UKRI Policy on Research and Innovation Involving Animals

Table of Contents

Poli	icy Statement	1
Maı	nagement Statement	1
1.	Purpose and scope	2
2.	Definitions	3
3.	Principles	3
4.	Responsibilities for ASPA-regulated R&I involving animals	4
5.	Responsibilities for R&I involving or impacting animals that is not regulated under ASPA	7
6.	Additional responsibilities and expectations	8
7.	Approval and Review	10

Policy Statement

As a non-departmental public body and responsible funder, UK Research and Innovation (UKRI) has a responsibility to ensure that activities that UKRI funds are aligned with UK legislation and other guiding principles of ethical research practice. This policy sets out the approach of UKRI in ensuring that the commitments within the UKRI Statement on Research and Innovation Involving Animals¹ are met in all funding activities involving animals, in the context of UKRI Statement of Ethics.²

In addition, this policy supports UKRI's position as a signatory to the Concordat on Openness in Animal Research³ and is consistent with the cross-funder guidance Responsibility in the Use of Animals in Bioscience Research⁴ which includes the principle of the *3Rs*: the replacement, reduction and refinement of the use of animals in Research and Innovation (R&I).

Management Statement

This policy was recommended for approval by the UKRI Simpler and Better Funding (SBF) Policy Advisory Group with ratification from the UKRI SBF Programme Board.

Version Number	Status	Revision Date	Summary of Changes
Version 1.0	Draft	February 2022	Stella Child, Stephanie Masefield, Lauren Swain – New policy created
Version 1.1	Approved	December 2023	Policy signed off through internal Policy Advisory Group

¹ https://www.ukri.org/manage-your-award/good-research-resource-hub/use-of-animals-in-research/

e https://www.ukri.org/manage-your-award/good-research-resource-hub/ethical-research-and-innovation/

³ https://concordatopenness.org.uk/

⁴ https://www.nc3rs.org.uk/sites/default/files/2022-

^{01/}Responsibility%20in%20the%20use%20of%20animals%20in%20bioscience%20research%202019.pdf

Version 1.2	Released	May 2024	Policy publicly released
-------------	----------	----------	--------------------------

Purpose and scope

1.1 This policy sets out the principles for funding R&I involving animals across UKRI in line with the commitments of the UKRI public statement on R&I involving animals and the UKRI Statement of Ethics.⁵

- 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 the following UKRI Councils and bodies:
 - o Arts and Humanities Research Council (AHRC)
 - o Biotechnology and Biological Sciences Research Council (BBSRC)
 - Economic and Social Research Council (ESRC)
 - o Engineering and Physical Sciences Research Council (EPSRC)
 - Medical Research Council (MRC)
 - Natural Environment Research Council (NERC)
 - Science and Technology Facilities Council (STFC)
 - o Innovate UK
 - o Research England
 - National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs)
- 1.4 This policy applies to all⁶:
 - 1.4.1 UKRI funding applications and awards, including fellowships, studentships and those taking place overseas;
 - 1.4.2 organisations that apply for and/or receive funding from UKRI, including those based overseas, and those that apply for and/or receive funding from UKRI indirectly through a partner organisation;
 - 1.4.3 organisations when conducting work that benefits from UKRI funding, for example when using of UKRI facilities or collaborating with individuals on UKRI-funded projects;
 - 1.4.4 individuals engaged in R&I activities at such organisations, whether directly employed by them or not, when using UKRI funds (either directly or indirectly, or those making UKRI funding applications);
 - 1.4.5 individuals employed by UKRI including those directly involved in research at centres, institutes, units and facilities;
 - 1.4.6 individuals while undertaking duties for UKRI such as assessing grant applications ('assessors'), serving on a decision-making body on behalf or providing strategic advice on issues related to R&I involving animals;
 - 1.4.7 UKRI's activities as a funder, including partnerships and collaborations

⁵ https://www.ukri.org/manage-your-award/good-research-resource-hub/ethical-research-and-innovation/

⁶ It is the responsibility of applicants for UKRI funding to ensure awareness of this policy throughout parties involved in the funding

with other funding partners; it also sets out our expectations for joint programmes co-funded with partners;

