Responsibility in the use of animals in bioscience research:

Expectations of the major research council and charitable funding bodies

Contents

Introduction

Co-ordinated by the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs), the Biotechnology and Biological Sciences Research Council (BBSRC), the Department for Environment, Food and Rural Affairs (Defra), the Medical Research Council (MRC), the Natural Environment Research Council (NERC), and the Wellcome Trust have produced this document to clarify their expectations with regard to responsibility in the use of animals in bioscience research.

Research in the United Kingdom (UK) involving scientific procedures that may cause living vertebrates (other than man) and cephalopods pain, suffering, distress or lasting harm must comply with the provisions of the Animals (Scientific Procedures) Act 1986 (ASPA), amended 2012, and any guidance and codes of practice issued under the Act.[1] The funding bodies are, however, committed to introducing and implementing standards which reflect contemporary good practice, including when these exceed the minimum requirements of legislation and codes of practice, for all research using animals, not just that regulated under the ASPA. High standards in the design and conduct of animal research and full implementation of the 3Rs are important for ethical reasons and to obtain the best possible scientific results.

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.

The scope of this guidance

This document is intended to provide general guidance to researchers and associated veterinary and animal care staff using vertebrates and cephalopods (live animals or animal products) in bioscience research funded by the BBSRC, Defra, MRC, NC3Rs, NERC and Wellcome Trust. It sets out the expectations of the funding bodies for the use of such animals in research and is therefore useful to ethics committees, referees, and Board and Committee members involved in reviewing research proposals. **Implementation of the principles in this guidance is a condition of receiving funds from the funding bodies.**

The guidance was developed by reviewing the published literature (including policy statements, legislation and scientific articles) and through consultation with the scientific community, veterinary and animal care staff, animal welfare organisations, and the Home Office Animals in Science Regulation Unit Inspectorate (ASRUI). The guidance covers:

- a summary of the legal controls on animal use
- the responsibilities of the relevant parties
- the principles and procedures of the funding bodies.

The guidance does not aim to be comprehensive. Rather, it sets out some general principles for good practice and refers to other publications that should be read for advice or instruction on specific aspects, including statutory requirements. The NC3Rs office, website and microsites offer further advice on good practice for the areas covered in this document (see www.nc3rs.org.uk).

1 Embryonic and fetal forms of mammals, birds and reptiles are protected during the last third of their gestation or incubation period. Fish and amphibians are protected once they can feed independently, and cephalopods at the point they hatch. Embryonic and fetal forms are protected from an earlier stage of development if they are going to live beyond the stage described above and the procedure is likely to cause them pain, suffering, distress or lasting harm after they have developed to that stage.

Legal controls on animal use

The funding bodies only support work involving the use of animals on the basis that researchers and those administering the funding comply with legal provisions, plus any related codes of conduct or guidance issued by government departments and the specific conditions of licences.

UK legislation and guidance relevant to animal research (e.g. on the use of animals in scientific procedures, the importation and transportation of animals, and international trade in endangered species) are listed on the NC3Rs website (see **www.nc3rs.org.uk/legislation**). Note that it is an offence for any person to cause unnecessary suffering to any captive vertebrate animal under the Animal Welfare Act 2006.[2]

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

ABOVE: Scientist preparing DNA samples prior to sequencing.
Wellcome Images

2 An animal is protected under this Act if: (a) it is of a kind which is commonly domesticated in the British Islands; (b) it is under the control of man, whether on a permanent or a temporary basis; or (c) it is not living in a wild state. Nothing in this Act applies to anything lawfully done under the ASPA.

Additional protection is afforded to animals used for farming purposes under regulations made under this Act. The welfare of animals which are not "protected animals" for the purposes of the Act is covered by other legislation such as the Wildlife and Countryside Act 1981 and the Wild Mammals (Protection) Act 1996.

