

Guidelines for Ethical Approval of Research Involving Animals

1 Introduction

- 1.1 The objectives of the Ethics Committee are to maintain ethical standards of practice in research, to protect the dignity, rights and welfare of research participants, both subjects and investigators, and to provide reassurance to the public that this is being done. In achieving these objectives, the members of the Ethics Committee should remember that research benefits society and that they should take care not to hinder it without good cause. The Ethics Committee also protects researchers from unjustified criticism.
- 1.2 The University has published a Policy Statement on the Use of Animals in Research¹ and these guidelines should be read in conjunction with the Policy Statement.
- 1.3 For the purposes of ethics review of research, the University uses the broadest definition of animal. All research involving animals other than humans² where the animal is the subject of the research, whether undertaken by the University's staff or students, must undergo an ethics review and a favourable opinion must be obtained before it commences.
- 1.4 The University has a responsibility to ensure the health and welfare of any animal used in research meets the highest standards. The University also has a responsibility to ensure that any such research has been considered ethically in terms of the harms and benefits, and whether there is an equally effective method of research that does not involve a living model.
- 1.5 The University is committed to the principles of the 3Rs of Reduction, Refinement and Replacement. For every project involving animals the Ethics Committee is responsible for ensuring, as far as is reasonably practicable, that no alternative to the use of animals is possible, that the number of animals used is minimised, that unnecessary duplication is avoided, and that procedures and husbandry are refined to maximise welfare.
- 1.6 It is the responsibility of the person proposing to carry out a research project involving animals to obtain the approval of the Ethics Committee. If a project is to be

¹ <https://www.essex.ac.uk/-/media/documents/directories/reo/animal-research.pdf>

² Research involving human participants will follow the University's [Guidelines for Ethical Approval of Research Involving Human Participants](#)

undertaken outside the University where a local ethics procedure exists (e.g. a project in collaboration with another institution with a Home Office Licence under the Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012 (ASPA)), the University's Committee need not necessarily be involved in an ethics review. However, approval of the local committee must be sought and obtained before research commences.

1.7 In designing a research project involving animals, investigators must be able to demonstrate a clear intention that it will contribute to the advancement of knowledge and that it is likely to lead to improvement of the health and welfare of animals or human beings or involves observations that will lead to a greater understanding of the animals themselves.

1.8 Investigators must ensure that there is no undeclared conflict of interest (which may be personal, academic or commercial) in their proposed work and that the relation between the sources of funding and researchers' control over results is made clear, specifically in relation to the ownership, publication and subsequent use of research data.

2 Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012 (ASPA)

2.1 The University does not hold a Home Office Licence under the Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012 (ASPA) so any research requiring a licence is not conducted on University premises. See Appendix A for examples of research that is conducted on University premises.

2.2 The ASPA applies to 'protected animals' which are defined as:

2.2.1 'any living vertebrate, other than human, and any living cephalopod'.

Cephalopods include squid, octopus, cuttlefish and nautilus;

2.2.2 'embryonic and foetal forms of mammals, birds and reptiles are protected once they have reached the last third of their gestation or incubation period';

2.2.3 'larval forms of fish and amphibians are protected once they are capable of feeding independently;

2.2.4 'Cephalopods are protected from the point at which they hatch'.

2.3 The ASPA defines 'scientific procedures' as:

2.3.1 'procedures that are carried out on 'protected animals' for scientific or educational purposes that may cause pain, suffering, distress or lasting harm;

2.3.2 'the methods used to kill protected animals';

2.3.3 'the breeding and supply of certain species of animals for use in regulated procedures, or for the scientific use of their organs and tissues'.

2.4 The ASPA does not regulate:

2.4.1 non-experimental agricultural practices;

2.4.2 non-experimental clinical veterinary practices;

2.4.3 practices undertaken for the purposes of recognised animal husbandry;

2.4.4 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 or the Veterinary Medicines Regulations 2013;

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

2.5 Any research regulated by the ASPA must be undertaken in collaboration with another institution / organisation that holds the necessary licences and is able to comply with the requirements of the ASPA. The host institution should provide the ethics review and approval for such work. The external application for ethics review and confirmation of approval must be submitted via the ERAMS to enable confirmation of authorisation to be issued before the research commences

2.6 Individuals proposing to undertake research or teaching activities involving protected animals for the purposes of the ASPA but not involving a scientific procedure for the purposes of the Act must contact the Home Office (<mailto:ASPA.London@homeoffice.gov.uk>) to confirm that the activity does not fall within the remit of the ASPA. Confirmation from the Home Office must be attached to the application for ethical approval

3 External Licences

3.1 **Wildlife Licence:** Research that affects wildlife and its habitat may require a wildlife licence from Natural England or DEFRA. A wildlife licence is required to:

3.1.1 prevent damage to agriculture, livestock, fisheries, property or archaeology;

3.1.2 protect public health and safety, such as demolishing an unsafe derelict building that hosts a bat roost;

- 3.1.3 maintain or develop land, for example converting farmland or a brownfield site to housing;
- 3.1.4 prevent disease among species;
- 3.1.5 keep or release species not native to England;
- 3.1.6 sell, own, exhibit or transport protected species;
- 3.1.7 survey for the presence of wildlife on your land for science or educational research or for conservation work.

