

ARIA Policy on Research and Innovation Involving Animals

Acknowledgement: This policy is based on the <u>UKRI Policy on Research and Innovation Involving Animals</u>. ARIA has adopted this policy to help contribute to consistent standards across the research community in the UK, making minor changes to account for differences in operating model.

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POLICY STATEMENT

As a non-departmental public body and responsible funder, the Advanced Research and Invention Agency ("ARIA") has a responsibility to ensure that the activities that ARIA funds are aligned with UK legislation and other guiding principles of ethical research practice. This policy sets out the approach of ARIA in ensuring that this commitment within is met in all funding activities involving animals, in the context of ARIA Ethical and Social Responsibility Policy.¹

In addition, this policy is consistent with the cross-funder guidance Responsibility in the Use of Animals in Bioscience Research² which includes the principle of the *3Rs*: the replacement, reduction and refinement of the use of animals in Research and Innovation ("**R&I**").

¹ https://www.aria.org.uk/wp-content/uploads/2024/04/ARIA-Ethical-and-Social-Responsibility-Policy.pdf ²https://www.nc3rs.org.uk/sites/default/files/2022-01/Responsibility%20in%20the%20use%20of%20animals%20in%20bioscience%20research%202019.pdf



1. PURPOSE AND SCOPE

- 1.1 This policy sets out the principles for funding R&I involving animals across ARIA's programmes.
- 1.2 This policy primarily relates to the impact of R&I involving animals on animal welfare. Where appropriate, conservation impacts are brought within the policy.
- 1.3 This policy applies to all³:
 - 1.3.1 ARIA funding;
 - 1.3.2 organisations that apply for and/or receive funding from ARIA, including those based outside of the UK, and those that apply for and/or receive funding from ARIA indirectly through a partner organisation;
 - 1.3.3 organisations conducting work that benefits from ARIA funding, for example, collaborating with individuals on ARIA-funded projects;
 - 1.3.4 individuals engaged in R&I activities at such organisations, whether directly employed by them or not, when using ARIA funds (either directly or indirectly, or those making ARIA funding applications);
 - 1.3.5 individuals employed by ARIA, including those directly involved in research at centres, institutes, units and facilities;
 - 1.3.6 individuals while undertaking duties for ARIA such as assessing applications ("expert reviewers"), serving on a decision-making body on behalf or providing strategic advice on issues related to R&I involving animals;
 - 1.3.7 ARIA's activities as a funder, including partnerships and collaborations with other funding partners; it also sets out our expectations for joint programmes co-funded with partners;
- 1.4 This policy references and is not intended to contradict existing guidance, particularly the 'Responsibility in the Use of Animals in Bioscience Research'⁴ and, where relevant, 'Sharing and Archiving of Genetically Altered Mice'⁵, ARRIVE Guidelines⁶, and 'Non-human Primate Accommodation, Care and Use'⁷.

2. DEFINITIONS

³ It is the responsibility of applicants for ARIA funding to ensure awareness of this policy throughout parties involved in the funding.

⁴ https://www.nc3rs.org.uk/responsibility-use-animals-bioscience-research

⁵ https://www.nc3rs.org.uk/3rs-resources/breeding-and-colony-management/sharing-and-archiving-ga-mice

⁶ https://arriveguidelines.org/

⁷ https://nc3rs.org.uk/non-human-primate-accommodation-care-and-use



- 2.1 For the purposes of this policy, the following terms are defined as:
 - 'Animals' are taken to mean all invertebrates and vertebrates in the Kingdom 2.1.1 Animalia, except where otherwise specified.
 - 2.1.2 'ASPA-regulated research' is defined in accordance with the Animals (Scientific Procedures) Act 1986 (ASPA)⁸, amended 2012, relating to species, life stages and procedures that are regulated by the Act.
 - 2.1.3 'Non-ASPA' R&I is that which involves the use, observation, or interaction with animals that are not covered by Animals (Scientific Procedures) Act 1986. It may be regulated by other legislation.
 - The '3Rs' principles⁹ are: Replacement avoiding or replacing the use of animals in 2.1.4 areas where they otherwise would have been used; Reduction - minimising the number of animals used consistent with research aims and robust, reproducible findings; and Refinement – minimising the pain, suffering, distress or lasting harm that individual animals might experience.