It is essential to contact the ASRUI where there is any doubt whether a procedure falls within the scope of the ASPA. Note that the production and breeding of genetically altered vertebrates should be presumed to be regulated under the ASPA unless a ruling regarding a particular line has been made otherwise. The controls of the ASPA do not extend to:

- procedures applied to animals in the course of non-experimental clinical veterinary practice, non-experimental agricultural practice or recognised animal husbandry; the Royal College of Veterinary Surgeons (**www.rcvs.org.uk**) can advise on what constitutes non-experimental clinical veterinary practice and the related professional standards

- the ringing, tagging or marking of an animal, or the application of any other humane procedure for the primary purpose of enabling the animal to be identified, provided that it causes no more than momentary pain or distress (or none at all) and no lasting harm

- the administration of any substance or article to an animal for research purposes in accordance with an animal test certificate granted under the Veterinary Medicines Regulations 2011

- the humane killing of an animal by a competent person using a method appropriate to the animal and listed under Schedule 1 to the ASPA, or specified in the establishment licence[3]

- the killing of an animal outwith an establishment licensed under the ASPA.

3 Humane killing may only be conducted by people adequately trained and listed on the establishment's register of competent persons.

Main provisions of the ASPA

Any procedure done for a scientific (including experimental) or educational purpose which may cause a protected animal pain, suffering, distress or lasting harm is a regulated procedure under the ASPA. Protected animals are all living vertebrates except man (including some immature forms) and cephalopods (excluding embryonic forms). The ASPA also regulates the breeding of animals for use of their organs or tissues in procedures.

The Act provides for licences granted by the Secretary of State and for inspectors who advise on these and monitor the operation of the controls. A regulated procedure can only be carried out legally by a person with a licence which specifies that procedure and as part of a programme of work authorised by a project licence, held by a person who undertakes overall responsibility for implementation of the programme. Both the personal and project licences must specify the place where the regulated procedure is carried out and be currently valid.

Unless the nature of the work requires otherwise (e.g. work in the wild), places where regulated procedures are carried out must hold an establishment licence. Places where the common laboratory animals are bred or held for supply must also hold an establishment licence. These licences are granted to a person in authority at the establishment and must specify a Named Veterinary Surgeon (NVS) to advise on animal health and welfare and a person responsible for the day-to-day care of the animals, called a Named Animal Care and Welfare Officer (NACWO). In addition, they must also specify a Named Compliance Officer responsible for ensuring compliance with the Act and conditions of licences (NCO), a Named Information Officer (NIO) and a Named Training and Competence Officer (NTCO).

Before a project licence is granted, the Secretary of State (advised by an inspector) must weigh the likely benefits from the programme of work against the likely harms to the animals involved. He or she must be satisfied that there are no reasonably practicable alternatives to using protected animals for the work, and that the procedures will use minimal numbers and least severity and be most likely to produce satisfactory results. Inspectors need to be provided with sufficient information to allow them to advise the Secretary of State on these points.

The Act requires the Secretary of State to place certain conditions on licences and allows him or her to specify others. Under conditions of the licences, all scientific procedures must be carried out under general or local anaesthesia, unless anaesthesia is judged to be more traumatic to the animal than the procedure itself or would be incompatible with the purpose of the procedure. Analgesia, or other appropriate pain-relieving methods, must also be used, unless to do so would frustrate the purpose of the procedure.

Personal and project licence holders must act at all times in a manner that is consistent with the principles of the 3Rs.

Every breeder, supplier and scientific procedure establishment must have an animal welfare and ethical review body (AWERB), which replaces the ethical review process (ERP). The AWERB should advise the establishment licence holder, support the named persons and licensees on animal welfare and ethical issues, and develop the widest possible application of the 3Rs.

ABOVE:
Animal technician assessing the health of rats used in studies of the parasite *Trichinella*.
RDS/Wellcome Images

Responsibilities of the relevant parties

Responsibilities of researchers and associated veterinary and animal care staff

Researchers (grant holders and staff) and associated veterinary and animal care staff are responsible for the design and conduct of research using animals. In addition to fulfilling any legal responsibilities, they are primarily responsible for applying the principles in this guidance, with support from their host establishments.

Researchers are expected to give appropriate consideration to the 3Rs in any research involving animals that has the potential to cause the animals harm and to explain in their research proposals (both in grant proposals to funding bodies and in research proposals and other information provided to ethics committees) how the 3Rs have been taken into account.

Researchers and associated veterinary and animal care staff should adopt a culture of care with regard to the animals and keep themselves informed of developments in good practice and advances in the 3Rs (e.g. by familiarising themselves with the NC3Rs website and microsites and the publications available therein; see www.nc3rs.org.uk).