3.2 CITES (the Convention on International Trade in Endangered Species of Wild Fauna and Flora): CITES aims to ensure that international trade in wild animals and plants is legal, sustainable and traceable, and does not threaten the survival of the species in the wild. It reflects all three dimensions of sustainable development - social, economic and ecological – and contributes to the achievement of Sustainable Development Goals through People, Planet, Prosperity, and Partnership. is an international agreement between governments. The aim is to ensure that international trade in specimens of wild animals and plants does not threaten the survival of the species.

CITES regulates international trade in specimens of species of wild fauna and flora based on a system of permits and certificates issued under certain conditions. It covers export, re-export, import and landing from the high seas of live and dead animals and plants and their parts and derivatives. CITES accords varying degrees of protection to more than 36,000 species of animals and plants by applying different provisions to species included in three Appendices:

- 3.2.1 Appendix I: Species threatened with extinction. International commercial trade is generally prohibited.
- 3.2.2 Appendix II: Species not necessarily threatened with extinction but may become so unless trade is regulated, and species whose specimens in trade look like those of species listed for conservation reasons. International commercial trade is allowed but controlled.
- 3.2.3 Appendix III: Species subject to regulation within the jurisdiction of a Party and for which the cooperation of other Parties is needed to control international trade.

There are exceptions in place for specimens designated for scientific purposes but a permit or certificate is often still required

3.3 The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity promotes the fair and equitable sharing of the benefits of research that uses genetic resources or related traditional knowledge. The Protocol includes obligations related to access, benefit-sharing and compliance, such as the prior informed consent from indigenous and local communities holding established rights, keeping in mind community laws and procedures as well as customary use and exchange..

It is the responsibility of the person proposing to undertake research involving animals to obtain the necessary licences from the appropriate authority and to demonstrate that the required licences are in place before a favourable ethical opinion will be granted. A copy of any required licence must be attached to an application for ethical approval. There may be other approvals and licences not listed above that are required.

4 Research Involving Humans and Animals

4.1 Where a research project involves both animal and human participants, and the University has the authority to approve the animal research, a single application for ethical approval covering both animal and human participants should be submitted.

5 Ethics Standards of External Bodies

5.1 In addition to University guidelines, researchers should be aware of ethics codes of the relevant professional or regulatory bodies related to their research. Such codes should be followed.

5.2 If research is to be conducted in an institutional setting other than the University, e.g. another university or research centre, researchers **must** follow any ethics standards, procedures and regulatory guidelines of that institution.

5.3 The following list of documents and websites, which is not exhaustive, may be useful:

A primer on research involving animals, February 2021, UKRIO (<https://ukrio.org/wp-content/uploads/UKRIO-Research-Integrity-A-primer-on-research-involving-animals-V2.0.pdf>)

Animal Welfare Act 2006 (<https://www.legislation.gov.uk/ukpga/2006/45/contents>)

Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012

(<https://www.legislation.gov.uk/ukpga/1986/14/contents> and <https://www.legislation.gov.uk/uksi/2012/3039/contents/made>)

BPS Guidelines for Psychologists Working with Animals

(<https://www.bps.org.uk/news-and-policy/bps-guidelines-psychologists-working-animals>)

Concordat on openness on animal research in the UK, May 2014

(<https://concordatopenness.org.uk/wp-content/uploads/2017/04/Concordat-Final-Digital.pdf>)

Convention on International Trade in Endangered Species of Wild Fauna and Flora

(CITES) <https://cites.org/sites/default/files/eng/disc/CITES-Convention-EN.pdf> and https://cites.org/sites/default/files/l/Brochure_UNEP_CITES_eng.pdf)

Government Guidance - Wildlife licences: when you need to apply. Natural England and DEFRA (<https://www.gov.uk/guidance/wildlife-licences>)

Government Office for Science: Rigour, Respect, Responsibility: A Universal Ethical Code for Scientists

(https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/283157/universal-ethical-code-scientists.pdf)

Medical Research Council: Good research practice: Principles and guidelines

(<https://mrc.ukri.org/publications/browse/good-research-practice-principles-and-guidelines/>)

Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, 2011 (<https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf>)

Responsibility in the use of animals in bioscience research: Expectations of the major research council and charitable funding bodies. April 2017, National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs)

(<https://www.ukri.org/wp-content/uploads/2022/03/BBSRC-040322-responsibility-animals-in-bioscience-research.pdf>)

Society of Editors' Code of Practice

(<https://www.societyofeditors.org/resources/editors-code-of-practice/>)

UK Research Integrity Office (UKRIO) (<https://ukrio.org/>)

University Code of Good Research Practice (<https://www.essex.ac.uk/-/media/documents/directories/reo/code-of-good-research-practice.pdf>)

Appendix A

Although the University of Essex does not undertake any research on University premises that requires a Home Office licence under the Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012 (ASPA), research is undertaken both on animals that are not 'protected species' under the ASPA and on 'protected species' where the activity is not regulated by the ASPA.

The following is a non-exhaustive list of animals and the types of procedures that might be performed. It is not a list of the procedures currently performed at the University but is simply for illustrative purposes. Such work might include:

- invertebrates (apart from cephalopods) such as oysters, mussels, drosophila, corals;
- mammals, birds and reptiles within the first two-thirds of gestation;
- larval forms of fish and amphibians before they are capable of independent feeding;
- ringing, tagging or marking animals primarily for identification purposes if the method causes no more than momentary pain and no lasting harm;
- non-experimental practices undertaken for the purposes of recognised animal husbandry as long as they comply with other animal welfare legislation or regulations;
- the non-invasive observation of unrestrained animals, or any research intervention that is unlikely to cause the animal pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle in accordance with good veterinary practice.