3. PRINCIPLES

- 3.1 ARIA recognises the existence of relevant legislation regulating R&I involving animals, in particular but not limited to the Animals (Scientific Procedures) Act 1986 (hereafter ASPA). 10 ARIA is not a regulator and does not itself have a statutory compliance role within the legal responsibilities of parties conducting R&I using animals in the UK. Compliance with and enforcement of the relevant legislation is the responsibility of the parties/organisations named within it.
- 3.2 As a non-departmental public body and responsible funder in respect to the distribution of public funds, ARIA requires funded R&I to align with legislation and guiding principles.
- 3.3 ARIA is committed to only funding R&I using animals and procedures covered under ASPA where no scientifically acceptable non-animal alternatives exist.
- 3.4 ARIA supports the principles of the 3Rs: the replacement, reduction, and refinement of animal use in R&I.
- 3.5 ARIA is committed to ensuring the highest possible standards of animal welfare throughout the R&I that we support.
- 3.6 ARIA expects those responsible for R&I involving animals to establish and maintain a culture of care that is upheld by all involved (including but not limited to investigators, technical and

https://www.gov.uk/government/publications/consolidated-version-of-aspa-1986

⁹ https://nc3rs.org.uk/who-we-are/3rs

¹⁰ https://www.gov.uk/government/publications/consolidated-version-of-aspa-1986. Other legislation of relevance but not referenced specifically includes: Animal Welfare Act 2006, Wildlife and Countryside Act 1981, Veterinary Surgeons Act 1966, Welfare of Farmed Animals (England) Regulations 2007 and devolved equivalents, and the Animal Sentience Act 2022.



veterinary staff, and students).

3.7 ARIA is committed to ensuring R&I involving animals does not endanger vulnerable animal populations.

4. RESPONSIBILITIES FOR ASPA-REGULATED R&I INVOLVING ANIMALS

- 4.1 This section sets out policy for ARIA as a funder, as a research-performing organisation and for organisations and individuals funded by ARIA, and expert reviewers involved in the funding processes of ARIA.
- 4.2 ASPA regulates procedures carried out for scientific and educational purposes that may cause pain, suffering, distress or lasting harm to living non-human vertebrates and living cephalopods (e.g., octopus, squid). Below, we describe the responsibilities of parties (as defined in Section 1), when R&I involves animals as regulated under ASPA or equivalent research in a country outside of ASPA regulations:

ARIA as a funder

- 4.2.1 As a funder, ARIA seeks to do the following:
 - ensure R&I is conducted in an ethical way, in accordance with the ARIA Ethics and Social Responsibility Policy¹¹, by obtaining assurances from applicants that ethical and legal approvals from the relevant body/bodies are granted before work starts, for work conducted both in UK and outside of the UK;
 - collect sufficient information from applicants to enable expert reviewers and decision-making bodies to review and determine the necessity and validity of the proposed work, including the robustness of the experimental or research design, consideration and application of alternatives to the use of animals, and measures planned to improve animal welfare (3Rs) and avoid endangering animal populations;
 - ensure there is appropriate expertise within the full application process to assess the robustness of the experimental design, application of the 3Rs, and welfare implications of any proposed work involving animals;
 - provide guidance for expert reviewers to aid them in assessing applications according to the principles in Section 3;
 - ensure additional review is conducted by NC3Rs for applications proposing use of certain species, including non-human primates, cats, dogs, equines, and pigs; ensure compliance with the guidelines 'Non-human Primate

^{11 [}insert]



Accommodation, Care and Use' 12 and other relevant guidance on the use of specific species;

- ensure that external expertise is sought and made available to Programme
 Directors for any funding opportunities led by a Programme Director that
 does not have primary expertise in R&I involving animals in assessment
 processes;
- ensure the principles of responsible conduct in R&I involving animals as set out in this policy are reflected in the contractual terms applicable to funding awarded by ARIA;
- obtain assurances and evidence from organisations in receipt of ARIA funding that they comply with existing legislation and best practice;
- seek opportunities to apply and promote the principles of the 3Rs, including by encouraging applications with potential to advance the 3Rs;
- when funding R&I involving non-human primates, conduct periodic reviews as to the impact and outputs, in accordance with the recommendations of the Bateson Review of Research using Non-Human Primates;¹³
- conduct appropriate portfolio-wide evaluation of the use of animals in ARIA-funded R&I, including monitoring and analysis of animal use, and 3Rs practices.

Organisations receiving funding from ARIA

- 4.2.2 Organisations receiving funding from ARIA shall:
 - support applicants to meet ARIA requirements, relevant legislation, and best practice, including via the provision of training for staff;
 - ensure legislative compliance, a culture of care, and encourage organisational best practice, for example, developing and implementing an organisation-wide 3Rs strategy to deliver active engagement on the 3Rs from all key stakeholder groups;
 - exercise due diligence when selecting commercial suppliers and service providers; and
 - if requested by ARIA, be able to provide assurance to ARIA that the requirements outlined above are met.