Everyone using animals, whether for experimentation, testing, the provision of tissue, or the breeding and maintenance of stock colonies, is responsible for ensuring the animals are afforded high levels of welfare and protection. Advice on animal welfare should be sought from the NACWO, NVS and, where appropriate, others with relevant animal welfare expertise.

Responsibilities of ethics committees

Ethics committees are responsible for reviewing animal use at a local level and addressing situations where there is a risk that the use of animals may be in conflict with the best welfare interests of the animals involved. They have a key role in ensuring high standards. It is therefore recommended that the research establishment's ethics committee, whether the AWERB established under the ASPA or otherwise, should be central to ensuring implementation of this guidance.

Responsibilities of peer reviewers assessing research grant proposals

Peer reviewers are responsible for critically assessing the validity, necessity and justification of research grant proposals in relation to the funding body's research directions and ethical framework. When considering proposals for support, peer reviewers have a key role in applying the principles in this guidance consistently across the research spectrum.

For each proposal that involves the use of animals, reviewers are asked to assess whether the research question can be addressed without the use of animals, whether the potential benefit justifies the possible adverse effects to the animals, whether the number of animals and the experimental design are appropriate, and whether the species is justified. These requirements apply whether or not the animals are to be purchased with funds requested within the proposal itself. These specific points are intended to provide both applicant and reviewer with the means by which a proposal may be judged on ethical grounds. If the applicant does not address these points, then the funding bodies will not support the research.

ABOVE:
Young rainbow trout used in ecotoxicology.

Research involving non-human primates, cats, dogs or equidae

A small proportion of the research or fellowships funded by the MRC, BBSRC, Royal Society, Wellcome Trust and other member charities of the Association of Medical Research Charities (AMRC) may involve the use of non-human primates, cats, dogs or equidae (members of the horse family). For research under the ASPA, these types of animal can only be used if no other animals are suitable. In recognition of particular public concern about the use of non-human primates, cats, dogs and equidae, the NC3Rs works in partnership with the above organisations to provide 3Rs and animal welfare review of research proposals involving their use. This is in addition to the independent scientific review co-ordinated by each of the funding bodies. The results of both the scientific and the 3Rs and animal welfare reviews are taken into account by Board and Committee members when making decisions on funding. Other research proposals that raise ethical issues may be referred to the NC3Rs or to a relevant funder's ethical review panel as appropriate.

All research involving non-human primates should comply with the NC3Rs Guidelines 'Primate accommodation, care and use', adopted by the above organisations (see www.nc3rs.org.uk/primatesguidelines).

Questions on compliance with the Guidelines may be asked of the applicant, ethics committee or named persons on licences issued under the ASPA, as part of the peer review process for research proposals. The NC3Rs may be asked by the funding bodies to give advice on compliance.

ABOVE:
Sprinting greyhound used in biomechanics research.
BBSRC/Structure and Motion Laboratory, The Royal Veterinary College

Principles and procedures of the funding bodies

The funding bodies require that researchers (grant holders and staff), associated veterinary and animal care staff, and all those involved in the ethical and peer review processes ensure that the principles and procedures set out below are applied in the design and conduct of research using animals.

Design of research and the 3Rs

All studies should take full account of the 3Rs including animal welfare. The funding bodies believe that implementation of the 3Rs is an integral part of good research and laboratory practice and will consider requests in grant proposals for resources for implementing the 3Rs that are appropriately justified. The funding bodies encourage researchers to look for opportunities for developing new 3Rs techniques as part of larger programmes of work.

All experimental work should seek where possible to avoid the use of animals if the work has the potential to cause animals pain, suffering, distress or lasting harm. Where use of animals is considered necessary, the researcher should advance sound scientific reasons for their use, explaining in proposals for support why no realistic alternative exists.

The species used should be that most likely to produce satisfactory results with the least degree of harm to the animals involved. Where possible, simple organisms should be used, such as invertebrates that have simple nervous systems.

The number of animals used in the entire programme of work should be minimised by careful planning and scheduling of breeding and experiments, and use of appropriate and efficient experimental designs. Grant applicants should describe and justify the experimental design or designs to be used, including the measures taken to reduce bias (e.g. randomisation, blinding).

The number of animals used in an experiment should be the minimum sufficient to answer the question posed. Grant applicants should justify the number of animals required, including sample size calculations where appropriate. Estimates of the number of animals needed should, where possible, take into account the required statistical significance and power level, the likely magnitude of the treatment effect (or other outcomes), the population variance and the factors that might affect this.