1.5 This policy references and is not intended to contradict existing guidance, particularly the 'Responsibility in the Use of Animals in Bioscience Research'⁷ and, where relevant, 'Sharing and Archiving of Genetically Altered Mice'⁸, ARRIVE Guidelines⁹, and 'Nonhuman Primate Accommodation, Care and Use'¹⁰, available on the UKRI Good Research Resource Hub.¹¹

2. Definitions

- 2.1 For the purposes of this policy, the following terms are defined as:
 - 2.1.1 *'Animals'* are taken to mean **all invertebrates and vertebrates** in the Kingdom Animalia, except where otherwise specified.
 - 2.1.2 'ASPA-regulated research' is defined in accordance with the Animals (Scientific Procedures) Act 1986 (ASPA)¹², 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.
 - 2.1.4 The '3Rs' principles¹³ are: Replacement avoiding or replacing the use of animals in 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 UKRI 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). UKRI 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, UKRI will ensure that funded R&I aligns with legislation and guiding principles.

⁷ https://www.nc3rs.org.uk/responsibility-use-animals-bioscience-research

⁸ https://www.nc3rs.org.uk/3rs-resources/breeding-and-colony-management/sharing-and-archiving-ga-mice

⁹ https://arriveguidelines.org/

¹⁰ https://nc3rs.org.uk/non-human-primate-accommodation-care-and-use

¹¹ https://www.ukri.org/about-us/policies-standards-and-data/good-research-resource-hub/use-of-animals-in-research/

¹² https://www.gov.uk/government/publications/consolidated-version-of-aspa-1986

¹³ https://nc3rs.org.uk/who-we-are/3rs

^{14 &}lt;a href="https://www.gov.uk/government/publications/consolidated-version-of-aspa-1986">https://www.gov.uk/government/publications/consolidated-version-of-aspa-1986. Other legislation of relevance but not referenced specifically includes: https://www.gov.uk/government/publications/consolidated-version-of-aspa-1986. Other legislation of relevance but not referenced specifically includes: https://www.gov.uk/government/publications/consolidated-version-of-aspa-1986. Other legislation of relevance but not referenced specifically includes: https://www.gov.uk/government/publications/consolidated-version-of-aspa-1986. Other legislation of relevance but not referenced specifically includes: https://www.gov.uk/government/publications/consolidated-version-of-aspa-1986. Other legislation of relevance but not reference and account not reference and reference an

- 3.3 UKRI is committed to only funding R&I using animals and procedures covered under ASPA where no scientifically acceptable non-animal alternatives exist.
- 3.4 UKRI supports the principles of the 3Rs: the replacement, reduction, and refinement of animal use in R&I, including by funding the development and dissemination of 3Rs approaches and technologies, including through the NC3Rs.¹⁵
- 3.5 UKRI is committed to ensuring the highest possible standards of animal welfare throughout the R&I that we support.
- 3.6 UKRI 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 veterinary staff, and students).
- 3.7 UKRI supports the Concordat on Openness on Animal Research¹⁶, including through annual publication of data about the use of animals in UKRI-owned establishments, the publication of a formal statement on the position of UKRI as funder with respect to R&I involving animals, as well as active engagement and communication in support of funded R&I involving animals.
- 3.8 UKRI 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 UKRI as a funder, as a research-performing organisation and for organisations and individuals funded by UKRI, and assessors involved in the funding processes of UKRI.
- 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:

UKRI as a Funder

- 4.2.1 As a funder, UKRI seeks to do the following:
 - ensure R&I is conducted in an ethical way, in accordance with UKRI
 Statement of Ethics¹⁷ 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 overseas;
 - collect sufficient information from applicants to enable assessors 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

¹⁶ https://www.understandinganimalresearch.org.uk/

¹⁵ https://nc3rs.org.uk/

¹⁷ https://www.ukri.org/manage-your-award/good-research-resource-hub/ethical-research-and-innovation/

avoid endangering animal populations;

- when selecting assessors, 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, in accordance with UKRI Principles of Assessment and Decision Making;¹⁸
- provide training and/or guidance for assessors 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 Accommodation, Care and Use'¹⁹ and other relevant guidance on the use of specific species (available on the Good Research Resource Hub²⁰);
- ensure that cross-council expertise is sought and made available for any funding opportunities led by a UKRI Council or body 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 Terms and Conditions of grants awarded by UKRI;
- in joint calls with other funders, request the funding partner(s) include provisions to ensure terms and conditions of any funding to the same effect of this policy;
- obtain assurances and evidence from organisations in receipt of UKRI funding that they comply with existing legislation and best practice²¹;
- 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;²²
- conduct appropriate portfolio-wide evaluation of the use of animals in UKRI-funded R&I, including monitoring and analysis of animal use, and 3Rs practices.