Individuals and organisations funded by ARIA

¹² https://nc3rs.org.uk/non-human-primate-accommodation-care-and-use

https://wellcome.org/sites/default/files/wtvm052279 1.pdf



- 4.2.3 Individuals or organisations conducting research funded by ARIA, or applying for ARIA funding in order to conduct, ASPA-regulated research or innovation shall be required to:
 - meet all the expectations set out in this Policy and the 'Responsibility in the Use of Animals in Bioscience Research'14 document, which include but are not limited to, where required, securing ethics approval before starting any work, conducting R&I in compliance with legislation, considering and applying the principles of the 3Rs, ensuring that research teams have appropriate training and competence and when reporting the results of the research, doing so in accordance with the ARRIVE Guidelines¹⁵;
 - in the event of work being contracted to third-party suppliers and service providers or carried out outside of the UK/by a partner outside of the UK, ensure that the work is performed in accordance with this policy;
 - ensure a culture of care, familiarise themselves with best practice and relevant guidance in their discipline, and seek continuing professional development (for example, by attending training provided by funders, research organisations, and other bodies);
 - exploit opportunities to reduce and refine the use of animals and, in relation to genetically altered animals, sharing and archiving strains (e.g. embryos or sperm) in accordance with the principles set out in Sharing and Archiving of Genetically Altered Mice'; 16
 - notify and consult with ARIA before any substantive changes are made to experimental plans where this affects animals involved in the R&I.

Expert reviewers involved in the funding processes of ARIA

4.2.4 Expert reviewers, including reviewers, panel members, or consultants involved in assessing R&I involving animals shall understand and continually develop their knowledge of principles of good research practice involving animals, including experimental design, the application of the 3Rs and principles of good welfare.

RESPONSIBILITIES FOR R&I INVOLVING OR IMPACTING ANIMALS THAT IS NOT **REGULATED UNDER ASPA**

5.1 ARIA may also fund a number of activities not regulated under ASPA, which involve or may impact upon animals. For example, this would include (but is not limited to) behavioural

15 https://arrivequidelines.org/

¹⁴ https://www.nc3rs.org.uk/responsibility-use-animals-bioscience-research

¹⁶ https://www.nc3rs.org.uk/3rs-resources/breeding-and-colony-management/sharing-and-archiving-ga-mice



observation studies of animals in the wild, non-invasive wildlife surveys, some research that impacts agricultural animals, and studies on cultural practices involving animals, and research involving invertebrates other than cephalopods. The requirements below also cover the use of animal materials such as tissues and primary cells. Below, we describe responsibilities of parties (as defined in Section 1), when R&I involves animals and is not regulated by ASPA. 17

5.1.1 As a funder, ARIA shall do the following:

- when sentient animals are involved (as defined under in Animal Welfare (Sentience) Act 2022), seek assurance of ethical approval before work starts, for work conducted both in the UK and internationally, or otherwise seek justification on why this is not appropriate;
- collect sufficient information from applicants to enable expert reviewers and decision-making bodies to review and determine the necessity and validity of the proposed work, including the robustness of the experimental or research design, consideration and application of alternatives to the use of animals, and measures planned to improve animal welfare (3Rs);
- when selecting expert reviewers, ensure there is appropriate expertise to assess the robustness of the experimental design, application of the 3Rs, and welfare implications of any proposed work involving animals within the application process;
- ensure additional reviews are conducted by NC3Rs for applications proposing use of non-human primates, cats, dogs, equines, and pigs; ensure compliance with the guidelines 'Non-human Primate Accommodation, Care and Use'18 and other relevant guidance on the use of specific species;
- provide training and/or guidance for peer reviewers, grant expert reviewers, and panel members to aid them in assessing applications according to the principles in Section 3;

Research performing organisations

- Organisations receiving funding from ARIA shall:
 - support applicants to meet ARIA requirements, relevant legislation and best practice, including via the provision of training for staff.

Individuals and organisations funded by ARIA

5.1.3 Individuals or organisations conducting research funded by ARIA or applying for ARIA funding in order to conduct non-ASPA-regulated R&I, including outside of the UK,

18 https://nc3rs.org.uk/non-human-primate-accommodation-care-and-use

¹⁷ ASPA Flow Chart - Professionals (rcvs.org.uk)



should:

- meet expectations as set out in this Policy and the 'Responsibility in the Use of Animals in Bioscience Research' guidelines, which include, where required, securing ethics approval before starting any work requiring approval, conducting R&I in compliance with other relevant legislation, considering and applying the principles of the 3Rs, impact on non-target species, and when reporting the results of the research, doing so in accordance with ARRIVE;
- ensure they and their team have appropriate training and expertise (for example, in animal handling, capture, and release), familiarise themselves with best practice and relevant guidance in their discipline, and seek continuing professional development (for example, by attending training provided by funders, research organisations, and other bodies).