All steps should be taken to minimise any pain, suffering, distress and lasting harm or other adverse effects (e.g. fear, anxiety, discomfort) arising from the scientific procedures, housing and husbandry, and to maintain high standards of animal welfare throughout the life of the animals.

The severity of any procedures performed upon animals should be kept to the minimum. Experiments that have the potential to cause harm should be as short as practically possible. Anaesthesia (local, regional or full, with or without recovery) and/or analgesia should be used to minimise pain and/or distress, and humane endpoints implemented, wherever possible and appropriate.

Careful consideration should be given at the project planning stage to the fate of the animals at the end of the programme of work (e.g. euthanasia, rehoming, release). Where an animal is to be euthanised, tissue and blood products of value to research should be utilised wherever possible, including sharing with other researchers.

Opportunities to minimise the use of animals by sharing data and resources (e.g. embryos and sperm) should be exploited.

See the NC3Rs website and microsites (www.nc3rs.org.uk) for resources on many aspects of research design, including 3Rs databases, ethical review, experimental design and statistical analysis, species selection, genetic alteration, dosing and sampling, biotelemetry, imaging, anaesthesia, analgesia, welfare assessment, humane endpoints, and euthanasia.

Ethical review

In the case of ASPA-regulated research, ethical review of the work is normally undertaken by the AWERB and the funding body, the former providing a local establishment perspective on relevant issues. Where research has the potential to cause harm to vertebrate animals and is regulated under legislation other than the ASPA, it is the researcher's and research establishment's responsibility to ensure that there is appropriate ethical review of the work, taking the principles in this guidance into account.

For resources on ethical review, see www.nc3rs.org.uk/ethicalreview.

Research or collaborations outside the UK

When collaborating with other laboratories, or where animal facilities are provided by third parties, researchers and the local ethics committee in the UK should satisfy themselves that welfare standards consistent with the principles of UK legislation (e.g. the ASPA) and set out in this guidance are applied and maintained.

Where there are significant deviations, prior approval from the funding body should be sought and agreed. International research should also be compliant with all relevant national and local regulatory systems in the host country where the research is to be conducted.

Studies of free-living animals

Studies of free-living animals in their natural habitats can cause disruption, particularly if feeding, capture, marking or scientific procedures are involved. Researchers studying free-living animals should take precautions to minimise interference with individual animals, as well as the populations and ecosystems of which they are part. People capturing animals should be trained and competent in humane methods of capture, handling and release, and in any scientific procedures used, to minimise the impact on animals and their environment.

For resources on studies of free-living animals, see www.nc3rs.org.uk/wildliferesearch.

Breeding and supply of animals

Animals should be obtained from a source with high welfare standards. In the case of ASPA-regulated research, unless the Secretary of State considers an exemption justified, use of the following animals is limited to those bred at a licensed breeding establishment or obtained from a licensed supplying establishment: mouse (*Mus musculus*), rat (*Rattus norvegicus*), gerbil (*Meriones unguiculatus*), hamster (*Mesocricetus auratus* or *Cricetulus griseus*), guinea pig, rabbit (*Oryctolagus cuniculus*), cat, dog, ferret, non-human primate species, pig (if genetically altered), sheep (if genetically altered), quail (*Coturnix coturnix*), zebrafish and frogs of the species *Xenopus laevis*, *Xenopus tropicalis*, *Rana temporaria* or *Rana pipiens*. Cats and dogs must have been bred at, and obtained from, a licensed breeding establishment. All these animals are listed in Schedule 2 of the ASPA.

Species caught from the wild should not be used for research without specific justification. Applicants proposing to use wild-caught animals will have to make a special case to the funding body justifying why captive-bred animals cannot be used.

Breeding should be carefully planned and regulated to meet research needs, with respect to number, uniformity and health. Avoidable over-breeding should be minimised, there should be no unnecessary culling, and the quality (e.g. health status) of the animals should be high to allow them to be used in minimal numbers. The MRC has issued codes of practice for the supply of rodents and aquatic species in research (see www.mrc.ac.uk/consumption/groups/public/documents/content/mrc004200.pdf and www.mrc.ac.uk/consumption/groups/public/documents/content/mrc003633.pdf).