Research performing organisations, including UKRI

4.2.2 Organisations receiving funding from UKRI or UKRI where it is an employer of

¹⁸ https://www.ukri.org/wp-content/uploads/2021/03/UKRI-310321-Principles-of-Assessment-and-Decision-Making-V2.pdf

¹⁹ https://nc3rs.org.uk/non-human-primate-accommodation-care-and-use

²⁰ https://www.ukri.org/about-us/policies-standards-and-data/good-research-resource-hub/use-of-animals-in-research/

²¹For examples see Good Research Resources Hub: https://www.ukri.org/about-us/policies-standards-and-data/good-research-resource-hub/

²² https://wellcome.org/sites/default/files/wtvm052279_1.pdf

researchers, shall:

- support applicants to meet UKRI requirements, relevant legislation, and best practice, including via the provision of training for staff. Training of students should meet the Statement of Expectations for Postgraduate Training²³ and UKRI Training Grant Terms and Conditions²⁴;
- 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, be able to provide assurance to UKRI that the requirements outlined above are met.

Individuals and organisations funded by UKRI

- 4.2.3 Individuals or organisations conducting research funded by UKRI, or applying for UKRI funding in order to conduct, ASPA-regulated research or innovation shall be required to:
 - meet all the expectations set out in UKRI's public statement on Research Involving Animals²⁵ and the 'Responsibility in the Use of Animals in Bioscience Research'²⁶ document, which include but are not limited to 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 Guidelines²⁷;
 - in the event of work being contracted to third-party suppliers and service providers or carried out overseas/by an overseas partner, 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 genetically altered animals by sharing and archiving strains (e.g. embryos or sperm) in accordance with the principles set out in Sharing and Archiving of Genetically Altered Mice';²⁸
 - notify and consult with UKRI before any substantive changes are made to

²³ https://www.ukri.org/wp-content/uploads/2020/10/UKRI-211020-StatementOfExpectationsPostGradTraining-Sep2016v2.pdf

²⁴ https://www.ukri.org/wp-content/uploads/2022/04/UKRI-050422-TrainingGrantTermsConditions-Apr2022.pdf

²⁵ https://www.ukri.org/manage-your-award/good-research-resource-hub/use-of-animals-in-research/

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

²⁷ https://arriveguidelines.org/

²⁸ https://www.nc3rs.org.uk/3rs-resources/breeding-and-colony-management/sharing-and-archiving-ga-mice

experimental plans where this affects animals involved in the R&I.

Assessors involved in the funding processes of UKRI

- 4.2.4 Assessors, including reviewers and panel members, 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 UKRI also undertakes and funds a number of activities not regulated under ASPA which involve or may impact upon animals. For example, this would include behavioural 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.²⁹,
 - 5.1.1 As a funder, UKRI 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 assessors 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 assessors, 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'³⁰ and other relevant guidance on the use of specific species (available on the Good Research Resource Hub³¹);
 - provide training and/or guidance for peer reviewers, grant assessors, and panel members to aid them in assessing applications according to the

²⁹ ASPA Flow Chart - Professionals (rcvs.org.uk)

³⁰ https://nc3rs.org.uk/non-human-primate-accommodation-care-and-use

³¹ https://www.ukri.org/about-us/policies-standards-and-data/good-research-resource-hub/use-of-animals-in-research/

principles in Section 3;

Research performing organisations, including UKRI

- 5.1.2 Organisations receiving funding from UKRI, and UKRI where is an employer of researchers shall:
 - support applicants to meet UKRI requirements, relevant legislation and best practice, including via the provision of training for staff. Training of students should meet the Statement of Expectations for Postgraduate Training³² and UKRI Training Grant Terms and Conditions³³.