Expert reviewers involved in the funding processes of ARIA

- 5.1.4 Expert reviewers, including reviewers and panel members, involved in assessing R&I involving animals should:
 - understand principles of good research practice involving animals, including 3Rs knowledge and application.

6. ADDITIONAL RESPONSIBILITIES AND EXPECTATIONS

Research outside of the UK

- 6.1 When ARIA funds R&I outside the UK that involves animals, including as part of international collaborations, ARIA requires that funded individuals and organisations establish and demonstrate that the welfare standards are no less stringent than those required in the UK.
 - 6.1.1 Applicants (whether based in the UK or outside of the UK) shall be required to:
 - provide additional information at the application stage regarding any animal facilities and care provided outside of the UK;
 - provide assurance that the international researcher / organisation is compliant with all relevant local and national regulatory systems;
 - ensure that work will be conducted to welfare standards at or above those expected if the work were performed in the UK;
 - seek ethical review approval prior to starting work the relevant ethical review bodies, as appropriate.

Animal Welfare



- 6.2 ARIA expects and supports the provision of excellent care and welfare standards for animals used in R&I, according to best practice and up to date guidance. ARIA expects that funded activities take account of UK societal values and considers animal welfare implications of research and innovation.
 - 6.2.1 Where there are deviations from expectations on animal welfare, as set out in the 'Responsibility in the Use of Animals in Bioscience Research' document¹⁹ and other relevant guidance, approval should be sought by the applicant during the application process and agreed by ARIA.
 - 6.2.2 In accordance with the relevant guidance, ARIA requires funded individuals and organisations to take a proactive approach to refinement of husbandry and scientific procedures, considering opportunities for improving welfare, including those featured in the NC3Rs resource library.²⁰ ARIA encourages funded individuals and organisations to publish and report refinement and positive welfare activities.
 - 6.2.3 ARIA expects consideration of animal welfare through the life of the animal from sourcing through to humane endpoints set out in the 'Responsibility in the Use of Animals in Bioscience Research' document²¹.
 - 6.2.4 ARIA expects the consideration of broad ethical aspects where the research may have direct or near-term implications for animal welfare, for example in genome editing, or farming practices.

Robust and reproducible research

- 6.3 ARIA is committed to funding robust and reproducible research. Individuals or organisations conducting research funded by ARIA or applying for ARIA funding are expected to:
 - describe the experimental design and analysis plans in proposals. The Experimental Design Assistant²² can provide support in planning experiments;
 - provide appropriate information on animal characteristics (e.g. sex, genetic background, age) where required; and
 - make use of measures to reduce the risk of bias including but not limited to randomisation, blinding (masking), sample size calculations, inclusion of both sexes, and inclusion and exclusion criteria.
- 6.4 Additionally, ARIA expects individuals or organisations conducting research funded by ARIA to be as open as possible in sharing information about their work while respecting possible constraints in respect of the protection of intellectual property rights, confidentiality and

¹⁹ https://www.nc3rs.org.uk/responsibility-use-animals-bioscience-research

²⁰ https://nc3rs.org.uk/3rs-resources

²¹ https://www.nc3rs.org.uk/responsibility-use-animals-bioscience-research

²² https://eda.nc3rs.org.uk/



commercial sensitivity. In that context, ARIA encourages individuals and organisations to:

- publish the results of all experiments that have been conducted (including so-called negative results);
- publish their protocols and methodologies allowing the animal research to be reproduced;
- report any animal research in adherence with the ARRIVE guidelines²³ including the source of animals in an officially recognised nomenclature; and
- publish datasets and make research data as open as possible.

ARIA encourages the use of research practices that support rigorous and reproducible research and the application of best practice such as Registered Reports and pre-registration.²⁴

Reporting requirements

- 6.5 ARIA is committed to the principle of transparency in funding research and innovation involving animals:
 - 6.5.1 As a funder, ARIA will collect and publish available summary information about the use of animals in grants awarded to external organisations. This includes, where available, the proportion of grants involving animal usage, species information and information relating to the severity of procedures undertaken.
 - 6.5.2 ARIA encourages individuals (notably researchers) to be transparent about the involvement of animals in their R&I, for example by clearly identifying the use of animals in project summaries. ARIA encourages individuals to consider public engagement in planning research and innovation.
 - 6.5.3 ARIA will handle other information about R&I involving animals with sensitivity and due respect to the individuals involved, including by seeking permission before publishing information that may identify individuals.

²³ https://arrivequidelines.org/

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²⁴ https://osf.io/8v2n7/download