For resources on breeding and supply of animals see www.nc3rs.org.uk/breeding and www.nc3rs.org.uk/sourcing.

Husbandry and transport of animals

Scrupulous husbandry should be observed for animals permanently or temporarily housed, or in transit. Animals should be properly fed and watered and should have a suitable environment that is not subject to extremes of temperature, humidity or pollution. They should not be kept or transported in overcrowded conditions. Where deviations are required (e.g. for studies of improved husbandry and transport practices), these should be justified in the research proposal.

Every effort should be taken to minimise journey times and any associated stress and/or distress caused by transport.

Transport of live mice should be avoided, wherever possible, by the use of fresh embryos or cryopreserved embryos and gametes.

For resources on transport of animals see www.nc3rs.org.uk/transport.

Housing and care

The majority of laboratory animals spend most of their time confined to cages or enclosures. Researchers and associated veterinary and animal care staff should therefore ensure that conditions for holding and experimentation are of a high standard. Immediate housing (e.g. cages and the surrounding environment) should provide animals with spacious, high-quality living space conducive to good animal welfare and to minimising stress and distress. Species-specific considerations, together with behavioural requirements and environmental enrichment, should be addressed.

The Home Office code of practice on animal care and accommodation, Annex III of Directive 2010/63/EU and Appendix A to the Council of Europe Convention ETS 123 set out minimum rather than optimum space allocations. Every effort should be made to exceed minimum space allowances, to provide the animals with a complex and varied physical environment and to house the animals in appropriate social groupings, with the aim of promoting exercise and performance of species-typical behaviours.

For resources on housing and care of animals see www.nc3rs.org.uk/housing.

ABOVE: Pigs developed from cryopreserved and surgically implanted embryos.
Agricultural Research Service

LEFT: Rats provided with substrate, nesting material and cardboard tubes.
Institute of Animal Technology

Capture, handling, restraint and training of animals

Methods of capture, handling, restraint and training should seek to minimise any stress and/or distress to the animals.

Positive reinforcement techniques should be utilised to train all appropriate laboratory animal species to co-operate with capture, handling, restraint and scientific procedures. Non-human primates, dogs, cats, rodents, farm species and birds can be trained in a variety of situations and for a variety of procedures (e.g. weighing, blood sampling, administration of substances).

Where restraint is necessary, the minimal level of restraint should be used and for the shortest possible time.

For resources on handling, restraint and training of animals, see **www.nc3rs.org.uk/handlingandrestraint** and **www.nc3rs.org.uk/traininganimals**.

Dosing and sampling

The method, route and frequency of dosing and sampling should be chosen carefully in order to minimise any pain, distress or discomfort to the animals. As a general principle, the volume of substance administered or tissue removed should be kept as low as possible.

For guidance on dosing mice and rats, see **www.procedureswithcare.org.uk**. For guidance on dose selection for regulatory toxicology studies of pharmaceuticals, see **www.nc3rs.org.uk/doseselection**. For guidance on blood sampling in common laboratory animal species, see **www.nc3rs.org.uk/bloodsamplingmicrosite**.

Animal health and welfare

Animals should be given due respect and care by all who look after, handle or perform experiments upon them. Animals should be healthy before and, as far as is in keeping with the aims of the research, during the experiment. Pain, physiological and psychological stress, and significant discomfort, whether immediate or in the long term, should be kept to a minimum at all times. All staff members are responsible for maintaining these standards.

The health and welfare of animals should be monitored using appropriate indicators and assessment and recording schemes. These should be tailored to individual projects, based on experience with the animal model and/or species and incorporating humane endpoints as appropriate (see page 20).

Use of genetically altered (GA) animals may raise particular problems in assessing welfare. All proposed research projects involving GA mice are expected to have taken account of the recommendations of the report ‘Assessing the welfare of genetically altered mice’, produced on behalf of the funding bodies (see **www.nc3rs.org.uk/GAmice**).

ABOVE: Young rhesus macaque socialising with an animal technician.
MRC/Wellcome Images

RIGHT: Group-housed rabbit in an enriched floor pen.
Novo Nordisk

Sufficient time and resources should be allocated to allow regular review of all aspects of animal health and welfare (e.g. housing, environmental enrichment, handling and restraint).

For resources on assessing animal health and welfare, see **www.nc3rs.org.uk/welfareassessment**.