Individuals and organisations funded by UKRI

- 5.1.3 Individuals or organisations conducting research funded by UKRI or applying for UKRI funding in order to conduct non-ASPA-regulated R&I, including outside of the UK, should:
 - meet expectations as set out in UKRI's public statement on Research Involving Animals and the 'Responsibility in the Use of Animals in Bioscience Research' guidelines, which include 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).

Assessors involved in the funding processes of UKRI.

- 5.1.4 Assessors, 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

- When UKRI funds R&I outside the UK that involves animals, including as part of international collaborations, UKRI 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 When seeking or receiving funding for such applications, applicants (whether

³² https://www.ukri.org/wp-content/uploads/2020/10/UKRI-211020-StatementOfExpectationsPostGradTraining-Sep2016v2.pdf

https://www.ukri.org/wp-content/uploads/2022/04/UKRI-050422-TrainingGrantTermsConditions-Apr2022.pdf

based in the UK or overseas) shall be required to:

- provide additional information at the application stage regarding any animal facilities and care provided overseas;
- 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 from both the UK and the relevant overseas ethical review body, as appropriate.

Animal Welfare

- 6.2 UKRI 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. UKRI 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' document³⁴ and other relevant guidance, approval should be sought by the applicant during the application process and agreed by UKRI.
 - 6.2.2 In accordance with the relevant guidance, UKRI 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.³⁵ UKRI encourages funded individuals and organisations to publish and report (for example through ResearchFish) refinement and positive welfare activities.
 - 6.2.3 UKRI 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' document³⁶.
 - 6.2.4 UKRI 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 UKRI is committed to funding robust and reproducible research. Individuals or organisations conducting research funded by UKRI or applying for UKRI funding are expected to:
 - describe the experimental design and analysis plans in proposals. The
 Experimental Design Assistant³⁷ can provide support in planning experiments;
 - provide appropriate information on animal characteristics (e.g. sex, genetic

³⁴ https://www.nc3rs.org.uk/responsibility-use-animals-bioscience-research

https://nc3rs.org.uk/3rs-resources

³⁶ https://www.nc3rs.org.uk/responsibility-use-animals-bioscience-research

³⁷ https://eda.nc3rs.org.uk/

background, age) and meet the requirements on the Inclusion of Sex in Experimental Design where required by the funding council;

- make use of measures to reduce the risk of bias including but not limited to randomisation, blinding (masking), sample size calculations, and inclusion and exclusion criteria;
- publish the results of all experiments that have been conducted (including so called negative results);
- publish their protocols and methodologies allowing the research to be reproduced
- report any animal research in adherence with the ARRIVE guidelines³⁸ including the source of animals in an officially recognised nomenclature; and
- publish datasets³⁹ and make research data as open as possible.

UKRI 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.⁴⁰

Reporting requirements

- As a signatory to the Concordat on Openness in Animal Research⁴¹, UKRI is committed to the principle of transparency in funding research and innovation involving animals.
 - 6.4.1 When acting in its role as a research performing organisation, UKRI will publicly release the figures of ASPA-regulated procedures on animals annually, including severity of the procedure and species of animal involved, in addition to reporting to the Home Office. Historical data will be maintained for 5 years, and thereafter archived in the National Archives.
 - 6.4.2 As a funder, UKRI will collect and publish available summary information about the use of animals in grants awarded to external organisations. This includes the proportion of grants involving animal usage, species information and 3Rs uptake.
 - 6.4.3 UKRI 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. UKRI encourages individuals to consider public engagement in planning research and innovation, where appropriate, in accordance with the Concordat on Openness in Animal Research.
 - 6.4.4 UKRI 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.

7. Approval and Review

- 7.1 The UKRI SBF Policy Advisory Group (PAG) recommended this policy for approval with final approval at the UKRI SBF Programme Board.
- 7.2 Associate Director of UKRI Funding Policy will act as policy owner.

³⁸ https://arrivequidelines.org/

³⁹ https://www.ukri.org/manage-your-award/publishing-your-research-findings/making-your-research-data-open/

⁴⁰ https://osf.io/8v2n7/download

⁴¹ https://concordatopenness.org.uk/

7.3	BBSRC, MRC and NC3Rs representatives to UKRI Animal Policy Forum will act as policy writers and lead policy monitoring and evaluation.				