathematical and computer modelling, and the development of new *in vitro* (non-animal technology) models. The Trust also promotes and encourages the archiving and sharing of resources as a means of reducing and refining animal use.
- b. **Conditions of support** – it is a condition of Trust support that the conduct of animal research is strictly in accordance with the law and complies with standards, guidance, and codes of conduct issued by the Home Office and Defra.

In addition, the animal research should comply with guidance documents published by National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs), particularly the “Responsibility in the use of animals in bioscience research” [<https://www.nc3rs.org.uk/3rs-resources/responsibility-use-animals-bioscience-research>] and the Animal Research: Reporting of In Vivo Experiments (ARRIVE) guidelines [<https://arriveguidelines.org>].

Where the animal research involves NHPs, the research must also comply with the NC3Rs Non-human primate accommodation, care and use guidelines [<https://www.nc3rs.org.uk/3rs-resources/non-human-primate-accommodation-care-and-use-guidelines>].

- c. **External Grant / Business Case application requirements** – it is a condition of Trust support that external funding body applications made by the lead organisation sponsoring the research must provide detailed information about the animal research to the funding body.

This must include clear justification in the application regarding the species, type, and number of animals to be used and the experimental design and statistical analysis.

Researchers undertaking animal research are encouraged to use the NC3Rs experimental design resources, including the online Experimental Design Assistant [<https://www.nc3rs.org.uk/our-portfolio/experimental-design-assistant-eda>], and the ARRIVE guidelines, to improve the reproducibility and reporting of animal research.

7 OPENNESS IN ANIMAL RESEARCH

The Trust strives to be open and honest about how, why, and when it supports animal research, and will only support animal research projects in line with this policy.

8 REFERENCES

The following documents have been referenced in the development of this policy.

- a. Animals (Scientific Procedures) Act 1986. Available at: <https://www.legislation.gov.uk/ukpga/1986/14/contents> [Accessed 05 Jan 2024].
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- c. The Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012. (SI2012/3039). Available at: <https://www.legislation.gov.uk/uksi/2012/3039/contents/made> [Accessed 05 Jan 2024].
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- f. Understanding Animal Research. *Concordat of Openness on Animal Research in the UK*. [online]. <https://concordatopenness.org.uk/>. [Accessed 18 Dec 2023].
- g. UK Government Home Office (2023). *Animal testing and research: guidance for the regulated community*. [online]. <https://www.gov.uk/guidance/research-and-testing-using-animals>. [Accessed 19 Dec 2023].
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- i. Percie du Sert N, Hurst V, Ahluwalia A, Alam S, Avey MT, Baker M, Browne WJ, Clark A, Cuthill IC, Dirnagl U, Emerson M, Garner P, Holgate ST, Howells DW, Karp NA, Lazic SE, Lidster K, MacCallum CJ, Macleod M, Pearl EJ, Petersen O, Rawle F, Peynolds P, Rooney K, Sena ES, Silberberg SD, Steckler T and Wurbel H (2020). *The ARRIVE guidelines 2.0: updated guidelines for reporting animal research*. **PLoS Biol.** doi: [10.1371/journal.pbio.3000410](https://doi.org/10.1371/journal.pbio.3000410). [Accessed 19 December 2023].
- j. National Centre for the Replacement, Refinement and Reduction of Animals in Research (2023). *ARRIVE guidelines*. [online]. <https://arriveguidelines.org/>. [Accessed 20 December 2023].

- k. National Centre for the Replacement, Refinement and Reduction of Animals in Research (2017). *Non-human primate accommodation, care and use*, 2nd edition. London: NC3Rs. [online]. <https://www.nc3rs.org.uk/3rs-resources/non-human-primate-accommodation-care-and-use-guidelines>. [Accessed 19 December 2023].
- l. Cardiff University. *Animal research*. [online]. <https://www.cardiff.ac.uk/research/our-research-environment/integrity-and-ethics/animal-research>. [Accessed 18 December 2023].