Humane endpoints

Where experiments have the potential to cause harm to animals, researchers should identify humane endpoints for each experiment before commencing the work, by consulting the NVS, NACWO, NIO, research colleagues and the literature.

The implementation and assessment of humane endpoints should be monitored and recorded during the experiment (e.g. using score sheets). Humane endpoints should be continually reviewed and refined as required based on experience.

For resources on humane endpoints and euthanasia, see **www.nc3rs.org.uk/humaneendpoints** and **www.nc3rs.org.uk/euthanasia**.

Staff training

Ensuring that staff members have the proper training, attitude, motivation and skills is key to maintaining a 'culture of care'. All staff involved in research using animals, and those involved in the breeding, handling and care of animals, should be trained to the level of expertise and responsibility they are required to exercise. They should possess relevant professional or other recognised qualifications. Their competence and the level of supervision and support required should be regularly assessed and recorded. The Named Training and Competence Officer (NTCO) established under the ASPA should be central to delivering these objectives.

Staff working with and caring for animals should be knowledgeable (at a level appropriate for their work) about the natural history, biology and behaviour of the species concerned. They should also have a good understanding of how the laboratory environment and scientific procedures can affect animal welfare, so that appropriate care can be given to provide the best possible quality of life and to minimise any pain, suffering, distress or lasting harm (see the NC3Rs website and *The UFAW Handbook on the Care and Management of Laboratory Animals*).

There should be an appropriately resourced programme of continuing professional development for staff at all levels.

All staff should be actively encouraged to extend their knowledge and experience and to spread good practice by visiting other establishments and attending training courses, meetings and symposia. Information on training and education opportunities in the 3Rs and animal use, care and welfare can be obtained from the NC3Rs Events Calendar (see **www.nc3rs.org.uk/events**). The funding bodies will consider requests for funding to attend events relevant to funded research and the 3Rs.

Communication of advances in the 3Rs

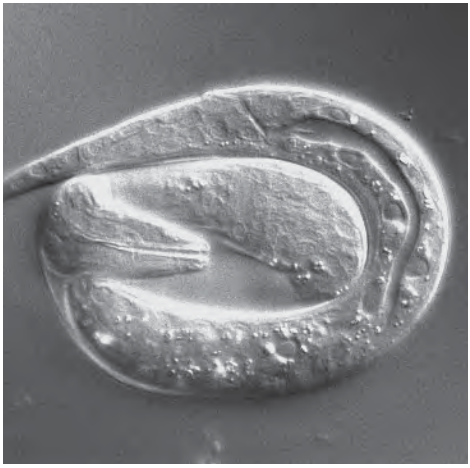
Researchers should ensure that any new procedures or improvements in techniques that avoid or replace animal use, reduce the number of animals needed for research, testing or diagnosis, or reduce the suffering arising from scientific procedures or husbandry and care are communicated to other researchers and to veterinary and animal care staff, as appropriate.

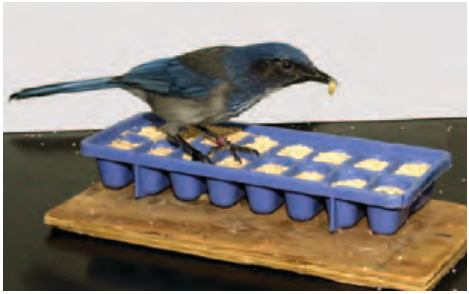
Where possible, grant holders and staff should include in their published papers information that would probably help others implement the 3Rs in similar experiments. This information should also be included when reporting research outcomes. Where appropriate, it will be made available to the NC3Rs for follow up (e.g. formal validation or outreach to the scientific community). Such information can also be submitted direct to the NC3Rs via its website and enquiries@nc3rs.org.uk.

The funding bodies will recognise the publishing of significant and original contributions to the development of the 3Rs in reviews of establishments and in reports on grants.

Reporting of animal-based studies

Researchers should ensure that they report animal-based studies in accordance with the ARRIVE guidelines (see www.nc3rs.org.uk/ARRIVE) as far as possible, taking into account the specific editorial policies of the journal concerned.





TOP: Hatching nematode (roundworm), *Caenorhabditis elegans*.
Sanger Institute/Wellcome Images

BOTTOM: Western scrubjay used in cognition studies.
University of Cambridge

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